SEPTEMBER 2024 • Vol. 10 • Issue 6
MONTHLY • Pages 64
₹ 200

RNI No.: DELENG/2015/67140; Published on: Every month; Posted at Lodi Road HPO, New Delhi on 9-10th of every month

THE AWARE CONSUMER

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World Patient Safety Day

17 September 2024

THEME:

IMPROVING DIAGNOSIS FOR PATIENT SAFETY

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VIEW  POINT

MESSAGE FROM PUBLISHER & EDITOR

Clinical Diagnosis in Patient Safety – Reliability and Credibility is Paramount

WHAT HAPPENS WHEN a person falls sick, is in pain or even feels some kind of discomfort? The primary recourse is to consult a doctor for medical treatment. The healthcare professional should conduct a physical examination and take a clinical history to formulate a diagnosis.

Identifying a patient's health problem – termed as clinical diagnosis – is the key to accessing the requisite care and treatment. Any failure to establish a correct understanding and timely explanation can lead to delayed, incorrect or missed diagnoses! This can prolong the suffering, lead to life-threatening consequences and even turn fatal.

The magnitude of diagnostic errors is profound, accounting for nearly 16% of preventable harm across health systems. With most adults likely to face at least one diagnostic error in their lifetime, improving the diagnostic processes remains crucial. While some instances are intrinsic and unavoidable, most can be overcome with diagnostic safety practices and protocols.

Ideally, clinical diagnosis precedes diagnostic testing as the doctor will decide which laboratory tests should be ordered based on the initial physical diagnosis. Hence, the doctors need to spend more time in patient consultation to understand his/her complaints and suffering. What is happening is most healthcare professionals hardly take the time to listen to the patient – after a cursory discussion, they order a battery of tests and rely on the reports to form a diagnosis. This is expensive, time-consuming and also reduces credibility in the healthcare system.

Former President, Dr APJ Abdul Kalam hit the nail on the head at the national consultation organised by our Partnership for Safe Medicines India in 2011, "When a patient goes to a doctor, he immediately prescribes many tests and screenings. And when the patient sees the long and heavy bill, he gets diagnostic pain!"

It cannot be denied that the rising complexity of healthcare, fuelled by the whopping advances in technology, treatment and medications, is making clinical diagnosis extremely intricate and challenging.

Given the costs and dangers involved, improving diagnostic accuracy is considered the next frontier for patient safety. On this World Patient Safety Day, we are advocating measures that will ensure accurate and timely medical diagnosis. In keeping with the theme, we will set the stage for clinical decision making that is tailored to the patients' specific health conditions and will afford them the best chances for a positive health outcome!

Prof. Bejon Kumar Misra
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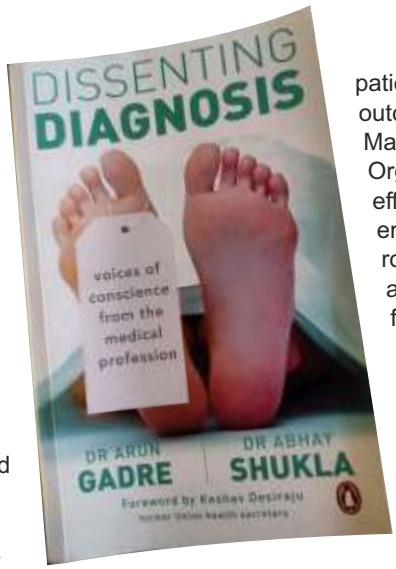
PRAFULL D. SHETH
Editorial Board Member

DESKTALK

CENTERING PATIENT SAFETY ON CLINICAL DIAGNOSTIC ACCURACY



THE PATHBREAKING BOOK 'Dissenting Diagnosis' exposed a chilling narrative of the malpractices in private hospitals during diagnosis. The authors, Dr Arun Gadre and Dr Abhay Shukla gathered evidence from 78 practising doctors, in both the private and public medical sectors, to expose the ways in which vulnerable patients are exploited through unnecessary investigations, procedures and other unscrupulous medical practices.

The eye-opening foreword penned by Keshav Desiraju, former Health Secretary, GoI takes me back to the committee formed in 2014 by then Union Minister of Health, Dr. Harsh Vardhan to expose the nexus between doctors and diagnostic centres. As part of the august committee, we submitted truckloads of evidence and recommendations on the cuts and commissions offered by pathological laboratories to doctors. Alas, patient safety went for a toss again as intense lobbying ensured that the data continues to gather dust in some forgotten corner of a government building…..

What triggered these reminisces is the theme of this fifth annual World Patient Safety Day - 'Improving Diagnosis for Patient Safety' - highlighting the critical importance of correct and timely diagnosis in ensuring patient safety and improving health outcomes. Through the slogan 'Get It Right, Make It Safe!', the World Health Organization (WHO) is calling for concerted efforts to significantly reduce diagnostic errors through multi-faceted interventions rooted in systems thinking, human factors and active engagement of patients, their families, health workers and healthcare leaders.

Recognising the critical nature of patient safety, the WHO observes World Patient Safety Day on 17th September every year. This has placed patient safety front and centre of quality healthcare with a strong emphasis on avoiding harm to patients during care. In simple terms, patient safety relates to putting an end to avoidable errors and negative practices suffered by patients within healthcare settings!

We will once again use this opportunity to raise public awareness and foster collaboration between patients, healthcare personnel and policymakers to improve diagnostic accuracy and reduce the excessive and expensive reliance on pathological testing. We definitely don't want the patients to spend so much on the initial diagnosis that they don't have any money left for the treatment and medications!

INSIDE

THE AWARE CONSUMER SEPTEMBER 2024

REGULARS

Medical conditions are primarily uncertain and it is usually a working diagnosis which dictates the provisional treatment.

A wrong diagnosis affects the entire treatment process and increases the health risks for the patients.

Despite the superlative advances in healthcare, effective clinical diagnosis continues to be a challenge on a global scale.

Vaidya Rajesh Kotecha
Secretary, Ministry of Ayush, Government of India

Our healthcare system is stretched thin and the healthcare professionals are heavily overburdened.

A physician's quintessential competency is proficiency in clinical reasoning.

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SEPTEMBER 2024 • Vol. 10 • Issue 6

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Published at:
B - 306, 1st Floor,
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Printed at:
M/s. Swastika Creation
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Total number of pages - 64, Including Covers

RIGHT DIAGNOSIS, RIGHT TREATMENT

The Impact of Diagnostic Errors

Diagnosis is the foundation of medicine and the cornerstone of healthcare. Treatment cannot begin until a diagnosis has been made. Accurate diagnosis goes a long way in ensuring that the patients receive the best possible treatment and care, which ultimately improves their safety and well-being.

A precise diagnosis is the foundation of effective healthcare management!

WHAT HAPPENS WHEN *you visit a doctor? Do you blindly trust his/her diagnosis and assume that you are getting the right treatment? Or are you plagued by misgivings and distrust about what the doctor is saying?*

Gone are the days when most of us used to believe that the doctor is right – as he/she should actually be! An atmosphere of suspicion and scepticism clouds healthcare as we can no longer take the reliability of medical diagnosis for granted?

What if a diagnosis is not actually as accurate as it appears to be? What if, say, recurrent cough and aspiration in a patient is erroneously diagnosed as pneumonia instead of a blockage in the lung? What if a case of multiple sclerosis is misdiagnosed as a viral infection? Or, what if your abdominal pain is dismissed as nothing serious, only to turn out to be bowel perforation?

Healthcare professionals study the patient's symptoms and laboratory reports to effectively diagnose ailments and prescribe an appropriate treatment or course of action. This is the first and most fundamental step in patient care. This may seem simple and straightforward, but is actually quite complex and prone to errors.

It can happen that the diagnosis is completely wrong, partially correct or correct but inappropriately late. Such errors are usually unintentional and can even be no-fault, remaining undetectable even after a reasonable evaluation. For instance, a stroke can cause dizziness or headache, which can be symptoms of many other things! Who can be blamed here?

The National Academy of Medicine, USA (earlier Institute of Medicine) defined diagnostic error as a "failure to establish an accurate and timely explanation of the patient's health problem(s), or to communicate that explanation to the patient."

Errors can occur at any stage of the diagnostic process and in any healthcare setting. They are broadly divided into three categories:

Diagnostic errors - not surgical mistakes or medication overdoses - account for the largest fraction of malpractice claims, most severe patient harm and highest total of penalty payouts in USA

- **Delayed Diagnosis –** The diagnosis is correct but was not diagnosed right away or was made later than it should have been, often leading to significant deterioration in the patient's health. Delayed diagnosis of cancer is a common example.
- **Incorrect Diagnosis** – This happens where the wrong diagnosis is made and the true cause is discovered later. For instance, the symptoms of a heart attack can be misdiagnosed as anxiety or indigestion!
- **Missed Diagnosis** – This refers to instances where a patient's illness or health condition is not identified. It is commonly seen in cases of chronic pain or fatigue, though more specific medical complaints may also remain undiagnosed.

The Fallout

Diagnostic errors can lead to preventable iatrogenic harm. Delays in diagnosis can deny the patients early and essential treatment, thus leading to serious harm or even fatal consequences. In fact, the longer it takes to make a correct diagnosis, the more the chances of disabilities, chronic illnesses and impairments.

What's more, in case of a wrong diagnosis, the patients not only miss out on the appropriate and potentially life-saving treatment for their condition, but may receive inappropriate or unnecessary treatments for a non-existent condition, that may prove to be harmful. A complete failure to diagnose can deny the patients any kind of treatment which will worsen their condition and can even cause irreparable harm.

All the above cases cause unnecessary pain, suffering and even financial hardship for the patients.

"Most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences!"

- 'Improving Diagnosis in Health Care' report by the National Academy of Medicine, USA

A study revealed that 5% of autopsies demonstrate diagnostic errors leading to lethal complications that could have been averted by treatment if the correct disease had been diagnosed!

Importance of Accurate Diagnosis

There are many reasons why prompt and accurate diagnosis is considered the crucial first step to optimal patient outcomes.

Correct Treatment: An accurate diagnosis is crucial to determine the correct treatment, thus significantly impacting the overall efficacy and health. It ensures that appropriate interventions and management strategies are implemented, which can slow down or halt the progression of the illness.

Tailored Treatment: Timely and accurate diagnosis ensures that the clinical treatment can be tailored to a correct understanding of the patient's health problem and other specific needs.

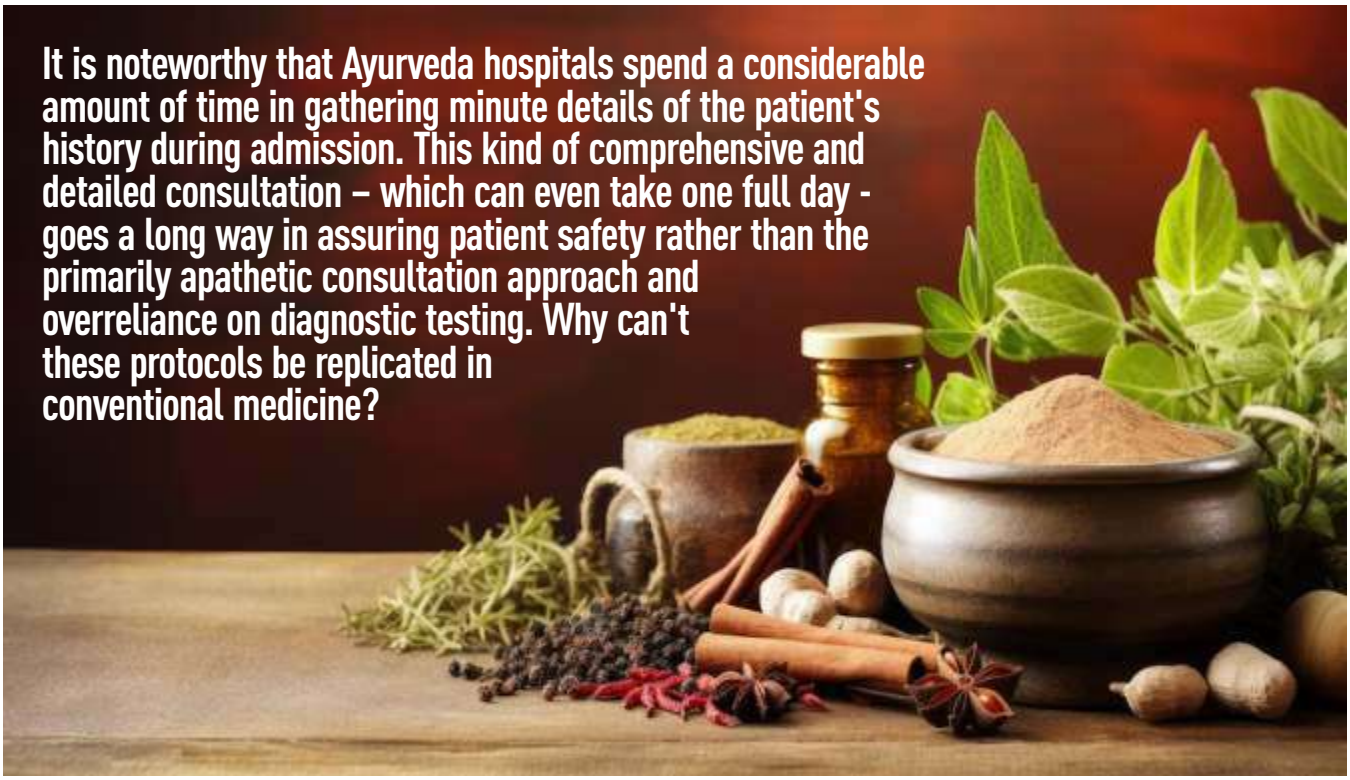
Early Detection of Diseases: An accurate diagnosis enables early detection of diseases. As serious health problems can be treated at an early stage, it improves the chances of recovery and can reduce healthcare costs.

Patient Participation: When a patient is certain that the diagnosis is correct, he/she will be more willing to actively participate in his/her own healthcare and comply with the medical instructions. This includes adhering to treatment plans, implementing lifestyle changes and collaborating with the treatment team.

Trust: A reliable diagnosis ensures that the patients and their families have trust in the healthcare system and healthcare professionals. A loss of trust can lead to uncertainty and dissatisfaction which slowly ripples through the entire community.

Resource Efficiency: An accurate diagnosis helps in efficient use of medical resources, like time, personnel, drugs and equipment as unnecessary treatments and procedures are eliminated. Also, the financial resources can be used more effectively as it prevents costly complications.

To sum up, reducing diagnostic uncertainty is essential for improving the reliability of the diagnostic process. Accurate clinical diagnostic performance will reduce the burden on both the patients and the healthcare systems!



Deciphering the Common Challenges in Clinical Diagnosis

Medical conditions are primarily uncertain and it is usually a working diagnosis which dictates the provisional treatment. This is based on clinical reasoning and experience. However, the process is fallible and the inherent vulnerability opens the doors to diagnostic errors. These errors can arise from various cognitive and systemic factors – awareness and action is crucial here!

Knowledge and experience are the cornerstones of strong diagnostic skills! However, understanding the cognitive process and other factors that underlie decision-making is crucial for improving clinical diagnosis.

A CLINICAL DIAGNOSIS provides an explanation for a patient's health problem. It involves understanding the patient's complaints and using medical knowledge and reasoning to decipher what happened, why it happened and what should be done to restore good health.

Certain illnesses and injuries are unambiguous and require simple pattern recognition. For instance, a sprain, fracture, throat infection, cellulitis, foreign body, etc. However, most health disorders are not so obvious as they do not fit into standard boxes. The complex scenarios call for clinical interpretations based on probabilistic inferences of the health issues that can cause the patient's current condition.

Diagnostic Process

This is how it usually plays out - within seconds of meeting a patient, the physician starts generating multiple possible diagnoses (these may be broad categories or even specific entities). The initial hypotheses direct further inquiry and investigations to get more specific data, by way of examination, testing, etc.

During this process of matching the observations and findings to the varied options, some hypotheses are rejected and new ones are generated before arriving at a working diagnosis. This may be either a list of potential diagnoses (termed differential diagnosis) or a single potential diagnosis.

The working diagnosis should ideally be coherent with the normal and abnormal findings and conform to the patient's condition. Yet, it may still be modified or refined with time as other possibilities arise. In fact, a continuous loop of information gathering, integration, interpretation and updating prior probabilities plays out in the clinical setting.

The uncertainty that is intrinsic to clinical judgment and reasoning should progressively reduce as more information is gathered. Finally, the verified diagnosis should meet a high-enough likelihood to merit treatment.

Please Note - Some health conditions may be identified immediately, while others may require the diagnostic process to play out before a diagnosis can be reached. This timeline is different for every disease and for every patient!

Clinical reasoning involves both analytical reasoning – which is rapid, sub-conscious and intuitive – and non-analytical decision-making - which is slow, deliberate and reflective.

Clinical reasoning is the cognitive process of putting the information together to assess and manage a patient's medical problems.

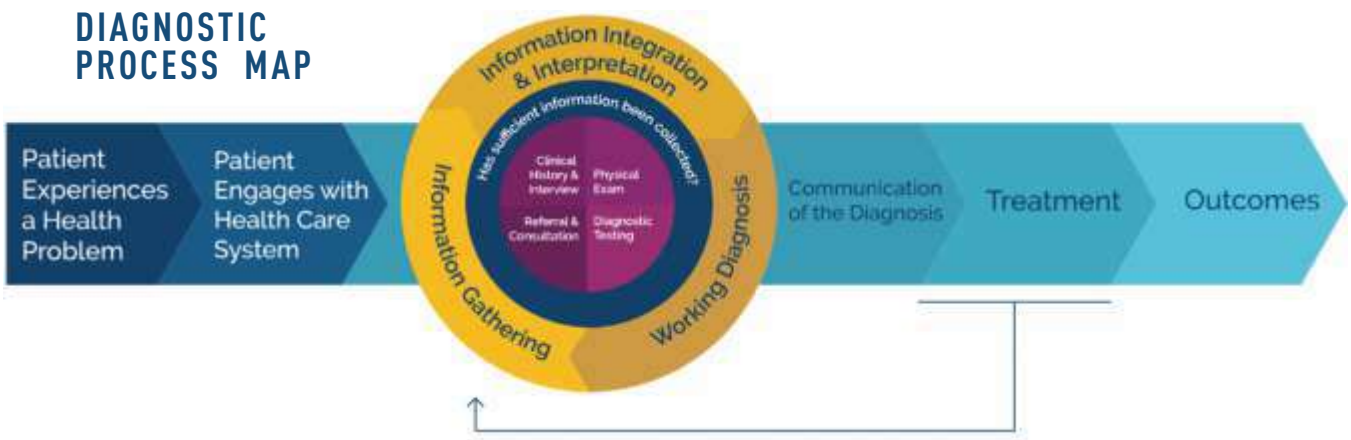
Demands of Clinical Decision Making

In most routine clinical situations, healthcare professionals use analytical reasoning driven by heuristics - mental shortcuts, educated guesses or rules of thumb - to come up with a provisional diagnosis, especially when faced with a patient with common symptoms. These shortcuts usually involve pattern recognition and rely on a subconscious integration of the patient data. They are ubiquitous, efficient and usually yield correct decisions.

The following heuristics are commonly employed in clinical practice:

Representative Heuristic – This involves judging the probability of a disease based on how closely the symptoms match the textbook description of a prototypical case. Here, the focus is on the presence or absence of classic manifestations of a disease, without taking into account disease prevalence. This is especially when the individual symptoms – like headache, nausea,

An intuitive understanding of probabilities combined with cognitive processes - called heuristics - guides clinical judgment.



The Diagnostic Process Map resource was developed by the National Academies of Sciences, Engineering, and Medicine, USA and offered by the Society to Improve Diagnosis in Medicine (SIDM) to help everyone understand and work to improve the diagnostic process.


Alvin Rajkomar Gurpreet Dhaliwal

> Intuitive reasoning can quickly sort through large volumes of data (which characterise many complex medical encounters) through an unknown algorithm with a reasonably high success rate.
>
> *- Improving Diagnostic Reasoning to Improve Patient Safety report by ALVIN RAJKOMAR, MD and GURPREET DHALIWAL, MD, University of California*

hypertension or palpitations - are commonly encountered in clinical practice.

Availability Heuristic – This is the tendency to judge the probability of a disease based on easy recall, even when there is low likelihood of the same. In other words, it involves choosing the first thing that comes to mind, driven by recent, memorable or even missed diagnosis. Experience of both good and bad cases can colour the memory of the physician, leading to overestimating – or even underestimating - the same possibility in other patients.

Anchoring Heuristic – This is characterised by the inclination to lock onto an initial hypothesis even as contradictory evidence accumulates. The preliminary diagnosis may be reasonable at first, but it may have to be revised eventually rather than dismissing conflicting evidence as anomalies.

For instance, although follow-up tests after diagnosing arthritis may yield abnormal results indicating that the patient is suffering from something else, the doctor may stick to the initial inference to the extent of misinterpreting the results, thus failing to diagnose the correct ailment of the patient!

Confirmation Heuristic – This is equivalent to 'cherry-picking' as it involves selectively accepting clinical data that supports a desired hypothesis and ignoring data that does not. It may even lead to misinterpreting ambiguous evidence to confirm the original diagnosis.

Premature Closure – This involves 'jumping to conclusions' by making a quick diagnosis based on pattern recognition and without full verification. The thinking ends here as the physician may fail to consider other possible diagnoses and prematurely stop collecting more data. This commonly happens in cases of exacerbation of a known disorder which makes the physician settle on an assumed diagnosis without seeking or carefully considering contradictory information.

Heuristics can facilitate decision making but can also lead to errors, especially when patients present with atypical symptoms. When a heuristic fails, it is referred to as a cognitive bias. This is a predisposition to think in a way that leads to failures in judgement!

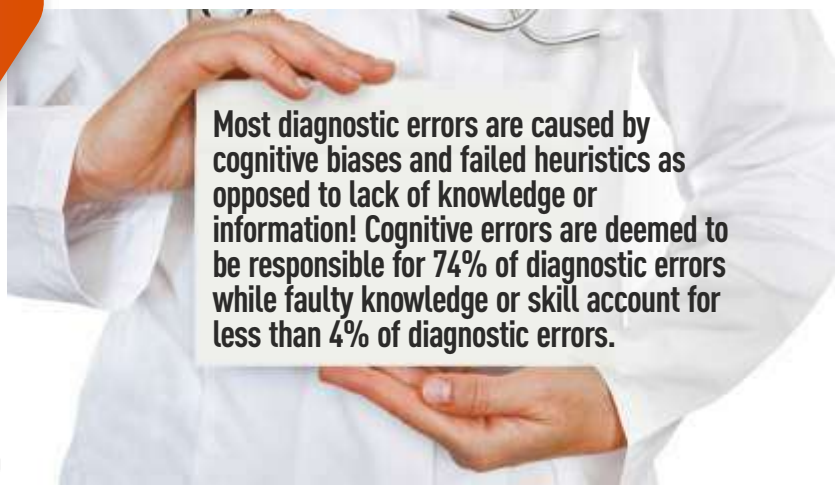
The single most common reason for a diagnostic error is simply, "I just didn't think of it!" This kind of faulty perception of not even considering the correct diagnosis as a possibility needs to be overcome.

Then there is 'attribution' which leads to making diagnostic decisions based on negative stereotypes – like alcoholism, drug abuse or mental health issues – and ignoring the possibility of other serious ailments. The 'affective' heuristic involves letting personal feelings (positive or negative) about a patient affect decisions.

The above kinds of informal reasoning driven by heuristics can be a double-edged sword as they are also prone to producing unconscious biases which translate into diagnostic errors. While there are many different types of predisposing cognitive errors, they tend to conform to either faulty assessment of pre-test probability or failure to seriously consider all relevant possibilities.

Other Challenges

Still more cognitive factors – like the healthcare professional's training, experience, fatigue and stress – play a significant role in making a correct and timely



The mushrooming of unregistered, unregulated and illegal pathological laboratories is a matter of grave concern. A majority of them are not accredited – even those that have been accredited may not renew their certification or may be 'extending' accreditation of few processes to the entire lab!

The results are unreliable and may even be deliberately falsified to promote expensive medical procedures! Not to mention that patients are often subject to unnecessary tests by doctors who are guided by the lure of commissions offered by diagnostic centres!

diagnosis. Inadequate knowledge, skills or experience will become a limiting factor, especially in the case of uncommon diseases/illnesses.

The physicians usually see a large number of patients every day. They are always short of time and have to think on their feet without the liberty to sit back and make diagnostic decisions at leisure. They may also be overworked, understaffed and sleep-deprived which will affect the quality of their clinical decision-making.

Then again, most patients come with several symptoms which increases the possibility of missing small, but critical, details. The test data may change or the patients may even have been diagnosed incorrectly earlier. In some cases, patients have two or more diseases which may be related to each other or completely unrelated. A doctor may diagnose only one of the diseases without even realising that there are others as well.

Then there are systemic factors in the form of organisational vulnerabilities - heavy workloads, shortage of resources and limited access to diagnostic tests. Poor teamwork, miscommunication between healthcare providers and communication failures between healthcare providers and patients are other predisposing factors for diagnostic errors.

It should be noted that our traditional healthcare practices lay a greater emphasis on personal diagnosis which ensures a more accurate analysis and effective treatment as well!

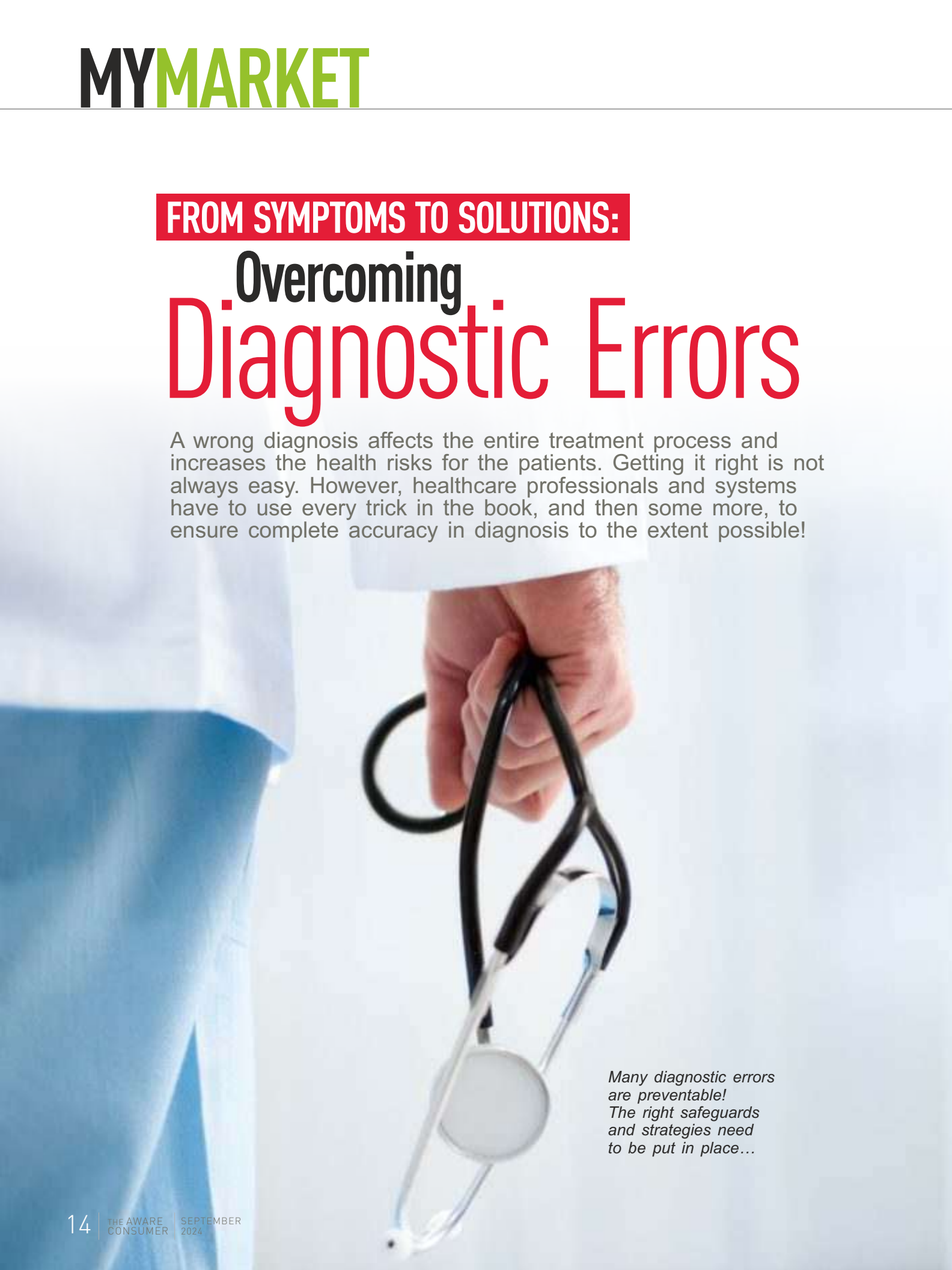
Above all, healthcare is becoming more and more complex marked by rapidly rising levels of evidence to inform clinical practice, ever-increasing options for medical treatment, and frequent comorbidities among patients. The sheer pace of technological advancements in diagnostic testing have left healthcare professionals behind. After all, they are only human and the volume of developments in testing, treatments and medications can outstrip their capacity to apply this new knowledge!

In conclusion, a basic understanding of the cognitive process that underlies diagnosis and the common cognitive biases that influence decision-making can help healthcare professionals recognise and avoid them. Additionally, addressing the other cognitive factors and systems-based issues can significantly improve diagnostic safety.

FROM SYMPTOMS TO SOLUTIONS:

Overcoming Diagnostic Errors

A wrong diagnosis affects the entire treatment process and increases the health risks for the patients. Getting it right is not always easy. However, healthcare professionals and systems have to use every trick in the book, and then some more, to ensure complete accuracy in diagnosis to the extent possible!



Many diagnostic errors are preventable! The right safeguards and strategies need to be put in place…

TO ERR IS human! Nobody is perfect! Everyone makes mistakes! – All these adages are true, but in the world of medicine, even small errors can have dire consequences!

While there is no arguing that healthcare professionals cannot be expected to be perfect all the time, there is an extra onus on them to be careful, attentive and knowledgeable when diagnosing patients.

Given the critical importance of correct and timely diagnosis in ensuring patient safety, preventive measures are essential to ensure that ailments are effectively diagnosed and the best treatment/course of action is prescribed sans any errors.

The World Health Organisation (WHO), under the theme of 'Improving Diagnosis for Patient Safety' for World Patient Safety Day 2024 – has stressed on the importance of ascertaining complete patient history, undertaking thorough clinical examination, improving access to diagnostic tests, implementing methods to measure and learn from diagnostic errors, and adopting technology-based solutions. It has concurred that arriving at a medical diagnosis is a complex process which requires clinical skills related to:

Taking an Accurate Medical History – Bedside evaluation involves obtaining the patient's medical history or verifying the accuracy of previously acquired medical details/reports. This is a versatile diagnostic tool as the clinical history is what directs subsequent information-gathering activities – done right, it will facilitate a productive and efficient physical exam and appropriate utilisation of diagnostic testing.

Many diseases have similar symptoms. The physician has to be very careful to avoid diagnosing the wrong ailment. For instance, abdominal pain can have many causes. The doctor needs to ask the patient the right questions and understand the complaints to be able to zero in on the actual cause.

Performing a Physical Examination – The next diagnostic step is a thorough examination of the patient. The patient is likely to be apprehensive and anxious when being examined as he/she may feel exposed, vulnerable or uncomfortable. The physician should try to relieve the anxiety while maintaining the dignity of the patient.

Everything from the eyes and hands to instruments should come into play to observe, evaluate and decipher

"The art of clinical diagnosis lies in the ability to ask the right questions!"
- Harriet B. Braiker

There are growing concerns that traditional 'bedside evaluation' skills (history, interview and physical exam) are receiving less attention due the huge growth in diagnostic testing in medicine. It is especially disheartening that we have moved away from our traditional healthcare practices - which relied on nadi chikitsa and other such 'personal touch' diagnostic processes to form an accurate evaluation - in favour of intricate instruments and machines which only amplify the cost burden of healthcare.

The ability to transform medical data into an accurate and actionable diagnosis is paramount for healthcare professionals!

the appearance, posture and symmetry of the patient along with the skin, body parts and organs. The physician needs to closely observe even the patient's behaviour – for pain, distress, etc. - as it will not only provide important clues for a diagnosis, but can also prevent unnecessary diagnostic testing and wastage of time. Here, the physical exam should cover all parts of the body, instead of just those suspected to be involved in the patient's current complaint, to avoid missing other ailments.

A physical examination is not just about visually noting the patient's signs and symptoms, but also confirming his/her complaints and claims.

Obtaining Diagnostic Testing - Laboratory tests and imaging studies serve as invaluable aids in making a diagnosis. However, there is a wide array of diagnostic tests and the physician needs to order the appropriate ones to confirm a suspected condition or to exclude other conditions. Only then can the results yield useful information for correctly identifying the underlying cause of a patient's symptoms.

The right tests can distinguish between similar diseases with different treatments, and even aid early detection of a disease, thus ensuring that patients receive the most appropriate and targeted care. Interpreting the test results correctly also remains crucial.

Here, the physician should not hesitate to send a patient for referrals or consultations to other professionals, if needed. The additional expertise can help confirm or reject the working diagnosis and even provide information on potential treatment options.

Assimilating the Information – Once the requisite information has been gathered, it has to be integrated and analysed before arriving at a clinical decision. Understanding the clinical reasoning process and the

Consistent clinical decision making strategies developed by the University of Utah, USA

factors that can impact it are important as they largely contribute to diagnostic errors. Here, the physician has to be consistent and proficient in both analytical and intuitive clinical reasoning.

Actively Seeking Feedback – The best way to improve judgement is through feedback. It is only when healthcare professionals realise that a diagnosis is incorrect, can they reflect on their knowledge and rationale and recalibrate the process. Else, they will become overconfident and continue to make mistakes!

However, most physicians remain largely unaware of the errors in their diagnosis. Due to fragmentation of care, some may not even get an opportunity to see how their diagnosis turns out. The ingrained culture of not providing clinician feedback, especially when there is a mistake, throws up a major hurdle on the landscape of improving diagnosis accuracy.

The onus falls on the healthcare professional to seek feedback on diagnostic performance in a systematic and comprehensive manner. This can be through scheduled follow-up visits, phone or electronic communications or even alerts on subsequent diagnostic tests.

System-Based Approaches

Preventing diagnostic errors is not just about the clinical diagnostic skills of the healthcare professionals alone. Even the healthcare institutions should realise the

> "To improve diagnostic safety, focus not just on individual performance, but also on the performance of the system where clinicians practice."
>
> - HARDEEP SINGH, MD, MPH, Expert in Diagnostic Safety, VA Medical Center, USA

financial, quality, safety and legal ramifications of diagnostic errors and provide support to the physicians in the diagnostic process to improve their accuracy.

Even the WHO has stated that healthcare professionals often operate in complex and rapidly-changing environments. Errors can be avoided when robust systems and processes are designed to support their work and aid them in making sound decisions.

Professional Education and Training Opportunities – A number of experts on medical education provided inputs to the Committee on Diagnostic Error in Health Care, National Academy of Medicine, USA that the healthcare professional education and training is not adequately preparing individuals to become skilled diagnosticians. In fact, the current modules

Clinicians learn from case studies that reflect prototypical cases, but face complexities of real patient cases in their clinical practice!

underemphasise clinical reasoning, including critical thinking skills and decision making in the diagnostic process. They stressed on continued training on optimal functioning in the diagnostic process to help reduce diagnostic errors.

The healthcare system has to institute ongoing learning across the career trajectory with a focus on how diagnostic errors occur, their impact and the strategies to mitigate them. This will also enhance understanding of real-life conditions and implications of medical diagnosis. It will also encourage them to think through decisions and interpret information well. Training programmes and simulations should encompass clinical reasoning, critical thinking, managing uncertainty, probability concepts, ordering diagnostic testing, applying results of diagnostic testing, understanding test limitations, using health IT, etc.

> "Training focused on the causes and impact of diagnostic error can help providers become more competent in error prevention."
> - WHO

Use of Information Technology - Technology can aid better clinical diagnosis and reduce potential errors. Various decision support tools have been developed to help healthcare professionals by suggesting diagnostic possibilities in real time after clinical data is entered. They can serve as a valuable resource by providing evidence-based information, guidelines and recommendations to aid the diagnostic process.

Mechanisms to Track Diagnostic Errors – Hardly any healthcare organisations are interested in identifying diagnostic errors, capturing adverse events or measuring error rates. Proper reporting of diagnostic errors and near-misses in clinical practice is key to evaluating and addressing the underlying causes of the same. This will develop a culture of learning from errors and preventing them in the future.

Hence, the healthcare organisations need to institute measures to routinely assess the quality of diagnostic care. This calls for a shift from the prevailing perception that diagnostic errors are inevitable and cannot be addressed. The measures that can be used are medical record reviews, medical malpractice claims analysis, health insurance claims analysis, second reviews in diagnostic testing and patient surveys, etc.

Promote a No-Blame Culture - Diagnostic errors will happen. Instead of making it a personal problem and tying it to an individual's failings, the healthcare institutions needs to think critically about the diagnostic process during the course of a patient's care. The historical shame-and-blame ethos should be replaced with a studied focus on identifying and addressing system-based improvements.

Respecting all the parties involved and addressing their concerns will create an environment where people are comfortable drawing attention to medical errors. Non-punitive and non-defensive discussions can help improve awareness and knowledge of how to avoid potential diagnostic errors.

Conclusion

Correct diagnosis is the key to effective treatment. Else, it can end up harming an unacceptable number of patients. Hence, what we need is ongoing improvement of diagnostic skills and a commitment to lifelong learning and expertise principles. This is a cornerstone of patient safety culture that will greatly improve the probability of a positive health outcome!

The National Academy of Medicine, USA has identified the following steps to decrease the chances of incorrect diagnosis:

- Facilitate teamwork
- Improve training around the diagnostic process
- Design medical systems to work for the patient and the provider
- Analyse the causes of incorrect diagnosis and formulate plans to avoid them
- Foster the medical field to appreciate and reward diagnostic thinking
- Utilise technology to catalogue diagnostic errors
- Increase funding of diagnostic studies

Improving Diagnosis Through Teamwork and Collaboration

The teamwork mantra of corporate environments extends to the healthcare realm as well. Indeed, interdisciplinary healthcare teams working together in coordination can invoke safety in numbers, thus reducing the scope of diagnostic errors.

Sharing patient care and decision-making by teams of healthcare professionals increases the propensity of accurate and timely diagnosis!

DIAGNOSIS IS THE troubleshooting stage of healthcare in response to symptoms of a problem presented by a patient. This is all about problem identification and diagnosis.

Given the incidence of diagnostic uncertainty and fallouts of diagnostic errors in various healthcare settings, can the task of diagnosing a patient's medical condition be left to a physician alone? What about the other specialists, non-physician healthcare professionals and support staff? Why can't they put their knowledge and skills together and work in collaboration when probabilistic inferences are required, thus improving diagnostic certainty?

Poor teamwork and communication between clinicians have been identified as major contributors for diagnostic errors!

The 2015 report on 'Improving Diagnosis in Health Care' by the National Academy of Medicine, USA clearly recognised that the diagnostic process is a dynamic team-based activity. It outlined the first goal for improving the diagnostic process as, **"Facilitate more effective teamwork in the diagnostic process amongst different healthcare professionals, patients and their families."**

Traditionally, diagnosis has been characterised as a solitary activity, taking place exclusively inside an individual physician's mind. This approach was acceptable till a few decades ago. However, diagnostic teamwork has become crucial today given the rapid developments in healthcare, overwhelming use of technology and potential toxic effect of medications.

In fact, patient-centred care is defined by shared decision-making arising out of effective communication and collaboration among multiple clinicians, diagnostic services and the patients.

This calls for both intra- and inter-professional collaboration between various types of healthcare professionals - depending on the patient's health problem - to maximise the odds of a correct diagnosis. This can range from physicians of other specialties, assistants and nurses to radiologists, therapists, social workers and even pharmacists.

> "The diagnostic process is a complex, patient-centred, collaborative activity that involves information gathering and clinical reasoning with the goal of determining a patient's health problem. This process occurs over time, within the context of a larger healthcare work system that influences the diagnostic process."
>
> - Improving Diagnosis in Health Care

Physician–patient communication remains paramount. The consulting physician will ultimately be responsible for integrating all the relevant information and communicating the diagnosis to the patient. He/she will become better equipped to make informed decisions and provide appropriate care.

Promoting Collaboration Between Healthcare Providers

Given that a patient's diagnosis can hinge on successful collaboration, the healthcare organisations have to work on modifying the professional norms and work culture to facilitate and support the various healthcare professionals to engage in diagnostic teamwork. This includes inculcating an environment that is conducive to collaboration, providing technology that assists with communication, establishing measurable processes and feedback mechanisms, and engaging patients and their families in the diagnostic process.

Here, the traditional hierarchy can pose a significant challenge as nurses, assistants and even junior clinicians may hesitate to voice their opinions about a potential error. For instance, a nurse or physical therapist may be the first to notice a change in the patient's condition that indicates a wrong diagnosis, but may shy away from questioning the physician. On the other hand, the experienced physicians may not be open to accepting any opposing views.

Hence, healthcare professionals need to be equipped with the appropriate knowledge, skills and resources to work together during the diagnostic process. Juniors should be empowered to help the physicians while the latter should be amenable to inputs from other members of the team. Even pathologists and radiologists should be engaged as full members of the diagnostic team, as they make significant contributions to the diagnosis. This can improve all aspects of the diagnostic testing process, like test ordering, analysis and interpretation, reporting, communicating and acting on the results.

Then again, intra-professional collaboration can be difficult to achieve in practice due to the complexity of diagnostic processes and demarcation of departments in healthcare. Facilitating access to second opinions from experts and soliciting colleagues to discuss challenging cases – can be through electronic consultations – will set the stage for collaborative diagnosis.

The treating healthcare professional should also partner with the patients and their families as

diagnostic team members to facilitate patient and family engagement.

To make the patients and their families critical partners in the diagnostic process, it is essential to provide them opportunities to learn about the diagnostic process. Also, create an environment where they feel comfortable engaging in the diagnostic process to the extent of sharing feedback and concerns about diagnostic errors and near misses.

The 'Improving Diagnosis in Health Care' report further outlines the following steps to ensure effective communication and information exchange for the diagnostic team:

- Ensure that health information technologies support patients and healthcare professionals in the diagnostic process. This means ensuring health IT is usable, incorporates human factors, integrates measurement capability, fits within the clinical workflow, provides clinical decision-making support, and facilitates timely flow of information between healthcare professionals, as well as to the patients.
- Establish a work system and culture that supports the diagnostic process and improvements in diagnostic performance. To this end, healthcare organisations should (among other things):
  - Promote open discussion and feedback
  - Design the work system in which the diagnostic process occurs to support the work and activities of healthcare professionals
  - Develop and implement processes to ensure effective and timely communication between diagnostic testing healthcare professionals and treating healthcare professionals across all care-delivery settings

The report concludes, “Without a dedicated focus on improving diagnosis, diagnostic errors will likely worsen. Just as the diagnostic process is a collaborative activity, improving diagnosis will require collaboration and a widespread commitment to change among healthcare professionals, healthcare organisations, patients and their families, researchers and policymakers.”

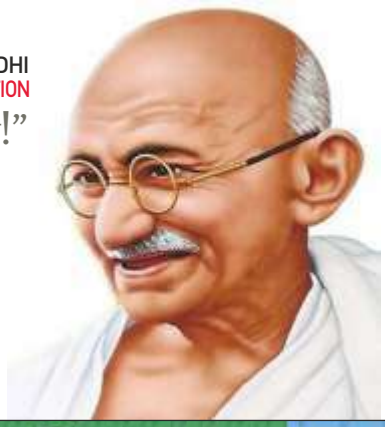
Summing Up

Team cohesion is vital to the diagnostic process. Reaching a correct and prompt diagnosis revolves heavily around how well a team of multiple healthcare professionals works together. This will improve clinical outcomes as well as build a culture of patient safety.

Obtuse Angle by Prof. B P Acharya

MAHATMA GANDHI
FATHER OF THE NATION

"A correct diagnosis is three-fourths the remedy!"



ROUNDUP

FIRST EVER

Patient Safety Rights Charter by WHO

IN APRIL 2024, the World Health Organisation (WHO) launched a Patient Safety Rights Charter at the sixth Global Ministerial Summit on Patient Safety in Chile. It is the first Charter to outline patients' rights in the context of safety and promotes the upholding of these rights, as established by international human rights standards, for everyone, everywhere. It is also designed to support stakeholders in formulating the legislation, policies and guidelines needed to ensure patient safety.

The Charter covers 10 patient safety rights crucial for mitigating risks and preventing inadvertent harm. It provides healthcare workers, healthcare leaders and governments with the tools to build patient-centred healthcare systems, improving patient safety and reducing the risk of harm. More importantly, the Charter provides patients with the language to advocate for themselves in healthcare settings, and will facilitate continued collaboration between patients, their families and caregivers, communities and health systems to ensure everyone has access to high-quality safe, healthcare.

DATA BRIEFING

Errors in diagnosis occur in 5% to 15% of all clinical encounters and cause serious patient harm in up to 1% of cases

Dr NEELAM DHINGRA

Head of Patient Safety Flagship Unit at WHO

"Everyone, everywhere, has the right to safety as a patient. The launch of the Charter is a tangible step forward in achieving a safer, more equitable world. The charter will be a key resource in assisting countries in integrating essential concepts such as patient and family engagement, equity, dignity, and access to information into their healthcare systems. Countries and all stakeholders are invited to adopt, disseminate and implement the Patient Safety Rights Charter."

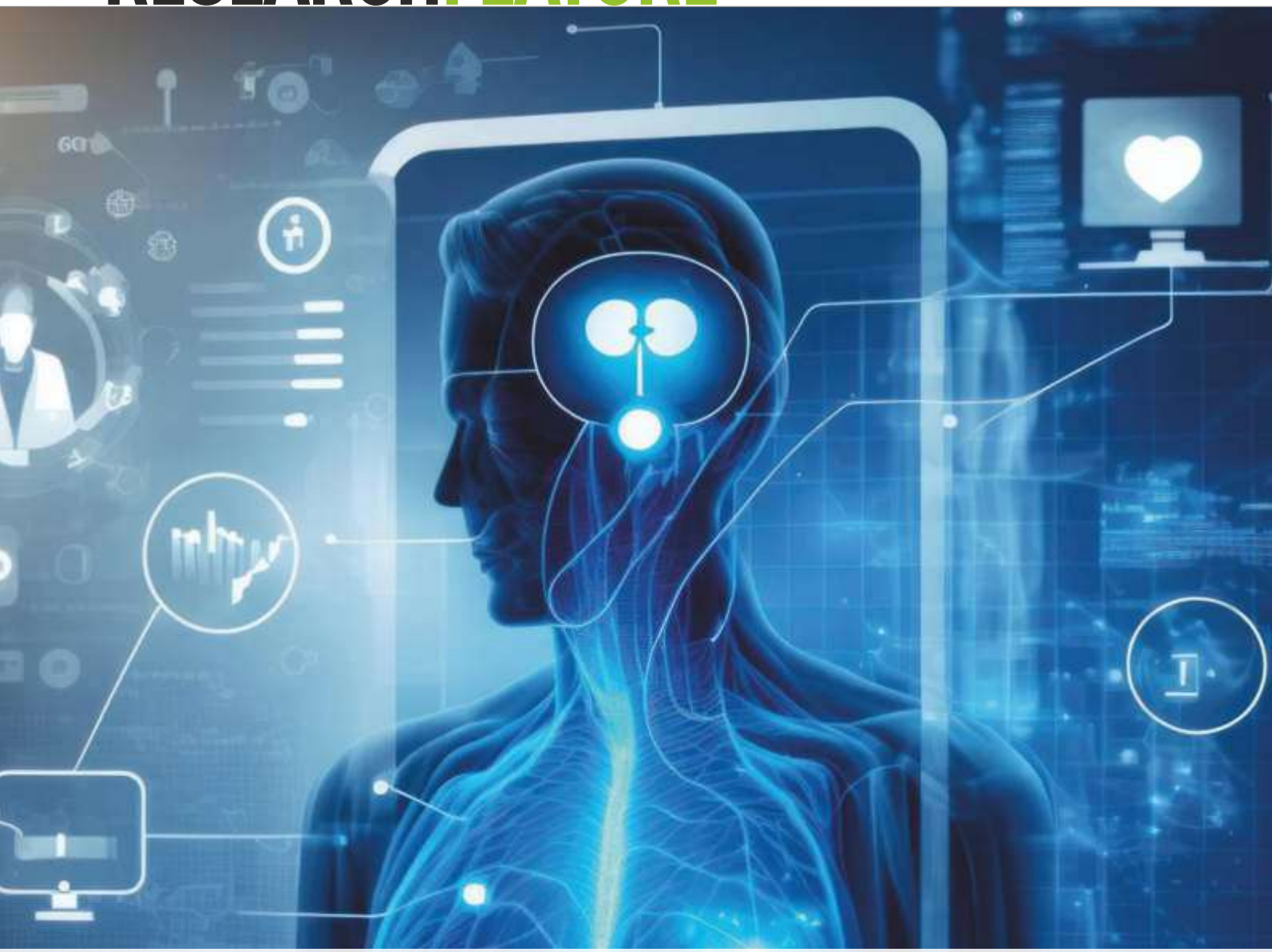
Dr RUDI EGGERS

WHO Director of Integrated Health Services

"Patient safety speaks to the first, fundamental principle of healthcare – 'Do no harm'. Assuring patient safety is a global priority, and a critical component needed to achieve the Sustainable Development Goals. Patient safety can be seen as an indicator of countries' broader commitment to respect, protect and fulfil health-related human rights."

The 10 fundamental patient safety rights outlined in the Charter are:

1. Right to timely, effective and appropriate care
2. Right to safe healthcare processes and practices
3. Right to qualified and competent health workers
4. Right to safe medical products and their safe and rational use
5. Right to safe and secure healthcare facilities
6. Right to dignity, respect, non-discrimination, privacy and confidentiality
7. Right to information, education and supported decision making
8. Right to access medical records
9. Right to be heard and fair resolution
10. Right to patient and family engagement



Delving into the Dilemma of Diagnostic Errors – A Pursuit for Precision

Despite the superlative advances in healthcare, effective clinical diagnosis continues to be a challenge on a global scale. The problem of diagnostic errors is now gaining international attention.

Clinical diagnostic errors occur more frequently than one would think!

THE PROCESS OF determining which disease or condition is responsible for a person's symptoms or complaints is termed as clinical diagnosis. Zeroing in on a patient's health problem involves diagnostic reasoning and this clinical decision making becomes the key to accessing the right care and treatment.

Identifying the correct diagnosis on time and informing the patients can save lives and improve the quality of care!

Diagnostic errors - both missed and delayed - are relatively common throughout all settings of care. They occur across patient populations and specialties and are prevalent in both inpatient and outpatient settings. They may involve common ailments as well as rare diseases and continue to harm an unacceptable number of patients.

Malignancies, surgical complications, and neurological, cardiac and urological issues are the most frequently misdiagnosed health conditions.

Low Focus on Improvement

A physician's most critical procedure is diagnosis. This complex first step in patient care remains prone to errors. Although healthcare quality and patient safety have been garnering international attention for the past few decades, diagnostic errors have mostly eluded scrutiny and innovations in improvement. This is despite the fact that landmark patient safety studies have consistently found that diagnostic errors are extremely common.

Diagnostic errors take a backseat to other errors of medical treatment primarily because the latter are quantifiable while the former remain subjective. Indeed, it is tough to detect these errors in clinical practice, let alone put a number on them! Given the lack of effective measures for diagnostic errors, even the current healthcare quality measurements do not take diagnostic accuracy into account at all. Alas, healthcare organisations may score well on quality measures even if the patients do not receive the correct diagnosis! Meanwhile, patients, families and caregivers continue to suffer diagnostic mishaps.

The target of reducing diagnostic errors has recently gained prominence in the international arena. It should ideally become a major focus in both healthcare practice and research.

Assessing a diagnostic error is a totally different proposition as it is all about trying to get inside someone's head to determine why they did or didn't think of a certain thing!

Shining the Spotlight

The Institute of Medicine, USA (renamed to National Academy of Medicine) released a report in 2000 titled *To Err Is Human: Building a Safer Health System* which catalysed the modern patient safety movement and led to many improvements in the provision of medical care as well as the healthcare conditions.

In continuation of this landmark series, the institute convened an expert committee to synthesise what is known about diagnostic errors and propose recommendations to improve diagnosis. The resultant

> **"Diagnosis - and, in particular, the occurrence of diagnostic errors - has been largely unappreciated in efforts to improve the quality and safety of healthcare. The result of this inattention is significant ... sometimes with devastating consequences. Urgent change is warranted to address this challenge. Improving the diagnostic process is not only possible, but also represents a moral, professional, and public health imperative."**
>
> ***– report by Institute of Medicine***

Compared to diagnostic errors, other types of medical errors - including medication errors, surgical errors and health care-acquired infections - have historically received more attention, both within healthcare organisations and on international platforms.

'Improving Diagnosis in Health Care' report was released in 2015 which termed diagnostic errors as a blind spot in the patient safety discipline!

This report recommended several healthcare system reforms for improving diagnosis, like promoting teamwork among interdisciplinary healthcare teams, implementing large-scale error reporting systems with feedback and corrective action, fostering learning from missed or delayed diagnoses, use of health information technology and increasing funding for research in diagnostic safety. By shifting the emphasis from the individual to the system, it opened the way for a more comprehensive taxonomy of diagnostic errors.

However, almost 25 years after the landmark call-to-action report, problems with patient safety remain all too common despite patient-centred strategies to create a culture of safety!

Enhancing patient engagement in the diagnostic process and shared decision-making are considered as critical aspects of improving healthcare quality!

Diagnostic errors occur in 5% to 20% of physician-patient encounters and are found in a minimum of 0.7% of adult admissions.

- WHO

Momentum for Change

The World Health Organization (WHO) has listed diagnostic errors as a high priority problem and states that such errors are prevalent in primary care, paediatrics, emergency medicine and surgery. They not only create health risks, but also have a large financial impact on the healthcare industry.

It was deduced that a sole focus on reducing diagnostic errors will not achieve the extensive change that is needed. Reducing diagnostic errors calls for a broader focus on *Improving Diagnosis* in healthcare.

Accordingly, the WHO released a **Technical Series on Safer Primary Care**. One of the monographs is dedicated to raising awareness among the Member States about strategies that can be implemented for reducing diagnostic errors in primary care. While diagnostic errors in hospitals have been found to be significant, the monograph suggests that it is also important to be aware that primary care remains a high-risk area for errors. This is because primary care providers typically see high numbers of people and their conditions are often difficult to diagnose due to potentially difficult clinical presentations. They may also have limited experience with uncommon diseases and varying access to diagnostic tests.

The monograph further suggests that the WHO Member States should consider prioritising strategies like supporting the workforce, using supportive tools, including patients as part of the care team, improving diagnostic facilities and prioritising areas for improvement.

It concludes that there is no 'one-size-fits-all' approach to reducing diagnostic errors in primary care. The solutions depend on the root causes and the local environment. The root causes of many diagnostic errors are likely to be inadequate clinical training, work overload, lack of essential facilities and other systems level issues. Addressing these issues lies at the heart of safer primary care.

> **"This patient safety issue affects every country and every diagnosis and involves many stakeholders. Diagnostic errors are relatively frequent and harmful in primary care, but much remains to be learned about them. There is no single intervention to prevent diagnostic errors and solutions need to be rigorously evaluated for benefits and unintended consequences. Research suggests the need for multi-faceted interventions that take into account the local context where they are implemented."**
>
> ***– WHO monograph on Diagnostic Errors***

> **"Because errors involve many common conditions and are prevalent across all countries, the WHO's leadership at a global level will be instrumental to address the problem. Based on our review, we recommend that the WHO consider bringing together primary care leaders, practicing frontline clinicians, safety experts, policymakers, the health IT community, medical education and accreditation organizations, researchers from multiple disciplines, patient advocates, and funding bodies among others, to address the many common challenges and opportunities to reduce diagnostic error. This could lead to prioritization of practice changes needed to improve primary care as well as setting research priorities for intervention development to reduce diagnostic error."**
>
> ***- report by Singh H, Schiff GD, Graber ML, et al on 'The Global Burden of Diagnostic Errors in Primary Care'***

World Patient Safety Day

The WHO has developed the **Global Patient Safety Action Plan 2021–2030: Towards Eliminating Avoidable Harm in Health Care** to provide a framework for action towards systemic change. It is working towards a world in which no one is harmed in healthcare, and every patient receives safe and respectful care, every time, everywhere.

This plan highlights the need for ensuring the safety of diagnostic processes. It encourages member countries to adopt strategies that reduce diagnostic errors which often arise from a combination of cognitive and system factors that impact the recognition of patients' key signs and symptoms, and the interpretation and communication of their test results.

The WHO has also centred this year's World Patient Safety Day on the theme of 'Improving Diagnosis for Patient Safety' to highlight this priority patient safety area that needs urgent and concerted action.

With the slogan 'Get It Right, Make It Safe!', this global public health day will drive all stakeholders to prioritise diagnostic safety and adopt a multi-faceted approach to strengthen systems, design safe diagnostic pathways, support health workers in making correct decisions, and engage patients throughout the diagnostic process.

World Patient Safety Day serves as a global platform to discuss, strategise and drive initiatives that place patient safety at the core of healthcare systems worldwide.

Accordingly, the WHO has set four objectives:

- Raise global awareness of errors in diagnosis and emphasise the pivotal role of correct, timely and safe diagnosis in improving patient safety.
- Give prominence to diagnostic safety at all levels of healthcare.
- Foster collaboration among policymakers, healthcare leaders, health workers, patient organisations and other stakeholders in advancing correct, timely and safe diagnosis.
- Empower patients and families to actively engage with health workers and healthcare leaders to improve diagnostic processes.

The overarching aim is to increase public awareness and engagement, enhance global understanding and work towards global solidarity and action by Member States to enhance patient safety and reduce patient harm. The shared goal is to eradicate avoidable errors and negative practices in healthcare settings by driving worldwide intervention for the safety of patients.

World Patient Safety Day is the cornerstone of action to promote global health and safety. It is firmly grounded in the fundamental principle of medicine. – *'First Do No Harm'*

Final Word

Research suggests that we are unlikely to find a 'magic bullet' and confirms the need for a multi-faceted approach to understand and address the many systems and cognitive issues involved in diagnostic errors!

Need for Reporting Mechanism for Diagnostic Errors

Diagnostic errors pop up routinely in clinical practice, have major implications for patients and impact the efficacy of subsequent treatments. However, most of them go undetected and unreported in the absence of a proper system for reporting diagnostic errors.

Developing a patient safety culture by identifying medical errors and implementing corrective interventions can make healthcare safer!

MEDICAL ERRORS – FROM surgical errors, diagnostic errors, medication errors and hospital-acquired infections to equipment failures, patient falls and communication failures - are a serious public health problem. They are associated with high morbidity, mortality and economic burden. Moreover, they negatively impact the patient, their family, involved healthcare providers, healthcare institutions and the community at large.

The British Medical Journal (BMJ) famously stated that if medical error had been a disease, it would be the third largest killer in the USA! It further stated that India, like any other developing country, is recording a lot of medical errors.

Alas, medical errors are a major challenge for ensuring patient safety in healthcare settings. It follows that the path to achieving patient safety begins with identifying the contributing factors and events that result in medical errors and culminates in viable solutions to avoid these errors from occurring. Indeed, once the causes are known, different prevention protocols can be developed and implemented across all levels of healthcare.

However, this is easier said than done. The challenge here is that healthcare professionals and institutions need to be made aware of the adverse events caused by medical errors. Only then can they understand the deficiencies or failures that led to such errors in the first place and identify corrective interventions to prevent them in the future. Reducing medical error rates in this manner will improve patient safety.

According to the National Patient Safety Implementation Framework (2018–2025), India, patient safety in a hospital setting consists of four definite areas:

- healthcare providers
- healthcare recipients
- infrastructure and facilities
- quality parameters and feedback system

Strengthening these areas will ensure better compliance and a more robust system.

Medical Error Reporting

Given that an average of 12.7 adverse events occur for every 100 hospitalisations in our country, it is evident that reporting of medical errors is essential to the process of ensuring patient safety.

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.
- World Health Organization

India has developed various pharmacovigilance systems under the Central Drug Standards Control Organisation (CDSCO). The systems form a network between all stakeholders including national and regional pharmacovigilance centres, health facilities (public and private), drug stores/pharmacies, patients/consumers and manufacturers, thus ensuring that all stakeholders participate in the reporting.

The following adverse event reporting systems are in place for drugs and medical devices:

PvPI - The Pharmacovigilance Programme of India (PvPI) is a flagship drug safety monitoring programme of the Ministry of Health & Family Welfare, Government of India

The overarching objective of the National Patient Safety Implementation Framework is to elevate patient safety standards across all tiers of healthcare, encompassing diverse modalities of healthcare provision. This includes activities related to prevention, diagnosis, treatment and follow-up, all within the broader context of enhancing the overall quality of care and advancing towards universal health coverage over the next decade.

which collects, collates and analyses drug-related adverse events received through the Adverse Drug Reaction Monitoring Centres (AMCs). Implemented by the Indian Pharmacopeia Commission (IPC), Ghaziabad - WHO Collaborating Centre for Pharmacovigilance - as the National Coordinating Centre (NCC), the vision of PvPI is to improve patient safety and welfare of the Indian population by monitoring drug safety and thereby sensitising the stakeholders regarding reducing the risks associated with use of medicines.

If a healthcare professional or patient suspects that an adverse event/reaction has occurred, he/she can report to the nearest AMC or on www.ipc.gov.in. Other reporting options are the toll free helpline number (1800-180-3024) and the ADR PvPI mobile app.

PvPI encourages reporting of all types of suspected adverse reactions with all pharmaceutical products irrespective of whether they are known or unknown, serious or non-serious and frequent or rare.

MvPI - Similarly, the Materiovigilance Programme of India (MvPI) is geared to monitor adverse events related to medical devices and reduce the risks associated with use of medical devices. It monitors adverse events, thus improving patient safety and welfare of the Indian population. It was approved by the Ministry of Health & Family Welfare, Government of India in 2015 and the Indian Pharmacopeia Commission (IPC) again functions as the National Coordination Centre (NCC) for the MvPI.

MINISTRY OF AYUSH

The Ministry of Ayush, Government of India has implemented a pharmacovigilance programme for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs to inculcate a culture of adverse drug reaction reporting, documentation and analysis for further regulatory action and surveillance of misleading advertisements of ASU&H drugs.
The All India Institute of Ayurveda, New Delhi is the National Pharmacovigilance Co-ordination Centre (NPvCC) for implementation of the pharmacovigilance program for ASU&H drugs. It receives inputs in terms of suspected Adverse Drug Reactions (ADRs) from the Intermediary Pharmacovigilance Centres (IPvCs).
The NPvCC undertakes the pharmacovigilance activities under the guidance and technical support of Indian Pharmacopoeia Commission and concerned programme officers at WHO Country Office-India, New Delhi.

Here again, Medical Device Adverse Event Monitoring Centres (MDMCs) have been established and the MvPIMDAE reporting form is available on the IPC website (www.ipc@gov.in). Errors can also be reported on the toll free number (1800-180-3024) or the ADR PvPI app.

It should be noted that there is a distinct haemovigilance system to ensure safe blood transfusion and blood products administration practices and monitor any adverse events thereof.

While the awareness and efficacy of such pharmacovigilance programs is still quite low in the country, the sad fact is that **no adverse event reporting mechanism is in place for diagnostic errors.**

"I have realised that people don't want to talk about medical errors. There hasn't been any increase in the awareness about patient safety but there has been a manifold increase in blaming doctors and the healthcare system."

- DR NIKHIL DATAR, gynaecologist and health activist who set up the Patient Safety Alliance in Mumbai to promote a healthy dialogue between patients and doctors on unintended medical errors

Need of the Hour

It is becoming increasingly important to have better processes and systems to identify and reduce diagnostic errors. Both patients and other individuals involved in every aspect of healthcare also need to be encouraged to watch out for and report such diagnostic errors.

Here, confidential reporting options are necessary to identify deficiencies or failures that may be prevalent in the healthcare system. Changing workplace culture and developing protocols for addressing diagnostic errors can also encourage reporting.

It should be noted that the emphasis is not on pinpointing the fallacies of a healthcare professional or institution, but enhancing overall understanding of diagnostic errors and the importance of corrective actions that can improve clinical outcomes.

The government, on its part, has brought in a definite push toward accreditations - for both hospitals and laboratories – and many private entities are maintaining the highest international standards. However, the overall scenario continues to put both quality and patient safety at stake!

In sum, reducing diagnostic errors requires a comprehensive approach that implements various strategies due to the many factors that can lead to these errors!

INTERVIEW

Vaidya Rajesh Kotecha

Secretary, Ministry of Ayush, Government of India

Padma Shri awardee and Ayurveda physician, Vaidya Rajesh Kotecha is also the former Vice Chancellor of Gujarat Ayurveda University, Jamnagar. He has authored two books, Concept of Atattvabhinivesha in Ayurveda and A Beginner's Guide to Ayurveda. He received the Global Ayurveda Physician Award in 2007, Ayurveda Ratna Award in 2008 and Padmashri Award for Medicine in 2015.

Under his leadership, the Ministry of Ayush has focused on enhancing research and education in Ayurveda, standardisation and quality control in Ayush medicines, digital transformation to improve access to Ayush healthcare, international collaboration and promotion of Ayurveda globally.

Vaidya Kotecha shares his views with the readers of The Aware Consumer on patient safety parameters and initiatives in traditional medicine.

Q What is the Pharmacovigilance program in Ayurveda, Siddha, Sowa-Rigpa, Unani, and Homoeopathy (ASSU &H) system? What is the vision of this program in the context of patient safety in ASSU& H system?

Pharmacovigilance became an important medical subject in recent times. What happens to a drug after its administration became crucial in these days. Pharmacovigilance is a kind of process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicines of all categories. The safety of traditional medicine also can be monitored through this system. Healthcare providers including doctors, nurses, caregivers, pharmacists, all other individuals associated with the health promotion, and disease prevention is a part of this system.

In this regard, the Ministry of Ayush has approved implementing the Central Sector Scheme of Pharmacovigilance of ASSU & H Drugs in December 2017 for inculcating the culture of reporting suspected adverse drug reactions and for surveillance of misleading advertisements of ASSU & H drugs.

Q Why patient safety is important in the context of ASSU & H systems of medicine?

Patient safety is a fundamental concern across all professional medical sciences, including traditional and modern systems. In India, where medical pluralism is deeply rooted, ensuring patient safety requires a multifaceted approach. This encompasses rigorous monitoring of adverse drug reactions, maintaining consistent quality through standardised processes, proper storage of medicines and addressing any misconceptions or misuses. Ayurveda, with its patient-centric approach, has always prioritised patient well-being.

As traditional medicine continues to gain popularity and expand globally, ensuring patient safety becomes increasingly critical. The rapid growth and acceptance of Ayush products underscore the need for stringent quality control measures and responsible use. Adverse reactions often stem from factors such as adulteration, poor raw material quality, improper drug processing, incorrect dosing and the use of contaminated products. The Ministry of Ayush's initiatives in maintaining high standards of safety and efficacy are essential to safeguarding public health and preserving the credibility of traditional medicine systems. This includes causality assessments to identify adverse effects, prompt investigations into suspect batches, halting further distribution to mitigate risks and ensuring accurate reporting. By prioritising patient safety, we can facilitate the effective integration of Ayush with conventional healthcare systems, ultimately leading to better health outcomes for all.

Q What are the common patient safety issues associated with traditional medicine?

Patient safety issues in traditional medicine include incorrect usage, social media hype spreading misinformation, improper identification of herbs, self-medication and lack of knowledge about proper use and potential side effects. Additionally, there is a tendency to prioritise OTC

drugs over prescription-based treatments, which sometimes lead to overuse and misuse.

To address these issues, robust pharmacovigilance systems like Ayushsuraksha have been established to monitor and manage adverse drug reactions. The Ministry of Ayush ensures traditional medicines adhere to strict quality standards, including accurate herb identification, standardised processing and correct dosing. Educational campaigns and guidelines help counter misinformation and promote safe usage. Additionally, regulatory frameworks and quality control measures are continually updated to address new safety challenges. These efforts aim to maintain high safety standards, integrate traditional and modern healthcare, and improve overall health outcomes.

The growing popularity of traditional medicine, with 80% global usage (WHO) and widespread use in India (NSSO survey), highlights the need for rigorous quality control. The exponential growth of the Ayush market and exports reaching $2.16 billion to over 150 countries reflect the increasing acceptance and quality of Ayush products. This underscores the importance of ongoing quality control initiatives by the Ministry of Ayush.

Q Why do you think there is need for pharmacovigilance in ASSU & H medicine today?

Pharmacovigilance is essential in traditional medicine to ensure safety, quality and efficacy. The World Health Organization (WHO) has emphasized the need for pharmacovigilance in traditional medicine, issuing guidelines in 2004 for the safety monitoring of herbal medicines. India's Pharmacovigilance Programme supports these guidelines, addressing the need for rigorous safety measures.

With the expanding popularity of Traditional Medicines, there is a growing demand for scientific validation and safety assurance. Pharmacovigilance plays a key role in monitoring adverse drug reactions, maintaining product quality and addressing any misconceptions. It supports regulatory compliance, advances research and improves patient outcomes by enabling early detection of adverse effects. This structured approach is vital to maintaining trust in traditional therapies and ensuring their safe integration into global healthcare practices.

Q What regulatory frameworks exist to ensure patient safety in Ayush medicine?

Pharmacovigilance is the science dedicated to mitigating drug-related harms to the patients. The Ministry of Ayush, Government of India, has initiated the Pharmacovigilance Program for ASSU & H drugs under the AOGUSY Scheme. The program is working through a three-tier network of a National Pharmacovigilance Centre (NPvCC), 5 Intermediary Pharmacovigilance Centers (IPvCs) and 99 Peripheral Pharmacovigilance Centers (PPvCs) across the country.

The nationwide programme is determined to establish and manage a database of Adverse Drug Reactions (ADR) for developing system-wise database of adverse drug reactions and evolving evidence-based recommendations towards clinical safety of ASSU & H Drugs. Besides this, it also undertakes surveillance of objectionable or misleading advertisements.

In other words, it will collect, collate and analyse data to establish evidence for the clinical safety of ASSU & H drugs in a scientific manner for documenting clinical evidence of safety and to undertake surveillance of misleading advertisements of ASSU & H drugs for regulatory actions.

PHARMACOVIGILANCE CENTRES DETAILS

National Pharmacovigilance Coordination Centre (NPvCC) (01)

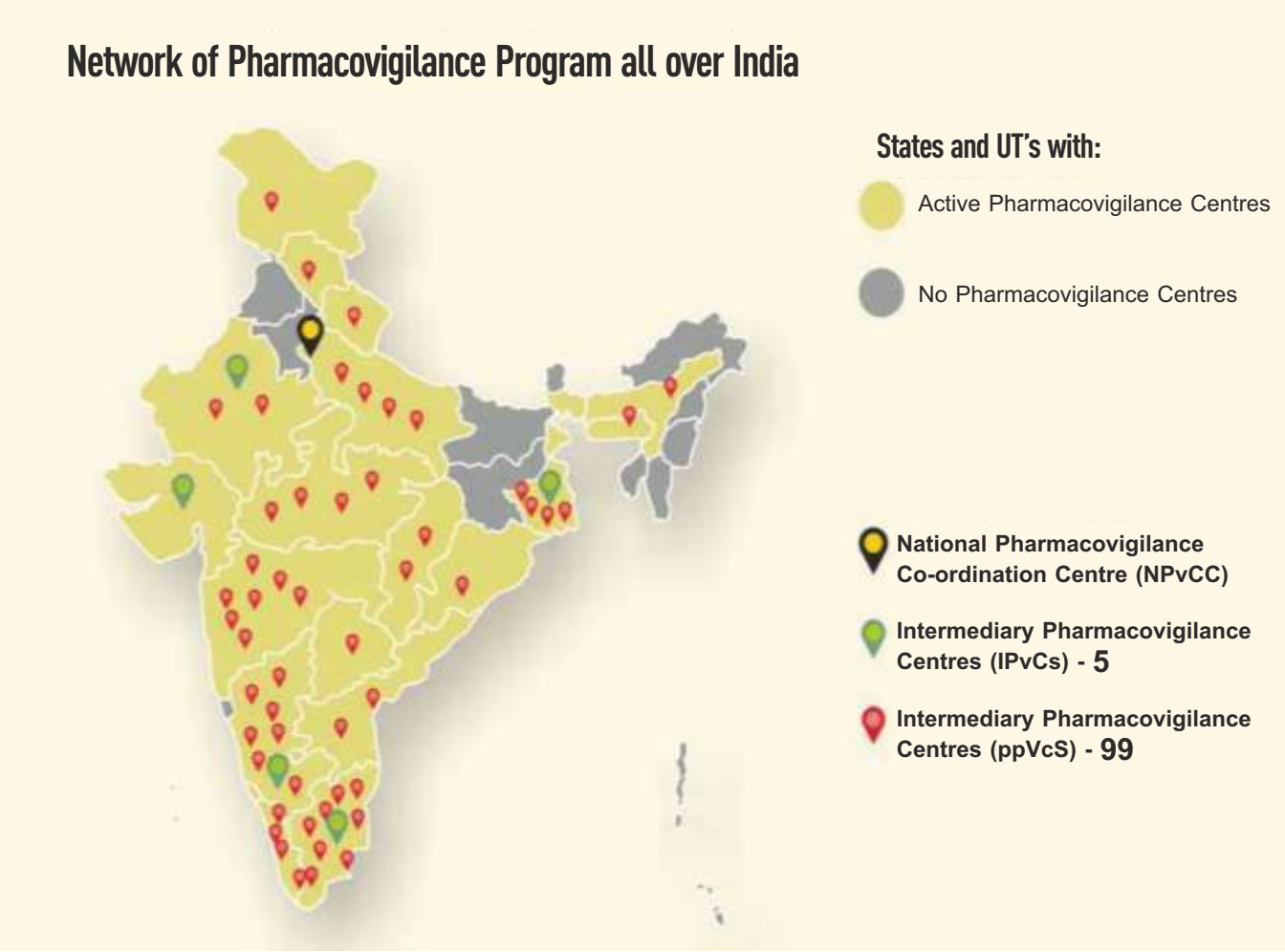
1.	All India Institute of Ayurveda, New Delhi

Intermediary Pharmacovigilance Centres (IPvCs) (05)

1.	National Institute of Ayurveda, Jaipur, Rajasthan
2.	Institute of Teaching and Research in Ayurveda, Jamnagar, Gujarat
3.	National Institute of Siddha, Chennai, Tamil Nadu
4.	National Institute of Homoeopathy, Kolkata, West Bengal
5.	National Institute of Unani Medicine, Bengaluru, Karnataka

Details of Peripheral Pharmacovigilance Centers (PPvC) (99)

	System	Number of Centers
1.	Ayurveda - Jamnagar	22
2.	Ayurveda - Jaipur	30
3.	Unani	15
4.	Siddha	15
5.	Homoeopathy	16
6.	Sowa Rigpa	01
	Total	**99**



Q What steps have been taken by the Ministry of Ayush for capacity building of health professionals in context of pharmacovigilance?

Skill development programmes are frequently being organised by the peripheral and intermediary centres to generate awareness regarding the pharmacovigilance program and to impart skills to the healthcare professionals, which in turn promote patient safety. These programs are being organised covering various cohorts including Ayush scholars, physicians, nurses, pharmacists, industrial professionals, licensing authorities, researchers, patients, and their caregivers etc. **The objective of these training programs is to:**

- Provide theoretical training to the healthcare professionals thereby enhancing and developing their skills.
- Enhance pharmacovigilance skills of the professionals.

Q Can you elaborate on the mechanism of reporting of suspected adverse drug reactions (ADRs)?

The program encourages reporting of all suspected drug related adverse events, including those suspected to have been caused by interaction with any other drugs or food incompatibilities using Suspected Adverse Drug Reaction Reporting Form for ASSU & H Drugs. The reporting of seemingly insignificant or common adverse reactions is important since they give an overview on prescription trends.

Any healthcare professional is eligible to report suspected adverse drug events to the concerned PPvCs/IPvCs using the Reporting Form for ASSU & H Drugs.

The information reported will be handled with confidentiality. Peripheral Pharmacovigilance Centres forward the form to the respective Intermediary Pharmacovigilance Centres who carry out the causality analysis. This information is forwarded to the National Pharmacovigilance Centre and from there to the Drug Policy Section, Ministry of Ayush.

Q Please highlight the current achievements of Ministry of Ayush under the Pharmacovigilance Program for ASSU&H Drugs.

Awareness Programs - To generate awareness regarding the Ayush therapeutic approaches and educate about the systematic use of Ayush drugs, and to inculcate the

reporting of any suspected adverse drug reaction in healthcare professionals; awareness events are being regularly organised across the country. Since inception in 2018 to July 2024, 1580 awareness programs have been conducted, wherein 1,21,272 beneficiaries have been sensitised.

Misleading advertisements - Objectionable advertisements are being identified from different regions of the country and in various languages by IPvCs and PPvCs. From January 2018 to July 2024, a total of 39,428 objectionable advertisements have been identified.

Suspected Adverse Drug Reactions (ADR) - Reporting of Suspected ADR has been initiated in January 2019 and since then the reporting is continuing. As of July 2024, a total of 1972 reports have been received. These are Individual Case Safety Reports, and majority of them were mild and self-limiting in nature. No additional hospitalisation was required in these cases. None of these reports were serious nor life threatening.

IEC Activities - NPVCC is also engaged in developing Information, Education and Communication (IEC) material for cautious dissemination of various concepts of pharmacovigilance in classics. IEC material indicating the 'Rational use of Ayush Medicines' was prepared and disseminated.

These efforts created a basic understanding in many of the Ayush healthcare professionals who are now engaged in further dissemination of related knowledge and are publishing technical documents. Professionals are also engaged in using artificial intelligence and other technology to develop various applications that can facilitate the program functioning. Some prototypes developed by Central Council for Research in Siddha (CCRS), Chennai are in final stages that may soon be implemented.

There is an increased use of ASSU & H drugs both at national and international levels. The global communities expect, and demand safety aspects before their actual utilisation in communities.

Q How can patients identify qualified practitioners of Ayush system of medicine?

The National Commission for Indian System of Medicine is the statutory body to provide for a medical education system that improves access to quality medical education and ensures availability of adequate and quality medical professionals of Indian System of Medicine in all parts of the country. State wise list of registered medical practitioner of Ayush system is available on the website of NCISM. [https://ncismindia.org/national-register-notifications.php]

Q What measures can be implemented to enhance patient safety in Ayush/traditional medicine?

Evidence-based practices, along with rigorous research and clinical trials, are essential to validate the safety and efficacy of Ayush medicines. Quality control for the efficiency and safety of medicinal products is of significant importance to safeguard consumer health. Besides quality control, regular monitoring of raw materials and finished products, implementing GMP principles in the production process, encouraging development of NABH accredited hospitals and NABL accredited laboratories dedicated for Ayush, will play a major role in ensuring safety as well as efficacy.

It is apt to mention here that Minimum Essential Standards, Assessment and Rating for Ayush UG Colleges Regulations, 2024 released by NCISM refers establishing Pharmacovigilance units in all the Ayush colleges. This initiative is expected to increase the awareness regarding pharmacovigilance on a faster pace among the Ayush professionals.

Apart from this, imparting efficient capacity building training in Ayush professionals, Ayush practitioners/Ayush healthcare workers and introducing modules on perspectives of pharmacovigilance in Ayush education is essential. Ayush emphasises holistic well-being. Integrating physical, mental, and emotional health aspects can enhance patient safety. Robust regulations, licensing, and monitoring mechanisms will ensure safe practices within Ayush systems.

Q How do you envisage the future of Ayush medicine evolving in terms of patient safety?

The masses in the country are very much aware of the Ayush system. These systems of healing and wellness have a huge following in the country. The Ayush sector has witnessed remarkable growth - it has grown by eight times in the last ten years due to the demand for Ayush & Ayush products in India & on global platforms.

Launching of WHO Global Traditional Medicine Centre (GTMC) at Jamnagar under Ministry of Ayush to provide leadership on global health matters pertaining to traditional medicine and to ensure quality, safety and efficacy, accessibility and rational use of traditional medicine, is truly a visionary approach which will pave the way for efficient healthcare delivery with an emphasis on patient safety.

In a nutshell, future of Ayush lies in making efforts for global recognition and adopting Ayush in mainstream as a part of integrative medicine. The involvement of the professionals at IPVCs and PPVCs is noteworthy to refer here who gave a shape to the existing program. Congratulations for their efforts. The program seeks support from all stakeholders including the academicians, physicians, pharmacists, policymakers, patients and all others associated.

AFTERWORD

Pyush Misra
Trustee,
Consumer Online Foundation

Checklists – The 'Best Practices' Tool for Reducing Diagnostic Errors

"Diagnostic reasoning is a critical aspect of clinical performance. Any gaps in this can lead to an error. Systematic reviews and best practice guidelines are invaluable in improving this aspect of medical care. In fact, checklists can prevent diagnostic errors by throwing up additional diagnostic possibilities!"

– Pyush Misra

Making a diagnosis is actually the most difficult task in healthcare! A checklist works as an effective systems-safety intervention!

THE BLIND SPOT of clinical diagnostic errors is not only extremely common in both in-patient and out-patient settings, but also quite preventable. Still, they continue to be a leading cause of patient mortality!

The problem here is that clinical diagnostic errors are difficult to detect and measure and even tougher to address and prevent. Then again, while there is some evidence on the causes of diagnostic errors, none exists on how to prevent them! While several approaches for reducing diagnostic errors have been tested, a reliable intervention continues to remain elusive. This can be attributed to the fact that diagnostic errors are not like other kinds of medical errors!

The significant human and financial cost of diagnostic errors has led the World Health Organisation to declare that reducing diagnostic errors should be considered a global priority!

Given that errors in clinical diagnosis are primarily tied to faulty reasoning and cognitive errors rather than a systemic problem, it requires a significant re-envisioning of the diagnostic process.

> "Diagnostic error is a complex and multifaceted problem; there is no single solution that is likely to achieve the changes that are needed."
>
> *- Committee on Diagnostic Error in Health Care, National Academy of Medicine, USA*

The Efficacy of Checklists

Checklists have been implemented with substantial success in various fields like agriculture, aviation and military. They have also proved to be a useful tool to improve patient safety in different healthcare settings, like averting healthcare–acquired infections and preventing errors in the surgical process.

A checklist organises the process into sequential, step-by-step tasks, thus simplifying complex work.

Accordingly, several checklists have been developed to reduce diagnostic errors by integrating the cognitive, systems and patient factors that have emerged as the root causes for diagnostic errors. They can help overcome failures to consider the correct diagnosis due to simple oversight or when the patient does not present the symptoms properly.

John W. Ely and Mark L. Graber in their path-breaking paper on 'Preventing Diagnostic Errors in Primary Care' recommend a simple two-part checklist developed specifically for family medicine. In their words, "Get a second opinion from yourself by using a diagnostic checklist and constructing an appropriate differential diagnosis. Even when the diagnosis seems straightforward, physicians should take a 'diagnostic time-out' to step back and review a checklist that may suggest other possibilities - an approach that would tend to counteract almost all of the common cognitive slips."

The first part is a process-focused checklist which triggers more deliberate thinking by prompting the physician to review the most troublesome cognitive failings when diagnosing a patient. It is basically 'debiasing' as it reduces errors caused to cognitive biases on the diagnostic reasoning process. The second part is more content-specific – it will provide relevant knowledge or trigger them to activate their knowledge by forcing consideration of all reasonable causes for a patient's symptoms. The specific diagnostic steps or suggestions are designed to generate a comprehensive clinically-oriented differential diagnosis.

The researchers have acknowledged that physicians often feel pressured to arrive at a diagnosis with little contemplation, because this helps assure patients that they know what they are doing. They have to make decisions under conditions of great uncertainty and limited time.

Common Types of Diagnostic Errors

The basic idea behind checklists is to provide an alternative to reliance on intuition and memory in clinical problem solving!

PART 1 - GENERAL CHECKLIST

These represent high-risk circumstances that should prompt a diagnostic 'time-out' and review of a differential diagnosis checklist:

- **Did I just accept the first diagnosis that came to mind without considering other possibilities? (anchoring bias)**
- **Did the patient come with a diagnosis that may not be correct?**
- **Are there data that should be reviewed before the patient leaves (e.g., information from old records, family members, ambulance crews, or previous clinicians)?**
- **Is there anything that doesn't fit or doesn't seem consistent with the diagnosis?**
- **Did I take the history, do the physical examination, and review the radiographs myself?**
- **Was the patient seen recently for the same problem? If so, what was done, and what has changed since then?**
- **Are there external pressures (e.g., physician fatigued, distracted, or angry; patient drunk or hostile; time pressure (behind schedule); 'quitting time' phenomenon (end of shift or 5:00 p.m. on a Friday)?**

While they may not be able to take a time-out, reviewing a checklist will take not more than a minute. What's more, the process can be carried out mentally after sometime. And, as the extra thought and systematic approach leads to better diagnosis, it will also inspire trust and confidence in the patients.

The following suggestions by various experts are further designed to support the physicians in their diagnostic decision-making by reminding them of the correct diagnostic steps and ensuring that any possible diagnosis is not overlooked:

- Listen closely to the patient's symptoms. Make them feel comfortable to share openly.
- Try to understand the concerns, ideas and expectations of the patients by asking open questions.
- Focus on the medical history of the patient as the current complications and issues can arise from previous health problems.
- Discuss with the family members or caregivers as they can provide valuable insights into the patient's problems and behaviour.
- Don't rely merely on intuition – Always construct a differential diagnosis. Diagnosis-specific decision support resources can help here.
- Ensure all ordered diagnostic tests and consults are completed and that you know the results.

Conclusion

Checklists are not a substitute for training and experience. However, they have the potential to lead to a more reliable and safe diagnosis!

Involved Patients can Reduce Diagnostic Errors

Every member of the clinical team plays a role in ensuring that the diagnosis is accurate and timely. This umbrella includes patients and their family members/caregivers as they can provide valuable inputs to facilitate the diagnostic process. In fact, the patients, families and healthcare professionals have to work together as partners to improve diagnostic safety. This will also set the stage for improved decision making about the path of care!

As patients, we should be more proactive and involved to reduce the risk of diagnostic errors!

WHEN A DIAGNOSIS is accurate and made in a timely manner, a patient has the best opportunity for a positive health outcome because clinical decision making will be tailored to a correct understanding of the patient's health problem (Assessing Clinical Reasoning - Holmboe ES, Durning SJ).

Research suggests that communication breakdowns during the patient-doctor interaction are a leading contributor to diagnostic errors. Indeed, some of the diagnostic misadventures can actually be mitigated by more aware and involved patients. This is why patients are now being encouraged to take a more proactive role in their own care and safety. In fact, suffering from diagnostic mishaps for a long time, patients themselves are now seeking more opportunities for participation in their own care!

Sometimes a diagnosis is the most 'likely' thing that is wrong, but it may not be the 'right' diagnosis!

What Patients Should Do?

As a patient, you play an integral role in helping the healthcare provider make an accurate diagnosis and co-creating an optimal treatment plan. Accordingly, you have several responsibilities to ensure that the diagnosis is correct and has the greatest chance of being effective.

One of the annual international Diagnostic Errors in Medicine conference – organised by the Society to Improve Diagnosis in Medicine (SIDM), a non-profit organisation focused solely on the problem of diagnostic errors and improving the accuracy and timeliness of diagnosis – laid out several recommendations for patients on how they can assist the physicians in reaching an accurate diagnosis:

- Tell your story well (careful communication)
- Be a good historian (attention to timing detail)
- Be a good record keeper (attention to documentation)
- Be an informed consumer (awareness)
- Facilitate communication and coordination among different people involved in care
- Ensure test results are known
- Ensure follow-up (do not assume no news is good news)
- Encourage your doctors to think broadly
- Understand uncertainty in diagnosis (assume you have a 'working diagnosis' that may change)

(The above list was compiled by three researchers from different medical universities in USA in their paper on 'The Patient Is In: Patient Involvement Strategies For Diagnostic Error Mitigation')

This requires you to take a hands-on approach from the beginning. Share all the minute facts related to your symptoms and medical history. Be clear, complete and accurate when elaborating on the ailment. Narrate the symptoms, their effects, their progress, home treatments (if any), your worries and other details in a chronological order to avoid confusion.

Make efforts to learn more about your health condition by taking second opinions and researching from reliable sources on the internet. (However, the latter can open the floodgates of information overload, contradictory information, misinformation and misguided self-diagnosis.) Be informed about the tests, procedures and medications that have been prescribed. Do not miss follow-up appointments or avoid diagnostic tests either.

Above all, do not hesitate to ask questions and get clarifications, as needed. Note down the information so that you can refer to it easily.

You can no longer afford to be lulled by the fallacy that no news is good news! Be proactive by taking charge of your own health during the diagnostic and treatment process.

While patients are encouraged to ask questions to the extent of, “What else could this be?”, “Do all my symptoms match your diagnosis?”, “Could there be more than one thing going on?”, etc. to encourage the doctors to think about other possible reasons for the illness, they often encounter various communication hurdles with their healthcare providers.

Key questions patients can ask their healthcare provider to reduce diagnostic problems:

- What are my primary concerns and symptoms?
- How confident are you about the diagnosis?
- What further tests might be helpful to improve your confidence?
- Will the tests you are proposing change the treatment plan?
- Are there findings/symptoms that do not fit your diagnosis?
- What else could it be?
- Can you facilitate a second opinion by providing me with my medical records?
- When should I expect to see my test results?
- What resources can you recommend for me to learn more about the diagnosis?

Source: Graedon and Graedon

For starters, the hierarchical relationship with physicians is characterised by less-than-candid conversations and information exchanges. The doctors are often 'authoritarians' and do not like being questioned by the patients. Many of them perceive any queries about the veracity of the diagnosis or possibility of other options/treatment as 'second guessing' and questioning their expertise. Such patients are often termed difficult or contrary. Even a patient's attempt to clearly understand the diagnosis can be summarily blocked by the consulting doctor.

The fact remains that many patients are reluctant/ scared to ask questions or assert themselves as this can even affect the quality of care they receive. They may also not be aware about which information is valuable for the diagnosis or when to be concerned that the diagnosis is off track.

The healthcare providers cannot always be blamed either, as most often, they don't have sufficient time and are in a hurry to move on to the next patient. Burdened by a busy schedule, they may prioritise diagnostics, sometimes at the expense of empathetic connections to the patient's point of view.

As a patient, you should continue to document your medical history and track changes in the symptoms/ illness presentation and share it in a timely manner. Always communicate clearly with the healthcare provider, be it primary care physician, assistant, nurse, therapist or other professionals involved in your care. Also ensure that your diagnostic test results are reviewed and be willing to participate in follow-up and feedback.

What Healthcare Providers Should Do?

The initial patient interaction is crucial as it sets the stage for the diagnosis and treatment. This calls for patient engagement and having a patient-centric approach right from the start.

When taking a patient's history, the focus should be on understanding the symptoms and how they build up over time. This calls for active listening skills and empathy so that the patient feels safe to share even sensitive information about their health and symptoms.

Key suggestion of the US National Academy of Medicine's report - Involve the patient as a partner in the diagnostic process!

Just listen to your patient, he is telling you the diagnosis!

- Dr William Osler, Father of Modern Medicine

How Patients can Prevent Errors in Diagnosis

Challenges Experienced by Patients and Their Families During the Diagnostic Journey

Patients and families sometimes:

- Fear complaining, being seen as difficult
- Feel powerless for many reasons (sick, scared, social status)
- Do not always take own problems seriously enough
- Are unsure about basics of the health system or involvement opportunities
- Have difficulty dealing with inexperienced doctors who are trying to appear experienced in the problem
- Are unsure how to get 'the supervisor' when issues are not resolved at frontline

Healthcare professionals sometimes:

- Dismiss patients' complaints and knowledge
- Do not listen to concerns about serious symptoms or deteriorations
- Give psychiatric, alcoholic or drug abuse diagnoses incorrectly during undiagnosed phase

Source: Synthesised from the Diagnostic Errors In Medicine conference by the researchers mentioned earlier

Furthermore, the physician should appreciate that the patient has minimal knowledge about the diagnostic journey and the destination is largely unknown. Therefore, gently prompt him/her to share not only the current concern, but also past medical history, family history, social history, current medications (prescription and over-the-counter) and dietary supplements. Also, use plain language and avoid medical jargon to ensure clear understanding.

In other words, healthcare professionals should create an environment where patients feel comfortable participating in the diagnostic process. Be open and approachable; encourage the patients to ask questions and discuss their doubts. They should not feel defensive when someone challenges their assumptions or seeks a second opinion.

Over and above this, share the working diagnosis with the patient and discuss any diagnostic uncertainties. Make sure the patient knows what symptoms to look for, what the expected time course of their illness is, when and how to initiate contact if their condition does not improve, the symptoms evolve or do not resolve as expected. Such empowered patients will act as a safety net as they themselves will watch for new symptoms emerging over time.

Hence, the healthcare professionals should adopt a patient perspective and realise that two-way communication with feedback will improve their clinical reasoning manifold. This calls for establishing a rapport with the patient through effective communication that is tailored to his/her needs, values and preferences. Then, the patient interview will not only yield important information for determining a diagnosis, but will also establish a solid foundation for the relationship.

To conclude, effective communication and collaboration among the healthcare professionals and the patients/their families is essential to reduce the risk of diagnostic errors as well as improve healthcare and outcomes.

Incidence of Medical Errors – Where Do We Stand?

Healthcare is becoming increasingly hazardous with a high incidence of medical errors. Diagnostic errors are a primary concern in both developing and developed countries. While exact numbers are not available for India, the situation is definitely alarming!

PATIENT SAFETY IS a serious global public health concern. The World Health Organisation (WHO) has unequivocally stated that while there is a 1 in a million chance of a person being harmed during air travel, there is a 1 in 300 chance of a patient being harmed during healthcare! So much so that, sectors with a perceived higher risk - such as aviation and nuclear industries - have a much better safety record than healthcare!

Alas, what is meant to save lives itself is putting people's health in jeopardy!

Patient harm is the 14th leading cause of the global disease burden, comparable to diseases such as tuberculosis and malaria! 2.6 million people die annually around the world due to medical errors. Nearly 138 million patients in low- and middle-income countries suffer harm due to medical errors every year.

– WHO

The WHO further estimates that of the 421 million annual hospitalisations around the world, around 42.7 million suffer from adverse events. Of this, approximately two-thirds occur in low- and middle-income countries (LMICs). As many as 1 in 10 patients is harmed while receiving hospital care in high income countries, with nearly 50% of them being preventable. In contrast, the rate of adverse events is around 8% across 26 LMICs, of which 83% could have been prevented and 30% led to death.

Furthermore, 15% of total hospital activity and expenditure in OECD (Organisation of Economic Cooperation and Development) countries is a direct result of such adverse events!

Other studies reveal that medical errors result in as high as 251,000 deaths annually. In Australia, around 140,000 cases of medical errors occur per year, resulting in almost 2000 to 4000 deaths. Numerous studies have confirmed that medical errors are more prevalent in the underdeveloped parts of the world.

Patient harm can be caused by a range of factors, including errors in diagnosis. However, not much is known about the full scope of harms related to medical misdiagnosis. The current estimates tend to vary widely.

Medical errors are the third leading cause of death

– National Academy of Medicine, USA.

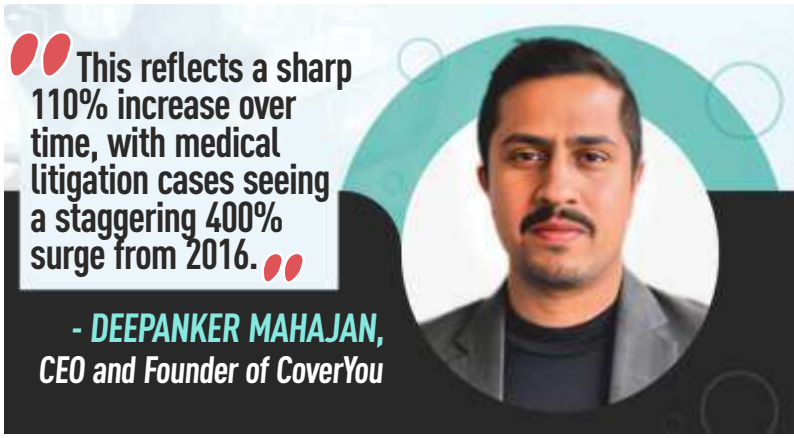
The most common estimate is that around 5% of adults in the United States experience a diagnostic error each year in outpatient settings. In the hospital setting, diagnostic error is responsible for 6% to 17% of adverse events. Evidence from low- and middle-income countries is limited; however, the expected rate is higher than their high-income counterparts.

The Indian Scenario

There isn't much data about the incidence of medical errors in India. The problem is further complicated by the lack of culture of reporting and recording medical errors. A study by Harvard University way back in 2013 estimated that 5.2 million medical errors occur annually across India each year with approximately 3 million years of healthy life lost due to them. An average of 12.7 adverse events occur for every 100 hospitalisations.

Medical malpractice litigation can give insights into the errors taking place in healthcare. This covers cases of negligence by a professional healthcare provider -be it a doctor, nurse, dentist, technician, hospital or hospital worker. It is basically any deviation from the accepted standard of care compared to similarly trained and experienced providers, often resulting in harm to a patient.

Research from the National Library of Medicine, published in 2022, shows an alarming annual incidence rate of up to 5.2 million cases related to medical malpractice across various healthcare settings in India.



When it comes to death due to medical errors, about 80% involve surgery. Reports suggest that most of the time the skill or knowledge of the healthcare professionals is not in question. Instead, it is the lack of communication and coordination among team members that is to be blamed. This kind of mismanagement during emergencies leads to around 70% of deaths.

In comparison, an average of 85,000 medical malpractice lawsuits are filed every year in the USA. However, given that a majority of such medical error cases go unreported/unrecognised in most countries, the actual numbers will be much higher!

Improving diagnosis in healthcare is a moral, professional and public health imperative!

- National Academy of Medicine, USA

Current Rate of Patient Safety in Indian Hospitals

NATHEALTH, Healthcare Federation of India conducted a research study on the critical safety challenges in Indian hospitals in association with the National Accreditation Board for Hospitals (NABH), a constituent of the Quality Council of India (QCI).

The report titled, 'Forging a Safer Future – India's Blueprint for Patient Safety Excellence' was released in March 2024. It involved surveys and interviews of healthcare professionals from over 1,100 NABH accredited hospitals pan India. More than 90% of them were privately owned. Nurses and hospital administrators formed the majority of participants, accounting for 29% and 28% respectively.

The findings indicate that patient safety has taken a backseat with the major factors affecting patient safety being safety vs efficiency mindset (42%), inadequate staffing (24%), lack of patient safety culture (24%), scarce learning and reporting (15%) and lack of patient awareness (15%). (see Table 1)

The study further revealed that around 58% of nurses felt pressured to compromise patient safety

TABLE 1

Factors affecting patient safety – Stakeholders' perspective

Top factors affecting patient safety (N = 1,125)

Factors affecting patient safety
(%, N = 1,125)

Region				Stakeholders				
North	South	East	West	Nurse	Doctors	Admins	Med. staff	Mgmt. team
378	***542***	***69***	***136***	***331***	***139***	***316***	***196***	***143***
40%	46%	33%	38%	58%	18%	39%	41%	37%
23%	26%	16%	25%	35%	21%	19%	23%	14%
26%	24%	24%	24%	32%	15%	20%	27%	21%
12%	17%	16%	13%	19%	12%	11%	20%	9%
17%	12%	16%	17%	9%	10%	18%	11%	31%
4%	6%	8%	5%	8%	7%	5%	7%	5%
4%	5%	7%	3%	4%	6%	6%	2%	7%
4%	3%	2%	3%	3%	5%	3%	1%	5%

1st reason 2nd reason

TABLE 2

Patient safety rating perception of stakeholders

Stakeholders	Region				Hospital size			Average
	North	South	East	West	Small	Medium	Large	
Nurses	8.50	7.95	8.20	7.10	7.94	8.33	8.00	8.10
Doctor	8.80	8.30	8.75	8.08	9.00	8.74	8.19	8.51
Admin / Supervisor	8.23	8.17	8.16	8.50	8.28	8.20	8.27	8.25
Medical staffs	8.85	8.25	7.67	7.17	7.64	8.27	8.38	8.19
Top management	8.33	7.97	8.17	7.52	8.03	8.02	8.17	8.06
Average safety rating	8.47	8.11	8.13	7.83	8.12	8.30	8.17	8.20

Low → High

Dr. ASHUTOSH RAGHUVANSHI

President, NATHEALTH; MD & CEO, Fortis Healthcare Ltd.

> **This white paper represents a crucial step towards enhancing patient safety in India, offering a detailed overview of the current landscape, challenges, and actionable recommendations for improvement.**

over the efficiency of hospitals. 35% of them complained of inadequate staff, while about 32% blamed poor patient safety norms for ineffective patient safety.

Doctors echoed similar concerns, with 18% of them claiming they are pressured to compromise on patient safety over efficiency. 21% blamed inadequate staff at health institutes as a significant challenge to patient safety.

On the other hand, the hospital managements focused on the challenge of balancing speed of services and safety (37%), and a limited focus on patients' rights (31%).

The average patient safety rating landed at 8.20, with doctors expressing the most confidence in patient safety (8.51) compared to other participants. Top management, on the other hand, had the lowest perception with an average rating of 8.06.

AI Can Pave the Way to Diagnostic Precision

Our healthcare system is stretched thin and the healthcare professionals are heavily overburdened. Artificial Intelligence (AI) can come to the rescue with tools that simulate human intelligence in machines, thus empowering them to perform tasks that typically require human cognitive abilities. This spells great promise in the clinical diagnosis realm!

AI has great potential to reduce diagnostic errors, enhance patient safety and improve healthcare!

WITH THE RAPID evolution of healthcare, the intricacies of medical diagnosis have also grown exponentially. Numerous interrelated factors can lead to diverse harms to the patients. The clinical cases have become more complex, copious amounts of data is generated which remains disorganised and the physicians are largely stressed and on the brink of burnout.

Ensuring patient safety in this dynamic environment poses a formidable challenge for healthcare professionals and institutions alike. They not only need to retain tons of available baseline knowledge, but also apply it in the challenging work environment. Here, the integration of AI into healthcare holds great potential for reducing - or even overcoming - some of the challenges, thus blazing a trail for achieving diagnostic excellence!

AI is already being deployed in various healthcare applications, especially in the developed world. The success curve is impressive, specifically in the field of laboratory testing and radiology imaging. In the past few years, some AI tools have demonstrated unmatched accuracy in reading and analysing medical test results and images, thus increasing diagnostic precision and reducing errors. Many studies have also indicated that AI-powered algorithms trained on vast datasets outperform evaluations by radiologists with lower false positives and false negatives.

Leveraging AI for Clinical Decision Support

AI has the potential to provide healthcare professionals with relevant information during patient examinations so that they can make better and more informed clinical decisions. It can suggest evidence-based diagnosis and treatment options or even caution against potential treatment-related complications.

Some non-AI clinical decision support systems are already in use since the past few decades. Integrating machine learning can further enhance their capabilities by allowing simultaneous consideration of multiple data sources. More advanced Direct Learning and Natural Language Processing (NLP) models can have a greater impact on patient safety.

Such AI models can analyse large amounts of texts and knowledge bases on the one hand and process real-time data from health records on the other. This will ensure that critical information that may impact a diagnostic decision does not go unnoticed. There will also be real-time access to evidence-based guidelines, up-to-date medical literature and a range of differential diagnoses.

The suggestions can complement the physicians' expertise to ensure that all possible diagnostic options are considered while also avoiding cognitive biases of human thinking. What's more, the evidence-based recommendations and predictions can also be dynamically adjusted based on new data about patients.

A scoping review in 2021 by the Patient Safety Network explored the impact of AI on eight main patient safety domains, suggesting that AI's influence would be most pronounced in domains where existing strategies have proven insufficient and where integration and analysis of new, unstructured data is crucial for accurate predictions. Such domains include adverse drug events and diagnostic errors.

It was further stated that diagnostic error is the most complex of the eight harm domains with vast opportunities for improvement using novel data sources and AI. AI can help reduce the frequency of diagnostic errors by leveraging pattern recognition, bias minimisation, and infinite capacity, areas where diagnosticians often falter.

AI is not intended to replace healthcare professionals; it will only augment their capabilities. AI technologies, such as chatbots and diagnostic algorithms, can serve as valuable decision support tools, assisting physicians in complex diagnostic scenarios and reducing the likelihood of errors.

In simple terms, healthcare professionals can use AI to efficiently validate their diagnostic assessments and ensure that common conditions are not overlooked!

Limitations

The use of AI in healthcare is an emerging field with research still in progress on how to implement these technologies in live clinical practice. It is hampered by the lack of availability of large databases that accurately report errors.

The algorithms also need to be reviewed by peers, tested prospectively and validated in clinical settings. Prospective evidence linking AI tools to positive physician experience, reduced diagnostic errors and improved patient outcomes are essential for them to translate into widespread implementation in real-world practice.

As with all AI applications, the inherent risks of data quality, bias, privacy and security also need to be carefully considered before and during implementation. Lack of good quality training data or underrepresentation of certain groups can lead to inequitable results. Not to mention that the tools may miss critical signs or generate false alarms. This calls for rigorous validation and ongoing monitoring of AI systems.

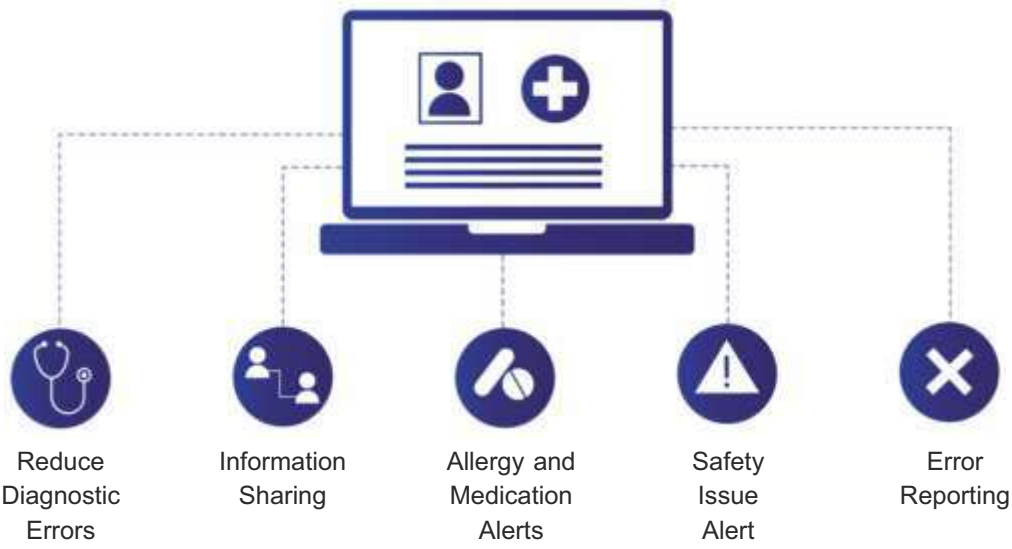
Responsible implementation is the need of the hour to maintain patient privacy and confidentiality. Informed consent is another avenue that calls for thoughtful consideration. Robust data security measures cannot be discounted either.

While integrating AI into healthcare for improving diagnostic safety poses a number of ethical and technical challenges, major opportunities for its adoption in daily clinical practice are visible on the horizon!

> **"As we tread this path of harnessing AI to prevent medical errors, collaboration is key. Healthcare professionals, policymakers, and technology developers must work together to navigate these complexities. Responsible and ethical AI deployment is vital to achieving safer and more efficient healthcare."**

PETER KIRPALANI-COLLINS
Global Clinical Director, Huma
– an international healthcare company

HOW CAN EHR TECHNOLOGIES HELP AVOID MEDICAL ERRORS



Glimpses of Pharmacovigilance and Patient Safety in Ayurveda

Prof. VAIDYA RABINARAYAN ACHARYA
Director General, Central Council for Research in Ayurvedic Sciences (CCRAS),
Ministry of Ayush, Govt. of India

Prof Acharya has more than 27 years of teaching and research experience in various fields of drug research and has more than 400 research articles in peer-reviewed journals, 5 books and 12 book chapters to his credit. Prior to DG, CCRAS, he has served in different capacities in the Ministry of Ayush, such as Dean, ITRA, Jamnagar, Chairman, Ayurvedic Pharmacopoeia Committee, Member Scientific Advisory Group for Drug Development CCRAS, Member Secretary of National Pharmacovigilance programme of ASU Drugs, etc.

PHARMACOVIGILANCE IS A crucial aspect of medical practice, dedicated to improving patient safety by evaluating the risk-benefit profile of medications. According to the WHO, it is defined as "the science and activities related to the detection, assessment, understanding, and prevention of adverse drug effects or any other potential drug-related problems."

Genesis of the Pharmacovigilance Program for Traditional Medicine in India

The concept of a pharmacovigilance program for traditional medicine in India began to take shape in November 2006, primarily spearheaded by the Department of Clinical Pharmacology at TNMC and BYL Nair Charitable Hospital, Mumbai. This initiative gained further momentum during a dedicated session at the Society of Pharmacovigilance of India, a seminar held at Aligarh Muslim University. In December 2007, the next major step, sponsored by the WHO, was taken by the Institute of Post Graduate Teaching and Research in Ayurveda (IPGTRA) at Gujarat Ayurveda University, Jamnagar.

Building on these efforts, in 2008, IPGTRA was designated as the National Pharmacovigilance Resource Centre for ASU (Ayurveda, Siddha, and Unani) Drugs

under the Department of Ayush, as part of the National Pharmacovigilance Program for ASU Drugs.

In 2018, the existing program underwent significant modifications, incorporating Homoeopathy and adding misleading advertisements as a key component of this national initiative. The All India Institute of Ayurveda (AIIA), New Delhi, was established as the National Pharmacovigilance Coordination Centre (NPvCC), overseeing 99 Peripheral Pharmacovigilance Centres nationwide.

Evidence of the Concept of Pharmacovigilance in Ayurveda

Pharmacovigilance, as understood today, finds its roots in the classical texts of Ayurveda, which have long emphasised the safety and efficacy of medicinal use. One such example is the verse, "*Yogadapi visham teekshnam uttamam bheshajam bhavet, bheshajam chapi duryuktam teekshnam sampadyate visham*," which translates to: "Even a poison, when administered prudently, can exhibit therapeutic potential; conversely, a medicine given without proper care can act as poison." This profound statement underlines the importance of correct drug administration which is a fundamental aspect of pharmacovigilance.

Safety Aspects of Medicines: As per *Charak Samhita*, an ideal drug, when administered in the right dose, should be easily metabolised, efficiently eliminate morbid *doshas* (regulatory functional factors of the body), pacify disease, and avoid any adverse effects. The verse emphasises the critical nature of dosage and the preparation of medicine to ensure safety. Before prescribing any drug, a thorough examination, considering factors like constitution (*prakriti*), age, tolerance, physical strength, and tissue quality, is recommended.

The classical texts also vividly describe the causes of drug-induced adverse effects, attributing them to untimely administration, incorrect dosing (whether too low or too high), expired drugs, improper processing, and unmetabolised substances. This awareness of potential harm reflects a sophisticated understanding of drug safety within Ayurveda.

The texts also describe traditional procedures for detoxifying poisonous substances, ensuring their safe therapeutic use. For instance, in cases of toxicity from *bhallataka* (marking nut), remedies like coriander and coconut oil are recommended as antidotes.

Ayurvedic *Nighantus* (lexicons focusing on medicinal plants) provide detailed descriptions of drug safety, including the possible side effects associated with various herbs. For example, safflower seed oil is noted to aggravate all three doshas, while excessive consumption of *kulthi* (*Dolichos biflorus* L) is linked to blood disorders. Such careful documentation refutes the notion that Ayurveda is inherently safe regardless of circumstances.

Safety Aspects of Therapeutic Procedures: Ayurvedic texts also dedicate specific chapters to managing side effects (*vyapad)*, particularly those arising from *Panchakarma* procedures, often due to faulty drug preparation, faulty administration or improper patient assessment. These ancient texts provide a comprehensive framework for ensuring patient safety, underscoring the long-standing tradition of pharmacovigilance in Ayurveda.

Safety Aspects Related to Diet: Dietary recommendations have been given for healthy individuals under '*nitya sevaniya*' i.e foods recommended for daily consumption as well as those which are contraindicated for consistent daily consumption. Seasonal regimens along with lifestyle changes have been denoted in order to acclimatise and safeguard health in the respective season. In addition to this, specific dietary conventions have been designated for peculiar pathological conditions that entails the concept of nutravigilance in Ayurveda.

In Ayurveda, the concept of food-drug incompatibility is well-documented, with specific reference to the effects of excessive consumption of certain tastes (*rasas*) on health, including during pregnancy, where it can lead to foetal anomalies.

Safety Aspects Related to Patients: The emphasis on patient safety is further evident in Ayurveda's holistic approach to healthcare delivery, which rests on four pillars: the physician, the caretaker, the patient, and the therapy. The texts prescribe specific behavioural norms, personal hygiene, and ethical conduct for the physician and support staff. Pertaining to patient, it refers that an ideal patient is one who is tolerant, obedient and conscious enough to narrate his symptoms.

Moreover, Ayurveda's detailed guidelines for surgical, parasurgical, and *Panchakarma* procedures include clear inclusion and exclusion criteria, along with contraindications for certain drugs like *Haritaki* (Harad) and *Panas* (Kathal). Vulnerable populations, including children, women, pregnant women, and the elderly, are given special consideration, with paediatric doses advised to be lower due to a child's tender constitution and dependency.

Initiatives of CCRAS in Context of Pharmacovigilance and Patient Safety

CCRAS has undertaken a retrospective observational study pertaining to gross safety and prescription trends of different Ayurvedic *Rasaushadhis* (herbo-mineral preparations) at different geographical regions across the country. No untoward effects were reported to be associated with the prescribed Rasaushadhis. CCRAS has also published research studies on safety profiles of Ayurveda Rasaushadhi.

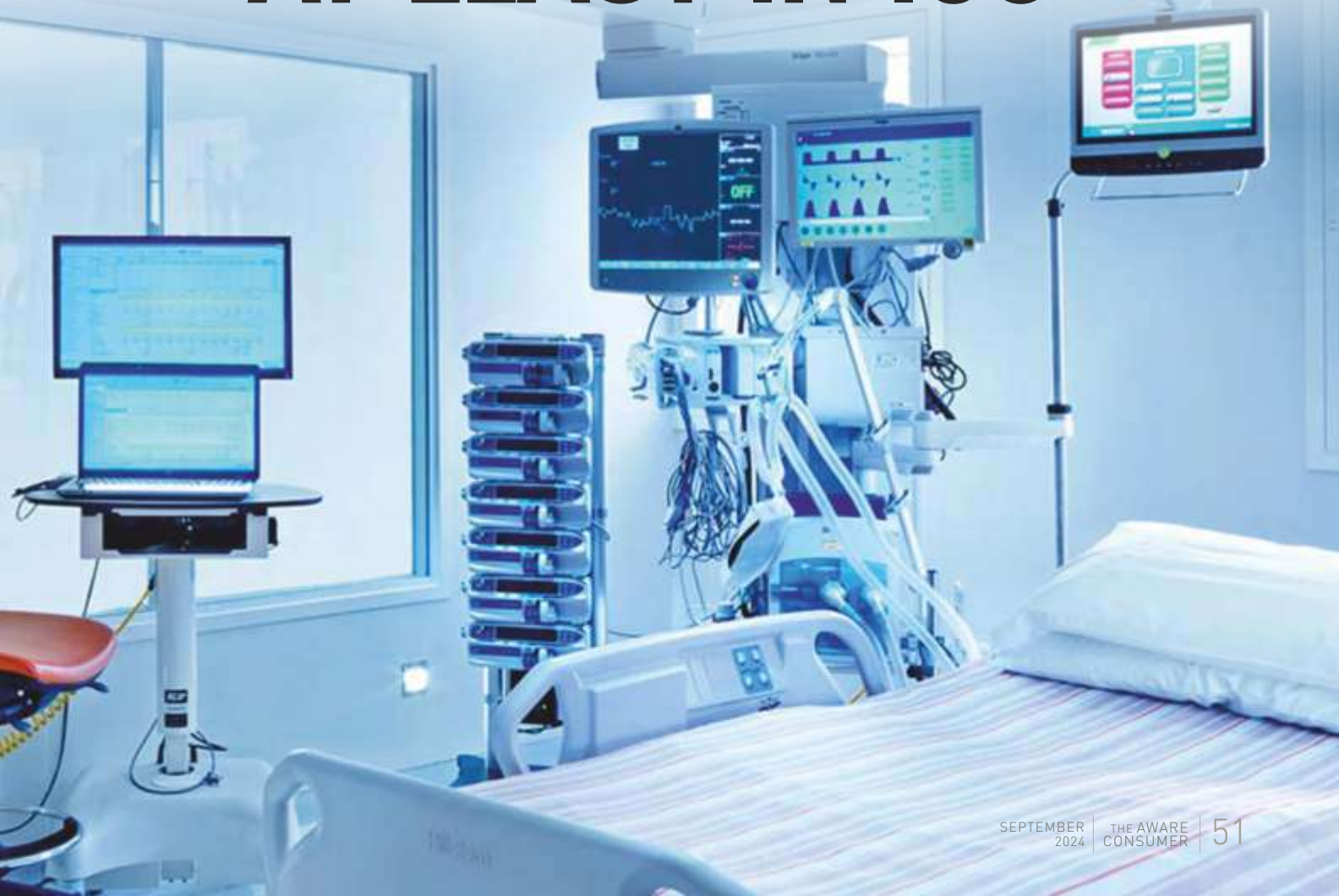
CCRAS has initiated some survey-based studies in various regions of India to obtain information on cognizance about the concept of pharmacovigilance and is also engaged in the documentation of prescription trends of Ayurvedic formulations and OTC drugs.

Thus, to conclude, prudent use of herbal/herbo-mineral formulations, cautious application of diagnostic methods and therapeutic procedures in accordance with basic Ayurvedic fundamentals emphasising patient safety can lead to a successful and safe healthcare delivery of Ayush.

Dr. VIJAY KUMAR
IAS (Retd.)
former Principal Secretary to Government of Andhra Pradesh

A qualified Healthcare Administrator (M.D.) and Dip. NBE in Health and Hospital Administration, Dr. Vijay Kumar possesses extensive work experience in medical and health genres. He is also an experienced executive officer with history of working for the government.

BE INFORMED... AT LEAST IN ICU



A Case for Statutory Intervention

Some time ago, a patient was admitted into the ICU of a private hospital in Delhi. One day, the treating doctor organised a video conference in which the doctor, patient and patient's family members participated. The treating doctor informed that the patient is recovering and will be shifted to a room. The patient's family members had given the medicine to the doctor which the patient was taking for seizures and clearly informed the doctor that these medicines are a must for the patient. If not given, the patient will get seizures and there will be medical consequences. The day next to the video conference, the patient got seizures and died because of cardiac arrest. This happened because the doctor did not give the medicine for seizures which resulted in the tragedy. It all happened because the patient's family members did not have right to information about the patient's treatment.

Right from the independence of the country, there have been several attempts in the form of Bhore Committee, Mudaliar Committee, Alma Ata Declaration, Health for all, etc., but no concrete steps were taken to implement reforms in the field of Right to Information about patient's treatment in the health sector.

The critical care in ICU requires highly complex decision making and by implication it is data intensive. Generally, the data available at the bedside monitor is, although visually available for use, not digitally stored to be provided to the patient. There is no standard analytical approach for this data across the globe. (The standard operating procedures may not be available on this issue).

There is a definite case for data interoperability and integration with the electronic medical record. This is at present the need of the hour and must be taken up in overall larger public interest, at least in the developing countries like India, where the patients do not have resources to have access to remedial measures like intervention by Court of Law. There are numerous

existing clinical information systems in the ICU, but they have limitations i.e., there is no provision or analysis of data to a great extent, limitation in terms of functionality, etc.

Of course, there is a legal provision to keep the information about patient's medical status confidential but this right to confidentiality (available with the treating doctor) is certainly not applicable to the patient's family members/care taking attendants, etc. and therefore the clash of interest on this aspect between treating doctor on one hand and patient on another hand is at the most only a myth and redundant.

In this milieu, there is a definite need for communication with the patient in the form of gestures, words, alphabets, head nods, writing etc. which becomes crucial for the patient to have access to 'Right to information' under the Charter prescribed by Government of India.

The Government of India in the year 2017 came out with a Charter of 17 rights available with the patient out of which the following rights have direct relevance to the present context in patient's life. Additionally, the Universal Declaration of Human Rights (Article 1, 3 and 25) deals with the rights of patients. The WHO defines patient's rights as those owed to the patient as a human being by physicians and by the State. These rights vary from State to State and depend on socio-cultural factors (paramount is that right should exist and be practiced). Even these factors have not agitated the State to take any action in this regard.

Basic rights of patients (In USA,

right to medical records and right to privacy are legally accepted as basic rights.) cannot be given unless they are made enforceable rights. This is only possible through a statutory intervention by making a law. The involvement of statutory bodies, professional associations, regulatory bodies etc. can only galvanise the State to act in the public interest.

In India, a rights-centric approach does not exist as rights have not been made enforceable. At present, the only remedy is to approach a Consumer Court. Violation of patient rights is not a cognizable offence in India (unlike USA & some European countries) and therefore criminal proceedings cannot be initiated.

The Medical Council of India (now National Medical Commission) issued the Code of Ethics Regulations (COER). This Code does not represent patient rights although it mentions certain rights incidental to the main charter of duties and responsibilities of the doctors.

There is definitely a clash of interest between the doctors and patients in terms of confidentiality about disease of the patient on one hand and the patients attendants knowing about the treatment given on the other hand. Therefore, there is a paramount need for tilting the balance in favour of public interest which obviously means in favour of the patient. The confidentiality clause applies only when the third party is involved, whereas we are only concerned about the rights to be made available to the patients.

There are different options available with the State e.g. Patients Advocacy Group, National Health Regulatory and Development Authority (NHRDA), NABH if given authority, any other platform etc. which the State or Planning Authority deems fit. and unless this statutory backing is given to the patient, it is going to be a mirage in a country like India. Although there are certain Statutes like Consumer Protection Act, Drugs and Cosmetics Act, Magic Remedies Act, etc. but these laws only provide limited protection to the patient and that too indirectly.

The NHS in England promulgated an order named as NHS Constitution for England in the year 2013 which sets the rights of patients but this order also is not legally enforceable and therefore the oldest democracy of the world is still finding ways to deal with the situation.

In this scenario, the different options available with us are

- Enforceable right through a Statute
- Enforceable right through a Charter and violation to result in cancellation of approvals
- Contract among patient and healthcare provider governed by Indian Contract Act, 1872 (All rights to form the ingredients of contract)

There was a window provided in the form of Andhra Pradesh Medicare Service Providers and Medicare Institutions (Prevention of Violence and Damage of Property) Act 2008 which acted as a deterrent. But the tragedy is that this law was enforced for the first time in the state of Telangana in 2018 only, which speaks about itself.

The Supreme Court of India in a number of judgments held the right to lead a healthy life as part of Right to Life as provided in Article 21 of the Constitution. It was further expanded to include the right to medical care and a telescopic expansion of that automatically is deemed to include the right to information about ongoing medical care. Therefore, the only solution is to provide a framework for implementing this constitutional obligation through a 'Mandamus' by the highest Court in the country.

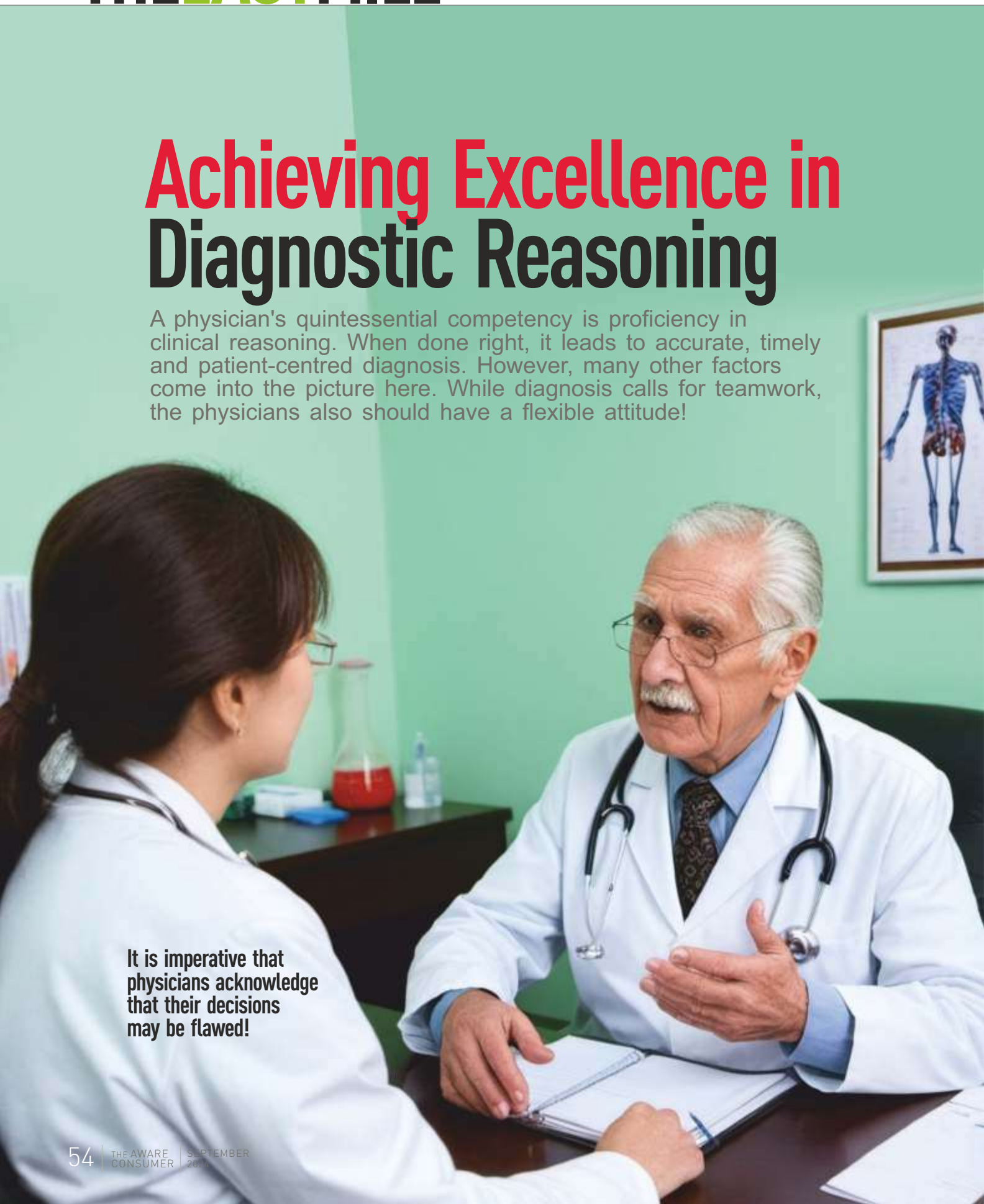
There is massive public interest (overt, covert) in the society to demand for such a right from the State which should be enforceable and there is a corresponding legitimate responsibility on the part of the State. The legitimate and reasonable expectation by the society should be honoured through the Doctrine of Legitimate Expectation as held by the Supreme Court of India in FCI Vs. Kamdhenu Cattle Feeds Private Limited, wherein a categorical reference was made about Article 14 of the Constitution.

If the law making responsibility is taken as a resource, then the Doctrine of Public Trust demands that the State uses this resource to attain and provide enforceable Right to Information in Health under Article 21 as envisaged by the constitution makers. It is the fundamental desire of any human being to control life i.e. to control health, and sine-qua-non for that is timely information about health service delivery in ICU as an enforceable right.

The State, as custodian of people in general, is to be committed to provide such a legal authorisation to ensure that the basic tenets of Article 14, 21 of the Constitution are realised not only in letter but in full spirit. That probably will be the first step towards realising the intent and dreams of the constitution makers in this great nation called India!

Achieving Excellence in Diagnostic Reasoning

A physician's quintessential competency is proficiency in clinical reasoning. When done right, it leads to accurate, timely and patient-centred diagnosis. However, many other factors come into the picture here. While diagnosis calls for teamwork, the physicians also should have a flexible attitude!



It is imperative that physicians acknowledge that their decisions may be flawed!

DIAGNOSTIC ERRORS ARE the most common cause of medical errors reported by patients. Given the level of trust patients have in physicians, a diagnostic error becomes scary and confusing. The experience not only impinges on a patient's confidence in the physician, but also reduces trust in the entire healthcare system.

Indeed, timely and accurate diagnosis is the foundation of a good clinical practice. The doctors learn and recall the information during the patient consultations. They use their knowledge and skills to diagnose the ailments, implement treatment plans and halt the progression of the diseases.

It is no secret that physicians equate their diagnostic skills with clinical acumen and expertise. There is no denying that they have a professional duty to perform their work so that it meets a certain standard of care. However, fallibility is intrinsic to all human beings, and the healthcare community is no exception!

Dr. SHERWIN B. NULAND
in his award-winning book,
'How We Die'

> **"Diagnosis is every doctor's measure of his own abilities; it is the most important ingredient in his professional self-image!"**

> **Every diagnostic error does not mean that a doctor has been grossly negligent, but awareness of their own fallibility and its consequences can help them become better at their job!**

Diagnostic errors can and will happen – it could be due to a physician's fault or other factors may be at play. However, physicians have a tendency to perceive such errors – both actual and perceived - as a personal failure of the physician. This can lead to profound psychological effects, like anger, guilt, inadequacy, depression and even suicidal ideation.

Healthcare professionals have to understand that medicine is complex and diagnosis is not an exact science. While the onus of diagnosis on the physician, they cannot always be right!

On the other hand, it is necessary for the physicians to reflect on their mistakes, rather than sweeping the errors under the carpet. After all, a human life could be at stake!

Doing Things Right

Optimising the diagnostic thought process calls for a deep commitment to lifelong learning and expertise principles. The physicians need to keep learning from the patient problems that they encounter in daily clinical practice and embrace the diagnostic challenges with a positive attitude.

There is a lot they can do to educate themselves about common diagnostic errors. A wealth of information, resources and evidence-based strategies are available – they can be applied by any physician trying to make a good diagnosis!

Overconfidence has been identified as a major cause of diagnostic errors in clinical settings. Overestimating one's skills and abilities can lead to complacency to the extent that errors may not even come to their attention. Not to mention the tendency to attribute a patient's medical complaint to their own specialty……

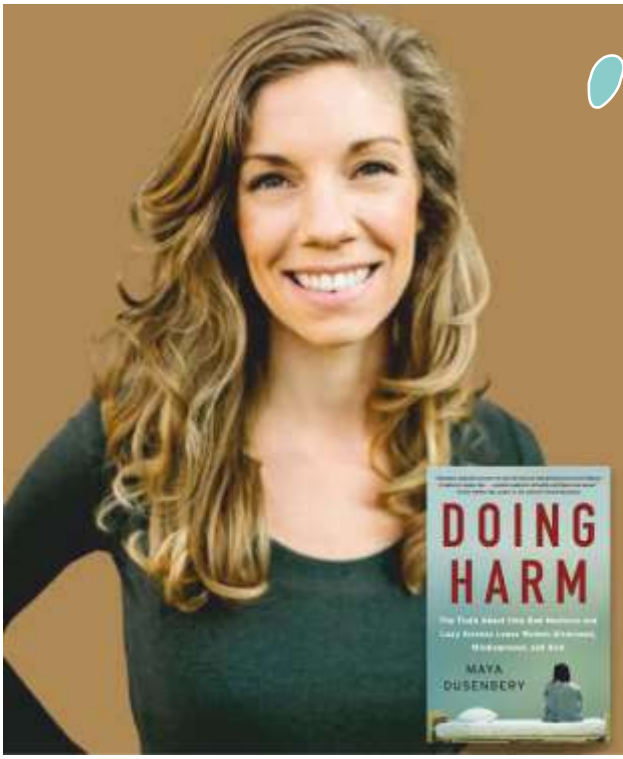
This can be balanced by reflective practice which requires critically considering their own reasoning and decisions, exploring alternative hypotheses and their consequences, willingness to test new, divergent or suggested diagnoses and openness toward deliberation.

The physicians also need to be flexible. This calls for a keen self-awareness so that they can recognise when

> **"Physicians acknowledge that diagnostic error exists, but seem to believe that the likelihood of error is less than it really is. They believe that they personally are unlikely to make a mistake. Indirect evidence of overconfidence emerges from the routine disregard that physicians show for tools that might be helpful."**
>
> *– American Journal of Medicine*

> **"The concept that they, personally, could err at a significant rate is inconceivable to most physicians!"**

Dr. MARK GRABER
Global leader in patient safety and pioneering efforts to address diagnostic errors



> The overconfidence is not necessarily their fault: doctors simply do not get the feedback needed to gain an accurate sense of their batting average. They assume their diagnoses are correct until they hear otherwise. Since there are few, if any, healthcare organisations that systematically measure diagnostic error rates, they typically learn of their mistakes only from the patients themselves.

- MAYA DUSENBERY
author of
Doing Harm: The Truth About How Bad Medicine and Lazy Science Leave Women Dismissed, Misdiagnosed, and Sick

DR MARK GRABER
provides the following suggestions for reducing errors in diagnosis:

- Be aware of the odds of being wrong. It is probably closer to 10% than 1%.
- Learn how diagnoses emerge from subconscious processing and the inherent biases that can lead to errors. Learn de-biasing approaches that might prevent these errors.
- Focus on the final common pathway. Once you've come up with a working hypothesis, examine it carefully and consciously. Consider the opposite, rethink your key assumptions, and think about diagnoses that you can't afford to miss. Learn the principles of reflective practice. Ensure follow-up, not only for the patient's sake but for your own cognitive education.
- Seek out feedback. Anything that allows you to learn from your own mistakes or those of others will increase the chances of correctly calling clinical "balls and strikes."

additional information is needed or when they have taken the wrong diagnostic path. It should be followed by the willingness to change.

Furthermore, the physicians should keep in mind that if they don't consider all possibilities or follow best diagnostic practices, they may underdiagnose or miss the chance to provide prompt treatment. Contradictory to this is the tendency to overdiagnose which will just end up wasting precious resources on conditions that are unlikely to affect the patient's health and well-being.

Last but not the least; the physicians should be open to speaking up and reporting diagnostic errors or adverse events. However, when healthcare professionals make a mistake or slip-up, they usually encounter a culture of blame and shame. The physician involved in the care is held responsible and may even be suspended, even if the error is unintentional. This kind of witch-hunting makes them fear reporting the slightest oversight, thus leading to bigger errors which are more likely because of system failures than individual mishaps. It should be noted here that system improvements cannot happen as long as the focus is on blaming individuals.

In conclusion, clinical diagnosis is both an art and a science, requiring a combination of skills and experience! The right approach to making accurate diagnostic assessments will balance out all potential problems, thus eliminating harms and reducing costs of care.

UPDATE ...

Moving a Step Ahead

Update on the July edition

Webinar on 'Can We Trust Used/ Refurbished Medical Devices?'

THE JULY MAGAZINE edition was a starting point for creating awareness on the drawbacks of used and refurbished medical devices. We followed up on this by organising a national webinar - in association with RJS Positive Media - on 28th July, Sunday at 11 am.

The event was graced by the presence of Mr Rajiv Nath as the Chief Guest. He is the Forum Coordinator of the Association of Indian Medical Devices Industry (AiMeD) and MD of Hindustan Syringe and Medical Device Ltd. The keynote speaker was Mr Gouri Sridhar, Managing Director, Surgical Instruments Group Holdings (SIGH) based in the U.K. Our editor and international consumer policy expert, Prof Bejon Misra chaired and moderated the webinar.

A number of noted national and international personalities across domains were in attendance – like, Dr Ramaiah Muthyala, Dr B R Jagashetty, Dr Jai Prakash, Dr Ravi Rathod, Dr Maneela, Dr Abhijit Chattoraj, Ms Bina Jain, Mr Rakesh Bhatia, Mr Rajiv Balakrishnan, Mr Chandrakant, Mr Ishaq Khan and others.

Mr Prafull Sheth delivered the welcome address wherein he raised some pertinent questions about the problems of using second-hand and refurbished medical devices, pricing structure of used medical devices, status of regulation in our country and how patients can be made aware about the drawbacks of refurbished medical devices.

Mr Gouri introduced himself by stating that his company's operations include manufacturing, repair and refurbishment of various medical devices in the UK. He informed the audience that refurbished devices have a lifespan of only 3 to 5 years in the UK. He highlighted the importance of calibration and regular servicing of refurbished medical devices for ensuring patient safety and regulatory compliance. He further elaborated that as the responsibility of the performance of medical devices rests with the manufacturers in the UK, the hospitals are confident about their quality and the patients are not saddled with the additional worry about the reliability of the medical devices. He clarified that though his company received inquiries for refurbished medical devices from India, he refrained from accepting such orders due to his ethics and sense of ownership.

Mr Gouri opined that India has a strong potential to develop its own medical devices. To fill the gap in the short-term, the used medical devices should be calibrated locally followed by annual service checks.

Chief Guest, Mr Rajiv Nath drew attention to the grave situation in India with imports of pre-owned medical devices in the range of Rs 25,000-30,000 crores. He stressed that he is also a consumer and patient like everyone else and is worried about the old machines being used on him when he visits a hospital. He highlighted that when used/refurbished devices are used during medical treatment, we don't even get the price benefit as there is no demarcation between new and old machines.

Mr Rajiv dwelled on the fact that PM Modi did not allow cheap imports of automobiles and mobile phones in India due to which the manufacturers had to set up manufacturing plants in India. This yielded great benefits to the consumers and the same should be replicated for medical devices.

Clarifying the regulation angle, Mr Rajiv informed that the medical device regulations were framed only for new

medical devices as they never thought that pre-owned ones would be imported. Given the current scenario, he stated that they were imploring the government that remanufacturing should be permitted only by manufacturers, that too, piece by piece and not batch wise. Each refurbished device should have a unique code and certificate before being introduced into the market to ensure traceability. Another plea to the government is to ensure that imported preowned medical devices are returned to their country of origin after their end-of-life to ensure that India does not become a dumping ground for e-waste.

He ended his speech by elucidating that device manufacturers are confused by the mixed signals of Make-in-India on the one hand and import of second-hand equipment on the other.

The resultant discussions clarified many aspects which laypersons are not aware of and also focused on the grey areas needing attention. For instance, for Mr Dhananjay's question about the need for checks and balances and lack of efficacy of regulators, Mr Gouri explained that standards, protocols and traceability are clearly defined in the UK. Every refurbished product is registered and the responsibility lies with the manufacturer. The exemplary policies in place in USA, UK and EU can definitely be replicated in India through policy decisions and proper implementation.

Dr Ramaiah spoke about the affordability of used medical devices and how the imports can counter the shortage of medical devices in India. He also inquired about what is done with the discarded preowned medical devices and if there is a separate department to recycle them or ensure that they are returned to the manufacturers. Mr Rajiv hit the nail on the head by stating that safe healthcare is more important than affordable healthcare. He cautioned that we are going into a dark hole in the name of affordability. He gave the example of a refurbished blood pressure monitor which showed a faulty high BP reading leading to unnecessary expenses of treatment and medication. Hence, the low cost of refurbished devices should not be at the cost of patient safety. He called for robust mechanisms and controls for refurbished medical devices while highlighting that over 70 countries have banned import of used medical devices as they don't have the necessary regulations.

Dr Abhijit raised the question of which body certifies whether a medical device is clinically appropriate, effective and affordable. Mr Rajiv discussed the need for rigorous testing, validation and risk management procedures for both new and refurbished equipment to ensure safety and functionality for clinical use, involving manufacturers and refurbishers. He also highlighted the lack of specific regulations for pre-owned medical devices in India and the importance of a controlled testing environment.

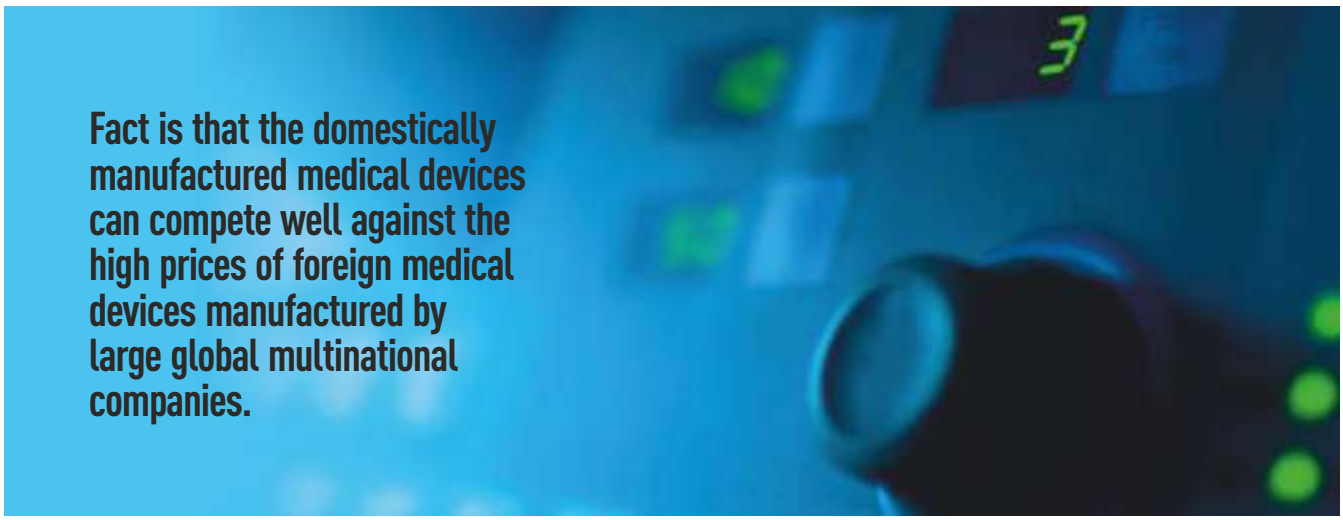
Ms Bina Jain inquired whether the cost of returning the medical device to the exporting country will raise the costs ultimately to which Mr Rajiv stressed that consumers tend to consider not just the price which may look cheaper, but the cost may work out to be much higher!

There was a discussion about the high costs of the healthcare system in India with Mr Gouri highlighting that some surgeries were working out to be much cheaper in the UK! To this, Mr Rajiv expressed concern about patients in India being exploited due to high costs!

Mr Rakesh Bhatia, a medical equipment marketing consultant, expressed concerns about the lack of thorough evaluation protocols for second-hand equipment, which could lead to safety hazards and equipment failure. Several other points emerged that need the attention of all stakeholders and those who want better healthcare for the people of our country.

The webinar ended on a high note with Ms Payal Agarwal thanking everyone for attending the webinar and expressing gratitude to the expert panel that emphasised patient safety and responsible medical practices.

The full webinar can be accessed at https://youtube.com/live/-sVUg97R_4E?feature=share.



Suggestions for Pricing Framework for Medical Devices

A LOT IS underway at the Department of Pharmaceuticals, Government of India as it works on developing a pricing framework for medical devices on the lines of the price caps imposed on various drugs by the NPPA. This move is buoyed by the price limits enforced on stents back in 2017 which successfully brought down the costs from around Rs 2.5 lakh to Rs 40000.

However, the on-ground scenario is actually quite different. Hospitals get around the price caps by charging astronomical amounts for the accessories and other services in their packages. Hence, the patients and consumers actually don't get any price benefit and still pay more or less the same amount. Hence, the medical device industry is calling on the government to not only cap the medical devices but also the accessories. In fact, it can consider fixing the package and reimbursement rates for the hospitals so that they cannot fleece the patients in an underhand manner!

Discussions are also ongoing on the propensity of healthcare institutions to opt for higher-priced imported medical devices as this allows them to levy higher rates on the patients. This works against the interests of local medical device manufacturers who are persevering to provide quality medical devices at much cheaper prices. The government needs to consider their interests while formulating suitable policies as it is already on a roll to promote Make in India!

> "The government's move to revise custom duty on key components of x-ray machines will foster local manufacturing."
>
> *- ASHUTOSH RAGHUVANSHI, MD and CEO of Fortis Healthcare*

Just In! – In the recently released Union Budget 2024-25, the central government lowered the custom duty on x-ray tube and flat panel detectors which are key components of a digital x-ray machine.

However, this move is unlikely to reduce the cost of imaging as it is primarily aimed at spurring domestic manufacturing of the machine which is used extensively in hospital settings to detect bone fractures, pneumonia and dental problems among others. It is likely to reduce the cost of x-rays in the long run.

It should be noted that some long standing healthcare sector demands remain unaddressed in the current budget – like increasing the expenditure on healthcare to 2.5% of the GDP!

The Department of Pharmaceuticals (DoP), Government of India has written to the Ministry of Environment, Forest and Climate Change (MoEFCC) to withdraw the memorandum permitting imports of refurbished preowned medical devices.

In the letter, Mr ARUNISH CHAWLA, Secretary, DoP expressly stated, "Considering the safety & quality aspects of refurbished devices as well as the interest of the domestic industry, it is requested that refurbished medical devices may only be permitted from the original equipment manufacturers located and making in India. We have no objection to the imports of new high end and high value medical equipment."

He also drew attention to the glaring fact that refurbished and used medical devices are not regulated under the Drugs and Cosmetics Act or Rules framed thereunder, with respect to safety, quality and performance, unlike the newly manufactured/imported medical devices.

JAGO GRAHAK JAGO

A snapshot of success stories of consumer activists who are relentlessly battling for consumer rights. We will highlight decisions and awards in favour of the consumers. This should motivate other youngsters to take up the cause of the consumer for not only social benefit, but their own good too! Jai Ho Grahak!

Your Rights Explained: Legal Recourse for Diagnostic Errors

THE SUPREME COURT has often upheld that the Right to Life as enshrined in Article 21 of the Constitution of India includes the right to health and medical treatment. Moreover, under section 42 of the Consumer Protection Act, 2019, medical negligence by healthcare practitioners is considered as a 'deficiency'. Here, medical negligence includes misdiagnosis as well as questionable delay in diagnosis. The doctor can be made liable for any injury or damages thereon.

Legal Rights

The victim has the right to seek compensatory, disciplinary or punitive action, such as:

- Appeal for monetary compensation before the civil courts, High Court or consumer dispute redressal commissions under the Constitutional Law, Law of Torts/Law of Contract and the Consumer Protection Act.
- File a criminal complaint against the doctor under the Indian Penal Code.
- Move professional bodies like the Indian Medical Council/State Medical Council for disciplinary action.
- Lodge a complaint before the National/State Human Rights Commission.

However, it's a long road to justice as is evident in the case of Havildar Satyanand Singh who was discharged from the Army due to a wrong diagnosis of AIDS in a military hospital in 2001.

The 23-year legal battle finally culminated in a logical conclusion in May 2024 when the Supreme Court ordered the Army to pay a compensation of Rs 50 lakh for the incorrect diagnosis by its doctors!

Satyanand Singh was inducted into the Indian Army on 30th October, 1993. After serving for over 8 years, he was declared HIV positive and was discharged at

the young age of 27 on the grounds of having been found medically unfit for further service.

Living with mental agony, loss of employment, social stigma and the fear of imminent death, Singh fought his case on all possible legal forums, including the Armed Forces Tribunal, High Court and the Supreme Court. He kept contending that there was an error in the diagnosis and he was hale and hearty even after years without any treatment.

A bench of Justices Sanjiv Khanna and Dipankar Datta pulled up the Army for its 'apathetic attitude' and trying to cover-up the false medical reports of its doctors. In view of the fact that reinstatement in service was not an available option now (at the age of 50), and taking into account the 'psychological, financial and physical trauma' suffered, the Court awarded Singh a lump sum monetary compensation of Rs 50 lakh towards compensation on account of wrongful termination of services, leave encashment dues, non-reimbursement of medical expenses and the social stigma faced. It also stated that he shall be entitled to pension in accordance with the law, as if he had continued in service.

The bench said, “We have no doubt in our mind that this is a case of wrong diagnosis and false alarm with imperilling consequences for the appellant. The respondents' contention that doctors in 2001 have used their best professional judgement to opine that the appellant was HIV+ve, in our opinion, should be rejected, in the absence of any medical literature to show that the test results as per the prevailing medical standards justify the diagnosis that the appellant was suffering from AIDS defining illness.”

It was further observed that, “The appellant, who was trained to live a disciplined life from the tender age of 19, was unnecessarily and without cogent reason thrust into civilian life with little warning or preparation. The psychological trauma that such displacement can bring about needs no elaboration.”

The bench also expressed concern over the prevailing social stigma and discriminatory approach towards HIV positive people.

The 23-year legal battle finally culminated in a logical conclusion in May 2024 when the Supreme Court ordered the Army to pay a compensation of Rs 50 lakh for the incorrect diagnosis by its doctors!

WATCH OUT

for the next issue in October dedicated to How Safe are the Toys Sold in India?

Parents are increasingly concerned about the presence of harmful chemicals, choking hazards and other safety risks of toys, especially the unregulated and counterfeit products. We will explore the multifaceted issue of toy safety in India, shedding light on the regulations and practices that govern the industry. We will also delve into the current state of toy safety standards in India, compare them with international benchmarks, and examine the role of government bodies, manufacturers, and retailers in safeguarding our children.

YOUR OPINION MATTERS

letters to the editor

We are truly humbled by the praise and acknowledgment that is flowing in from varied sources. Please feel free to send in your comments, views or feedback on The Aware Consumer magazine at bejonmisra@theawareconsumer.in – we will publish your opinions and implement your feedback while ensuring that your voice is heard on the right platforms.

(July issue: Can We Trust Used/Refurbished Medical Devices?)

I completely agree! We are a progressive nation, one that should be given respect for the knowledgeable and highly educated professionals we churn out. We shouldn't accept anyone else's cast off at the cost of lives and health. I'm sure our country is capable of manufacturing superior quality medical equipment that we need.

-- ***Ila Yellore Shirali,*** *Pune*
• *ilayellore@yahoo.com*

Prof Bejon Misra is a no nonsense consumer activist as far as patient safety is concerned. He is a stickler for no compromise when it comes to quality of care and safety of patients. His The Aware Consumer magazine is a mirror of his concern for consumers in all aspects of life.

The latest issue dealing with import of refurbished medical devices including surgical robots in India is timely and most pertinent. These secondhand medical devices directly impact the health of people. But till hawk eye and vigil of Prof Bejon exists, no one can play with the lives of patients in India. The said edition has dealt sternly with the issue of import of refurbished medical devices. The powers that be must take notice of issues raised in The Aware Consumer. That import of used medical devices also unmakes 'Make in India' is also his concern. I have no doubt that this issue will go a long way.

As a health journalist of over two decades in Delhi NCR, I can vouch that this issue embodies every aspect of import of medical devices. It has given me a complete view of the domain and it has increased my knowledge to a great extent. It will come handy in writing credible stories for Medicare News.

-- ***Dhananjay Kumar,*** *Delhi*
• *dhananjay.kumar0903@gmail.com*

Medical devices form the backbone of healthcare infrastructure and are essential to achievement of the goal of 'Health for All'. It is also necessary to put in place suitable standards for the medical devices, including the refurbished ones, and ensure effective regulatory arrangements for enforcement of the standards. The present issue of The Aware Consumer brings out the various facets of this subject in a succinct manner, for which the authors and the editorial team deserve full compliments.

-- ***Sudhir Krishna,*** *IAS (Retd.) - Gurugram (Haryana)*
• *sudhir.krishna2013@gmail.com*

I was shocked and disturbed to read about the dangers of importing used medical devices in your recent magazine. As a consumer, I had no idea that so many used devices were being brought into our country without proper testing or regulation. The recent developments are particularly alarming. It's unacceptable that someone's life is put at risk due to a lack of oversight.

I agree that the cost savings of importing used devices can be tempting, but it's clear that the risks far outweigh any potential benefits. We need stricter regulations and enforcement to ensure that all medical devices, regardless of their origin, meet the highest safety standards.

Thank you for shedding light on this critical issue. I hope that your magazine will spark meaningful change and protect patients from the dangers of substandard medical devices.

-- ***Abhinav Jhunjhunwala,*** *Goa*
• *abhinavj01@gmail.com*

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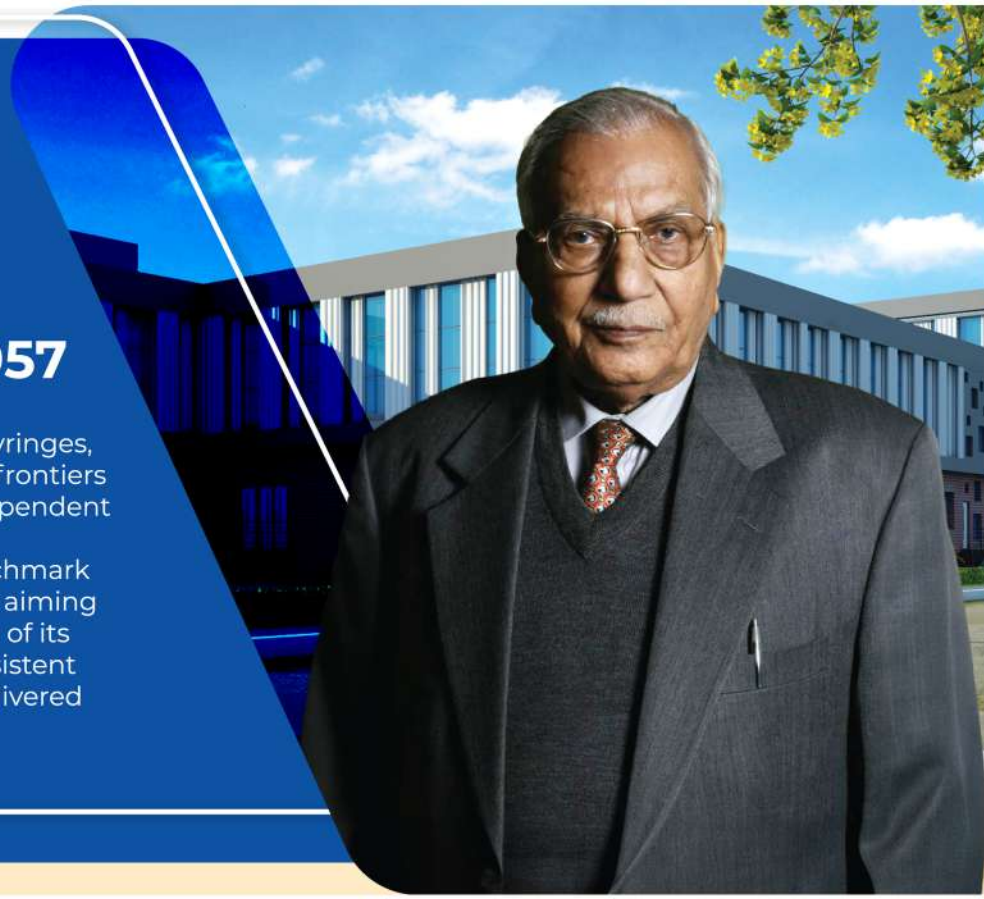
Late Mr. Narindra Nath,
Founder, Hindustan Syringes and Medical Devices Ltd.



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Posted at Lodi Road HPO, New Delhi on 9-10th of every month
Published on 6th of every month

RNI No. DELENG/2015/67140
REG. NO. DL (S)–17/3523/2017-19