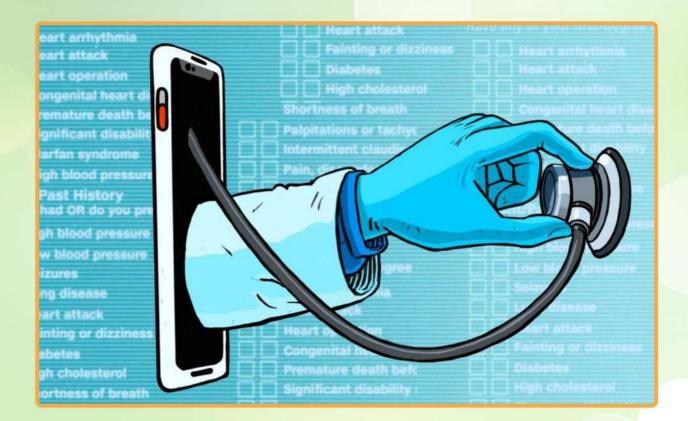


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# **DIGITAL MEDICAL CARE: BENEFITS AND BARRIERS**

Dr. Chakrapani M Editor in Chief Dr. B Sadananda Naik Executive Editor Dr. Kishan Delampady Production Editor

# www.apidk.org

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# PRESIDENTS MESSAGE



Warm greetings to you.

I am very happy that the seventh issue of 'Lahari' - the quarterly e-magazine of API DK chapter is ready to be released with the theme "Digital Medical Care: Benefits and Barriers". Dr C R Bhat is the aptly chosen guest editor, and he has done excellent work for the issue. We are indebted to him.

'Lahari' is coming out well due to the expert guidance from editor in chief - Dr Chakrapani, executive editor - Dr Sadananda Naik and the wholehearted editorial board members team work.

My sincere regards to them.

The authors from different parts of the world have been contributing intellectual articles keeping up the quality of 'Lahari'. We are thankful to them.

After this issue of 'Lahari', the team of 2022-23 will be taking over the baton. My best wishes to the team which will be lead by Dr Suresh G.

My special thanks again to Dr. Archith Boloor, Dr. Smitha Bhat who were the guest editors for the previous two issues and to the editor in chief, Dr Chakrapani, executive editor, Dr Sadananda Naik and the editorial board members.

With best wishes to everyone,

Dr. Ganesh Khandige President API DK 11-3-2022

# **VOICE OF EDITORS**

Dear colleagues,

We are happy to bring out the 7<sup>th</sup> issue of API-DK LAHARI. Theme of this issue is **Digital Medical care : Benefits and Barriers.** Dr C.Ramachandra Bhat , guest editor for this issue has done a wonderful job of compiling high quality articles covering every aspect of digital health. The articles are of high academic quality and of immense practical use. In addition to the articles related to the theme, the issue also has other academic articles, clinical point of view, non-academic articles etc.

As this happens to be the last issue of Lahari under the present editorial board, we would like to thank all our readers, authors who supported us during the last two years. The editorial board is indebted to the API-DK presidents of these two years who gave us complete editorial freedom and rendered all logistic support. We request you to continue the same kind of support to the new editorial team and hope that our E-Magazine API-DK LAHARI touches greater heights in the years to come.

# DR CHAKRAPANI M -EDITOR IN CHIEF DR B. SADANANDA NAIK-EXECUTIVE EDITOR

# **OUR EDITORIAL TEAM**

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EDITORIAL BOARD MEMBER (EX PRESIDENT -API 2020)	DR BM VENKATESH	

# **SECRETARY'S REPORT**



#### Greetings from API D.K. Chapter.

Our monthly meeting was on December 12, 2021 at Hotel Sai Palace. Dr M Chakrapani, moderated panel discussion on "Invasive fungal infections in ICU." Dr Srikala Baliga, Dr Vishak Acharya, Dr Deepak Madi and Dr Jayaprakash K were the panel members. The monthly meeting was attended by 50 delegates, concluded with question and answer sessions. The monthly meeting on January 21, 2022 was conducted at Hotel GoldFinch. Dr Rajesh Krishna, Consultant Hematologist, gave talk on "Hematological emergencies and session was moderated by Dr Sudhindra Rao. Dr Gangarathna, Consultant Rheumatologist, gave talk on "Rheumatological emergencies" and Dr Venugopala D moderated the session.

The monthly meeting was attended by 45 delegates and was followed by stimulating discussion. The monthly meeting was on March 18, 2022 conducted at Hotel Ocean pearl. Dr Suresh Shenoy gave talk on "Newer modalities in the treatment on gastric varices" and Dr Anurag shetty spoke on "Changing face in management of achalasia cardia". This was followed by annual general body meeting.

# **Physicians Day Celebration**

Physicians' day was celebrated on 23<sup>rd</sup> December 2021 at Hotel Goldfinch and 3 distinguished members Dr RC Sahoo, Dr JP Alva and Dr PS Prakash were felicated by chief guest Shree N Vinaya Hegde.

# **API DK Orations**

Dr KP Ganesan oration was given by Dr Mohammed Ismail on topic "Clinical medicine by Dr KP Ganesan to me" and Dr VV Mody oration was delivered by Dr Narasimha Hegde on topic "Passive income for physicians: myth or reality" Meeting was conducted at Hotel Ocean pearl and attended by 55 members.





Dr. Kishan Delampady,

API DK Secretary, 2021-22

Consultant Endocrinologist, AJ Hospital, Mangalore.

# **Guest Editorial**



Dr. C. Ramachandra Bhat. Professor & Head, Dept. of General Medicine, KVG Medical College, Sullia. crbhat1@rediff.com 9448328511

Greetings and welcome to the 7<sup>th</sup> issue of API DK Lahari. The theme of this issue is **Digital** 

## **Medical care: Benefits and Barriers**

"THE BIGGEST INNOVATIONS OF 21st CENTURY WILL BE THE INTERSECTION OF BIOLOGY AND TECHNOLOGY" – Steve Jobs quoted several decades ago.

Digital technologies currently are an integral part of everyone's day-to-day life as digital innovations are happening at a lightning speed in all fields. Populations across the globe are interconnected via digital platforms making it a Global digital village. Digital Health includes the tools and services that use information and communication technologies, for purposes connected to health. The World Health Organization defines digital health as "a broad umbrella term encompassing eHealth, as well as emerging areas, such as the use of advanced computing sciences in "big data, genomics and artificial intelligence".

COVID pandemic uncovered the significant healthcare inequalities that have existed in our society / worldwide for a long time, propelling the digital transformation in the health care system. Digital technologies in health care entitle, improving clinical processes By utilizing the vast amount of clinical data, resource utilization, supporting clinical decision making, ensuring improved quality of care and improved patient engagement and satisfaction. Digital health would lead to reduced healthcare costs, streamline healthcare delivery, enhance clinician efficiency and satisfaction. With about 66 % of the world's population using mobile phones, and the technology getting cheaper, it is easier to transform into Digital health.

Investments in Digital Health and its growth has surpassed all previous records since the COVID pandemic, so much so that the tech 'solutions' are in search of a problem!. So the need of the hour is to focus on addressing the health need which is appropriate to the local context, but not just duplicating the existing digital tools or system. Remote monitoring with help of biosensors, wearable's, mobiles, voice etc will help in health promotion, prevention of disease with chronic disease monitoring and management. Artificial intelligence - analytic driven care will improve image interpretation, ECG reading, many Echocardiography applications, risk predictions, diagnostic and therapeutic recommendations. Virtual care will augment or replace what we do now, improving access, efficiency, communication and patient experience. Even though there are tremendous advancements in the field of digital platforms, applications of Deep learning, algorithms & Artificial intelligence, the utilization of these advances by the healthcare system is suboptimal. It is mostly due to fear of data security, a slower learning curve, difficulties in the adaptation of new technologies by the doctors, and fear of loss of human touch inpatient care.

Social determinants of health like socioeconomic factors, physical environment, and behavioral factors have a tremendous effect on individual health regardless of age, race or ethnicity. Transformation in Digital health should bring about "Health Equity"- "the absence of unfair or remediable differences in health care among population groups defined socially, economically, demographically or geographically" (WHO) Digital health should harness the technology to move healthcare from episodic "sick care" to continuous and integrated "healthcare": "health promotion and disease prevention". Technology & innovations should integrate into healthcare for "health equity".

Digital health is not a panacea for all of the healthcare needs, but it is the foundation of a future modernized healthcare system providing value-based healthcare.

The health care system has to harness the power of digital technologies and health innovations to accelerate the attainment of global health and wellbeing. In future, the Digital modalities in the healthcare sector are not just the NEED but the Necessity. Digital transformation in healthcare had reached a peak during the COVID pandemic with the interplay of remote monitoring, Virtual care and AI-driven care.

Will this momentum last?

In this issue of API DK Lahari , esteemed authors from worldwide have contributed, enlightening us on various aspects of Digital health. Wishing you all happy reading on Digital health.

#### **CALL FOR ARTICLES**

Readers are hereby requested to submit their articles for the next issue.

Submit to : editorapidk2020@gmail.com

Author instructions@page 124

# **Electronic Health Record - Basics and specifications.**



# Mr. Vishnu Shashank B CEO, Isiri Technologies Pvt Ltd. 9986038992

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#### AyusCare

ISIRI Technologies Pvt Ltd IH-10, Hemavathi Nagar, Alape, Mangalore, Karnataka, India – 575 007 Ph: +91-88880016018 Email : info@ayuslab.com www.ayuslab.com / www.ayuscare.in 'AyusCare' on Google Play and App Store. COI: The author is CEO and stakeholder in the company Isiri technologies Private Limited, with EMR brand AyusCare.

#### What is an EHR / EMR?

An Electronic Health or Medical Record (EHR/ EMR) system refers to the health and medical information of individuals stored in a digital form. It comprises patient identification details, details of history and medical examination, allergies, immunizations, diagnoses, medical tests, doctor's notes, treatment plans medicines, and procedures. It can also contain details of insurance and billing. These medical records

can be accessed by all healthcare providers who are taking care of patients and helping them plan and execute the course of treatment.

A hospital management system (HMS) also known as a Hospital Information system (HIS) is a comprehensive, integrated system, on all information of the hospital, designed to manage the overall operations of the hospital. It includes electronic medical records, intradepartmental communications, Radiology information system(RIS), Laboratory information system (LIS),hospital administrative tools like manpower management, financial management, patient communication system and processing of pharmacy, hospital inventory services etc.

#### **Generation/Version of EHR?**

There are different forms of EHR software such as

**Desktop system**: This is a primitive and basic system where software is installed on a desktop computer. The software can be operated only on that computer and requires an arrangement for a periodic data backup. Also, data interchange between departments is not possible in such a system. Desktop systems are now being replaced due to their obvious limitations.

The on-premise server system(offline): The EHR software is installed in a server system that can be accessed through LAN within the clinic, hospital or institution. This allows for data interchange between departments and streamlines the process. The initial cost of such a system is high as it involves setting up high performing servers with backup. In addition, it also requires dedicated IT support for smooth functioning.

**Online cloud system**: Modern systems are predominantly online and cloud-based. This does not necessitate any additional hardware as the software is enabled to work on web browsers and mobile applications. A significant benefit of this system is that data can be easily shared between doctors and patients. The concerns to be addressed in this system are mainly data security and internet speed.

## **System Requirements for EHR**

A cloud-based EHR requires a working internet connection and computer systems with a minimum configuration of core i3 with 2GB RAM and 250 GB HDD. The number of computer systems depends on the setup of the hospital. Typically for the hospital, 2 systems

at the reception and billing, 2 systems at the triage and nursing counter, 2 systems at the pharmacy, 2 systems at the lab, one system for the administrator, one system at the x-ray/radiology department and one each for individual consultant physicians are required. This can vary depending on the size and layout of the clinic. The software is accessed through a secure login. The individual logins and access rights will be provided as per the work area during the setup of the application and may be modified by the admins. Transaction views, editing and report generation will be customisable and possible only by the authorised worker and the admins.

#### How records are maintained in EHR?

The software has broadly two components, **application** and a **database**. The application provides an interface to store and access data from the database. In the cloud-based EMR, the application is hosted on remote cloud servers with multiple database servers. Data is stored in an encrypted format to prevent unauthorised access and misuse of the data. Patient data is segregated and maintained as appointments, visits, basic details, triage, history, examination findings, doctors notes, test reports, images, diagnosis with ICD 10 coding, doctors prescriptions, treatment plan, follow-up, billing and payment. Each patient is given a unique identification number apart from the OP number and a lab number. All records of a patient will be mapped to this patient number. The doctor will be able to search individual patients using patient numbers/name/telephone numbers or by scanning a barcode. The profile page of the patient gives all the necessary details of the patient like treatment and medication history, enabling the physician for a quicker and more efficient consultation.

#### **Cost of Cloud EHR?**

Cloud EHR applications are typically priced on the Software as Service (SaS) model. In such a model, the initial cost of the software will be less as it does not warrant any additional hardware and networking at the premises. There will be a monthly charge paid to avail of the service. The main benefit is that this model ensures perpetual support during the course of usage. The provider also provides continuous availability of software maintains the server and also undertakes necessary upgrades and improvements with technology.

#### **Benefits and barriers of Cloud EHR**

Systematic maintenance of health records in a digital form is beneficial for both patients and doctors.

- For patients,
  - 1. Ready access to medical records for reference.

2. Compare results, make lifestyle changes and follow regimens for preventive care

3. Better and quicker treatment and care.

4. Receive follow up alerts and reminders.

5. No loss of reports and prescriptions.

6. Improved quality of care with lesser errors.

7. Easily share records in case of a medical emergency or during specialist consultation.

- For doctors and clinics
  - 1. Analyse outcome of a treatment based on historical data
  - 2. Ready accessibility to patient records at the point of care
  - 3. Faster decision making and planning the line of treatment
  - 4. Avoid duplicate tests
  - 5. Reduce error during documentation and improve patient care
  - 6. Enables information exchange between healthcare providers.
  - 7. Efficient management of chronic illness by comparing treatment outcomes

8. Enables to keep printouts of mandatory records like Form 3C and accounts for doctors.

9. The glance at the dashboard will give details of various reports and help in monitoring the progress of the clinic/ lab/ hospital. Apart from the above, it also helps clinics to streamline operations, manage insurance, billing and payments and improve the productivity of the healthcare personnel.

Barriers to EMR are very few and minor ones,

1. High initial time of physicians and learning curve

2. **EMR adoption** usually requires changes in workflow and set up can be time consuming

3. Concerns over privacy and data security

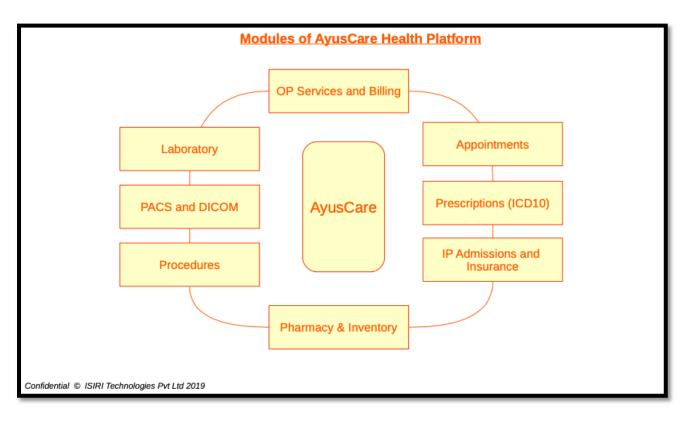
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- 4. Interoperability issues between different systems
- 5. Cost of maintenance and availability of IT support
- 6. Lack of standardisation and government policies

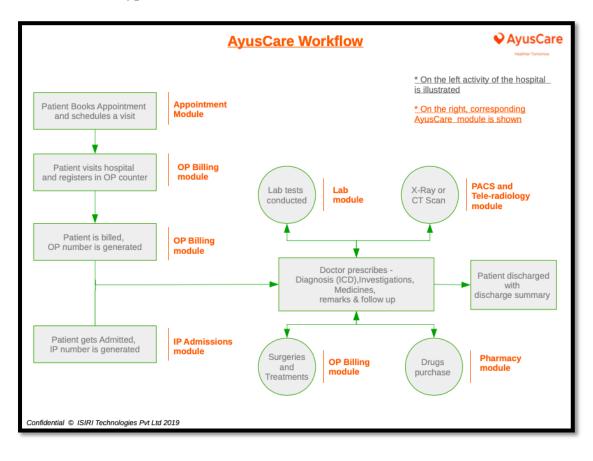
Most of these barriers may be overcome easily with minimal effort from the user.

**AyusCare of ISIRI technology** is one of the pioneers providing a secure, cloud-hosted EHR platform for efficient management of a clinic or health centre. The core focus of this software is simplicity and ease of usage. In a healthcare setup, the physician's time is most precious and the software ensures that no additional time is spent on record maintenance with information being presented in a meaningful way. The platform is continuously evolving adopting the latest technological tools and advancements. With efficient software design, the overall cost of maintenance of this software is kept low.

#### Modules in AyusCare EMR



# Workflow in a typical EMR



# How is the Data security maintained?

Security is handled at multiple levels in the cloud platform.

Security @Cloud Server and Operating System

The application is hosted on a Digital Ocean cloud server set up with Linux Operating System. Linux is robust and is inherently immune to any kind of virus attack.

Security @ Network Level

All network communication with the application server is encrypted through an SSL (Secure Socket Layer) connection, to ensure that the connection cannot be intercepted by any third party.

Security @Application Level Application is allowed to the user through a secure password. Password is stored in the database with bcrypt encryption. This means that the password can't be read by hackers even if they access the database.

# Security@DatabaseLevel

The database is accessed is secured through a password. The database is backed up at 3 different servers to ensure integrity in case of unforeseen circumstances. All modifications to the data are recorded with timestamps. An audit trail is displayed to the admin for each record. User can be restricted to only relevant modules within the system and is in control of the administrator. Users log in and the IP of computers is recorded for each login and is displayed to the administrator.

#### Summary:

- Electronic Medical / Health Records is a systematic and secure way of organizing patient health records for easy future retrieval.
- EMR can help prevent human error and prevent mistakes in treatment when patient records are incomplete.
- EMR will improve the quality of care by saving clinician's time accessing, retrieving and recording data.
- A patient record can be accessed across multiple locations
- EMR can track results of patient's tests, allowing clinicians to determine patient's progress
- By keeping a record of patients' medications or allergies, it can alert clinicians on potential conflicts.
- Comprehensive patient dashboard displaying basic information, vitals, allergies and test results in one view.
- EMR enables better collaboration with patients with mobile apps.
- EMR can be accessed by any handheld device, making it easy for the staff to use and adopt.
- Smooth information flow between clinicians and other health professionals across departments.
- EMR can improve patient safety and the quality of healthcare delivery.

• EMR is a **simple to use, Centralized, Cloud-Based** application to manage patient health records.





**Statutory Regulations for Telemedicine in India** 

Dr. Kishore Kumar Ubrangala, Professor, Department of Geriatric Medicine, Yenepoya Medical College, Deralakatte, Mangalore – 575018. Contact: 9448144297 sankish@gmail.com

India is a pioneer among developing countries in starting telemedicine. On 24th, March 2000, the then US President Bill Clinton inaugurated a teleclinic in Andhra Pradesh. In 2001, ISRO (Indian Space Research Organisation) established the 'Telemedicine Pilot Project'.

Telemedicine includes all channels of communication with the patient that leverage information. Technology platforms including Voice, Audio, Text & Digital Data exchange may be of the following types:

- Telemedicine chat-based applications (specialized telemedicine smartphone Apps, Websites, other internet-based systems etc.)
- General messaging / text/chat platforms (WhatsApp , Google Hangouts, Facebook Messenger etc.)
- Asynchronous (email / Fax etc.)

# **TELEMEDICINE PRACTICE GUIDELINES (25TH MARCH 2020)**

This was published by the Board of Governors in supersession of the Medical Council of India and prepared in partnership with NITI Aayog. This constitutes Appendix 5 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics Regulation, 2002) & are meant for Registered Medical Practitioners (RMPs) under the IMC Act 1956. These guidelines cover the norms and standards of the RMP to consult patients via telemedicine.

- Using telemedicine is now legally permissible for consultation/prescription/health education.
- Does not provide for consultations outside the jurisdiction of India.
- These guidelines are permanent in nature. Would remain applicable and relevant even after the Pandemic is over.
- But this is not a complete code and needs to be used in conjunction with other SOP, Policies, Protocols.
- Online courses would be made available by the Board of Governors for training to be undergone by the doctors within 3 years of notification of such a course.

# **Role of Telemedicine**:

- Can play an important role in cases where there is no need for the patient to physically see a doctor e.g., for regular, routine check-ups or continuous monitoring.
- Provides patient safety, as well as health workers safety especially in situations where there is the risk of contagious infections (present Covid pandemic).
- Can provide rapid access to doctors who may not be available in person.
- It makes extra working hands to provide physical care at the respective health institutions.
- Higher likelihood of maintenance of records and documentation.

# Types of Consultation (according to the purpose of the consultation):

First consult Follow-Up consult, Emergency consult.

First Consult means:

- The patient is consulting with the RMP for the first time; or
- The patient has consulted with the RMP earlier, but more than 6 months have elapsed since the previous consultation; or
- The patient has consulted with the RMP earlier, but for a different health condition.

Follow-Up Consult(s)means

- The patient is consulting with the same RMP within 6 months of his/her previous in-person consultation and this is for the continuation of care of the same health condition. However, it will not be considered a follow up if:
- There are new symptoms that are not in the spectrum of the same health condition; and/or
- RMP does not recall the context of previous treatment and advice.

# *Emergency* Consult:

- Telemedicine services should however be avoided for emergency care when alternative in-person care is available, and telemedicine consultation should be limited to first aid, life-saving measures, counselling and advice on referral.
- In all cases of emergency, the patient must be advised for in-person interaction with an RMP at the earliest.

# **Technologies used:**

- A real-time consultation may be preferable over an asynchronous exchange of information.
- Voice interaction may be preferred to an email or text for a diagnosis.
- There are also situations where the RMP needs to visually examine the patient and make a diagnosis. In such a case, the RMP could recommend a video consultation.
- Considering the situation, using his/her best judgment, an RMP may decide the best technology to use to diagnose and treat.

# 4 types of Consultation(according to the individuals involved):

- Patient to RMP
- Caregiver to RMP
- Health worker to RMP
- RMP to RMP

#### **Consent:**

- Before providing telemedicine, care is imperative.
- No anonymous consultation both patient and RMP need to know each other's identity.

- If the patient initiates the telemedicine consultation, then consent is **implied**.
- **Explicit patient** consent is needed if:

A Health worker, RMP or a Caregiver initiates a telemedicine consultation.

 Must be recorded in patient's record in any format for subsequent verification or retrieval (e.g., "Yes, I consent to avail consultation via telemedicine" or any such communication in simple words – by email, text or audio/video, text or email message.

There is no difference between the standard of care between telemedicine & in-person care.

Telemedicine is only an interphase or medium used in delivering medical care to patients.

Patient safety continues to be a central part of healthcare.

Use of discretion before adapting telemedicine:

The doctor is well-positioned to decide whether telemedicine consultation is sufficient or in personal review needed.

If the doctor feels it is essential to physically examine the patient then he shall do so without adopting technology.

The situation of **inherent limitation** for telemedicine:

If the physical examination is critical, RMP may insist on personal consultation Or recommend video consultation or examination by another RMP/ health worker.

If the condition can be appropriately managed via telemedicine, based on the type of consultation, then the RMP may proceed with a professional judgment to:

- Provide *Health Education* as appropriate in the case; and/or
- Provide *Counseling* related to specific clinical condition; and/or
- Prescribe Medicines
- RMP has to gather sufficient medical information about the patient's condition before making any professional judgment

#### **Prescription of medicine:**

- A provisional diagnosis must be made before prescribing.
- "Prescribing medicine without an appropriate diagnosis/provisional diagnosis will amount to a professional misconduct".

On July 25, 2018, the Bombay High Court delivered a judgement (Deepa Sanjeev Pawaskar and Anr vs the State of Maharashtra) – observing that prescribing medicines to the patient (on phone) without diagnosis amounted to culpable negligence, the court turned down the anticipatory bail pleas of a doctor couple booked under 304 IPC for the death of a woman patient. (Many medical practitioners observed and interpreted it to be 'against' the practice of teleconsultation, but that interpretation is said to be without basics & incorrect. The court was only concerned by the failure of the doctor to diagnose the patient).

The duty of standard of care should therefore be administered at a higher level to avoid medical negligence cases.

#### Drug classification:

List Group	Mode of Consultation [Video/Audio/Text]	Nature of Consultation [First	List of Medicines
		consultation/Follow-up]	
0	Any	Any	List O <sup>1</sup>
A	Video	First Consultation, Follow-up, for continuation of medications	List A <sup>2</sup>
В	Any	Follow-up	List B <sup>3</sup>
Prohibited	Not to be prescribed	Not to be prescribed	Schedule X of Drug and Cosmetic Act and Rules or any Narcotic And Psychotropic substance listed in the
			Narcotic Drugs and Psychotropic Substances, Act, 19854

Table: Matrix of the permissible drug lists based on the type and mode of consultation:

List 0: This list included commonly used 'over-the counter 'medications such as Paracetamol,ORS packets, Antacids, Iron, Folic acid, Vit D supplement, cough medications etc.

This list also includes medicines that may be deemed necessary during emergencies and would be notified from time to time.

1. List A: This list includes usually prescribed medications for which diagnosis is possible only by video for Tinea Cruris, Ciprofloxacin eye drops for Conjunctivitis, local ear drops etc.and Re-fill medications (follow-up consult for chronic diseases such as Diabetes, Hypertension, Asthma etc.

**3**. **List B**: This list includes 'addon' medications which are used to optimize an existing condition. For instance, if the patient is already on Atenolol for hypertension and the blood pressure is not controlled, an ACE inhibitor such as Enalapril, addition of Sitaglipt in to Metformin for diabetes etc.

**Prohibited**: Which have a high potential of abuse and could harm the patient or the society at large if used improperly. For instance, Anti-Cancer drugs; Narcotics such as Morphine, Codeineetc.

\* Drugs such as Phenobarbitone, Clonazepam, and Clobazam were added to List A in a modification to the guidelines (April 2020).

# **Issue a Prescription and Transmit:**

- If the RMP has prescribed medicines, RMP shall issue a prescription as per the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations and shall not contravene the provisions of the Drugs and Cosmetics Act and Rules. A sample format is suggested in Annexure 2.
- RMP shall provide a photo, scan, digital copy of a signed prescription or e-Prescription to the patient via email or any messaging platform.
- In case the RMP is transmitting the prescription directly to a pharmacy, he/she must ensure **explicit consent** of the patient that entitles him/her to get the medicines dispensed from any pharmacy of his/ her choice.

# Ethics, data privacy and confidentiality:

- As there is the propensity of data compromise in this digital world, the doctor should ensure that a reasonable degree of care is undertaken.
- RMP is absolved from liability if confidentiality is breached by a technology breach or by any other person other than the doctor.

# Fee consideration for telemedicine services:

- The doctor may charge an appropriate fee for the telemedicine services provided.
- For the fees charged, Doctor should provide a fee receipt.

# Technological, Legal and Ethical concerns:

Maintain a trail /documentation of consultation:

- It is incumbent on RMP to maintain the following records/ documents for the period as prescribed from time to time.
- Log or record of Telemedicine interaction (e.g., Phone logs, email records, chat/ text record, video interaction logs etc.).
- Patient records, reports, documents, images, diagnostics, data etc. (Digital or non-Digital) utilized in the telemedicine consultation should be retained by the RMP.
- Specifically, incase a prescription is shared with the patient, the RMP is required to maintain the prescription records as required for in-person consultations.

# **Misconduct & Penalties:**

It is specifically noted that in addition to all general requirements under the MCI Act for professional conduct, actions that wilfully compromise patient care or privacy and confidentiality, or violate any prevailing law are explicitly not permissible.

Some examples of actions that are not permissible:

- RMPs insist on Telemedicine, when the patient is willing to travel to a facility and/or requests an in-person consultation
- RMPs misuse patient images and data, especially private and sensitive in nature (e.g., RMP uploads an explicit picture of a patient on social media etc.)
- RMPs who use telemedicine to prescribe medicines from the specific restricted list.
- RMPs are not permitted to solicit patients for telemedicine through any advertisements or inducements.

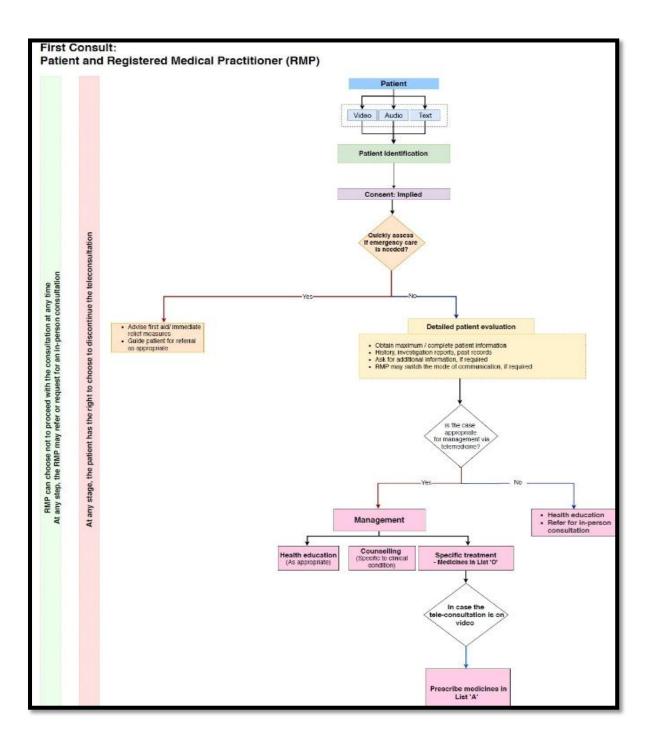
# **Penalties**:

• As per IMC Act, ethics and other prevailing laws.

# **Conclusion:**

The introduction of Telemedicine guidelines is a very positive step in the development of the medical sector in India. The fact that this guideline came during the course of the ongoing Covid-19 pandemic has given it the necessary thrust – helping both the patients and doctors. Telemedicine has the potential of flourishing in the future with the developments in legislation and the security of the stakeholders. The gaps in the legal framework and the risks of data protection and confidentiality in telemedicine services needs to be firmed up.

Annexure 1: Flow chart showing how consultation will proceed.



REGISTERED MEDIC QUALIFICATION REGISTRATION NUMBER ADDRESS CONTACT DETAILS (EMAIL	AL PRACTITIONER'S NAM	E	
Date Of Consultation		T.	
Name of Patient		Age 0	ender
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EXAMINATION / LAB FINDINGS	2. NAME OF MEDICINE (in ca	pital letters only withgenetic n ency of administration & dura pital letters only withgenetic n ency of administration & dura	tion. ame)
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SPECIAL INSTRUCTIONS			

# **References**:

- Telemedicine guidelines 2020, Appendix 5, Indian Medical Council (Professional Conduct, Etiquette and Ethics Regulations, 2002)
- Inputs are taken during 'Basic legal issues Medical Practice': Live Medico-legal Course, July 31<sup>st</sup>& August 1<sup>st</sup>, 2021 (Sponsored by AMC Mangalore, AMC Mumbai, IMA Mangaluru, IMA Tiruchirapalli, & MILAG Chandigarh).

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# **Telemedicine in India: Benefits and Barriers**



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# Telemedicine in India: Benefits and Barriers Introduction

Telemedicine has evolved since the first transmission of ECG over telephone lines in the first half of the 20th century. The first real-time Video consultation happened at the University of Nebraska in 1959 for neurological examination. Switching to the Indian Scenario, the concept of Telemedicine has been around, for about 3 decades, in the government-funded programmes away from the public sight of the urban private medical healthcare, delivering its services to the much needed underprivileged citizens. This rollout has happened, following a Government of India backing this technology. You might be surprised that, as of 17 March 2021, Govt. of India's telemedicine service completed 3 million consultations, which include daily over 35,000 patients who use e-Sanjeevani to seek health services remotely. The first deployment of telemedicine in India started in 1996 at SGPGIMS and the pilot programme rolled out in 1999. First National Conference on Telemedicine was constituted in 2005 by MOHFW and the first school of Telemedicine and Biomedical informatics was set up in 2006 at SGPGIMS Lucknow.

In India, providing In-person healthcare is challenging, due to geographical vastness and limited road transport communication, affected by a multitude of reasons beyond human limitations. One of the major advantages of telemedicine can be for the saving of cost and effort especially of rural patients, as they need not travel long distances for obtaining consultation and treatment vice versa. Even the doctor can cover a larger area to address a larger patient pool. In this type of scenario, telemedicine can provide an optimal solution for providing timely and faster access.

Covid 19 and the nationwide lockdown saw every nook and corner of this nation come to a standstill, and we doctors or old teachers assumed we could not do without a casualty running for 24 hours. The health industry come to a standstill and people with the simple itch or a nagging pain were all holed up in their residences lest the fear of the police baton. At that time, a new lexicon tele-consult popped around, which many of us were apprehensive for the reason of spam ware, privacy, financial transparency and foremost its legal use.

A 2018 judgment by the Bombay High Court in the case of Deepa Sanjeev Pawaskar And Anr v. The State of Maharashtra ("DSP Case") had created uncertainty in the minds of RMPs on whether it was permissible for them to provide medical advice over the telephone or not. In the DSP Case, the Bombay High Court had rejected the anticipatory bail application filed by the applicant (Dr. Deepa) who apprehended arrest under Section 304 (culpable homicide) of the Indian Penal Code, 1860. While the decision of the Bombay High Court was reversed in appeal by the Supreme Court ,still apprehension continued in our minds.

#### The Telemedicine Practice Guidelines

The Telemedicine Practice Guidelines (TPG) was issued on 25th March 2020 drafted by the erstwhile MCI in consultation with the Niti Aayog by the Board of Governors which enables Registered Medical Practitioners to Provide Healthcare Using Telemedicine (which Provides Legal Recognition to the Practice of Telemedicine). The TPG explicitly states that an RMP is entitled to provide telemedicine consultation from any part of India. The formal legal recognition helps lay to rest legal ambiguities on whether RMPs are permitted to provide medical consultation over the telephone or not.

The guidelines lack clarity about privacy and data usage, for patients and practitioners. The guidelines place the onus entirely on doctors to maintain records of all exchanges of communication between themselves and patients which can be tedious without a proper software backup. The guidelines do not yet specify the duration for storing data nor limits to further use of that data which can have legal implications as against current medical record

storage. The guidelines simply require the practitioner to be aware of the data protection and privacy laws and follow them which is just beating around the bush.

Privacy concerns arise as details, including a patient's address and other 'reasonable' identification, is required to be recorded by the practitioner which many doctors may not be adept at handling in current practice which is mostly done by ancillary staff in hospitals.

The guidelines explain the concepts of implicit and explicit consent—but a mere initiation of a telemedicine consultation by an individual is considered as implicit consent, which opens up a Pandora box of litigations where doctors have been dragged for not taking specific consent as against generic consent in hospitals. The guidelines need to elaborate more on consent in a teleconsultation and ways to obtain and record it.

The guidelines also lack any mechanism for resolving grievances of patients or practitioners which is true. Since any online interaction which is virtual has limitations as against the conventional mode of the doctor-patient relationship, the confidence or the trust which normally exists may fail to develop.

#### Novel but Critical issues that may arise in Telemedicine

Misinterpretation is a potential hazard in an Indian scenario with poor literacy levels and language barrier which is another potential litigation window.

Privacy of data, which is of utmost importance when your data is on the World Wide Web ready to be hacked or sold by nefarious individuals or companies for corporate interests, is a major concern. An ethereal question would be that ,when governments fail to reign corporate , how would a doctor fight them.

All persons involved in the data exchange should bind to HIPPA laws prevailing or should be trained to do such and enter into an agreement which again requires legal backing.

Financial reimbursement for the services provided has to be clearly defined in an Indian semi-urban or rural scenario and what pricing mechanism works out, needs to be clarified.

The technical requirements for a successful telemedicine program include a secure, highspeed internet connection, a clinical telemedicine cart to serve as the hub for the interaction, patient access software, and round the clock IT assistance for malfunction which might escalate the cost.

Telemedicine may not be everyone's cup as everyone may not be trained or may not be a master of jugglery in handling smart phones, computers writing digital prescriptions and finger touch typing, to be a successful telemedicine expert.

#### **Benefits for patients**

Telemedicine can help treat a range of medical conditions. It is most successful when a person seeks care from a qualified physician and provides clear details about their symptoms.

Lower costs: translation may be due to lower transport costs, Time at work,

No Requirement for Family members to skip work.

**Improved access to Trusted Healthcare:** Telemedicine makes it easier for people with disabilities, elderly, geographically disadvantaged, isolated population to access care who they already trust due to past interaction or local reputation.

Preventive care: can be synchronously delivered to needy people in a short duration.

Convenience: to avail services at their comfortable locations and surroundings

Mitigating Infection: so true in the current pandemic to limit the movement of people and avoid cross-infection.

#### **Benefits for healthcare providers**

**Office expenses**: Reduction in office expenses can be done by avoiding multiple practice places and limited peripheral visits.

Additional revenue stream: Clinicians may find that telemedicine supplements their income as it allows them to provide care to lot more patients.

**Less exposure to illness and infections**: When providers see patients remotely, they do not have to worry about exposure to any pathogens that the patient may carry.

**<u>Patient satisfaction</u>**: When a patient does not have to travel to the office or wait for care, they may be happier with their provider.

Nothing is perfect and there are certain deadly barriers for Telemedicine to be ubiquitously accepted by the medical fraternity and people at large

- Financial implications may not matter to the provider but for the interaction to be good at both ends require devices, with quality high-speed net, cameras, clarity which comes with a cost.
- Regulations have not yet been addressed completely, from the patient and doctor's perspective to their confidence level.
- There is at thinking that, will telemedicine be like a social media addiction which people might take lightly or, would it be a genuinely interesting tool to use as an alternative -only time will be the answer.

• Technology has its limitations, as not everyone is a gadget freak nor every individual is at ease with technology. No one Size fits all is true again.

These are not new to any change but part of general healthcare which may be catalogued and expressed distinctly in this presentation of medical examination.

This shortcoming may be addressed to a possible extent by effective use of

- Electronic Health Records (EHR) provides doctors with a complete history
- Monitoring The Patients by apps linked to the doctor or healthcare provider
- Robust stable Broadband network with uniformity which requires state and private funding
- Uniformity in Telemedicine training as part of the curriculum in Undergraduate and Postgraduate medical school.
- Clearest guidelines on the disparity of reimbursements and their redressal.

# Summary

Telemedicine is a convenient option for people who cannot go to the doctor's office and those who prefer to stay home. However, patients must check the credentials of the doctor providing care. Vice versa doctors also need to be careful on using the interface to be familiar with glitches of software, online rating system of doctors which can be sabotaged.

Nevertheless, this system is going to be a parallel income for many doctors.

To conclude, with the passage of the TPG combined with the increased enthusiasm of the government of India in streamlining the storage and processing of health data, India appears to be at the cusp of the digital health revolution.

# Digital technology and Imaging – A Radiologist's perspective



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#### The earlier Radiology departments

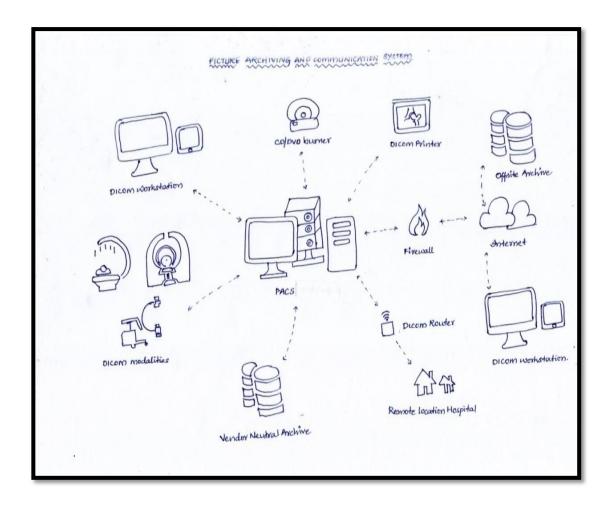
The evolution of digital technology and innovations has played a vital role not only in the invention and advancement of new imaging modalities but also in the layout, workflow and ergonomics of the Imaging department itself. From being a dreaded, dark (darkroom) messy place with smelling chemicals and black and white pictures of skeletons akin to a neglected and haunted castle to the present day sophisticated, attractive, professional and corporate like workplace, the journey of Radiology has been transformational - thanks to Digitization.

The earlier Radiology departments always faced a crunch of storage spaces, manpower and time. It was a common scene to see huge stacks and piles of physical copies of Image plates/ radiographic films and reports stored in the large warehouse-like spaces anticipating the need for retrieval in future. The actual workflow, right from registration of patients, imaging, developing till storage and retrieval of previous copies, was tedious and time-consuming as they were entirely dependent on Human resources. There was a large scope for physical damage, degradation of image quality over time and loss of Radiographs. Another significant problem was that of sharing images and reports with referring doctors and for expert opinion.

Radiographs and reports had to be physically carried either manually or sent through mail [1-2].

### How technology changed Radiology: PACS, RIS and HIS

Picture Archiving and Communication System (PACS) was developed as the Panacea for all the problems of traditional imaging rooms. PACS is a network of computers, servers and Imaging modality gateways that provide for seamless sharing, storage and retrieval of digitised images across different systems, departments and even geographical locations (figure 1).



#### Courtesy : Dr Meghavardhan Guptha

#### Figure 1: Layout of PACS

All the imaging modalities can be connected to PACS networks from radiography and ultrasonography to CT, MRI, PET, DSA and beyond. Even conventionally acquired

radiographic plates can be scanned and converted into a particular format and added to PACS. To facilitate this sharing of digitized images across different types of computer systems, software and operating systems, a uniform, standardized format of Images was used by all service providers across the world called DICOM. DICOM refers to Digital Imaging and Communication in Medicine. All images are acquired, stored, transferred and retrieved in DICOM format across the globe. DICOM images can be viewed in any DICOM viewing software in any system. These images can also be printed, stored and transferred into other formats like jpeg, png etc. Most DICOM viewer software also provides a variety of algorithms like Multi-planar reformation (MPR), Volume Reconstructions (VR), Virtual imaging (Virtual endoscopy), Spectroscopy, perfusion maps etc.

As PACS is to images/pictures; RIS (Radiology Information System) and HIS (Hospital Information System) are for Documentation. Whereas RIS provide for uniform digitized formats ofwork-flow processes in Radiology Departments like registration of patients, scheduling of different imaging modalities, reporting and further tagging of these reports into the electronic medical records of patients; HIS deals with other Hospital processes including registration, electronic case sheets, requisitioning, billing, laboratory reports, OPD records, Discharge summaries, referrals etc. An interesting addition to RIS is Report Dictation/ Voice recognition software which can be customized [2-3].

Software systems offering a comprehensive amalgamation of PACS, RIS and HIS are best suited for Hospital setups, wherein images, reports and other necessary documents can be accessed in a single system installed anywhere by authorized personnel, be it in the wards, OPD consultation rooms, billing, registration, pharmacy etc. Consultants get immediate access to images and reports as they are generated, right in the comforts of their cabins.

#### **Tele-Radiology**

Tele-Radiology is an extension of PACS and RIS, where Radiologists located elsewhere, get secured access to the Hospital PACS through cloud sharing or VPN (virtual private network). Radiologists can scroll, toggle images, in their electronic devices like laptops, use advanced applications like MPR, VR etc. and generate reports. Tele-Radiology is a boon that solves the problem of scarcity of Radiologists to a large extent. It is especially beneficial to remote locations where imaging is performed but lacks in-house Radiologists. There are many Tele-

Radiology hubs and platforms which cater to large sections of such diagnostic centers and hospitals. Equipped with a wide network of Radiologists located in various parts of the Country and the Globe, they provide cost-effective reporting solutions [4].

#### **Artificial Intelligence**

Another breakthrough development has been the increasing application of Artificial Intelligence (AI) in the field of Radiology. Other than the advanced software application discussed earlier, the major utility of AI has been in helping detect and characterize abnormalities on different modalities. Earlier versions of Computer-Aided Detection (CAD), especially used in Mammography pointed at subtle possible abnormalities which could be easily overlooked by human eyes. Now the scope of AI in Radiology has expanded widely. Detection and characterization of Lung nodules, Liver masses, and brain lesions on cross-sectional imaging, vascular imaging, and the most widely used algorithms for diagnosing TB and lately COVID-19 on Radiographs are just a few examples. With many advanced AI-based Machine learning models like artificial neural networks, convolution designs, deep learning etc. the field of Radiology and Healthcare is only going to be further enriched towards resolving many contentious issues in the management of ill health and promoting well-being.

#### Disadvantages of technology-driven workflow

As with every other part of this existence, increasing digitization in Radiology has its disadvantages as well. The most important among them is the lack of scope for Radiologist-patient interaction in the present workflow designs. Earlier, Radiologists had to interact with every patient referred, to perform imaging. This gave him a chance to elicit any relevant or crucial information needed. In fact, in one of the recent online courses that I attended, many of the participants expressed strongly to try and accommodate 'Radiologist-patient interaction' as part of the routine workflow [5-6]. With the increasing mushrooming of tele-reporting firms, reducing remunerations, and increasing workload, the quality of tele-reporting has taken a beating. Another important factor is the unavailability of clinical details to the reporting Radiologist. Tele-Radiologist is sometimes kept totally 'blind' to clinical information.

A crucial decision making element in procuring PACS/HIS/RIS is the cost of installation, updating, maintenance and need of training. However, as they obviate the need for additional manpower, space and create efficient workflow designs operable in a limited time; they have been found more beneficial and profitable overall.

The problem of loss of data due to software or storage device malfunction is to a large extent solved by redundancy in storage, i.e. storage at multiple levels and locations both online and offline.

The widely debated legal issue about digital records is their security. Password-protected access to systems, only authorized physical access to computer systems, repeated changing of pins and passwords, mobile OTP's should be practiced as part of standard operating procedure. AI algorithms work on the availability of enormous amounts of data, risking personal data security. Sharing of data with others should be strictly restricted only for academic and clinical management purposes, ensuring anonymization of patients' personal information before sharing. Even securing the patient's consent is advisable. There is a need for enacting laws providing for mechanisms for personal data storage and sharing [1-2].

#### The eternal question

Increasing digitization and technology have made the present 'Dream-run of Radiology' possible. Tele-reporting has provided much-needed means and access to advanced Radiology services in remote locations lacking Radiologists. In fact, Tele-Radiology is a vital cog of healthcare during these pandemic times.

With this comes the eternal question, 'Will AI gradually replace Human interface in the field of Health care? Will it make us jobless?' Machines and software will continue to facilitate health care professionals and not replace humans.

# No matter how much technology advances, Doctors will continue to be that 'Human touch' and 'Healing hand' the patient craves.

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# Tele-ICU Care - An expert review of the Current Scenario, Barriers and Solutions in India.



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**Keywords:** COVID-19; SARS-COV2; Cloudphysician; Pandemic; Critical care; Tele-ICU, LMICs

**COI**: SM, APVA and DR are employees or stakeholders in the company Cloudphysician Healthcare Private Limited. CB works as a consultant at Cloudphysician Healthcare Private Limited

# Summary

Healthcare services, with critical care services, in particular, are far and few between in India. With 95,000 ICU beds and less than 5000 qualified ICU doctors available to the Indian population and largely confined to tier 1 and 2 cities, large gaps remain in the accessibility of quality critical care. Cloudphysician has developed an indigenous tele-ICU model that uses technological solutions and strategies to bridge these chasms in geography and expertise in the Indian context, thus contributing to a reduction in preventable mortality, duration of ICU stay, healthcare worker burnout and improved compliance to best care practices and patient

safety. While barriers to the effective deployment of these services exist, tailored solutions using local resources would help in its establishment in a feasible, immediate and cost-effective manner.

#### Introduction

Healthcare services in India are quantitatively and geographically disproportionate to the current Indian demographic distribution with a doctor: patient ratio (1:1456 on combining both public and private sector) that still falls short of the WHO prescribed limit of 1:1000<sup>1</sup>, Critical care resources are even more scarce at approximately 2.3 beds per 100,000 population<sup>2</sup> An estimation at the start of the SARS-CoV2 (COVID-19) pandemic revealed only 1.9 million hospital beds, 95,000 ICU beds and 48,000 ventilators<sup>3</sup>. There are a meager 12,945 ICU doctors (consultants and trainees) registered with the Indian Society of Critical Care Medicine as of 2020<sup>4</sup> (of which only about 5,000 are formally trained intensivists) with the added constraints in specialty trained nursing staff.

The paucity of resources is further compounded by the erratic geographical distribution where most high-quality ICUs are confined to tier 1 and 2 cities, and most beds and ventilators appear to be concentrated in a handful of states, largely in the South (Karnataka, Telangana, Tamil Nadu, Kerala, Maharashtra, West Bengal and Uttar Pradesh)<sup>3</sup>. Furthermore, many rural areas remain poorly connected by rail or road to the nearest tertiary care centre, resulting in high mortality and morbidity rates for individuals who are critically ill or injured.

The recent SARS-CoV2 (COVID-19) pandemic exposed various lacunae in the country's health services indicating the need to rapidly upscale skilled human resources and health infrastructure. The dire need to bridge the gap to this development can be filled by leveraging advanced technologies and telecommunication services.

#### Tele-medicine, critical care and its outcomes

The dispensation of medical advice over significant geographical distances using telecommunication is not a new concept. With the earliest recorded instance in the mid-19th century<sup>5</sup>, the development of sophisticated equipment and services have increased the scope of telehealth services, particularly in the 21st century. Out-patient teleconsultation services exploded during the pandemic, yet, tele-ICUs did not grow with quite the same vigor. Tele ICUs connect distant hospitals with geographically remote specialists trained in critical care, who assist in the evaluation, monitoring and management of critical patients through the use of telecommunication equipment and services. While both centralized and decentralized models have been deployed, depending on the service provider, at its core, tele-ICUs help

bridge many lacunae in the medical system and may even contribute to the development of medical research, education and public health. A summary of the issues, advantages, barriers and solutions are detailed in Table1

#### **Patient-centered** outcomes

Several studies have noted improvement in patient outcomes following the implementation of tele-ICU services in different formats. Two meta-analyses<sup>6,7</sup> observed a significant improvement in ICU mortality rates after the introduction of tele-ICU services. However, all studies included in both these meta-analyses were observational. Furthermore, one analysis<sup>7</sup> included moderate quality studies with moderate-high heterogeneity, and another<sup>6</sup> included studies with moderate to high risk of bias. The former also noted lower durations of hospital and ICU stay with the introduction of tele-ICU services. Furthermore, a subgroup analysis in the review by Fusaro et al<sup>6</sup> showed an improvement dependent on baseline performance, with maximum improvement in outcomes seen in ICUs with poorer baseline patient mortality rates. Kalb et al<sup>8</sup> conducted a multi-centre study to identify the effect of structured tele-ICU rounds on ICU mortality, duration of ventilation and compliance to best practices, all of which showed statistically significant improvements. Lilly et al<sup>9</sup> not only demonstrated an improvement in ICU mortality and duration of ICU stay with the introduction of tele-ICU support but also identified the contributing elements as more rapid response to physiological instability alerts and review of the care plan by off-site intensivists during the off-hour period. The effect on medical errors, patient safety and timeliness to interventions have been poorly studied.

#### Provider centered outcomes

A meta-analysis by Young et al<sup>10</sup> determined a high rate of staff acceptance and perceived improvement in patient outcomes. The impact of tele-ICUs on collaboration and autonomy of staff were variable citing several barriers (Table 1, point 3). Tele-ICUs did demonstrate an improvement in psychological burnout among staff<sup>11</sup> and lower reported rates of "feeling overwhelmed" by residents<sup>12</sup>. Only a little over a third of residents in one study reported that it was a valuable educational experience with more than half appearing neutral of tele-ICU services in resident education<sup>12</sup>.

#### Cloud physician services

The development and expansion of tele-ICU services in the US occurred at the turn of the century in response to the Leapfrog group's quality improvement recommendations in critical care<sup>5</sup>. In 2017, Cloud physician, a healthcare technology enterprise aiming to democratize high-quality intensive care, brought a similar, indigenously adapted solution to bridge the chasms in the availability of critical care services in India (Figure 1). Over the course of 18 months (June 2020-December 2021), Cloud physician catered to 21,613 patients (3681 with COVID-19) in over 450 ICU beds in 60 hospitals across 16 states from its command centre in Bengaluru, with a team of 22 intensivists, 55 ICU nurses, dieticians and engineers. It has thus demonstrated its viability as a solution to tide over our deficits in infrastructure and expertise and connect geographically isolated areas with quality care. Cloud physician has also made inroads into the field of medical education, innovation and research, through the introduction of training courses for healthcare workers and the publication of clinical research in medical journals. It aims to leverage its proprietary technology used in the delivery of tele-ICU services and machine learning expertise, to advance medical research through the analysis of big data harvested from its member ICUs. Cloud physician has also contributed to the field of public health awareness with the development of publicly available protocols for COVID-19 critical care management. Table 1 lists the lacunae in the health service sector in India and the associated benefits of tele-ICUs, potential barriers and Cloud physician solutions for the same.

Table 1: Current issues in healthcare, advantages of tele-ICUs, their barriers and proposed solutions..

Current Healthcare Issues	Advantages of tele- ICUs	Barriers associated	Proposed solutions	
1. Paucity of adequate critical care resources & experts and disparities in their geographical distribution	Increased availability of critical care expertise over wide geographical distribution, by linking critical care specialists in tier 1 and 2 cities nation- wide with rural & under-served areas.	1. Tele-communication services subject to local tele-communication services, landscape, weather and unstable geo-political situations.	Use of technology that requires low internet bandwidth for data transmission and to work with local tele- com companies in establishing the necessary infrastructure for the use of advanced technological solutions.	
2. Lack of trained healthcare workers (nurses, assistants etc) in care of a critically ill patient	Tele-ICU services can fill lacunae in expertise of healthcare workers, particularly in the field of critical care.	2. Training of ground team healthcare workers require extensive time and resources investments	Organizing training sessions for ground teams in basic critical care to ensure uniform competency among remote hospitals	
3. Varied knowledge among consultants/health teams on best care practices and poor access to health information resources like testing, treatment guidelines etc resulting in inconsistent implementation and avoidable complications.	A single tele-ICU team can act as a center for healthcare information and resources and help remind staff of protocols and best care practices, thus enforcing consistent implementation of the same and avoiding complications	Non-acceptance by staff, scrutiny by the tele-ICU team and conflicting medical advice between the hub and ground teams are barriers to a good working relationship between them.	Studies have shown that even amid initial ambiguous acceptance in some cases, overall acceptance of tele-ICU services by ground staff is high with high levels of perceived better patient outcomes. A good working relationship between the tele-ICU and ground teams, with clear division of responsibilities would be required.	



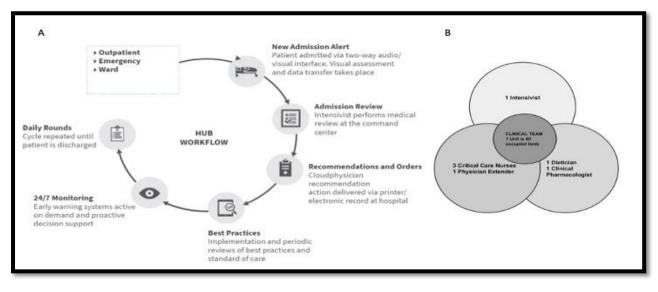


Figure 1A: Workflow of the Cloud physician model. 1B: Composition of tele-ICU team

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# Artificial Intelligence in Diabetic Retinopathy screening -Indian innovation to prevent Blindness



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# Diabetic Retinopathy: A Global Disease Burden

Diabetes mellitus is a global disease burden. Considering data pooled in since 1980 in terms of age-standardized data, diabetes mellitus (DM) prevalence has increased by 110% in men and by 58% in women, reaching, respectively, 9% and 7.9% global prevalence in 2014 (1). In India's case, the IDF atlas of 2020 estimates 77 million people live with diabetes. 20% of 24.4 million patients with Impaired Glucose Tolerance (IGT) add up to this number each year and along with 44 million undiagnosed cases quoted in the Atlas, takes the total close to 120 million. This contributes majorly to the global disease burden and given India's mammoth population, diabetes remains a major concern for healthcare practitioners in the subcontinent and even, globally (2).

Diabetic retinopathy (DR) affects roughly a third of patients affected with diabetes. It is the most common cause of preventable blindness in working-age adults (3). DR aligns patients

with risks of developing cardiovascular complications like stroke, coronary heart disease, and heart failure. With an estimated prevalence of 35.12% (in patients living with diabetes after 5 years of being diagnosed), the International Association for Prevention of Blindness (IAPB) predicts that about 45 million have vision-threatening DR. Meta-analysis published in diabetes care mentions that DR blinded 1 out of every 39 blind people and impaired vision in 1 out of 52 of those visually impaired (2).

As per research conducted by CINDI (chronic complications in newly diagnosed patients with type 2 diabetes in India) in 2014, around 6.1% of cases of newly diagnosed type 2 patients had established DR at diagnosis itself. Another report in 2016 (CINDI 2) concluded that in terms of complications in newly detected Type 2 Diabetes Mellitus patients below the age of 40 years (young-onset T2 DM) there were 5.1% of the study population with established DR at diagnosis (2)(4)(5).

#### **Diabetic Retinopathy Screening: Challenges and Possible Solutions**

As far as global data is concerned, in 2008 DR prevalence data collected from 35 studies reported a global overall prevalence of 34.6% for any DR, with DR risk increasing with diabetes duration. Taking into consideration that in the last decade multiple factors have contributed to the changing patterns of DR epidemiology, including DM burden trends, advances in DM and DR diagnosis and treatment, behavioral and population-level DM, and DR risk factors' distribution and healthcare service delivery across different regions, it has become all the more imperative to have effective screening programs to assess the disease in its early stages (1).

In most lower and middle-income countries, most physicians face the challenge of lack of facilities and/or the necessary ophthalmologic setup to assess the condition and severity of the DR patients, 70% of whom remain asymptomatic during their early stages. It is only evident when advanced macular edema or vitreous hemorrhage occurs and poses the risk of permanent blindness. Referrals made during such situations do not really help. Even if the referral visits are made, factors like additional costs, age, altered vision post-pupil-dilation, unavailability of referring ophthalmologists become the main barriers between patients and the treatments (2).

Early screening of DR is not only necessary to assess the patient's DR status, but it also leads to controlling one's glycaemic index, hypertension and dyslipidaemia; to ensure smoking

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cessation, and to look for early markers of diabetic nephropathy as well (2)(6). There have been some attempts at tele retinal screening programs, wherein fundus images are sent to reading centres via the Internet for evaluation by trained doctors for grading as per international norms as no DR, mild Non-Proliferative DR (NPDR), moderate NPDR, severe NPDR, Proliferative DR and Diabetic macular edema (DME) (6). Unfortunately, developing countries like India do not have "dedicated" reading centers for teleophthalmology unlike other countries (7). Among the few centers with specialized infrastructure to grade images, doctor fatigue, variable image quality, pixel size variations in cameras, reader screen type, upgradable images and infrastructural issues like access to the internet are some of the reasons for poor-quality grading and screening outcomes (2). Thus, manual grading of images, may not be a scalable model for DR screening, especially in developing nations. At the same time, the high cost of traditional retinal imaging devices, and the need for trained workforce (usually optometrists) in using these devices, make it unviable to implement large scale. All these concerns compel us to look for affordable, and if possible portable options for DR screenings, mainly in primary care settings to ensure maximum reach among patients (7). Cameras that are affordable and simple to use, and which have been clinically validated in literature to provide excellent sensitivity and specificity compared to well-accepted gold standard retinal imaging systems, in screening for DR continue to be a clear and present need, for implementing large scale models for DR Screening.

#### **Smartphone based Non Mydriatic Retinal Imaging Systems**

Owing to extensive research, there have been several cost-effective retinal imaging devices that have entered the market. Among many such cameras available in the global market, the Remidio FOP (Fundus on Phone) is the only FDA-approved, non-mydriatic, smartphone based, cost-effective camera. The use of a Smartphone interface to acquire images simplifies the image acquisition process, and thus the burden of training. This camera has been compared with the other high-end cameras like Topcon TRC50DX and Zeiss FF 450 in separate studies in literature and has been found to have high sensitivity and specificity and substantial agreement with conventional retinal photography (16), (17). Backed extensively by scientific data, studies have reported that "the rate of "upgradable" images is acceptably low and in case of Remidio NMFOP, image quality was marginally better than even a traditional desktop imaging device (17). This portable camera can be used as a "hand-held"

device or can be easily mounted on a tabletop. Remidio FOP takes both mydriatic and nonmydriatic images of high quality. Most importantly it eliminates the need to have specifically trained personnel to take retinal photographs. People can be trained to use the device in a day (2).

#### Artificial Intelligence in Automated Diabetic Retinopathy Screening

Artificial Intelligence is a boon for biomedical research that has potential applications in medicine and healthcare. Machine Learning (ML) and Deep Learning (DL) techniques use algorithms that employ trained neural networks – a mapping between input images and the clinical ground truth from an ophthalmologist/ specialist, generated using large historical datasets. Since they use different levels of permutation and combination between the inputs, constantly learning from the repetitions and self-corrections before arriving at a reasoned conclusion on any given case, their accuracy quotient automatically becomes higher (8)(9).

DR has evolved to be a hotspot for AI. DR being a global health burden, tele retinal screening programs using automated algorithms and retinal imaging systems are being shown to have a positive impact on screening. A host of studies have been reported by various ophthalmologists who have implemented DL algorithms for detection of micro aneurysm, haemorrhage, exudation, cotton-wool spot and revascularization among DR patients. Some of the algorithms used in this respect included morphological component analysis (MCA), Lattice Neural Network with Dendritic Processing (LNNDP) & k-nearest neighbor (kNN)

(10)(11).

A potential benefit of AI-enhanced diagnosis is the sheer increased number of patients who get screened and receive an instant report on their diagnosis. This not only gives them an edge in terms of early initiation of treatment but also imparts educational insights to the

patient immediately after scanning, which motivates them to adhere to their treatment regimen and subsequently increases compliance (12).

DL algorithms for DR detection have been reported to have higher sensitivity (~97%) as compared to manual efforts by ophthalmologists (~83%) (8,13).

There have been several different companies, that have demonstrated the efficacy of automated DR analysis and a comprehensive review of these AI solutions and their reported sensitivity and specificity in clinical validation studies are presented in TABLE 1.

In recent years, there has been a move towards "offline" AI algorithms – that allow inferencing or automated AI analysis of the images captured on the imaging device itself,

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without the need for the images to be sent to the cloud (15), thanks to the neural net running on the device itself. Such approaches that enable the use of mobile GPU's to run the neural net, are particularly relevant in infrastructure poor settings, where access to the internet may in some places only be intermittent. The Medios AI, from Medios Technologies, Singapore, is one such company.

# Table 1:Efficacy of AI in Detecting Referable Diabetic Retinopathy Based on Trials with various Retinal Imaging Devices focused on "edge" based AI solutions in healthcare.

Study (Authors)	Type of Study	Camera Used	AI Algorithm	Dataset	Condition	Sensitivity (%)	Specificity (%)
Rajalakshmi et al."	Retrospective	Remidio, Fundus on Phone (FOP)	EyeArt	Internall y generated dataset	RDR	99.3	66.8
Abràmoff et al.ª	Retrospective	Topcon TRC NW6 non- mydriatic fundus camera	AlexNet/ VGG	Messidor -2	RDR	96.8	87
Gulshan et al."	Retrospective	Topcon TRC NW6 non- mydriatic camera	Inception-V3	Messidor -2	RDR	87	98.5
Gulshan et al. <sup>"</sup>	Retrospective			EyePACS -1	RDR	90.3	98.1
Gargeya and Leng <sup>:</sup>	Retrospective		Customised CNN	Kaggle Images	RDR	No data	No Data
Ting et al."	Retrospective	FundusVue, Canon, Topcon, and Carl Zeiss	VGG-19	SiDRP 14–15	RDR	90.5	91.6
Ting et al. <sup>19</sup>				Guangdo ng	RDR	98.7	81.6
Ting et al. <sup>19</sup>				SIMES	RDR	97.1	82.0
Ting et al."				SINDI	RDR	99.3	73.3
Ting et al.»				SCES	RDR	100	76.3
Ting et al."				BES	RDR	94.4	88.5

Ting et al. <sup></sup> "				AFEDS	RDR	98.8	86.5
Ting et al. <sup>∞</sup>				RVEEH	RDR	98.9	92.2
Ting et al. <sup>»</sup>				Mexican	RDR	91.8	84.8
Ting et al. <sup>™</sup>				СИНК	RDR	99.3	83.1
Ting et al.»				HKU	RDR	100	81.3
Abràmoff et al.ª	Prospective	Non-mydriatic retinal camera (NW400, Topcon Medical Systems, Oakland, NJ)	Alex/VGG	10 primary care practice sites from the USA	RDR	87.2	90.7
Ramachandra n et al.*	Retrospective	'Canon CR-2 Plus Digital Non-Mydriatic Retinal Camera (Canon Inc., Melville, New York, USA)	Visiona	ODEMS	RDR	84.6	79.7
Ramachandra n et al.*	Retrospective	'Canon CR-2 Plus Digital Non-Mydriatic Retinal Camera (Canon Inc., Melville, New York, USA)	Visiona	Messidor	RDR	96	90
Natarajan et al.≝	Prospective	Remidio Non Mydriatic Fundus on Phone (NM FOP 10)	Medios AI	Internal dataset generated	RDR	100	88.4
Sosale et al. <sup>∞</sup>	Prospective	Remidio Non Mydriatic Fundus on Phone (NM FOP 10)	Medios AI	Internal dataset generated	RDR	98.8	86.7

#### **Offline Artificial Intelligence: Medios AI & Its Potential**

Amidst multiple AI software that are available in the western world, IDX & EyeNuk are the only two to have cleared FDA's approval in 2018. A majority of organizations use cloud based "online" software support for arriving upon a reasoned conclusion in terms of DR diagnosis and hence need Internet support. India probably records the highest mobile usage in the world, but internet connectivity is still a major concern (2).

Medios is a Singapore-based company that has developed an AI-based solution and has partnered with Bangalore-based Remidio Innovative Solutions Pvt. Ltd. that manufactures cost-effective, FDA-approved fundus camera, the Remidio FOP (Fundus on phone). The main USP of Medios AI based software is that works "Offline" and does not need Internet connectivity to transfer data for referrals and opinions (2). An iPhone fit on the back of the camera has inbuilt DR detection software and diagnosis is made in less than 20 seconds. FOP provides a 40° field of view for nonmydriatic fundus imaging and can be used in a handheld mode or be fit onto any standard slit lamp. Autofocus and Image Capture facility, makes it easier for anyone not trained also to take good images. A PDF report generated after initial examination shows Lesions as heat maps indicating the presence of DR that needs "referral". AI also checks the quality of the images before making the diagnosis and poor-quality images are discarded to avoid false reporting (2)(14).

A recent study conducted with fundus images of 301 patients with diabetes were run on the Medios Software at Dr. Mohan's Diabetes specialties Hospital in Chennai. The images were graded by an ophthalmologist according to the International Diabetic Retinopathy Classification System. The ophthalmologist was blinded to the diagnosis of the AI. The AI reported the images as REFER (mod, severe NPDR, PDR, and DME) or NO REFER (mild NPDR or no DR). The diagnosis of the AI was compared to that of the ophthalmologist. Results presented at APTOS July 2018 conference at Singapore (under publication) showed sensitivity for referable DR (mod, severe NPDR and PDR) as 96.6% (95% CI 92.1–98.9) and for severe NPDR and PDR showed was 100% (95% CI 94.8–100) (2).

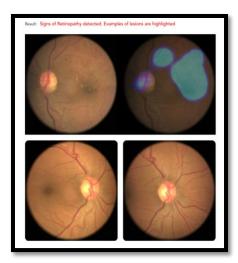
Another study aimed at evaluating the performance of the Medios AI to detect RDR on images taken on Remidio's Fundus on Phone (NMFOP10). This study analyzed a total of 231 patients with Diabetes Mellitus visiting various dispensaries under the municipality of Greater Mumbai (15). These results were presented at 2018 RSSDI conference (under publication). This study showed the ease of usage of this Remidio FOP and AI by healthcare workers who were trained just for a day to take fundus images.

The results showed impeccable sensitivity and specificity of an offline AI algorithm in grading RDR with values of 100% and 88.4% respectively and of any grade of DR as 85.2% and 92% respectively, when compared to manual reports generated by trained ophthalmologists (15).

A team at Diacon Hospital in association with Retina Institute of Karnataka, Bangalore, has conducted two large studies. In the first study, three mydriatic images per eye were taken and the AI diagnosis was compared with that of two senior retina vitreous surgeons. A total of six images per patient from 304 patients were analyzed and results have been presented at ATTD 2019 conference in Berlin in February. Sensitivity and specificity for referable DR (mod NPDR and more severe or the presence of DME) were 98.84 and 86.73. Sensitivity for sight threatening DR (severe NPDR, PDR or the presence of DME) was 100%. Sensitivity and specificity for any DR (mild, mod NPDR and more severe) was 86.78% and 95.45% (under publication) (2).

The largest study from India using an offline AI (SMART STUDY) on a portable costeffective FOP camera was presented at ADA 2019 in San Francisco by the same team. The results of AI diagnosis using non-mydriatic retinal images of 900 patients were compared to the diagnosis of 5 ophthalmologists (considered as ground truth) (2) (24). Sensitivity and Specificity for Referable DR was 93% and 92.5 % in the SMART study and is very impressive and far exceeds FDA's cut off for approval. Many other researchers have shown similar results with Remidio FOP and AI-driven diagnosis. This is the only AI system that works offline and produces real-time reports on a smartphone.

#### Figure1 A typical report generated by the offline Medios AI algorithm





#### Conclusion

Deep learning and artificial intelligence are here to assist physicians in their endeavour to solve the challenge of mass DR screening. Also, the use of Artificial intelligence (AI) along with Smartphone-based fundus photography for Diabetic retinopathy (DR) detection and classification is a practical way forward, given the currently available clinical validation data (14).

Devices like the Remidio NMFOP that are portable, cost effective, easy to use, FDAapproved, and clinically validated, may thus be relevant in 'Clinician set ups' and large scale public health driven DR Screening programs. Offline AI algorithms for DR screening like the Medios AI that work directly on the retinal imaging devices, including on low processor environments like a Smartphone, giving instant reports highlighting lesions (heat maps as in Figure 1), will definitely be highly relevant in large scale DR screening programs. The studies conducted so far have shown that the offline AI algorithm by Medios, when combined with effective imaging devices like the Remidio NM FOP, can be used for screening for diabetic retinopathy, effectively, in non-specialist contexts like in primary care (15), (18).

The sensitivity of the Medios AI with mydriatic and non-mydriatic images exceeds the FDAmandated superiority endpoints. This has the potential to open new doors to make DR screening more accessible. Larger and multi-centre studies would be helpful in validating these results further and provide the possible solution to India's DR screening challenge (2).

The use of AI when used wisely and cautiously, with the proper amount of tracking and reporting, could most definitely provide the desired output that would help patients to improvise on their treatment regimens and increase adherence and compliance. It also promises to reduce the cognitive workload for physicians and ophthalmologists, thus improving care and diagnostic accuracy while improving clinical and operational efficiency (2).

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Wearable devices and wearable technology in healthcare



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#### Introduction

Chronic diseases like diabetes, hypertension, cardiovascular diseases, neurological diseases etc account for nearly three-fourths of deaths worldwide and impose a significant economic burden. Effective management of these diseases requires continuous monitoring. Different strategies are required for the diagnosis and management of these diseases including methods for real-time monitoring. Maintaining a good lifestyle with regular exercise and a count on consumed or burnt calories is helpful in the primary prevention of many chronic lifestyle disorders. Advances in electronics, communication and data sciences are bringing out devices that are miniaturized and easily worn on the body resulting in the evolution of newer wearable devices and wearable technology.

Wearable technology is a category of electronic devices that can be worn as accessories on the wrist, arm, and waist or can be even implanted in the user's body/clothing. These hands-free devices powered by microprocessors can help measure body temperature, heart rate,

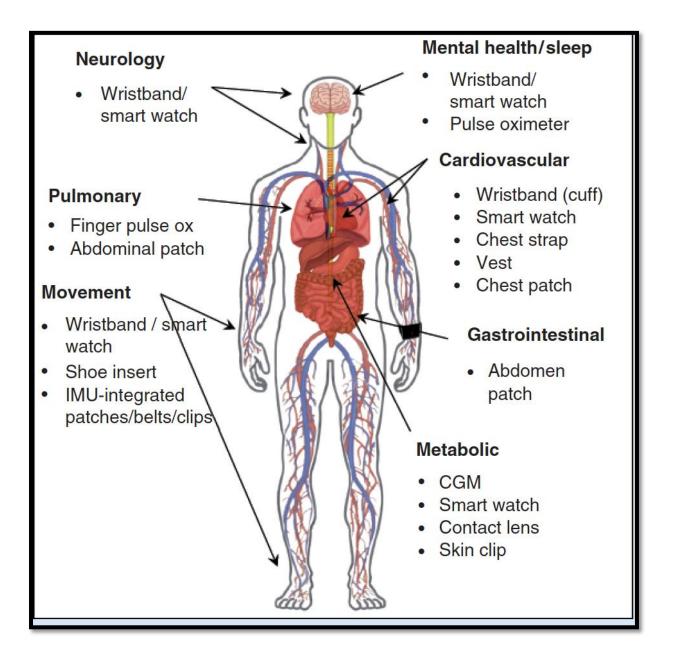
breathing, movements, direction, location, blood oxygen, sleep, and electrocardiogram. These devices have the added ability to send and receive data over the internet. With the advances in mobile technology, sensors, and the growth of the internet, these devices are gaining popularity in terms of product development and consumer usage. These devices are small, simple, and wearable and have features like wireless mobility with intelligent functions.<sup>1</sup>

#### **Types of wearable devices:**

Wearable devices (WD) are of different types based on the site of use. Most devices are worn on limbs like watches, bands and rings. Some can be worn on the head like glasses or goggles, helmets etc. Some devices are embedded in fabrics and can be worn on the body like clothing. Wearable's can measure biochemical parameters like glucose, physiological functions like breathing, sleep etc. or movements like step counts or exercises. They may be used as consumer devices like watches, fitness bands or clinical tools like continuous glucose measurement systems (CGMS) or even as research tools.<sup>2</sup>

- a. Smart watches are worn on the wrist and connected to Smartphone devices. Apple watch dominates the smart watches landscape and is currently in the 7<sup>th</sup> generation of development. Initially designed as a fitness tracker with step counts, calorie spent, heart rate etc. current generation of Apple watches can record single channel ECG, measure oxygen saturation, and to an extent sleep and breathing pattern. Many android versions of smart watches are available from Google, Samsung, Xiaomi, Oppo, Amazon etc. with similar features.
- b. Fitness trackers are simple wrist bands with features to measure step counts, calorie burnt, few notifications etc. and are convenient for people who do not want a mini phone featured device or a complicated sports watch with multiple metrics. The Fit bit sport band, Xiaomi Mi band etc. are popular wristbands used for walking or jogging.
- c. Headgears or Goggles like Google glass provide an experience of virtual surroundings and can simulate any environment virtually and are used for applications of virtual reality or augmented reality.
- d. Wearable health devices can be in the form of clothing. Smart clothing, which uses computer chips to exchange electrical signals and data, or uses special materials to connect with a Smartphone to apply various functions, can measure changes in blood flow, biological rhythm, breathing, and the health of their users and accumulate data.
- e. Implanted sensor devices are small sensors that are inserted below the skin or tattooed on the skin. Examples include CGMS applications in diabetes management,

abdominal patches for pregnant women to measure maternal and fetal heart rate and or uterine contractions etc.



Wearable devices in different medical conditions (Image source: Dunn J, Runge R, Snyder M. Wearables and the medical revolution. Per Med. 2018 Sep;15(5):429-448. (Use of this content is permitted **under the Attribution-Non Commercial-No Derivatives 4.0 Un ported License. To view a copy of this license,** 

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#### Use of Wearable technology in healthcare:

WDs are useful in a variety of functions for general good health management and in several clinical situations for in hospital/ clinic or at home monitoring of many chronic medical conditions. Daily use of WD for exercise tracking, calorie burnt etc. are more common and present-day wearable technology has developed much beyond these simple functions. Analyzing the collected data with artificial intelligence (AI) have made these devices suggest the user trends of their daily exercise, heart rate variability, sleep pattern etc. and prompt them to take appropriate actions. With the ability to detect falls, WDs are useful in remote monitoring of health events of elderly people and can alert a trusted contact or an emergency service number about an impending serious medical event. WD is used for gait and fall quantification in older adults, monitoring the viability of older adults' daily activities in an unattended home environment and recognizing the main types of movement (walking, standing, sitting, lying) to help older adults to live independently.<sup>3</sup> A wearable fall detection system to detect falls by rapidly uploading data for the position of older adult individuals to the medical Centre and ensuring timely help and treatment has been developed.<sup>4</sup> Devices with GPS tracking abilities like watches or bracelets are also developed for tracking location, exercises of children.<sup>5</sup> Pregnant women can monitor physiological states like heart rate, sleep, emotion etc. and also can use the device for fetal heart rate monitoring, uterine contractions and to seek medical help in an urgent situation.

Wearables by continuous data collection and analytics can provide actionable insights in the management of patients with many chronic conditions like diabetes, hypertension, chronic obstructive lung diseases, parkinsonism etc.

#### Wearables in cardiovascular diseases management:

Cardiovascular conditions can cause sudden life-threatening events due to ischemia, arrhythmia, or cardiac failure. Traditionally continuous monitoring of cardiac functions is limited to in hospital management of cardiac rhythm with monitors or at home monitor with Holter monitoring. However, both have limitations like hospitalization or wearing a big device. Smart watches like Apple watch can record single channel ECG which can be triggered by the wearer himself and transfer the recording to a doctor. The device was shown to have similar accuracy to 12-lead ECGs in detecting atrial fibrillation, AV blocks and QRS duration extension.<sup>6</sup> A wearable cardioverter-defibrillator has been shown to protect from sudden cardiac arrest in nonhospital settings till the implantation of a cardioverter-defibrillator.<sup>7</sup> Measurement of electrolytes like potassium based on ECG and AI based

algorithms could be a future potential area of clinical use in patients with chronic kidney disease.

Wearable's are being developed in another important area of hypertension management. Blood pressure variability and diurnal fluctuations are well known and the "white coat hypertension" effect makes decisions based on single BP recording to be erroneous. Though ambulatory BP monitoring has become a vital tool in such situations, the inconvenience caused by repeated cuff inflations, disturbed sleep, has prompted for an alternative, less intrusive, wearable device for ambulatory or home monitoring of BP. New devices that promise to change the current paradigm of hypertension monitoring use either inflating wristband cuffs (e.g., Omron Heart Guide, currently undergoing clinical testing) or optical pulse wave-based metrics of BP. Other BP monitoring methods used case prediction algorithms based on heart rate and steps. A WD that can measure dynamic blood pressure accurately and comfortably without a cuff would be an attractive prospect. A wearable sleeveless device developed based on optical technology to monitor blood pressure changes by measuring the pulse arrival time (the pulse transit time from the heart to the peripheral blood vessels) is currently under testing.<sup>8</sup> These devices currently in development could make ambulatory BP monitoring easier and more convenient.

#### **Pulmonary diseases:**

Many wearables available today can measure heart rate, respiratory rate and even oxygen saturation, ECG and using predictive analysis could help the user with alerts regarding impending worsening of COPD, asthma etc. which can be helpful in early treatment and or to avoid hospitalization. The same features can be used for assessing the effectiveness of therapy of COPD. When combined with the weather forecast and air quality index information based on the location of the individual, timely alerts can be given about the possibility of worsening respiratory symptoms.

# Role of wearables in diabetes care:

Effective control of sugars helps to achieve a good long term prognosis and reduction in long term complications of diabetes. Blood glucose monitoring is an important first step in the effective control of blood sugars in diabetic individuals. Most of the methods of blood glucose measurements currently need a finger prick, inconvenient, or intrusive to a patient's daily life especially in those who need to test sugars several times in a day or week. Because blood sugar values frequently fluctuate for a variety of reasons, single point blood sugar estimation are unreliable in assessing glycemic control. With improvements in sensors and

wearable technology, various dynamic blood sugar testing products have emerged. Continuous glucose monitoring systems (CGMS) using a sensor inserted subcutaneously and results captured on a device with NFC or Bluetooth connection (flash CGMS) or connected to a mobile app for real time sugar values (Realtime CGMS) have become common in diabetes management and will not be discussed in detail in this article. Future CGMS using noninvasive technologies using alternative body fluids like tears, or optical methods which are noninvasive are in development. GlucoWatch is a noninvasive, painless blood glucose level monitoring product approved by the US FDA, has proven its applicability and feasibility in diabetes monitoring. Smartwatches with the ability to measure glucose with an optical sensor will be a reality in near future. CGMS devices combined with insulin delivery pumps are being developed to have an effective artificial pancreas and a few devices Medtronic's Minimed 670G have already made progress in this regard.

#### Wearable in neurology and rehabilitation:

Wearable devices can be used to analyze gait disturbances and detect falls which can be useful in early diagnosis or assessing treatment efficiency in Parkinson Disease (PD) or Alzheimer disease. Shoes fixed with sensors have been shown to detect gait disturbance of PD comparable to video-based assessments. A study using wearable (VitalConnect's HealthPatch) found that a tri-axial accelerometer worn at any location of a participant's body, and in any orientation, could detect falls with a sensitivity of 99% and specificity of100%.<sup>9</sup>

The *Emphatic Embrace*, a smart watch developed by MIT Media Lab, can detect seizures using electro dermal activity and accelerometry and can also notify emergency contacts.<sup>10.</sup>

Wearable sensors have made monitoring of sleep easier. Many smart watches measure the quality of sleep and can detect sleep duration, disturbed sleep, or even obstructive sleep apnea. Analyzing data received from movement sensors, heart rate sensors, oximetry and plethysmography, smart watches or wrist bands connected to mobile phones can monitor sleep duration, sleep disturbances or apneic spells. A WD, Oura ring was capable of detecting sleep and could detect 'light sleep', 'deep sleep' and REM sleep with good sensitivity and specificity comparable with polysomnography. Wearable and mobile apps together are used to assess mood disorders, depressive symptoms and with machine learning models could be used in the detection of bipolar disorders.

Wearable devices are used in sports rehabilitation, cognitive rehabilitation, and as rehabilitation aids for people with disabilities. Wearable with gait sensors can help to assess the progress of any rehabilitation program and to give feedback to the doctor. Devices capable of Virtual reality and augmented reality technology can be useful in making the rehabilitation program interesting and are tried in cognitive rehabilitation following stroke or neurosurgery.

#### Limitations of wearable devices:

Despite the advancements made in this field, there are several bottlenecks before they become a mainstay in healthcare. Some of the limitations of WD include the high cost of devices which make them not affordable to many and devices being tethered to smartphones, costs add up further. Rapid upgrades in the devices which makes new features added to new devices only can make old devices redundant or force the consumer to upgrade. Difficulty in using technology in a less tech-savvy population is another limitation for wider acceptance. With the devices being locked to either android or iOS platforms, incompatibility of devices in different platforms is another issue faced by consumers. The predictive functions of the algorithms in the devices can issue a false alarm which can cause unnecessary hospital visits and increase anxiety. Many of the features and applications explained above or in development and are yet to be widely available. Though useful from a consumer angle, to be accepted as a medical device, they must clear regulatory hurdles and proper testing in clinical trials. Like in any digital environment concerns about individual privacy, the safety of data and ethical sharing of data remain with WD technology and need to evolve in future as the usage of these devices increases.

#### **Conclusions:**

WD is rapidly evolving in technology and is assuming a vital role in maintaining the health of individuals by promoting exercise, activity, good sleep, etc. They are gaining ground in the detection and monitoring of several disease conditions and can be a useful tool in remote monitoring of patients, especially the elderly. Despite some limitations, the rapid stride in technology of wearable devices and mobile technology combined with AI, WD will hold promise for better personalized medicine in years to come. As the technology evolves and

takes shape many of the concerns about individual privacy, data safety, ethical sharing of data between different stakeholders also need to be addressed.

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# **Diabetes Technology: Digital technology of insulin delivery**



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#### Introduction

People living with Type 1 diabetes mellitus (T1DM) face a constant struggle daily to maintain normal glucose levels by frequently measuring their glucose and administering insulin as and when required. In contrast, in a person without diabetes, these routines are uncalled for, and the body seamlessly maintains glucose levels. The efforts to develop new technologies over the last two decades to improve the quality of life of these people with T1DM have resulted in smart devices that mimic the pancreas. Thus, they may be collectively referred to as artificial pancreas or artificial pancreas technology (APT).

The path gnomonic feature of T1DM is the autoimmune destruction of pancreatic  $\beta$  cells, resulting in insulin deficiency with subsequent hyperglycemia. Chronic hyperglycemia leads to several complications throughout the body, including neuropathy, retinopathy, nephropathy, and cardiac disease. The Diabetes Control and Complications Trial (DCCT) established that intensive insulin therapy (IIT) effectively delays the onset and slows the progression of these complications.<sup>1</sup> Yet, hypoglycemia remains the fundamental obstacle in applying IIT in children and adults with T1DM.<sup>2</sup>Nocturnal hypoglycemia has been associated

with increased morbidity, and prolonged hypoglycemic episodes often precede seizure activity and, more importantly, can lead to the sudden dead-in-bed syndrome.<sup>3,4</sup> So far, there have been no significant breakthroughs to prevent the onset of T1DM. Therefore, the best option is to manage it effectively. Treatment of T1DM has seen a paradigm shift from regimens based on understanding historical glucose logs to algorithm-controlled automatic insulin delivery (AID) systems based on real-time continuous glucose monitoring systems (CGMS).

Following the DCCT, several remarkable advancements in insulin formulations have allowed the use of long/ultra long-acting and rapid-acting insulin analogs via needles and insulin pens for multiple daily injection (MDI) therapy. MDI therapy can achieve strict glycemic control without hypoglycemia in some people with T1DM, especially those who are motivated and have undergone formal diabetes education and with high levels of ongoing input from healthcare professionals.<sup>5</sup> One of the critical issues with long-acting/ultra long-acting insulin is that it cannot be modulated after injection. Another reason for poor glycemic control in people living with T1DM is the erratic absorption and action of subcutaneously injected insulin that triggers unpredictable swings in glucose levels.<sup>6</sup> Continuous subcutaneous insulin infusion (CSII) via IP is effective in those people living with T1DM who have not achieved target HbA1c levels without disabling hypoglycemia using best attempts with MDI.<sup>5</sup> IP therapy also helps with lower glucose variability, better glycemic control, and higher treatment satisfaction than MDI therapy.<sup>7</sup>

#### **Basics of Insulin Pump Technology**

Medtronic Diabetes, Tandem Diabetes Care (TDC), and Insulet Corporation (Omnipod) are the three major companies manufacturing and developing insulin pumps in the United States. User-friendly and compact-design insulin pumps (IPs) started appearing in the US market for commercial use in early 1980, and by 1996 they were introduced in India.<sup>8,9</sup> Most modernday IPs are pager-sized, electronic gizmos consisting of a reservoir to store 200-300 units of insulin, a Teflon infusion cannula, or a stainless-steel needle inserted subcutaneously, and a tubing system (flexible plastic tube, 60-110 cm) that connects the reservoir to the cannula (Medtronic and Tandem pumps). IPs are either powered by an AA/AAA alkaline or lithium battery (Medtronic) or rechargeable via a USB port (Tandem). They usually have a screen for

displaying information and controls (buttons or touch screens) to allow the pumper to input data. IPs infuse insulin at a slow basal rate, round the clock with patient-activated bolus administered at mealtime and for hyperglycemia corrections. The anterior abdominal wall is the most commonly used infusion site. Other anatomical locations used include lateralabdominal walls, outer thighs, arms, hips, and buttocks. The infusion site needs to be changed once every 2-3 days and moved to a new location. CSII operates only on rapid-acting insulin (Lispro or Apart or Glulisine or Fiasp) and removes the need for ultra long-acting and longacting insulin (Glargine, Detemir, or Degludec). Modern-day IPs have the capacity for downloading data to a computer for clinical evaluation, which allows the caretaker to identify problems and aid in fine-tuning IP settings. Alternatively, IPs can be completely tubeless, attached to the skin with an adhesive, and connected to a wireless device for controlling insulin administration (Omnipod).

IP therapy can improve glycemic control in people living with T1DM due to its inherent capacity to reduce the intra-day and inter-day glycemic variability that is noted with MDI.<sup>7,10,11</sup> CSII via IPs is superior to MDI in several aspects: decreases the burden of daily injections, allows for fixing dawn phenomenon, prevents insulin stacking, permits temporary adjustments for anticipated and unanticipated glucose excursions, easy bolus for meals and high-glucose levels with inbuilt bolus calculators, accurate insulin administration, and allows for ultralow (0.01units) insulin dose delivery. The continuous ability to control insulin delivery provides the user or the "pumper" the enhanced flexibility in their day-to-day activities, both for planned and unplanned events.

#### **Insulin Pump Programming**

Traditionally, IPs are programmed to dispense insulin at a defined basal rate (single rate or multiple rates, generally as a continuous drip) and bolus for incremental doses before meals (meal bolus) or for correcting hyperglycemia (correction bolus). The IP settings are calculated from the pre-pump total daily dose (TDD) used with MDI therapy. Traditionally, a 20% reduction in TDD is used when commencing IP therapy. Half (50%) of the TDD is delivered as basal insulin. The basal rate is the number of insulin units delivered per hour. The total daily basal (TDB) is the number of insulin units a pump is set to deliver in 24-hours. Most pumpers have one to six basal rates. Pumpers can assign multiple basal patterns

or profiles, with each providing different TDB to accommodate for activity, illness, medications, physical exercise, and menstruation.

Once the basal is set, three other vital settings need to be programmed into the pump

- Insulin-to-carbohydrate ratio (ICR)
- Insulin Sensitivity (IS) or Correction factor (CF)
- Active Insulin Time (AIT)

ICR is how many grams of carbohydrates one unit of insulin covers. The recommended formula to estimate the ICR is the 450-rule (450 divided by TDD).<sup>12</sup> Previously, a 500-rule (500 divided by TDD) was employed as an initial setting in children.<sup>13</sup> If a pumper has an ICR of 1:15 (15 grams of carbohydrates /1 unit of insulin) and plans to eat 60 grams of carbohydrates, the IP will suggest four units (60/15 = 4). Furthermore, no additional insulin is administered if the pre-meal glucose is in the set target range. But, if the pre-meal glucose is above the set target range, more insulin is needed. This is referred to as IS or CF: how much one unit of insulin is expected to lower blood glucose. The currently recommended formula for estimating this factor is 1700 divided by the TDD. <sup>12</sup> If a pumper has an IS or CF of 1:50 (1 unit of insulin drops glucose by 50 mg/dl), target glucose of 150 mg/dl and the blood glucose is 250 mg/dl, the pump will suggest two units (250-150 divided by 50). IS or CF can be employed for glucose corrections pre-meal or at any random time glucose levels are not in range. AIT refers to the duration of insulin activity that has been delivered to the pump. AIT provides the residual activity of insulin delivered by a previous bolus and thus modifies subsequent boluses. This modification helps to minimize the "stacking" effect of multiple boluses. Traditionally, AIT is set between 4-6 hrs.<sup>14</sup> The pumper has complete control over the IP bolus calculations and always has the autonomy to manually override the suggested estimates; however, this override should be used in only certain odd circumstances.

#### **Continuous Glucose Monitoring Systems**

Several advancements in glucose monitoring have introduced and improved continuous glucose monitoring systems (CGMS). CGMS measure, analyze and display the interstitial-fluid glucose concentrations every 1-5 minutes and provide the user with interstitial glucose data regarding

- the past glucose levels,
- the current glucose levels,

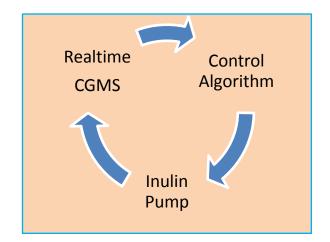
- the future direction of change, and
- the rate of change in glucose levels.

Most importantly, CGMS provides real-time audio, visual and vibratory alerts to the user when they detect or predict hyperglycemia or hypoglycemia up to 30 minutes into the future. Today's CGMS comprises a sensor that measures interstitial glucose, a transmitter that remotely transfers glucose data, and a receiver for the user to view the glucose readings. Most modern CGMS does not require finger stick calibrations, and sensor accuracy has significantly improved since its inception and continues to improve. Dexcom G6 and Freestyle Libre 2 CGMS are factory calibrated and do not need routine calibrations, whereas Medtronic Guardian 3 needs to be calibrated two-four times daily. Medtronic Guardian 4 is not yet available in the US. In contrast, the Ever sense CGMS is an implantable, under-theskin sensor that works with a removable and rechargeable smart transmitter worn over the sensor and a smartphone app for real-time glucose monitoring. Each sensor lasts 90 days. The Mean Absolute Relative Difference (MARD) is used to characterize the measurement performance of CGMS. The MARD is computed using temporally matched glucose data from CGMS and comparison glucose measurements obtained by capillary blood glucose of all subjects in a clinical study. A CGMS with a MARD < 10% is considered to have good analytical performance.<sup>15</sup> Real-time CGMS are now considered standard of care for people living with T1DM using IIT to minimize diabetes-related complications.<sup>16</sup>

#### **Recent Advances in Pump Technology**

An open-loop insulin delivery system is simply the administration of insulin by the patient at different times of the day.<sup>17</sup> The mode of insulin delivery could be via a syringe, insulin pen, insulin patch, inhaled insulin, or even an insulin pump. In contrast, a closed-loop system is an evolution to the open-loop system, in which patient involvement in maintaining glucose control is minimal. This system will calculate insulin requirements at all times and even deliver the appropriate insulin dose. "Looping," sometimes loosely referred to as artificial pancreas system or automated insulin dosing, is the ability to not only connect IPs to CGMs but also allow algorithm-driven automatic insulin dosing based on real-time CGM data. And "loopers" are people who use this technology.

Fig: 1 Schematic of a closed-loop insulin delivery system. A CGM wirelessly transmits realtime interstitial glucose data to an AI-based algorithm anchored in an insulin pump or smartphone that constantly adjusts insulin delivery.



#### Evolution of insulin pumps technology

Older IPs that did not have CGM system integration ability are considered open-loop systems. Subsequently came the sensor-augmented pump (SAP) therapy which integrated IP and CGMS technology. The Sensor-Augmented Pump Therapy for A1c Reduction (STAR) 3 study showed SAP therapy resulted in lower glycated hemoglobin(A1c) compared to MDI, with no increased risk of hypoglycemia.<sup>18</sup>

SAP therapy can be broadly divided into two generations.

- 1<sup>st</sup> generation SAP: the insulin dosing software functions independently of CGMS values; thus, the user must make manual basal insulin adjustments based on real-time CGMS data.
- 2<sup>nd</sup> generation SAP: the insulin dosing software and the real-time CGM values are linked into one system, allowing automatic suspension of basal insulin delivery for (A) a detected glucose threshold or (B) predicted low glucose.<sup>19</sup>

One of the landmark steps to reach a true artificial pancreas was developing low-glucose suspend systems, wherein insulin delivery is stopped when the sensor glucose falls below a predefined low-glucose threshold using a sensor-augmented insulin pump.<sup>20</sup> The MiniMed Paradigm Veo and Minimed 530G can suspend insulin delivery in response to sensor glucose

(SG) values at or below a prespecified threshold (Low Glucose Suspend or Threshold Suspend). The only difference between threshold suspend and low glucose suspend is the SG range for insulin suspension. Decreasing nocturnal hypoglycemia by stopping insulin delivery with threshold suspend was one of the first aims of AID.

Subsequently came the predictive glucose management systems, wherein insulin delivery is stopped when an algorithm anticipates the sensor glucose to likely fall below a predefined low-glucose threshold.<sup>21</sup> This function is called predictive low-glucose suspend (PLGS). The MiniMed 640G was the first commercially available IP with SAP technology that has both suspend on low (Low Glucose Suspend) as well as "suspend before low" features: basal insulin delivery is stopped if the SG value is predicted to reach or fall below a preset low limit (50-90 mg/dl) within 30 min. This IP also came with an "auto resume" feature: insulin delivery resumes 30 minutes after suspension if SG value is above the low limit and is predicted to remain above the low limit for the next 30 min. MiniMed 640G was launched internationally in 2015 but is not FDA approved for use in the US. The US equivalent of MiniMed 640G is MiniMed 630G, which the FDA approved in 2016.<sup>8</sup>

In multiple randomized controlled trials, home use of a predictive low-glucose suspension system substantially reduced the frequency and duration of nocturnal hypoglycemia compared with SAPs without automated insulin suspension function.<sup>22–24</sup>For both SAP generations, meal bolus and correction bolus are manually controlled, preferentially, with built-in bolus calculators in the IP.<sup>19</sup>

The next phase in the evolution of APT was the development of Hybrid Closed Loop (HCL) systems. The MiniMed 670G with Guardian Sensor 3 CGMS was the first commercially available HCL system, available since September 2016. The system functions in two modes, manual mode, and auto mode. Manual mode allows the pump to function as a traditional IP, and when paired with the CGMS, it operates in "Auto Mode," which has the added benefit of PLGS. Auto Mode is the Medtronic's propriety name for the hybrid closed-loop functionality and targets SG to120 mg/dL. The MiniMed 670G system responds to the SG value and automatically adjusts basal insulin delivery.<sup>25,26</sup> It runs by delivering insulin as a "micro bolus." MiniMed 770G has the same technology as MiniMed 670G but also includes the

ability to mirror the IP screen to one or more smart phones and extends the age indication to two years and older.<sup>8</sup>

The TDC's Basal IQ Technology, a PLGS feature designed to help reduce the frequency and duration of hypoglycemia, was approved by the Food and Drug Administration (FDA) in June 2018. The device suspends insulin delivery when low glucose is predicted to drop below 80 mg/dL or if glucose is currently below 70 mg/dL and falling, then automatically resumes insulin delivery once glucose levels begin to rise. The algorithm works with SG data obtained from Dexcom G6 CGMS and is designed to analyze 30 minutes into the future to predict where glucose levels are heading. <sup>27</sup> This technology is now referred to as standard HCL (sHCL) to differentiate it from the Advanced Hybrid Closed Loop System (aHCL).

A step above the sHCL system is the aHCL. The Control IQ technology from TDC was the first FDA-approved aHCL system for commercial use in the US since January 2020. It works with the Dexcom CGMS. Once the Control-IQ feature is activated, the pumper does not need to switch modes or reactivate closed-loop, as the AID system will adjust insulin delivery as soon as SG measurements are received. Also, finger stick capillary blood glucose calibrations are not required. This aHCL algorithm is unique in that it will administer an automated correction bolus in addition to automated basal rate adjustments and hypoglycemia suspension.<sup>28</sup>

Medtronic 780G is another aHCL system available in the European courtiers since 2020 and recently launched in India in January 2022,<sup>29</sup> but not yet in the US. This system's algorithm will accommodate insulin delivery for various physiological changes in glucose levels. In addition to the abilities of sHCL systems, these pumps are equipped with technology to provide additional insulin bolus for missed meal-bolus and errors in carbohydrate counting. These systems are still considered "hybrid" since they still involve user interaction for recording carbohydrates, mealtime bolusing, and optional correction bolusing to optimize glucose control.

Insulet's Omnipod 5 AID system (Omnipod 5) was FDA approved in January 2022. This system is the first tubeless AID system and integrates with Dexcom G6 CGMS. This system consists of two components,

• Pod: a disposable, waterproof, tubeless, adhesive insulin patch pump with inbuilt insulin reservoir, batteries, and a soft indwelling infusion cannula that can be worn up to 72 hours.

• Personal Diabetes Manager (PDM): a wireless, touch screen Android device to remotely program the Pod, control insulin delivery, and periodically monitor Pod status.

The pump reservoir holds 200 units of insulin and delivers insulin in increments of 0.05 units. The single-use disposable Pod attaches to the body with a standard medical-grade adhesive. The latest PDM is called Omnipod DASH. Compared to previous generations of PDMs, the Omni pod DASH system has a touch screen, is Bluetooth compatible and capable of displaying CGMS data, and has other added features.<sup>30</sup> The HCL algorithms are contained within the patch pump or Pod, and therefore, if the PDM is misplaced or left behind, the HCL system will continue to run. The algorithm design also favors automated personalized tuning from 110-150 mg/dl.<sup>28</sup>

The use of a hybrid closed-loop system was associated with a more significant percentage of time spent in a target glycemic range than the use of a sensor-augmented insulin pump in two multicenter randomized trials involving children and adults.<sup>31,32</sup>

#### The Algorithm

Control algorithms have been used in various industrial processes and recently applied to diabetes management to maintain glucose in the target range.

Some of the algorithms used for automated titration of insulin include

- Model Predictive Control (MPC)<sup>33</sup>
- Proportional-Integral-Derivative (PID)<sup>34</sup>
- MD-Logic Artificial Pancreas or Fuzzy-logic<sup>35</sup>
- many more in the pipeline, including the use of artificial neural networks.<sup>36</sup>

MPC algorithms calculate insulin delivery by minimizing the difference between modelpredicted glucose concentrations and target glucose over a prespecified prediction time horizon. PID controllers adjust insulin delivery by assessing glucose excursions from three perspectives:

- (1) deviation from target glucose (proportional component);
- (2) area under the curve between measured and target glucose (integral component); and
- (3) rate of change of measured glucose (derivative component).<sup>37</sup>

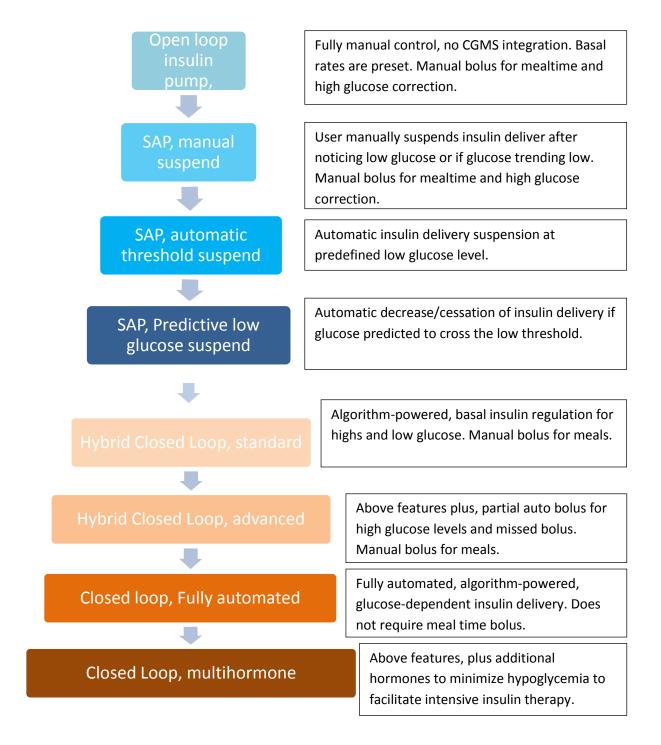


Fig: 2 The path to the artificial pancreas: Key technology milestones in insulin pump therapy

#### **Control Parameters**

A1c is currently recognized as the key element for assessing glycemic control and as a surrogate marker for developing long-term complications in people living with T1DM.

However, A1c has multiple limitations and, more importantly, cannot identify inter-and intraday glucose variability. Unlike A1C measurement, the use of CGMS allows for the direct observation of glycemic excursions on a daily basis, which renders immediate therapy decisions and lifestyle modifications. CGMS also provides the ability to identify patterns of hypo- and hyperglycemia.<sup>38</sup> Glucose variability is known to be correlated with the risk of hypoglycemia. The Coefficient of variability (CV) threshold of 36% is used to define stable and unstable glycemia in diabetes because, beyond this limit, the frequency of hypoglycemia is significantly increased.<sup>39</sup>

Based on the international consensus following the Advanced Technologies & Treatments for Diabetes (ATTD) Congress in February 2019, a good glycemic control is defined as:

- Time in Range (TIR) (70-180 mg/dl): > 70%,
- Time Below Range (TBR) (<70 mg/dl): <4%,
- TBR<54 mg/dl: < 1%,
- Time Above Range (TAR) (>180 mg/dl): < 25%,
- TAR>250 mg/dl: <1%.<sup>38</sup>

Glucose management Indicator (GMI) is the new term for estimated A1c (eA1C). GMI is a measure converting the mean glucose from CGMS or self-monitored blood glucose readings, using a formula derived from glucose readings from a population of individuals, into an estimate of a simultaneously measured laboratory A1C.<sup>40</sup>

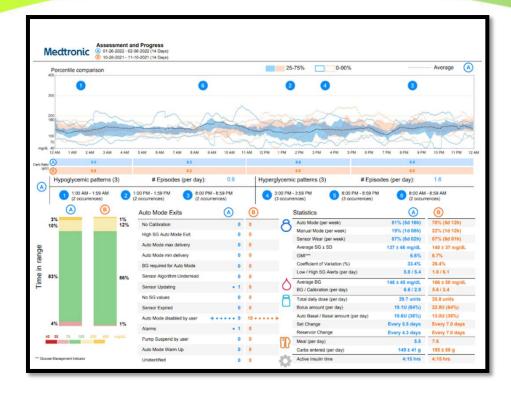
#### **DIY** looping

The #WeAreNotWaiting DIY (do-it-yourself) closed-loop movement emerged following a group discussion at the initial Diabetes Mine D-Data Exchange in November 2013 at Stanford University.<sup>41</sup> The foundation of these technologically savvy individuals is to enhance their insulin pump's capabilities beyond what is commercially available.<sup>42</sup> The

algorithms involved in DIY systems are typically created and built into a phone app installed on a cell phone. They then use an insulin pump and a CGM to run the algorithm an administer insulin. Different DIY algorithms are published as open-source code however, none of them are currently approved for use by the FDA as they have not undergone rigorous testing to determine safety and efficacy.<sup>28</sup> Open Artificial Pancreas System project (#OpenAPS) is a widely used open and transparent platform available to anyone with compatible medical devices willing to build their own looping systems. Open APS is a crowd-sourced safety-focused design and reference program that serves as a template for a DIY looper.<sup>43</sup>

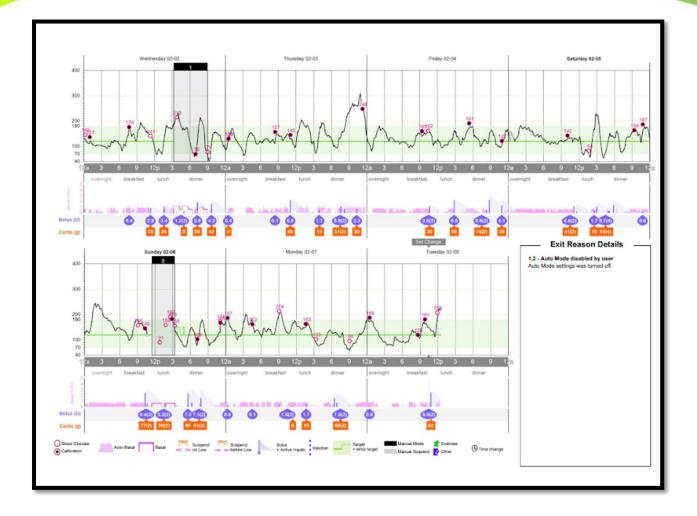
#### **Future Technologies**

In the future, closed-loop systems will require minimal to almost-no user interaction.<sup>44</sup> Closed-loop technology will eliminate the need for manual carbohydrate entry, mealtime bolus, and optional bolus for correction, thus significantly reducing the burden of diabetes. Breakthroughs in artificial intelligence (AI), new generation CGMs, smarter IPs, and Smartphone applications have opened new vistas to achieve increased time in range, reduce hypoglycemic episodes, and improve patient satisfaction and outcomes.<sup>45,46</sup> The impaired physiological response to hypoglycemia in people with T1DM offers a potential benefit in using glucagon in a closed-loop system. In a review and metanalysis of randomized controlled trials comparing artificial pancreas systems (insulin only or insulin plus glucagon), the use of a closed-loop system revealed significant improvement in overall glucose control compared to conventional pump therapy.<sup>47</sup> Glucagon is expected to prevent hypoglycemia and allow for the finest of IIT. However, there are several challenges: requirement for two separate infusion systems and non-availability of room-temperature-stable glucagon for prolonged subcutaneous use. There are no dual-hormone closed-loop systems commercially available, although several are in the clinical development stage.<sup>37</sup> Soon, we might see IPs operating with adjunctive medications like Pramlintide and Glucagon-like peptide-1 (GLP-1) agonists in multi-hormone closed loop pumps.<sup>48</sup> We are almost at a point where closed-loop systems will entirely mimic the pancreas.



#### Fig: 3 Pump download from MiniMed770G.

The top part shows 24 hours SG trends for the last four weeks; the previous two weeks appear in blue, and the previous two weeks in peach. The solid portion represents 25-75% of the SG values. The black dotted line represents the overall average SG. Midportion shows hypo/hyperglycemic events and hypo/hyperglycemic patterns. The bottom left portion shows time in range and different causes of auto mode exits. The bottom right shows several statistical information, including but not limited to average SG, GMI, and total daily insulin.



**Fig 4**: MiniMed 770G Weekly Review Report. The light green area in the graph represents target SG between 70-180 mg/dl. The solid black line represents the actual SG tracings. Pink lines represent micro bolus. Pink solid lines represent basal rates when the IP exists auto mode and defaults to manual mode. The purple lines show user-activated bolus for mealtimes and high glucose corrections. Carbohydrate entry is noted in orange. The box on the right bottom shows information for closed-loop exists.

Highest CGM Rea	ading Average CGM Reading		Average Reading		150 mg/dl
	150	12	Time in Use	97%	13 d 15 hrs.
40		40	Control-IQ Set to Off	0%	0 min.
			CGM Inactive1	2%	5 hrs. 57 min.
ime in Range			Pump Inactive <sup>2</sup>	1%	2 hrs. 42 min.
inte in trange			Avg. Sleep & Exerci	ise	
Above Target 19%	> 180 mg/dL		Daily Sleep		1 hr. 18 min.
Farget Range 80%	70 - 180 mg/dL	Number of Days CGM in Use 13.8 days	Weekly Exercise Eve	ents	0 times
Average Daily Insulin Sun Basal	amary				F0.07 10.00
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					35% 7.37 ulday
Food Bolus	-				
Food Bolus Correction Bolus					35% 7.37 ulday
Food Bolus Correction Bolus Control-IQ Auto Bolus	21.19 units / day				35% 7.37 ulday 5% 1.01 ulday
Food Bolus Correction Bolus Control-IQ Auto Bolus werage Total Daily Dose					35% 7.37 ulday 5% 1.01 ulday
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Food Bolus Correction Bolus Control-IQ Auto Bolus werage Total Daily Dose werage BG Tests	21.19 units / day 0.07 times / day	Tubing	Site/Canne		35% 7.37 ulday 5% 1.01 ulday
Food Bolus Correction Bolus Control-IQ Auto Bolus Average Total Daily Dose Average BG Tests Average CGM Readings Avg. Change Frequency	21.19 units / day 0.07 times / day 283.50 times / day	Tubing Every 4.00 days	Site/Cannx		35% 7.37 ulday 5% 1.01 ulday

Fig 5: Dashboard data from Tandem t:slimX2 with Dexcom G6 CGMS: Top left shows the overall average, highest, and lowest SG and TIR data. The top-right portion shows the total time pump runs in a closed-loop (Control IQ Technology) and time spent in sleep and exercise modes. Midportion shows insulin utility summary including average total daily dose. Bottom-portion shows the insulin cartridge and tubing changing frequency and the amount of insulin used.

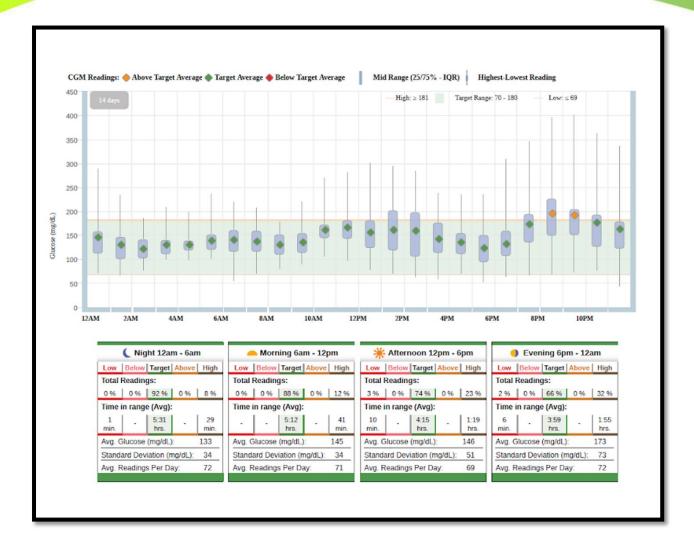


Fig:6: Tandem t:slimX2 with Dexcom G6 CGMS: CGM Hourly data

In the upper-half, the light green area represents target SG between 70-180 mg/dl. The solid gray regions represent 25-75% midrange, and the grey lines represent the highest-lowest readings. The diamonds (green denotes average in-range and orange denotes average out-of-range) represents the overall average SG for each hour averaged over the last 14 days. The lower-half represents daily TIR, TAR and TBR in four-equal quarters.

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#### **Panel discussion on Fungal Infections**

Excerpts from the Panel discussion on "Fungal infection in the ICU" which was organized by API, DK chapter on 17.Dec.2021.

Moderator: Dr. Chakrapani M

**Panelists:** 

Dr. SrikalaBaliga, Associate Dean, KMC, Mangalore

Dr. VishakAcharya, Professor, Department of PTCD, KMC, Mangalore

Dr. Deepak Madi, Additional Professor, Department of Medicine, KMC, Mangalore

Dr. JayaprakashKonkodi, Consultant Intensivist, Mangalore

#### Burden of these fungal infections in ICU :

Dr. Deepak Madi

There is a popular saying in ID circle - We live in a world ruled by microbes . Whenever we take a walk in our garden, there are lots of molds. About Candida, the burden of infection is 6.5 per 1000 ICU admissions. Candida Tropicalis was the dominant strain. Then there are Rare fungi, especially in immunocompromised patients histoplasma, Pneumocystis pneumonia and mucormycosis.

COVID has bought both Aspergillus and Mucormycosis to forefront. In 2021, in KMC Hospital, there were 21 cases of Canadida -17 were from Blood, 4 were from other samples. Interestingly, 2 wherein COVID- both were Candida and both of them died.

#### **Epidemiology of the fungal infections now**

#### Dr. Srikala Baliga

When we talk about invasive fungal infections broadly, we can tell it as yeast infections and mold infections. So when we talk about Candida infections, it will mostly be candidemia. Candidemia means isolation of Canada from blood, Or deep seated tissues like splenic abscess or liver Abscess. IV lines or total parenteral nutrition central lines can be the risk

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factors for candidemia. Source can either be exogenous through these lines or endogenous where patient's own gastrointestinal tract can be a source of infection. Whenever there is a GI urgery that could predispose or prolonged treatment with antibiotic that also can change the gut flora and predispose to Candida infection.

Of late we are seeing much more of the non albicans and it is very important. So we started speciating the Candida into albicans and non albicans, and further over the years we have started even speciating the non albicans. About 79% of invasive candida infections were because of non albicans candida. Among the non albicans. Candida Tropicalis was the one which was the most prevalent - about 40% was tropicalis . 50% of our ICU isolates were candida parapsylosis . But in the non ICU we had more of Candida albicans compared to the others.

Mold infections that we have seen is mainly aspergillosis and zygomycosis. The mortality is extremely high for invasive mold infections. Over the years, there is an upward trend in the incidence of mucormycosis. In aspergillosis, the most common predisposing conditions are solid organ tumors, Hemopoietic malignancy and neutropenia. It is also seen nowadays that aspergillosis can also happen in immunocompetent patients. 63% of patients had aspergillosis without the non classical risk factors. Most of these people have liver cirrhosis, previously diseased lung or OAD. The most common most common predisposing condition is diabetic ketoacidosis in our country, whereas abroad, it is mostly the solid organ tumors.

#### Dr.Vishak Acharya

There are certain risk factors, which might indicate a fungal infection- these, not very common in immune competent patients. We think of and suspect fungal infections in immune compromised patients and those with neutropenia, those with prolonged hospitalizations and who have received multiple or prolonged course of antibiotics.

Dr. Chakrapani: When you suspect fungal infection because many of these patients are already on antibiotics, they have many other diseases. At what point of time you start seriously thinking in term in terms of looking for a fungus?

#### Dr. Jayaprakash Konkody

Invasive fungal infection may be suspected in an ICU patient if -

1. Patient is suffering from septic shock and multiorgan dysfunction with the risk factors for developing invasive fungal infections

2. A sufficient good trial of antibiotics given for 7 days and there is no clinical improvement

In a study conducted by Arunalok Chakravarthy, mean duration of identification invasive fungal infection was around 8 days in Indian ICUs.

Risk factors for developing Invasive fungal infections in ICU -

- 1. Peritonitis, multiple abdominal surgeries, anastomotic leaks
- 2. Total parenteral nutrition, Central lines
- 3. Multiple dialysis
- 4. Infected Acute pancreatitis
- 5. Hematopoietic stem cell transplantation, cancer chemotherapy
- 6. Immunosuppressant (transplantation or autoimmune diseases)
- 7. HIV, Diabetes, steroids
- 8. >3 broad spectrum antibiotics

Fundoscopic examination done in 5-7 days of illness non-neutropenic patients and after recovery from neutropenia in neutropenic patients. Endophthalmitis more common in Candida albicans. Hence eye findings less common in non-albicans candida.

#### Prediction models- Colonization Index and Candida score

Risk prediction models have high negative predictive value and should be used for identifying high risk patients. Candida score can be done bedside with relevant clinical information. But Colonization index is given by the microbiology department. Colonization index > 0.5 and Candida score >2.5 may be helpful in predicting invasive fungal infection in ICU.

#### **Colonization Index = Number of sites positive for candida / number of sites screened**

## **Candida Score**

Predictive factor	Rounded risk score
Surgery	1
Multifocal colonisation*	1
Total parenteral nutrition	1
Severe sepsis	2
	specificity 74%) equates to sepsis plus g risk factors; or the presence of all of

Biomarkers – BDG, candidamannan, Germ tube antibody, antimannan antibody.

And further, there are biomarkers like Beta D-glucan, candida Mannan, Germ tube antibody, antimannanantibody. Out of them beta D-glucan is in common practice. But they are known for their negative predictive value. Canbe used to de-escalate and stop antifungals.

Finally, the suspicion and treatment of invasive fungal infection in ICU is **mainly a clinical decision** rather than lab-based decision.

Dr. Chakrapani. M

Other risk factor is constructions in the hospital. Can you throw some more light on construction activity as a risk factor for fungal infections?

Dr. Deepak Madi

It's mainly for molds. Aspergillus thrives in this environment. That's why you always say anything you are constructing in hospital. Please take opinion from the ICC. These fungi are everywhere and whenever any and all hospitals there will be construction going on, so we should be.

#### Dr. Chakrapani. M

Is there any difference in the clinical presentation or severity of albicanss and non albicans and the response to treatment?

Dr. Jayaprakash Konkody

Candida albicans is more virulent compared to non-albicans. Albicans causes more severe and acute disease with high spiking fever compared to non-albicans. But albicans is less common worldwide as per the epidemiological data. C. albicans has more predilection for eye involvement including endophthalmitis.

Antifungal resistance (native and acquired) is common in non-albicans.

- □ C. glabrata is not sensitive to azoles at a lower dose. High dose fluconazole used to treat C. glabrata.
- □ C. krusie is resistant intrinsically to fluconazole, but sensitive to voriconazole.
- □ Moreover, krusie and glabrata are only intermediate susceptible to AmB. Hence krusie and glabrata requires longer duration of AmB.
- Chance of MDR (resistance to atleast one agent each in at least 2 classes) and XDR (atleast 2 agents each in at least 3 classes) are more frequent in non-albicans. (There are 4 classes of antifungals)
- □ Non-albicans may have prior azole exposure and associated with central lines.
- $\Box$  C. albicans is generally a susceptible to azoles at usual doses.

Laboratory procedure for identifying albicansVsother species:

#### Dr. Srikala Baliga

As soon as the specimen is recieved, we will put it on to routine culture media. The gram staining - will be gram positive yeast like budding cells. Then, we put it on to routine culture media, maybe, Blood Agar, a chocolate Agar, and Mckonkie agar. A basic method, is the germ tube test. We take a few colonies mix it with pooled serum incubated at 37 degrees and again look at it after 3 hours under the microscope. If it is albicans, it produces something called as a germ tube. Germ tube is a small tube like structure which grows out of the yeast cell. So if there is a germ tube it is definitely Candida albicans , if there is no germ tube it is a non albicans candida. But nowadays we have other improved methods. one of them what we use is called as a Chrome Agar plate. When we see Candida, which has grown in any one of

our basic primary culture, we just plate it onto this Chrome Agar. we incubate this plate for about 48 hours and We can differentiate between Candida albicans, Candida tropicalis, Candida Glabrata and Candida krusei all based on the color of the colonies on this particular medium. But we have even more faster automated methods, that is by the Vitek. Identification can be done within 2-4 hours.

If it is Candida albicans, most of them are sensitive to azoles. I took all the candidate data from last one year and we found just one Candida glabrata which was resistant to all fluconazole, amphotericin B and echinocandins and one Candida krusei which was resistant to Fluconazole. Tropicalis generally behaves like Canada albicans and is not very resistant.

#### Invasive fungal infections in the COVID era.

#### Dr. Vishak Acharya

Apart from mucor, we also have been seeing a lot of other invasive fungal infections, especially Canadida and even Aspergillus. These have been seen in a section of population who had severe COVID pneumonia who stayed in ICU for more than a week or 10 days and patient received biologicals. These are the section of people who actually had fungal infections following COVID. They were not very commonly seen in a mild to moderate COVID. We used a lot of serum galactomannan assays during COVID. Surprisingly, majority patients had high level, Probably they were colonizing the Aspergillus at some point of time. There are a few categories of patients who have some radiological signs, which might fit into aspergillosis. They might show a Halo sign or the image for multiple nodules, especially central nodules.

#### Dr. Srikala Baliga

If It's not possible to go in for invasive procedures, we can do a galactomannan antigen test. In Neutropenic patients, it has a very high predictive value and good specificity but not in immunocompetent persons. If we do a BAL Galactomannan, the sensitivity increases to 80 to 90%. In post COVID aspergillosis, the only thing is to have a high index of suspicion. The clinical context is important, If there's a probable case, in the presence of appropriate host factors,mycological finding in any respiratory sample, It is better to treat it. Even in aspergillosis, we have angio invasion, and it is a rapidly spreading infection.

Dr. Vishak Acharya

There are certain CT patterns which are not very typical of COVID. In COVID patient when you see certain patterns which might not fit into classical COVID pattern, think of a bacterial infections, or maybe you think of a fungal cause. But there's no specific sign for fungal infection apart from a Halo sign. Apart from that, there is no classical signs of invasive aspergillosis.

Dr. Jayaprakash Konkody

IDSA recommends -

- □ Voriconazole, liposomal amphotericin B or conventional amphotericin B
- □ Conventional amphotericin B nebulization used in neutropenia, HSCT, Induction chemo, lung transplant.
- $\Box$  Echinocandin not recommended.
- □ Therapeutic drug monitoring should be done for triazoles when given with interacting medications or failure of clinical response to the trial of triazoles.
- $\Box$  Combinations of antifungals no evidence.
- □ Sensitivity testing not required routinely.

#### What about prophylactic antifungal?

Dr. Jayaprakash Konkody

Prophylaxis in high-risk for developing invasive candidiasis (Stem cell transplant patients, a neutropenic patients induction chemotherapy, HIV patient with low CD4 count). Routine use not justified.

Empirical therapy in clinical sepsis with high risk for invasive candida.

- 1. Septic shock and MODS with proven candida colonization in more than 1 extra digestive site urine, mouth, throat, resp, skin folds, drains, wound)
- 2. No Rx without septic shock and MODS
- 3. Candida growth in respiratory tract without clinical and radiological signs no Rx.

Pre-emptive Rx for those with positive biomarkers (glucan, candida antibody and candida Mannan antigen assay) but no proof of invasive disease due to candida sp. Latest guidelines have dropped this approach.Targeted Rx for positive blood culture.

#### **Biomarkers.**

#### Dr. Srikala Baliga

The common biomarkers are the beta D glucanand thegalactomannan. Procalcitonin is also a good biomarker for fungal infections. Beta D glucan is a substance which is present in almost all the fungal cell walls except that of zygomycosis and Cryptococcus. It has a high sensitivity and low specificity. Galactomannan is a substance which is seen only in the cell wall of Aspergillus. when it is seen in the serum, it is a it is a good biomarker, but it will be seen mostly in neutropenic patients.

#### Management of patients with mucormycosis?

#### Dr. Deepak Madi

For mucor, there are 3 things to look at. 1. source control - unless you clean the sinuses thoroughly, it's no point bombarding the patient with Amphotericin. 2. Management of other predisposing causes like diabetes. 3rd is the drugs. The drug of choice is Liposomal amphotericin B, Conventional amphotericin is quite good. Total duration of antifungal would be at least 3 to 4 months.

#### Candida auris

#### Dr. Srikala Baliga

it's one of the non albicans candida . When do we suspect Candida Auris? When a patient has been in the ICU for a long time, When he/she has a total parenteral nutrition for a prolonged period, if the person has already been on antifungal treatment earlier, so these are some of the predisposing conditions. Main issue with Canada Auris is, it's very difficult to get rid of it. It's mainly an infection control issue. If there is candidemia, we may pick it up in the blood. Patient may recover, blood cultures may be negative, but again after 2 or 3 months again he will come with another episode of Candida Auris . it generally does not given rise to any mortality as such. But it's just given rise to these kind of chronic infections and very difficult to get it off. We have to do a thorough cleaning of all the patient's surroundings with any of the cleaning agents like quaternary ammonium compounds or even hypo chlorite. It differs from other Candida by 2 things. It grows at a higher temperature. So if we incubate it at 42 degrees, it will still produce color on the Chrome Agar. It is very sensitive to chlorhexidine.

#### Question from Dr. J C Adiga: Management of Aspergilloma?

#### Dr. Vishak Acharya

For aspergilloma many times in case fungal ball is there and the patient has no symptoms, we don't have to treat actively. Because usually the response to treatment, as with antifungals are usually poor even after, 6 months of antifungal like itraconazole. Surgery is a better and curative option in recurrent hemoptysis in selective patients with diseased lung, focal disease and fit patients with good lung functions.

#### CALL FOR ARTICLES

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Author instructions@page 124

#### Summary of "Long-term cardiovascular outcomes of COVID-19"



Dr. Subramanyam K Professor & Head, Department of Cardiology, K.S.Hegde Medical Academy, Mangalore Dr. Dilip Johny

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Post-acute sequelae of severe acute respiratory syndrome corona virus 2 (SARS-CoV-2)—the virus that causes corona virus disease 2019 (COVID-19)—can involve the pulmonary and several extra pulmonary organs, including the cardiovascular system. The cardiovascular complications of acute corona virus disease 2019 (COVID-19) are well described, but the post-acute cardiovascular manifestations of COVID-19 have not yet been comprehensively characterized.

The following are the key points from the study "Long-term cardiovascular outcomes of COVID-19" published in Nature-Medicine, 07 February 2022. A cohort of 153,760 individuals with COVID-19, as well as two sets of control cohorts with 5,637,647 (contemporary controls) and 5,859,411 (historical controls) individuals, to estimate risks and 1-year burdens of a set of pre-specified incident cardiovascular outcomes was taken in this study from the national healthcare databases of the US Department of Veterans Affairs.

#### Key points of the study:

- Beyond the first 30 days after infection, individuals with COVID-19 are at increased risk of incident cardiovascular disease spanning several categories, including :
  - · Cerebrovascular disorders- Stroke and TIA.
  - Dysrhythmias- Atrial fibrillation, sinus bradycardia, sinus tachycardia, ventricular arrhythmias and atrial flutter.

- · Inflammatory heart disease- pericarditis, myocarditis.
- · Ischemic heart disease-Acute coronary syndrome, myocardial infarction, ischemic cardiomyopathy.
- Thromboembolic disease- Pulmonary embolism, deep vein thrombosis and superficial vein thrombosis.
- Other cardiac disorders- Heart failure, non-ischemic cardiomyopathy, cardiogenic shock and cardiac arrest.
- The risks were evident regardless of age, race, sex and other cardiovascular risk factors, including obesity, hypertension, diabetes, chronic kidney disease and hyperlipidemia; they were also evident in people without any cardiovascular disease before exposure to COVID-19, providing evidence that these risks might manifest even in people at low risk of cardiovascular disease.
- Analyses of the risks and burdens of cardiovascular outcomes across care settings of the acute infection revealed two key findings:
  - The risks and associated burdens were evident among those who were not hospitalized during the acute phase of the disease- this group represents the majority of people with COVID-19; and
  - 2. The risks and associated burdens exhibited a graded increase across the severity spectrum of the acute phase of COVID-19 (from non-hospitalized to hospitalized individuals to those admitted to intensive care).
- Study examined the associations using two large control groups: a contemporary and a historical control; this approach allowed to deduce that the associations between COVID-19 and risks of cardiovascular outcomes are not related to the broader temporal changes between the pre-pandemic and the pandemic eras but, rather, are related to exposure to COVID19 itself.
- Study also showed that the risk of incident cardiovascular disease extends well beyond the acute phase of COVID-19. The findings emphasize the need for continued optimization of strategies for primary prevention of SARS-CoV-2 infections; that is, the best way to prevent Long COVID and its myriad complications, including the risk of serious cardiovascular sequelae, is to prevent SARS-CoV-2 infection.

 Analyses censoring participants at the time of vaccination and controlling for vaccination as a time-varying covariate shows that the increased risk of myocarditis and pericarditis reported in the study was significant in people who were not vaccinated and was evident regardless of vaccination status.

# The proposed mechanisms that underlie the association between COVID-19 and development of cardiovascular diseases in the post-acute phase of the disease.

- > The lingering damage from direct viral invasion of cardiomyocytes and subsequent cell death, endothelial cell infection and endotheliitis, transcriptional alteration of multiple cell types in heart tissue, complement activation and complement-mediated coagulopathy and microangiopathy, down regulation of ACE2 and dysregulation of the renin–angiotensin– aldosterone system, autonomic dysfunction, elevated levels of pro-inflammatory cytokines and activation of TGF- $\beta$  signaling through the Smad pathway to induce subsequent fibrosis and scarring of cardiac tissue.
- An aberrant persistent hyper activated immune response, autoimmunity or persistence of the virus in immune-privileged sites for the development of extra pulmonary (including cardiovascular) post-acute sequelae of COVID-19.
- Integration of the SARS-CoV-2 genome into DNA of infected human cells, which might then be expressed as chimeric transcripts fusing viral with cellular sequences, has also been hypothesized as a putative mechanism for continued activation of the immuneinflammatory-procoagulant cascade.

#### Limitations of the study:

- 1. The demographic composition of our cohort (majority White and male) might limit the generalizability of study findings.
- 2. Misclassification bias and residual confounding due to the collection of data from the electronic heathcare database.
- 3. Enrolling people in the control group who might have had COVID-19 but were not tested for it; if present in large numbers, might have biased the results toward the null.

4. Finally, as the pandemic, with all its dynamic features, continues to progress, as the virus continues to mutate and as new variants emerge, as treatment strategies of acute and post-acute COVID-19 evolve and as vaccine uptake improves, it is possible that the epidemiology of cardiovascular manifestations in COVID-19 might also change over time.

#### **Conclusion:**

In summary, using a national cohort of people with COVID-19, the study showed that risk and 12-month burden of incident cardiovascular disease are substantial and span several cardiovascular disease categories (ischemic and non-ischemic heart disease, dysrhythmias and others).

The risks and burdens of cardiovascular disease were evident even among those whose acute COVID-19 did not necessitate hospitalization. Care pathways of people who survived the acute episode of COVID-19 should include attention to cardiovascular health and disease.

Governments and health systems around the world should be prepared to deal with the likely significant contribution of the COVID-19 pandemic to a rise in the burden of cardiovascular diseases. Because of the chronic nature of these conditions, they will likely have long-lasting consequences for patients and health systems and also have broad implications on economic productivity and life expectancy. Addressing the challenges posed by Long COVID will require a much-needed, but so far lacking, urgent and coordinated long-term global response strategy.

#### **Reference:**

Xie, Y., Xu, E., Bowe, B. *et al.* Long-term cardiovascular outcomes of COVID-19. *Nat Med* (2022). https://doi.org/10.1038/s41591-022-01689-3.

#### **RESIDENTS CORNER: YOU DON'T GIVE UP**



## Dr. Mintu John Resident KSHEMA

I would like to narrate an incident that touched my heart deeply in my career life as well as my personal life. I've heard about lots of miracle stories in medical science but this was the first time I'm witnessing it and I thought of sharing it with you all.

The story starts when I got a call from an ICU staff regarding a patient who was desaturating. I immediately went into the ICU and found a young male around 30 years old and he was struggling to breathe. I checked the saturation level, and it was only 80 % on room air and he was tachypneic with a respiratory rate around 35/mt. The patient was conscious, and he could talk. He didn't have any co morbidities or any other addictions. I was told that he had fever for the previous 4 days and had decreased urine output. Upon doing a blood investigation, I realized that his renal and liver parameters were abnormal, and he was in severe sepsis. As time passes I saw his condition deteriorating. I shifted him to a non- covid ICU after a negative Covid test. Then I sought an anesthesia opinion for airway management and discussed the need for intubation. And the patient was incubated and connected to a ventilator as advised. I knew that I have taken the right move.

But it was a bit hard to explain the situation to the patient's bystanders because he was normally a healthy person and how could they accept the fact that he was in such a critical stage after having fever for just a few days. Somehow I managed to make them understand his illness.

The patient's condition became worse the next day and I talked to the bystanders to keep them aware that he was very unlikely to survive. I got a call again while I was having lunch saying that the patient had a cardiac arrest. I ran to the ICU and saw him being given CPR and luckily his heart started beating again. His chest X-ray report didn't show any signs for him to come back to normal life. I informed his relatives that there was not much hope for recovery. We were unable to do any diagnosis until then.

Even after being on a ventilator for 3 days, his condition was getting worse each day. The relatives were given a chance to see him once a day and I saw a young girl with them. I was told that it was the patient's fiancée whom he was getting married to in a month. The poor girl was looking at him with tears as if she won't be able to see him again. I wished no other girl would face such a heartbreaking moment.

We tried our best to decrease the oxygen level but in vain and we had to keep him with the ventilator support. So, tracheostomy was advised. Initially, we were a bit hesitant to make that decision because we were having a feeling that why would we let him bear more pain during his last hours. Anyway, we had mild hope somewhere in our minds. So, he had undergone tracheostomy and I told his relatives including his sister and brother-in-law that I wasn't sure whether there would be any improvements. But I could still see some rays of hope in their eyes.

I kept an eye on him every day, checked whether he was urinating, passing motion, any bedsores, but I was thinking he wouldn't last long then why am I doing this. But I knew that as a doctor, I should be determined to save the lives of people until the last moment. I used to talk to him every day and uttered most of the time that "YOU DON'T GIVE UP".

One fine morning I went to see him as usual, but to my surprise, he opened his eyes and looked at me. I couldn't believe it and I pinched myself to make sure that it wasn't a dream. Then I asked him to lift his right hand and he did it, then I said to lift the other hand, and he was able to do that too. He did everything I told him to do. I was so happy that I felt like jumping up and down. I have no idea what miracle happened overnight to make his life change. He was fully active apart from the fact that he couldn't talk due to a tracheostomy. But he tried to communicate through writing. He wrote a lot of things on the paper that I gave him and he raised his concerns about not being able to talk. I was still in shock seeing a man who was in severe sepsis and had no signs of survival until the previous night behaving like completely normal. I immediately went out to share this glad news with his sister. She didn't say a word but cried aloud. How else would people react in these sorts of situations? The next day his fiancée came for a visit and she was overjoyed to see him.

The patient recovered slowly, and he got discharged after about 2 months of hospitalization.

A few days back my colleague came to me and said that a patient was waiting outside to meet me. I went there to see who it was and I was so pleased to see that face again. It was him - the miracle patient. He looked so energetic with a smiley face.

I could read his eyes saying "Thank you". But I don't know who deserves that "Thanks". We talked for some time, and he left. I'm so glad to be in this profession because I think it allows me to give comfort to people when they are unwell and walk them to a better life. I hope this incident would be an inspiration to others who come across similar situations. Miracles can happen anywhere, anytime. There could be some supernatural power that's making it happen. but who knows??? But he didn't give up !!!

Thanks



## JOURNAL SCAN

Section Editors Dr Chakrapani M Dr B.Sadananda Naik

## Summaries of important published articles

### **Proton Pump Inhibitors and risk of Gastric Cancer**

Abrahami D, McDonald EG, Schnitzer ME, Barkun AN, Suissa S, Azoulay L. Proton pump inhibitors and risk of gastric cancer: population-based cohort study. Gut. 2022 Jan;71(1):16-24. doi: 10.1136/gutjnl-2021-325097.

In this population-based cohort study risk of gastric cancers were studied in new users of PPI and new users of histamine-2 receptor antagonists. The study concluded that the use of PPIs is associated with an increased risk of gastric cancer compared with the use of H2RAs, although the absolute risk remains low.

### Kidney Failure Risk Equation [KFRE] a new tool to predict ESRD

Bundy JD, Mills KT, Anderson AH, Yang W, Chen J, He J; CRIC Study Investigators\*. Prediction of End-Stage Kidney Disease Using Estimated Glomerular Filtration Rate with and Without Race: A Prospective Cohort Study. Ann Intern Med. 2022 Jan 11. doi: 10.7326/M21-2928.

In patients with chronic kidney disease, an important use of the estimated glomerular filtration rate (eGFR) is to predict progression to end-stage renal disease (ESRD) so that clinicians can initiate appropriate interventions — including referral for specialist care — in a

timely fashion. A tool called the Kidney Failure Risk Equation (KFRE. opens in new tab) uses four variables — age, sex, eGFR, and urinary albumin–creatinine ratio — to generate an estimate of 2-year risk for progression to ESRD.

Compared to other available tools, the KFRE has proved to more accurate in predicting 2year incidence of ESRD in CKD patients.

#### Better protection when Covid-19 infection boosted with vaccination

Hall V et al. SIREN Study Group. Protection against SARS-CoV-2 after Covid-19 Vaccination and Previous Infection. N Engl J Med. 2022 Feb 16. doi: 10.1056/NEJMoa2118691

The authors investigated the duration and effectiveness of immunity in a prospective cohort of asymptomatic health care workers. Vaccine effectiveness ( $\leq 10$  months after the first dose of vaccine) and infection-acquired immunity were assessed by comparing the time to PCR-confirmed infection in vaccinated persons with that in unvaccinated persons, stratified according to previous infection status.

Infection-acquired immunity boosted with vaccination remained high more than 1 year after infection as compared to those who received only vaccine.

#### Can we predict left main disease in patients with an abnormal stress test?

Senior R, Reynolds HR, Min JK, Berman DS, Picard MH, Chaitman BR, Shaw LJ, Page CB, Govindan SC, Lopez-Sendon J, Peteiro J, Wander GS, Drozdz J, Marin-Neto J, Selvanayagam JB, Newman JD, Thuaire C, Christopher J, Jang JJ, Kwong RY, Bangalore S, Stone GW, O'Brien SM, Boden WE, Maron DJ, Hochman JS; ISCHEMIA Research Group. Predictors of Left Main Coronary Artery Disease in the ISCHEMIA Trial. J Am Coll Cardiol. 2022 Feb 22;79(7):651-661. doi: 10.1016/j.jacc.2021.11.052

Detection of left main coronary artery disease (LMD) has prognostic and therapeutic implications. In this study authors compared the efficacy of TMT in detecting LMD. The study found that clinical and stress testing are weak predictors of LMD as compared to anatomical imaging like CTA.

## JOURNAL PUBLICATIONS OF OUR MEMBERS FOR THIS QUARTER

#### **Dr Archith Boloor**

Book published

An Insider's Guide to Clinical Medicine - Second Edition - Jaypee Publishers

- GBD 2019 Adolescent Young Adult Cancer Collaborators. The global burden of adolescent and young adult cancer in 2019: a systematic analysis for the Global Burden of Disease Study 2019. Lancet Oncol. 2022 Jan;23(1):27-52. DOI: 10.1016/S1470-2045(21)00581-7. Epub 2021 Dec 3. PMID: 34871551; PMCID: PMC8716339.
- GBD 2019 Dementia Forecasting Collaborators. Estimation of the global prevalence of dementia in 2019 and forecasted prevalence in 2050: an analysis for the Global Burden of Disease Study 2019. Lancet Public Health. 2022 Feb;7(2):e105-e125. DOI: 10.1016/S2468-2667(21)00249-8. Epub 2022 Jan 6. PMID: 34998485; PMCID: PMC8810394.

#### Dr B.Sadananda naik et al

 Naik SB, Ramesha K. Paternal diabetes screening: Obstetrician's novel and noble obligation to an unborn child. APIK J Int Med [Epub ahead of print] [cited 2022 Mar 14]. Available from: <u>https://www.ajim.in/preprintarticle.asp?id=338895</u>

#### Dr Chakrapani M et al

 A. Rangnekar et al., Impact of baseline fluorescent antinuclear antibody positivity on the clinical outcome of patientswith primary autoimmune hemolyticanemia, Hematology, Transfusion and Cell Therapy (2022), https://doi.org/10.1016/j.htct.2022.01.013

### **ON INTUITION: A Brief Review**



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Conflict of Interest: None declared Financial support of Sponsorship: None.

#### Abstract

Intuition is a faculty of the mind wherein knowledge is instantly acquired without systematic thinking. Its role in clinical medicine is briefly discussed.

Key words: Intuition, Feeling, Reasoning

#### Introduction

"The intuitive mind is a sacred gift and the rational mind is a faithful servant. We have created a society that honours the servant and has forgotten the gift". ---Albert Einstein "Fortune Favours the prepared mind." ----Louis Pasteur

"There can be as much value in the blink of an eye as in months of rational analysis." ---Malcolm Glad well

The Oxford dictionary defines intuition as "The ability to know something by using your feelings rather than considering the facts". In recent years there has been a large amount of interest on this faculty. Malcom Glad well, quoted above, best- selling author, calls it 'thinking without thinking' in his best seller book, 'Blink'. As a clinician with experience of

four decades I have often wondered about this faculty of the human mind. It is common knowledge that it plays a part in our daily life. In this article, I have attempted to review this topic from the clinician's viewpoint. There are two parts in this brief essay. First, about understanding the nature of the phenomenon of intuition. This is followed by case scenarios from my practice which possesses a component of intuition and its application.

#### What is intuition?

The essential aspect of intuition is the ability to rapidly arrive at a given conclusion without systematic and logical methods that are time consuming. In recent years, there has been extensive work in many areas such as business, industry, finance, art etc, with respect to this faculty. Hogarth <sup>(1)</sup> who has made a large contribution defines: "The essence of intuition or intuitive responses is that they are reached with little apparent effort, and typically, without conscious awareness. They involve little or no conscious deliberation." Most definitions agree that intuitive experiences are based more on overall impressions rather than on specific limited perceptions. These events are a result of learning and based on data.<sup>(2.3)</sup>When a clinician subconsciously recognises patterns, the body fires neurochemicals both in certain areas of the brain and the gut. The instant sense results that something is right or otherwise. They are naturally much faster than rational and logical processing. There has been interest in this subject as it relates to nursing profession.<sup>(4)</sup>Interesting studies, in areas such as its role in data driven situations by Hertz<sup>(5)</sup>have been reported. Shtulman and Harrington<sup>(6)</sup> have studied the faculty of intuition over a lifespan. McCrea has reviewed the role of intuition and insight in behaviour management <sup>(7)</sup> <sup>;</sup> here the neural networks associated with intuition and insight have been studied. This author makes a distinction between intuition and insight.

#### **Illustrative case scenarios**

1. Mr S R, a 60 -year-old man had longstanding bronchial asthma. He also had mild hypertension, which was well controlled. He used proton pump inhibitor for mild reflux related discomfort. One morning, his wife called me and wanted to bring him to hospital. He arrived soon and did not look ill. His blood pressure was 140/90 mm Hg ; SpO2 was 92 % ; breath sounds were normal. At this point, his wife volunteered that he had epigastric discomfort, 'unlike his usual acidity', ringing an alarm bell in my mind. An electrocardiogram, echocardiogram and cardiac ischemic markers were performed. He had acute myocardial ischemia. Coronary angiogram revealed a 80% lesion in the distal left main coronary artery ; this was stented and he was placed on ant platelet drugs and diltiazem.

His asthma medications were continued. One might shrug and say that an ECG was called for anyway; but unlike the lungs, cardia is less forgiving. My senior resident reminded me with a wry remark that absence of wheeze was often indicative of trouble elsewhere.

2. Mr SG was a 56 -year-old businessman who had longstanding diabetes mellitus; he was under the care of a specialist and his blood sugars were well controlled. He knew me as I used to see him me occasionally for minor problems, and was always impeccably dressed. His present visit at the suggestion of his diabetologist as he was losing weight, about 5 kilograms in 4 months. At this visit, I noted that he was without his tie! What he said next was, 'Doctor, for the last two months I am not able to wear my tie !'

An examination of the neck showed bilateral large lymph nodes. Further investigations led to the diagnosis Hodgkin's lymphoma which was managed by a team of oncologists.

3. As a family physician, I knew Mr A M ever since he was five years old. Over the years, one gets to become friends and at times, confidants for a joint family. I mention this because as we are close to them, you might not be as objective as the situation demands. Mr A M's wife called me one evening to see her husband who was not well. I drove to their home on the way back and saw him lying down. Knowing him, this was unusual! He had a fever of 100 F; he had a mind headache and felt weak. The chest was clear. Throat showed an infected oropharynx and fauces, with no follicles on the tonsils. I prescribed oral paracetamol and asked him to call me in the morning. On the way back, I felt a vague feeling of misgiving. I am sure most of us have had this feeling some time or another. Suddenly, it struck me that we were in the very beginning of the H1N1 which swept through. I bought a supply of Oseltamavirand went to his home, made sure he swallowed the first dose. The throat swab was positive and he recovered. In this case, the reward was a gift of choice imported chocolates my grandchildren love !

5.Mr T G, 46 years old, had been a sufferer of bronchial asthma for over 15 years. In the initial years it was seasonal but over the past five years it had bothered him perennially. He was compliant with his medications. One evening I got a call from the hospital that he was admitted for an exacerbations. The registrar had initiated treatment. A few minutes later, the patient's wife called me, anxiety making her voice quiver. I tried to reassure her, but she kept saying, 'I know his problem, doctor but he has never been so breathless !' That made me drive to the ICU and saw that he was very breathless, and the SpO2 was 92% on supplemental 6 L/min oxygen.

We got a portable chest X Ray ----you guessed it right ! A right sided 30% pneumothorax. An immediate intercostals tube insertion relieved his dyspnea dramatically. He recovered and

was released from hospital in five days. The registrar was crestfallen; I had to reassure him that in exacerbated asthma auscultation is a foe and rather than a friend. After a few days, during rounds I quoted this case and called it a classical case of intuition by proxy ! The credit goes to the concerned wife.

#### **Discussion.**

It is common knowledge that clinical diagnosis rests on an assumption, a 'working diagnoses is made and it is proved or otherwise. This is the case in a large majority of people who are admitted as patients. Yet, in the outpatient setting, particularly in urban India, time is of essence. The mean time in most medical OPD's varies from 3-4 minutes to 10-15 minutes. Even as the patient settles down and communicates the experienced clinician is deciding about possibility of organic vs psychosomatic illnesses. In other words, whether they recognise it or not, they are making short cuts based on a large treasure-trove of clinical wisdom, before deciding about the diagnosis. This is the reason why an intern struggles with her/his with her debut cases, while her grey-haired senior works with admirable alacrity and skill. In the illustrative cases success depended on rapidity of decision-making; needless to say, checks and balances are there in any reputed institution so that optimal diagnosis and plan of action prescribed. I am certain that clinicians across various specialties will have had their own similar experiences.

Intuition is a faculty of the mind that is commonly employed in various in various aspects of daily life. Medical science is no exception. While there can be no argument about the need for systematic approach in arriving at a definitive diagnosis; the judicious use of the intuitive mind lends a leading and helping hand. More often than not, it saves a lot of time and more importantly, effort and expense on needless tests. Personally I feel that it strengthens the doctor patient relationship. Admittedly, we are in an era of technology driven approaches and a seemingly subjective rather than purely objective method will likely be frowned upon. Yet, evidence is growing that neurosciences are asking the question of how intuition works, rather than if it does. There is evidence that it is possible to teach this faculty; it will be particularly relevant in the context of clinical medicine. Perhaps we can collect and collate similar case notes and make an attempt to enrich the bedside teaching.

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5. Evidence vs Intuition :Is there room for clinical hunches in an increasing data driven profession?

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#### Hari uvacha .....



from the director's perspective

Premam Poojyam has successfully finished 100 days of theatrical run garnering love and appreciation from the audience and the critics. Here are a few excerpts of Dr. Archith's interview with the maker Dr. Raghavendra B S

Congratulations on the success of the movie. The movie is a wonderfully poignant depiction of college love, and as medicos, I think many of the moments in the movie struck all the right chords. What was the inspiration behind making this movie? How do you think your medical college experience shaped your creativity to make this movie?

Thank you so much for congratulating me and my team. yes, it is a perfect depiction of college love .It was a perfect amalgamation of teamwork. It did strike all the right chords.

Inspiration yes, as in medicine we say MR begets MR, right from my days in KMC we used to watch all the movies in theaters with my favorite senior like you, and watching movies itself inspired me to make a movie. Seminar presentation during college days was considered boring I used to try to make it very jovial and more hilarious type, by adding movie clips and dialogues

Everyone remember my presentation even now, may not be the subject content but definitely the movie bits . Probably if I was an engineering student, probably my movie would have been based on engineering but since I was a doctor and I had the experience of my colleagues and my patients and seniors and juniors so it becomes very easy for me to set the love story in medical campus rather than a non-medical campus so.

As someone completely out of this field, I imagine you would have had to learn a lot of new techniques and skills to execute your vision. What do you think is the biggest challenge for someone?

You know, being in a different field is a lot of difficulties will be there. It's not so easy. But what I feel is the path we choose.

If you have passion, dedication, determination, and devotion and you know the discipline. You can win. Because movies are entertainment and entertainment come from the heart and if you put your heart, you will succeed. It is as easy as or easier than at least clearing MD and DM.

Probably I was writing the script in between the patients and in between the hospitals rounds, penning down the lyrics and composing tunes, and creating a team for a music background. And searching for a good cameraman and getting a good camera. The costume, the locations...I was spending time whenever I used to get time. I believe you are a good player if you make a good team.

Probably you take responsibility on your shoulder and involve in every field, even if you are not a cameraman, even if you're not an editor. Even if you are not a costume designer, you get involved in every department as a director. Ultimately, they will listen to you what you want, you know, even the performance of an artist depends upon how the director takes it out from them. So putting all together probably passion and involvement is what matters.



One of the aspects of the movie which received unanimous praise was the soundtrack. Since you also served as the music director and curator for the movie, how did being involved in that aspect of the film affect you as a storyteller? Did it make the process easier or harder for you?

The movie was romantic, I knew from the beginning that my movie has three pillars, one is the performance of artists, the Second, will be a visual cinematographic treat and the third thing will be music.

I always believed that music conveys emotions & feelings are better than dialogues.

Music will convey the feelings, whether, happiness or sorrow, or the message will be very easily transferred to another mind and heart.

More than a quarter of the budget went on music & sound track. Whether it is background scoring or whether it is the songs I spent enough time selecting musicians and instruments. We got many instruments from abroad. like, Bazooki , baglama , Rabaa , Pipa .because I knew the same tune if we played different instruments, it will give a lot of different feelings. So from beginning to end that's why I kept all songs and background scoring and the recording was done Chennai, Hyderabad, Bangalore , Mysore ,Cochin, Bombay everywhere. So I wanted the best singers. Best musicians, programmers, and, music is a most important part of the movie So if you ask me, yes, the music helped me as a storyteller and the whole process becomes easier.

How did you balance the hectic life of being a doctor with that of an artist? Everyone hears that once you become a doctor or in the healthcare field, your entire life becomes about that. I think the audience would also like to know how your journey as a top doctor in Mangalore impacted your urge to make films.

Yes, it is hectic life for any doctor. Even from interns to a super specialty DM Professor, ours is a hectic profession. So, it's not an easy job you know to become an artist or a Director of a movie.

But definitely what I feel is your passion and your hobby are always important.

Many of our colleagues have given up their passion and their hobbies.

But I believe we must give time to ourselves and for our passion and that matters. We should never think that that will interfere in your add more stress your job. Whenever I got little time, I spend time on music or lyrics or scriptwriting, which rejuvenated me in such a way that instead of becoming tired, I became stronger. So much so that again, I could see the patient more nicely.

So whenever I was tired of my work or hectic schedule, the break was the screenplay script and the music. And whenever I spend too much time and the script and music, I would go back to the hospital. So both are complementary to each other.

But it should never interfere with your profession. As we say "Vrithi" and "Pravritthi" in Kannada i.e Profession & Passion - we should always try to keep them separate and complementary. It should be a synergism type rather than counteracting. I feel this is possible; professionalism and passion should go hand in hand and probably that will help us. It's not so easy finding the time and you must find time for yourself and your passion.

What advice would you give to people who want to create art in the form of music and films? As a doctor, I am sure that you have incomparable life experience and personal stories. But how would you advise people to create something meaningful out of that?

I don't know. It's just one movie I have done so I don't know whether I can advise people. But I always feel forget movies., For that matter, sports or a painting or instruments or music, or a script writing I am telling you, there are many, many doctors who are talented in poetry and singing Many doctors have acted in our film Dr.Archith, Dr. Deepti , Dr. Priya Ballal, Dr. Ismail , Dr. Anjan , Dr. Nitin, Dr.Nishan. So many people, they're all doctors. They acted very well and they played the role of Co-producers. Dr. Sandeep sang very nicely 3 songs.

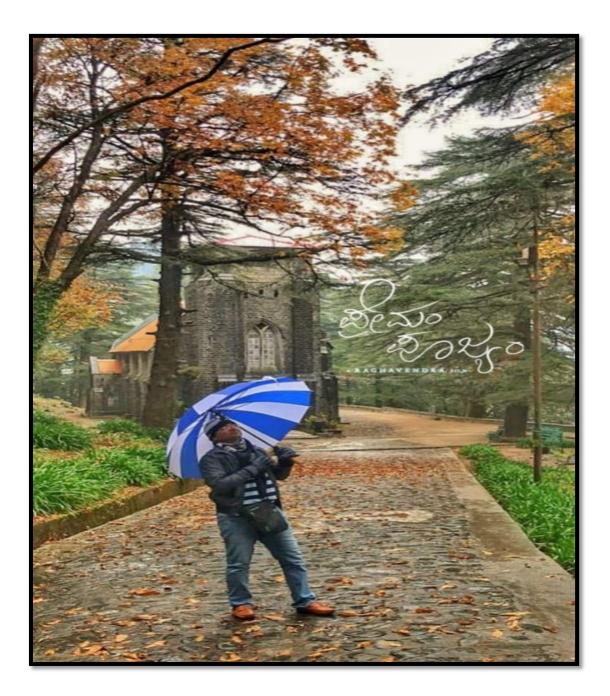
Dr. Smriti Shetty sang one song so these are all hidden talents. so I feel God has given you know some talent to all of us. Each of us we need to explore in that field improves our self and I think the time to you know, handle both profession and passion.

Fresh from the astounding success of your debut film, please tell us what your hopes and aspirations are for your future as a filmmaker. What upcoming projects do you have? Are you going to dive into other parts of movie-making as well, maybe a cameo role?

A long way to go. We are heading towards our 125 days celebration. We're planning to keep a huge celebration success party in Bangalore. It's so very happy to know that the first movie has been appreciated. For its content, for its purity, without any vulgarity with a lot of messages. In this 21st century about pure love in all aspects, not only lovers but also for parents, friends, and colleagues,

They are calling it Painting. Our music, lyrics performances by the artists, costume, and cinematography has been all thoroughly appreciated Another good news, the big news is it's going to come soon in OTT platform and satellite Premier show in TV. Also, we're getting offers for dubbing in Hindi and the remake in Tamil, Telugu & Malayalam. And 2-3 scripts are already ready: there is the sequel of Premam Poojyam and also an action movie completely ready, including music and lyrics. But for now, I just want to enjoy & relish, the ongoing success of Premam Poojyam and soon will come back with the new announcements As far as acting is concerned, I love acting. The director is the one who brings out the acting among the actors because the same actor may have done the best performance in one movie. In other movies he wouldn't have done the good performance that is purely dependent upon. Director, they say is always a good actor.

But as of now I am very happy behind the screen behind the camera and I do act in the caravan and when narrating the script to my artist I act and show an act and show. They laugh. They cry, they, they clap. Probably I don't mind peeping in and just coming and going.



## LEADERSHIP ACHIEVEMENTS



API DK CHAPTER congratulates Dr. M Venkataraya Prabhu, ex dean KMC Mangalore on his promotion to the post of PRO VICE CHANCELLOR – HEALTH SCIENCES, MAHE, MANIPAL. We wish him all the best in all his future endeavors and hope he continues to bring laurels to his new post. He is renowned for his administrative skills and visionary role in NIRF ranking of KMC Mangalore and in aiming to take KMC Mangalore to the top league of best medical colleges in India. He was the longest serving dean in the history of KMC Mangalore. We wish you sir all the best and an illustrious journey ahead.

#### **Oops!... I missed that!**



**Christopher C. Pais** 

Our editorial team's term comes to an end and it's time to say Adieus, Adieu, Adios, Au Revoir, goodbye from all of us! Our best wishes to the new team too.

A few days back a visit from a patient brought back memories, in fact, it was his wife who put me off balance for the first time since I started private practice. It was something which I did not understand, but kept a straight face, and still managed to keep a straight one, once I deciphered what she meant. The person in question started speaking to me in English though both she and I, though I am not good at languages, knew the local language as it was my mother tongue, Konkani. I asked in Konkani what her problem was, and pat came the reply in English, which was not Queen's English, but certainly would have put the queen in extreme distress. "Doctor" she said, "I have a swallowing problem". "Do you cough while having food?" I asked. "No doctor not that, it's the swallowing". "What is it then? Pain while swallowing?". "No, no, it's that my left leg has swallowing". "Oh I see, when did the swallowing, I mean swelling start?" I enquired. Well, the consultation ended well, of course in Konkani. This patient passed away a few years later, with a problem not connected with the "swallowing" she had come for, and as I write this, must be looking at me from heaven above, with a forgiving heart saying..."forgive him Lord for he knows not what he is writing".

The other instance was, when a young lady, this time in Queen's English, said she had problems with her chums. "Well, they come at a time I don't want them to come, are troublesome and they hurt me too" she said."Then tell your chums not to disturb you at the wrong time", I said. "That's exactly why I have come to you" she said. I knew something

was wrong and quick thinking saved my day. I politely told her I don't deal with "chums" and referred her to a gynaecologist. It was a "word" learnt for me. A little research on this topic enlightened me further. I was waiting for a chance to spit out this knowledge and that's exactly what I did when another smarty came for consultation. After a brief history, I asked her "When was the last visit from Aunt Flo?" She stared at me, "I do not have an Aunt called Flo" she said. From that moment onwards I was back to my "pre-chums" vocabulary.

Clinical practice is taxing, but many such instances and interactions with different types of patients keeps life going.

Christopher C. Pais 12-03-2022

#### THE DEAD SEA



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My interest in Archaeology has taken me to various sites of archaeological and geological treasures across the world. Dead sea is one of such marvellous sites. I had the unique privilege of floating on this water body seven times during the past two decades.



Dead Sea is the lowest water body on Earth, with the lowest elevation on land.

In Hebrew, the Dead Sea is Yām ha-Melah, meaning "sea of salt"

In Hebrew literature, sometimes the term *Yām ha-Māvet* ("sea of death") is used, due to the scarcity of aquatic life there.

In Arabic, the Dead Sea is called *al-Bahr al-Mayyit* ("the Dead Sea"), or less commonly  $bahr^{u} l\bar{u}t$ ( "the Sea of Lot"). Another historic name in Arabic was the "Sea of Zo'ar", after a nearby town in biblical times. The Greeks called it 'Lake Asphaltites *Thálatta asphaltītēs*, "the Asphaltite sea").

The Jordan River is the only major water source flowing into the Dead Sea, although there are small perennial springs under and around the Dead Sea, forming pools and quicksand pits along the edges. There are no outlet streams.

Rainfall is scarcely 100 mm (4 in) per year in the northern part of the Dead Sea and barely 50 mm (2 in) in the southern part.

To the west of the Dead Sea, the Judean mountains rise less steeply and are much lower than the mountains to the east. Along the south-western side of the lake is a 210 m (700 ft) tall halite mineral formation called Mount Sodom.

With 34.2% salinity (in 2011), it is one of the world's saltiest bodies of water,

In the 19th century and the early 20th century, the surface layers of the Dead Sea were less salty than today, which resulted in an average density in the range of 1.15-1.17 g/cm<sup>3</sup> instead of the present value of around 1.25 g/cm<sup>3</sup>. A sample tested by Bernays in the 19th century had a salinity of 19%. By the year 1926, the salinity had increased.

Beginning in the 1960s, water inflow to the Dead Sea from the Jordan River was reduced as a result of large-scale irrigation and generally low rainfall. By 1975, the upper water layer was saltier than the lower layer. Nevertheless, the upper layer remained suspended above the lower layer because its waters were warmer and thus less dense. When the upper layer cooled so its density was greater than the lower layer, the waters mixed (1978–79). For the first time in centuries, the lake was a homogeneous body of water.

The mineral content of the Dead Sea is very different from that of ocean water. The exact composition of the Dead Sea water varies mainly with season, depth and temperature. In the early 1980s, the concentration of ionic species (in g/kg) of Dead Sea surface water was  $Cl^{-}(181.4)$ ,  $Br^{-}(4.2)$ ,  $SO_{4}^{2-}(0.4)$ ,  $HCO_{3}^{-}(0.2)$ ,  $Ca^{2+}(14.1)$ ,  $Na^{+}(32.5)$ ,  $K^{+}(6.2)$  and  $Mg^{2+}(35.2)$ . The total salinity was 276 g/kg. These results showed that the composition of the salt, as anhydrous chlorides on a weight percentage basis, was calcium chloride (CaCl<sub>2</sub>) 14.4%, potassium chloride (KCl) 4.4%, magnesium chloride (MgCl<sub>2</sub>) 50.8% and sodium chloride (NaCl) 30.4%. In comparison, the salt in the water of most oceans and seas is approximately 85% sodium chloride. The concentration of sulphate ions ( $SO_{4}^{2-}$ ) is very low, and the concentration of bromide ions ( $Br^{-}$ ) is the highest of all waters on Earth.

The salt concentration of the Dead Sea fluctuates around 31.5%. This is unusually high and results in a density of 1.24 kg/l. Anyone can easily float in the Dead Sea because of natural buoyancy. In this respect the Dead Sea is similar to the Great Salt Lake in Utah in the United States.

An unusual feature of the Dead Sea is its discharge of asphalt. From deep seeps ,the Dead Sea constantly spits up small pebbles and blocks of the black substance. Asphalt-coated figurines and bitumen-coated Neolithic skulls from archaeological sites have been found. Egyptian mummification processes used asphalt imported from the Dead Sea region.

The world's lowest roads, Highway 90, run along the Israeli and West Bank shores of the Dead Sea, along with Highway 65 on the Jordanian side, at 393 m (1,289 ft) below sea level.

Since 1930, when its surface was  $1,050 \text{ km}^2$  (410 sq. mi) and its level was 390 m (1,280 ft) below sea level, the Dead Sea has been monitored continuously. The Dead Sea has been rapidly shrinking since the 1960s because of diversion of incoming water from the Jordan River to the north as part of the National Water Carrier scheme, completed in 1964.

The Dead Sea level drop has been followed by a groundwater level drop, causing brines that used to occupy underground layers near the shoreline to be flushed out by freshwater. This is believed to be the cause of the recent appearance of large sinkholes along the western shore—incoming freshwater dissolves salt layers, rapidly creating subsurface cavities that subsequently collapse to form these sinkholes. As of 2021 Ein Gedi, on the western coast, has been subject to a large number of sinkholes appearing in the area, attributed to the decline in the water level of the Dead Sea.

As of 2021, the surface of the Sea has shrunk by about 33 per cent since the 1960s, which is partly attributed to the much-reduced flow of the Jordan River since the construction of the National Water Carrier project, and the amount of water from the rains reaching the Dead Sea has diminished even further since flash floods started pouring into the sinkholes. The Eco Peace Middle East, a joint Israeli-Palestinian-Jordanian environmental group, has estimated that the annual flow into the Dead Sea from the Jordan is as of 2021 less than 100,000,000 cubic metres  $(3.5 \times 10^9 \text{ cu ft})$  of water, compared with former flows of between 1,200,000,000 cubic metres  $(4.2 \times 10^{10} \text{ cu ft})$  and 1,300,000,000 cubic metres  $(4.6 \times 10^{10} \text{ cu ft})$ .

Whenever I float on the Dead Sea, walk on its shores and the Judean desert I feel that it reflects on human mindset too. One can be as selfish as the Dead Sea as it has only input from river Jordan and no output. The jealousy, cruelty, hatred selfishness, and our self-centred attitude building within us make us isolated from rest of the society. No fellow human being will enjoy our company and eventually our life become stagnant and we evaporate and shrink like the Dead Sea.

When we cultivate open mindedness, allow the fresh noble thoughts to refresh our minds and generously give out our time talent ad treasure for the betterment of the society our life will flourish.

Enjoy floating on the Dead Sea but do not be like a dead sea

"Progress is impossible without change, and those who cannot change their minds cannot change anything."

- George Bernard Shaw.





# **AUTHOR INSTRUCTIONS**

## **GUIDANCE FOR AUTHORS AND CONTRIBUTORS**

API DK LAHARI is a quarterly published e magazine of API D. K. CHAPTER, released in the <u>www.apidk.org</u> website with archival options of all the issues released stored in pdf format ( each issue ) also with download option .The magazine will include academic and non academic articles .The languages included will be English and Kannada. We are hopeful that this will give a unique opportunity to all API members to share their vision and views on various aspects of our profession and beyond.

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#### Instructions on preparation of the manuscript to be submitted

- 1. Manuscript may be in English/Kannada.
- 2. Font size -12 (Times New Roman), double spacing, 1.5 inches margins all around the page.
- 3. All the write ups should include a Title page with author information
- 4. Title Page should contain the following : Full name/names of all the authors with contact address, cell number, email id, designation, position in the Institution and a passport sized recent photo

## Paper/write up categories

- 1. Scientific articles
- 2. Member's accomplishments
- 3. Obituaries
- 4. News and Views
- 5. Residents corner
- 6. View point
- 7. Medico legal pearls
- 8. Journal Watch
- 9. Patient page
- 10. Listen to legend
- 11. Life beyond medicine [Non-medical topics]
- 12. General health articles [more for lay public]

#### **Scientific articles**

#### 1. Case reports

Word count- 1500, Maximum of 03 tables & or figs, 07 Refs

#### 2. Review article

Word count- 3500, Maximum of 5 tables or figs

#### 3. Academic challenge

An interesting case presentation with detailed academic discussion

Abstract, word count -3500, Maximum of 5 tables or figs

## 4. Diagnostic test and interpretation

Word count- 1500

#### 5. Images in Medicine

Photos with good resolution and quality, Word count -500

Abstract is required for case report, Review article, Academic Challenge, and Diagnostic test and interpretation. Word count is inclusive of abstract.

References should be in Vancouver style.

#### Member's accomplishments

Brief information by self or others on the accomplishments of our API members in profession, public life, academics and other walks of life

Word count- 1000

#### Obituaries

Condolence message and short write up on the deceased member, One message -500 words

#### **News and Views**

Write up on medical happenings with a personal opinion expressed

Word count -1000

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Medical article by post graduates/interns

Word count as per the criteria mentioned for the scientific articles by the members

#### View point

Write up on various problems or happenings in field of medicine or medical profession

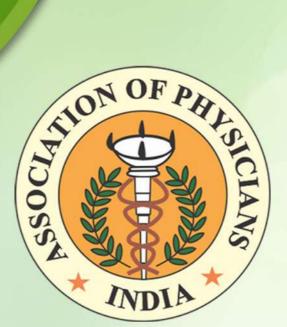
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#### **Medico legal pearls**

Articles on medical legal aspects of including consumer protection act and other acts applicable to the medical profession

No word limits

**Journal Watch** 



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