**Development of an Internet of Thing Based** **(IOT) Device for Screening of Patients for Arrhythmias Disease**

**BY**

**ENEH AFAM SAMUEL**

**ESUT/PG/Ph.D./BME/202110000415**

**A Ph.D RESEARCH SEMINAR II**

**A Ph.D. SEMINAR SUBMITTED TO**

**THE DEPARTMENT OF BIOMEDICAL ENGINEERING TECHNOLOGY**

**FACULTY OF ENGINEERING AND BASIC MEDICAL SCIENCE**

**ENUGU STATE UNIVERSITY OF SCIENCE AND TECHNOLOGY**

**SUPERVISORS:**

**ENGR (DR) HARMONY NNENNA NZERIBE NWOBODO**

**SEPTEMBER, 2023.**

**DECLARATION**

This thesis titled “**Development of Internet of Things (IOT) Based Device for Screening of Patients for Arrhythmias”** is my original work. I declare that it has not been submitted in part or full to any assessing body.

…………………………………….. ………………………………



**ENEH AFAM SAMUEL Date**

**ESUT/PG/Ph.D./202110000415**



**APPROVAL**

This thesis “**Development of Artificial Internet of thing (IOT) Based Device for Screening of Patients for Arrhythmias** with Reg. No**. ESUT/PG/Ph.D./202110000415** has been examined and found acceptable for the Award of Doctor of Philosophy (Ph.D.) in Biomedical Engineering Technology, Faculty of Engineering, Enugu State University of Science and Technology, Enugu.

**……………………………… ………………………………**

**Dr Nwobodo-Nzeribe H.N Date**

Project Supervisor

**……………………………… ………………………………..**

**Dr Nwobodo-Nzeribe H.N**

coordinator of BME **Date**

**………………………………. …………………………………..**

**Prof. G. O. Mbah Date**

**Dean, Faculty of Engineering**

**………………………………. …………………………………..**

**Prof. Akpa Date**

**Dean, Faculty of Basic Medical Science**

**DEDICATION**

**This dissertation is dedicated to God Almighty who made it possible for me to achieve this success.**

My profound gratitude goes to my supervisor in the person of Dr H.N Nwobodo-Nzeribe for providing vital ideas and for his unending support during the duration of this project and my parents. I also thank

**TABLE OF CONTENTS**

Title Page - - - - - - - - - - i

Certification - - - - - - - - - - ii

Dedication - - - - -- - - - - - iii

Acknowledgements - - - - - - - - - iv

Abstract - - - - - - - - - - v

Table of Contents - - - - - - - - - vi

**CHAPTER ONE: INTRODUCTION - - - - - - 1**

1.1 Background of the Study - - - - - - - - 1

1.2 Problem Statement - - - - - - - - 6

1.3 Objectives of the Study - - - - - - - - 7

1.4 Justification - - - - - - - - - 8

1.5 Scope of the Thesis - - - - - - - - 8

1.6 Limitations of the Study - - - - - - - - 8

**LIST OF TABLE**

**LIST OF FIGURES**

**Abstract**

**Chapter One**

**Introduction**

* 1. **Background of Study**

Chronic disease (for example, cardiovascular disease, diabetes, Alzheimer’s,) has increased, with mortality associated with a rise in coronial health disease to 66% by 2030. Telehealth is the use of digital information and communication technologies to access health care services remotely and manage your health care. Technologies can include computers and mobile devices, such as tablets and smartphones. This may be technology you use from home. Or a nurse or other health care professional may provide telehealth from a medical office or mobile van, such as in rural areas. Telehealth can also be technology that your health care provider uses to improve or support health care services. It also includes virtual healthcare, makes use of technology to improve communication between doctors, clinics, and patients. Clinics, doctors, and patients can share information, monitor, and follow up on care plans using electronic communication technology, which allows for maximum virtual participation throughout medical treatment. We now live in a globe where technology can execute procedures, perform pre-operative planning, and monitor results from afar (Perumal and Manohar.,2017), in accordance with the World Health Organization (WHO). It is necessary to monitor patients continuously with chronic illnesses to avert life-threatening scenarios.

An erratic and frequently abnormally high heart beat is the result of the cardiac ailment known as atrial fibrillation. When you're at rest, your heart rate should be regular and between 60 to 100 beats per minute. By feeling your pulse at your wrist or neck, you can determine your heart rate. Atrial fibrillation is characterized by an erratic heartbeat, which can occasionally be quite fast. It can occasionally be significantly more than 100 beats per minute. This may result in issues such as

1. Dizziness
2. shortness of breath
3. tiredness

The heart palpitations—which can feel like it's pounding, fluttering, or beating erratically—may be apparent to you. They often last a few seconds or, in rare circumstances, a few minutes. Atrial fibrillation can occasionally have no symptoms, and the patient is totally ignorant that their heart rate is abnormal.

This decade, the Internet of Things has been hailed as the beginning of a new era of interconnectedness for everyday devices everywhere. Remote health monitoring mechanisms (Rahaman et al,2019); (Islam et al, 2015) parking management (Rivano et al., 2017), smart houses (Al-Ali et al., 2017), smart cities (Zanella et al,2014), smart environment (Mois, and Folea,2017), industrial sites (Chen et al.,2017), and agricultural lands (Ayaz et al,2019). Health and environmental conditions can be tracked using IoT in healthcare management. The importance of IoT systems has been increased in real-time applications because of their simple structure. IoT connects computers to the internet through sensors and networks in order to process data in real-time (Hasan et al, 2019);(Nooruddin et al,2020). Figure 1.1 shows the IoT applications in real-time systems. Cardiac arrhythmia is categorized as the irregular beating of the heart (Perumal and Manohar.,2017). This irregularity may either be a slow or fast heartbeat. A heart rate of over 100 beats per minute (bpm) is categorized as tachycardia, while the instance of a pulse lower than 60 bpm is alluded to as bradycardia. Global statistics reveal that a significant population suffers from heart diseases which manifest in the form of heart attacks, strokes, etc.; furthermore, these afflictions are one of the significant reasons for death all over the planet. Heart arrhythmias may not cause any signs or symptoms. A doctor may notice the irregular heartbeat when examining you for another health reason.

In general, signs and symptoms of arrhythmias may include:

1. A fluttering in the chest
2. A racing heartbeat (tachycardia)
3. A slow heartbeat (bradycardia)
4. Chest pain
5. Shortness of breath

Other symptoms may include:

1. Anxiety
2. Fatigue
3. Lightheadedness or dizziness
4. Sweating
5. Fainting (syncope) or near fainting

The intervention of a dedicated system for monitoring patient’s heart, otherwise known as a portable EGG will go a long way to reduce service cost for hospitals and medical agencies to a great extent. Moreover, treatment for heart diseases is too costly, and only a limited number of patients have the luxury of affording it (Rahaman et al,2019)

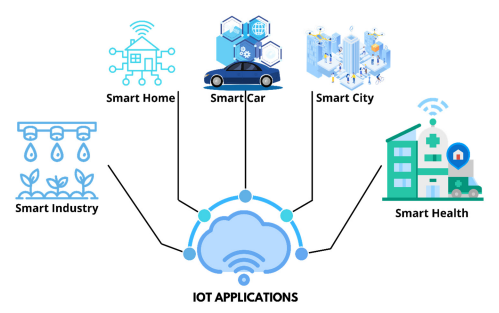


Figure 1.1 Figure 1. IoT applications in daily life. (Perumal and Manohar.,2017

Also, timely recording of patient’s ECG is vital for the provision of emergency and quick solution by the medical personnel. Moreover, the increasing number of patients further emphasized the need for a virtual communication between the patients and the doctors. Also, doctors can manage time easily, thereby increasing the quality of service and simultaneously get alerted for any emergency kind of service. The system will monitor the electrical activity of the heart of the user that surfer arrhythmias, otherwise known as electrocardiogram (ECG) through repeated cardiac cycles when the probes are placed in the proper position on his body and upload it to an Ubidots.IoT Online Platform, so that it is visible to anyone with access, especially his doctor. Thus, giving the patient the privilege of knowing his health status without having to travel for medical trip.

This dissertation will develop a system that will monitor the heart of an individual that have arrhythmia disease and upload it on the internet so that it is visible to physician alone.

Thus, providing a virtual contact between the patient and doctor especially in the case of emergency. However, it is possible to monitor other health parameters like Heart Rate, Body Temperature, Saline Level, etcetera, using this system. **Ubidots Online Application will be developed to do the online monitor. Here, it can be achieved by interfacing AD8232 ECG Sensor Module with ESP32 Development Board as a Microcontroller.**The system will monitor the Electrocardiogram **of a patient when he places the probes on his body in the proper position. This system is a portable low-cost Smart Health Monitoring Device that can measure ECG of the user when he properly placed the probes on his body, and display the value graphically on Ubidots IoT Platform so that anyone with access can see it, especially his doctor.** It was designed in the form of a wearable device that can be used by athletes or anyone to monitor their **ECG levels** during a workout. This internet connection was made possible through the use of Wi-Fi property of ESP32. The recorded data is also made to display on an OLED screen attached to the system. The ESP32 serves a Microcontroller that control and coordinates the activities of all the components used in this system as well as providing internet access. The whole system was contained inside a Perspex container to protect it from moisture and dust. A switch was used to ON and OFF the system to safe the battery life. The system is powered by a 5 V rechargeable DC source

* 1. **Problem statement**

Hospital accessibility is one of the most common issues in physical treatment because it has a direct impact on patient adherence, which often determines the success of patients’ treatment plans. Common problems to access include;

1. Transportation
2. proximity to clinics
3. cost, wait times,
4. lack of knowledge about physical therapy.

Healthcare is one of the most rapidly evolving industries in the world today, and advances in technology are propelling a large part of this transformation. The Internet of Things (IoT) is one of the most influential technological breakthroughs in recent years, and it has had a considerable effect on healthcare.

Internet of Things (IoT) technologies allow building a digital representation of people, objects, or physical phenomena to be available on the Internet. Thus, stakeholders can access this information from remote places or computational systems could analyze this data to find patterns, make decisions, or execute actions. For instance, a doctor could diagnose patients by analyzing the received data from an IoT system even when patients are located in a remote place.

Arrhythmia entails a broad spectrum of disorders of heart rate and rhythm abnormalities. Arrhythmia is broadly categorized into bradyarrhythmias and tachyarrhythmia based on the heart rate. this work, propose a system device monitoring the patient's heart signal and analyzing the heart data by using machine learning for detecting arrhythmias. Thus, when the machine-learning algorithm detects an arrhythmia, it generates an alert. In order to allow Doctors to see the patient's heart activity, the system provides a web application that displays the ECG chart and the generated alerts.

* 1. **Aim and Objectives**

The aim of dissertation is to Develop a internet of thing **(IOT)** based Health Monitoring, Diagnosing Environmental Control System for Cardiac arrhythmia, this  dissertation intends to achieve the following specific objectives

1. To characterize the problem of monitoring and diagnosis of Cardiac arrhythmias in healthcare system
2. To develop a smart device that will monitor and diagnose a patient suffering Cardiac arrhythmias remotely
3. To use **AD8232 ECG Sensor Module** to monitor the heart movement **of patients and displays the reading on an OLED screen.**
4. To develop a device that will provide the live location, GSM messages, and an email to the doctors during emergency conditions
5. To validate the developing device and model with existing system in monitoring Cardiac arrhythmias
   1. **Scope of Study**

This work focuses on the developing real time smart device that will monitor patient in rural area suffering from arrhythmias remotely. Only Cardiac arrhythmias will be considering in this work. no other heart disease will be considered. The work is centered on the development of IoT Based ECG Monitoring System that will monitor the electrical impulse of the heart, otherwise known as electrocardiogram or ECG, and displays it on an OLED screen. Thus, giving the patient the opportunity to monitor his health status to check the tendency of Cardiac arrhythmias, especially in the case of emergency. This, we have achieved using **AD8232 ECG Sensor Module interfaced to an Arduino Nano Microcontroller.** Here, the primary concern is to monitor the most important health parameters – Electrocardiogram (ECG), as it has been proven that most health related challenges have their origin rooted to this electrical signal of the heart, otherwise known as ECG. It is also possible to monitor other health parameters like Heart Rate, Blood Oxygen, Body Temperature, Saline Level, etcetera, using this system. However, for the sake of clarity, the project has limit our research to the measurement of irregular pattern. The system will also upload this ECG value online, and display it graphically on Ubidots IoT Online Platform. The system is a portable low-cost **Smart Health Monitoring Device**that can measure **ECG** of the user and displays it on a 1602 LCD. The testing results shows that the system can effectively measure **ECG** in **BPM** (Beat Per Minute) of the user when he places the probes on his body in the proper position**.** The system is powered by a 5 V rechargeable DC source

* 1. **Significant of Study**

According to the [report of Research and Markets](https://www.marketsandmarkets.com/Market-Reports/remote-patient-monitoring-market-77155492.html), the projected growth of the Global RPM (Remote Patient Monitoring) systems market to over $1.7 billion by 2027 indicates that there is a significant and growing demand for [remote patient monitoring](https://www.peerbits.com/case-studies/remote-patient-monitoring-software-development.html) technologies. Remote health monitoring via connected devices can save lives in the event of a medical emergency like heart failure, diabetes, asthma attacks, etc.

1. It will help the doctor or healthcare worker to collect data from sensor
2. The device decides whether to act or send the information to the cloud.
3. Doctors or health practitioners can make actionable and informed decisions based on the data provided by IoT healthcare solutions.
4. The system will go a long way to save life since the patient can easily examine himself at any time.
5. The system will provide a virtual contact between the patient and his doctor.
6. The system will go a long way to reduce the stress of medical trip as the patient will be in the position to monitor his health status.
7. The system will drastically reduce the cost of medical treatment.
8. The system will give the doctors more time to attend to many patients.
9. The system will provide emergency services in the case of emergency.
10. The system can be modified to monitor other health parameters such as Heart Rate, Blood Oxygen, Body Temperature, Saline Level, etc.

**1.6 Limitations of the study**

Some of the limitations of this system include:

* Majority of the materials used to build the system were imported and therefore takes a lot of time to arrive.
* The system cannot monitor other health parameters like Body Temperature and Saline Level.
* The system cannot function well in an area of poor internet access.

**1.7 Organization of the report**

**Chapter one** of this project report outlines the overview and background to this study, problem definition, aim and objectives, the significance of the study, project scope, limitations, and definition of terms. A summary of the chapter concludes the first chapter. The rest of this report is organized as follows:

**Chapter two** centers on the review of literature related to the study. This chapter explains all the relevant materials to the project area whilst taking note of the studies of the current system and the technologies to be implemented.

**Chapter three** highlights the concepts, performance analysis, activities, and methods. It also discusses the project objectives, their deliverables, and how they will be accomplished.

**Chapter four** highlights the results we were able to achieve so far, both the rewards and shortcomings. Some of the challenges encountered in the course of this project were highlighted too, including the possible ways we have tried to overcome the challenges. Some suggestions were also made here in the form of discussion.

**Chapter five** concludes the report, and as well, made some vital recommendations concerning future improvement of the system based on our observations so far.

**1.8 Definition of terms**

**Emergency:** An emergency is an urgent, unexpected, and usually dangerous situation that poses an immediate risk to health, life, property, or environment and requires immediate action.

**System:** A system is a group of interacting or interrelated elements that act according to a set of rules to form a unified whole. A system, surrounded and influenced by its environment, is described by its boundaries, structure and purpose and expressed in its functioning.

**Pulse**: A rhythmical throbbing of the arteries as blood is propelled through them, typically as felt in the wrists or neck.

**Electrocardiogram (ECG):** Electrocardiography is the process of producing an electrocardiogram, a recording of the heart's electrical activity through repeated cardiac cycles. It is an electrogram of the heart which is a graph of voltage versus time of the electrical activity of the heart using electrodes placed on the skin.

**Heart Rate:** Heart rate is the frequency of the heartbeat measured by the number of contractions of the heart per minute

**ESP32**:ESP32 is a series of low-cost, low-power [system on a chip](https://en.wikipedia.org/wiki/System_on_a_chip) [microcontroller](https://en.wikipedia.org/wiki/Microcontroller) with integrated [Wi-Fi](https://en.wikipedia.org/wiki/Wi-Fi) and dual-mode [Bluetooth](https://en.wikipedia.org/wiki/Bluetooth).

**Chapter Two**

**Literature Review**

**2.1 Health Monitoring and Diagnosing**

Continuous measurement of patient parameters such as heart rate and rhythm, respiratory rate, blood pressure, blood-oxygen saturation, and many other parameters have become a common feature of the care of critically ill patients. When accurate and immediate decision-making is crucial for effective patient care, electronic monitors frequently are used to collect and display physiological data. Increasingly, such data are collected using non-invasive sensors from less seriously ill patients in a hospital’s medical-surgical units, labor and delivery suites, nursing homes, or patients’ own homes to detect unexpected life-threatening conditions or to record routine but required data efficiently. With rapid increment in population, the number of patient and requirement of health monitoring is increasing. Currently, quality and affordability of health care system becoming major issue. Large amount of population facing problem with increasing cost of health care system. As per the world population data sheet, world population in 2017 is 7.5 billion and health monitoring of this huge population is challenging thing. According to 2016 Global Burden of Disease Report, heart disease is leading cause of death in India, killing 1.7millions Indians in 2016 nearly 53%. There is need to focus on health monitoring system. Recently health monitoring system playing crucial role in order to reduce cost of hospitalization, medical staff burden in addition with consultation time and waiting lists (Megha et al., 2018)

Basically the health monitoring system classified in three types. Classification of health monitoring is shown in figure1. Mobile health monitoring system (MHM) deals with smartphone, PC etc., Large number of smartphone based mobile devices are becoming popular day by day. In Mobile health monitoring, one can take care of their health any time without more efforts and this system is easy to use. Remote health monitoring systems (RHM) are important to monitor the patie.nt and treatment is done by sending/receiving data from remote location. This type of system can measure variety of symptoms and can be implement at homes as well as hospitals. Wearable health monitoring systems (WHM) deals with wearable devices or biosensors that can use to measure vital parameters of human body consisting of WHM, RHM and/or MHM.

Smart health monitoring systems (SHM) is advanced technology and new approach to health monitoring.General health monitoring system includes measurement of heart rate (HR), blood pressure (BP), electrocardiography (ECG), oxygen saturation (SpO2), body temperature and respiratory rate.

During last few decades, advancement in health care system growing rapidly. Smart health monitoring plays crucial role in hospitals, residential and outdoor settings by different communication technologies like global positioning system (GPS), radio frequency identification(RFID). (Baig et.al, 2012)

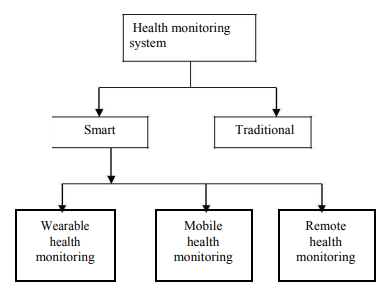


Fig.2.1 Classification of health monitoring systems

Increment in health care technology concern with medical data quality, security, stability and accuracy of system acceptance by the medical staff as well as patients with the frequency of false alarms being generated. In health monitoring system, data quality, security and privacy are major consideration. In wearable health monitoring user comfort, data transmission rate power consumption, context awareness needs to take into account. Secure data transmission, real-time availability, Middleware design with User-friendliness are major part of remote health monitoring whereas Power consumption, Energy required with efficiency, User-friendliness, Security and Privacy are important constraint in mobile health monitoring. Fig 2. Show basic architecture of smart health monitoring platform. In most system uses similar architecture with variation in software and technologies.

Amitabh Yadav et al.(2017) introduce a structure of embedded system that keeps track of position and health condition of patient all the time. This system makes use of active RFID card for tracking position of patient and WSN of xbee radio where data received in local database of PC.

Use of xbee radio increases the cost of system. Shintaro Izumi et al. [6] describe processor for electrocardiography in addition with a wearable healthcare system. In order to achieve better accuracy of detected heart rate instantaneous heart rate monitor with short term autocorrelation algorithm (STAC) is used. The ECG processor chipconsumes13.7 A for heart rate logging application.

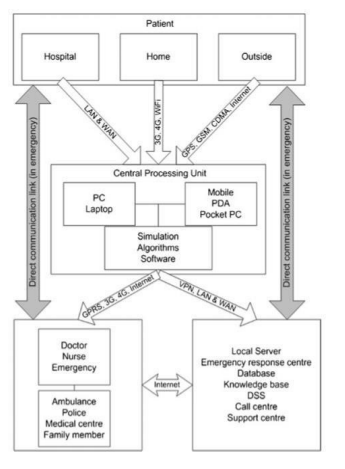


Fig2.2 Basic architecture of smart health monitoring system (Source: Mirzeet.al, 2012).

**2.1.1 Smart Health Monitoring Approaches**

Various techniques to enhance health care services with the consideration of various parameters mention in this section. Smart health monitoring systems have both advantages and disadvantages which need to take into account. In the system describe below uses various communication protocol.

Lou et al. (2013) describe mobile health monitoring consist of 3AHcare node and android application. 3AHcare is acquisition module with embedded Bluetooth for measurement of ECG, blood pressure blood oxygenation, respiration, temperature and motion. Android application will receive parameter, data is processed by special algorithm for obtaining steady waves and store on micro SD flash. They have found that system is easy to use and gives high precision. This system is interchangeable.

A new approach of development of mobile health platform based on cloud computing which mainly focus on heart rate viability to access simultaneously the risk of vascular events and of falls by P.Melillo et al (2015).This platform provides proactive monitoring via data mining functionalities. Author describes designing of smart health monitoring system under UE-funded research project” Smart health and artificial intelligence for risk estimation”. The architecture consists of three layers i.e. user base layer, function base layer and data base layer. While designing architecture user comfort, security and privacy and scalability are taken into consideration.

Wearable noncontact arm band for mobile ECG monitoring system by Vega Pradana Rachim and **Wan-Young Chung** [2016] proposed system consist embedded armband with capacitive coupled electrode. In this system reliability is achieve through proper placement of sensors in arm band. To ignore distractions from body movements or noise and in order to achieve robustness, real-time heartbeat detection and a filter algorithm is used. Author use capacitive coupled electrode for measurement of bio-signals i.e. ECG signal. In addition to that, android application was created to show ECG signal in real time on graph which is useful for analysis. Proposed algorithm was tested on PC for validating system and they have analyzed that error rate is less than 10% in comparison with standard system.

To enhance healthcare system Soumen Kanrar et al 2016., has developed a prototype for monitors patient’s vital parameters with the help of android application. This E-health care system has capability to collect not only biological and personal information of patient but also vital parameters and stores this information into the health care database server. They make use of Gaussian mixture model (GMM). It is soft presentation of different feature classes. In (Yunzhou Zhan et al., 2015), focus on remote health monitoring system with mobile phone and web service capabilities which provide pervasive and continuous health monitoring of patient. Multilayer architecture is designed for the work flow consists of portable terminal, smartphone and remote server. Bluetooth protocol for communication purpose and Zephyr BioHarness sensor as a portable terminal is used. This system provides two modes i.e. normal status monitoring and emergent response. Indoor localization algorithm in smart phone is used in emergency situation. It gives stable performance but it is only for real time monitoring of patient’s status and not for the professional analysis. Priyanka Kakria et al. (2015) have developed real time heart rate monitoring system with the consideration of cost, simplicity of application with accuracy and data security. It is having ability to extract cardiac parameters. These parameters are transmitted to android application using Bluetooth and provided to web application for further process. Low power wearable ECG monitoring system by is based on IoT platform which integrate heterogeneous nodes and applications. This system is useful in monitoring multiple patients in large indoor area. ECG prototype sensor used low energy and architecture provides low marginal cost.

**2.1.2 Traditional Health**

As per World Health Organization (2002), The “Traditional medicine” may be defined as health practices, approaches, knowledge and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well-being (WHO, 2001). Africa is one of the heritage continent also known as cradle of human being and the concept of traditional medicine in Africa is existed long back without documentation as a hidden evidence less practices for human beings who have been struggling with various unknown diseases. African people have their own ancestral practices to heal using different methods (Dawit and Ahadu 1993). According to World Health Organization report more than 80% of the people in Africa depend on traditional medicine for their health care needs (WHO, 2003). The African people have been depending on various plants and animals source for their drug to treat various physical and mental illness. Nearly, 4000 medicinal plants have been documented towards their various Pharmacological activities (WHO,2003) Any Traditional medicine consists of medical treatment with an ancient root that has been passed over generations to maintain health, as well as to prevent, diagnose, improve or treat illnesses. Various cultural and historic conditions have been influenced in the development of traditional medicine. The common basis for any Traditional medicine concept is a holistic healing to maintain life equilibrium between the body, mind and soul with external environment. Even the Traditional African Medicine is not an exception from this universal holistic approach. Some of the Traditional healing systems and concepts have been supported by huge volume of literature and are in transition towards evidence healing concepts.

Traditional African Medicine is still has not been documented and under process of documentation as from generations to generations, this was hidden as secret concept of healing. Still to date, in most parts of the africa, the major population have been continuing to rely on traditional medicine to meet their primary health care needs (WHO,2020). In Africa, Traditional medicine is a healing belief system having its own health and disease concept. This is considered as a hidden treasure or knowledge that will pass from father to his only one beloved son of that family. The various healing concepts in Traditional African medicine (TAM) includes herbalism, surgery, bone setting, spinal manipulation, psychotheraphy, hydrotherapy, occultism, hydrotheraphy etc.

However, lack of indepth scientific validation of these african traditional medicine and their documentation is a greatest lacuna and very much attention is required by the modern herbalists to safegaurd this healing concept. In the herbalism, vegetable, animal, and mineral substances have been used. In the metaphysical healing concept, Spirtualism concepts like prayers, invocations, or incantations have been offered to some mysterious and powerful forces in the various belief concept system like exorcism, divination, libation etc., were also been practicing to heal several diseases, however, scientific validation and documentation is still challenging (Busia., 2005) ;( James et al., 2018). Some of plants used in herbalism by traditional african healers are Foeniculum vulgare Mill (Badgujar et al.,2015).

**2.1.3 Wearable Health Monitoring**

With the increase of world population, the health monitoring system is also necessary which monitors subject’s health status if the subject is not present in the hospital or near a medical professional. The cost of healthcare increases day by day so a cost effective, reliable and comfortable WHM (Seoane et al.,2014; Yilmaz et al., 2010) can play important role to predict and prevent the effects of the fatal diseases. A WHM can provide Real time monitoring and information about the affected person to the hospital or a medical professional, which can take immediate preventive measures for the patient (Marco et al, 2005).

A WHM is very useful in the case of elderly peoples, persons with chronic diseases (Bonato ,2005; Bonato 2003)etc. The main components of a WHM system are sensors that acquires different body parameters such as body temperature, blood pressure, sweat rate, heart rate, electrocardiogram, respiration rate etc. After the acquisition of signal its preprocessing is required, where the elimination of undesired signal as well as A/D conversion can be done. Further the feature extraction part plays an important role, after feature extraction process the desired signal either stored in a storage device that may be a hard disk of a computer or transmitted to the remote location through a wireless network in the case of real time diagnosis. A WHM system have some basic characteristics such as weight and size should be compatible with the patient, minimum power consumption, highly efficient, accurate and quick responsive system(Raskovic et 2004; Sarith et al., 2008 etc.

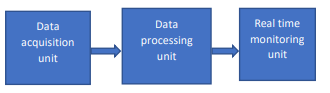


Fig.2.2 Typical block diagram of wearable health monitoring system

**Data Acquisition**

Data acquisition is the primarily goal of any WHM system, various sensors are available for this data acquisition process. Human body has different electrical/bio signals that correlate with the health status of the body. These signals can be acquired by various wearable devices and the information extracted from these signals plays a vital role to detect the abnormal condition of any particular subject. While monitoring the activity of subject if any abnormality detected then immediate diagnostic support is required by the medical professional/doctor.

Various Important Body Signals and Their Acquisition Techniques: Human body has various physiological signals that can be measured by different sensors. The range of these signals are different from their optimal values in case of any abnormality, so by acquiring these physiological signals one can detect the health condition of human body.

**Some useful body signals are explained below:**

1. Electrocardiogram (ECG): In electrocardiography the electrodes are placed on skin or chest. With the help of these electrodes the heart electrical activity can be recorded / visualized. A typical ECG waveform consists few peaks and valleys named P, Q, R, S, T and U. the R peak in QRS complex is mostly used to measure the heart cycle (Anliker.et al.,2004). These ECG waves are useful to understand the cardiac rhythm and to predict myocardial infractions(Xu et al.,2008) Herat attack detection Anliker.et al.,2004) and coronary artery diseases can also be treated from the information of this QRS complex. Ag/AgCl electrodes are commonly used for ECG waveform detection.it is a type of wet electrode so during longer period acquisition the gel dries that increases the impedance between the human body and the electrode that’s why the signal quality can be distorted.to avoid such issues now a day several dry electrodes available in the market that may also use outside the medical environment (Seoane et al., 2014; Xu et al, 2008; Luo et al.,2014.
2. Heart Rate (HR): Heart rate is one of the most common parameter that indicates either the person is fit or ill. It is the speed of the heartbeat measured by the number of beats of the heart per minute. The crucial information (Chan et al, 2014) can be extracted from ECG R-R peak or photoplethysmography (PPG) signal. It is also useful to know how the heart react during physical exercise or any mental exercise and if there is any correlation between these two state of body. It is also a parameter with the help of which a medical professional can predict abnormality or fatal condition of the patient. Human body react differently when doing various mental or physical tasks the heart rate is also different in such conditions stress and fatigue measurements also related with heart rate (Ahrens,2008; Xiao-Fei et al,2008).
3. Electroencephalogram (EEG): Data of different parts of human brain can be acquired with the help of EEG. It also measures spontaneous brain activities (Millan et al.,2014); Different electrodes such as Ag/Agcl, jelly electrodes and dry electrodes are available in the market for the EEG data acquisition purpose (Nakasaki.et al, 1989)
4. Blood pressure (systolic and diastolic): it is referred as the force exerted by the circulating blood on the walls of blood vessels. Blood pressure can also indirectly correlate with the functioning (during contraction and relaxation) of heart. Hypertension is one of the major threat for the world that can also be detected by BP monitoring and preventive actions can be taken before brain damage (Elliott.,2012; Turner et al.,2015)
5. Respiration rate: It is a fundamental body parameter that plays important role in patient’s observation. In critical illness such as hypoxia (Elliott.,2012) it is the most important indicator of patient’s health condition. Cardiac arrest (Xiao-Fei et al,2008) can also be predicted by respiration rate. Pulmonary diseases in children can also be monitored by separation rate monitoring (Xiao-Fei et al., 2008) In the case of sleep apnea syndrome, asthma and other respiratory diseases the respiration rate monitoring is important
6. Blood Oxygen Saturation (Spo2): Photoplethysmography (PPG) and pulse oximetry principles makes easy to estimate the blood oxygen saturation. Normal (95-100%) range of oxygen present in the blood can be lowered (below 95%) when the patient health is abnormal. An insufficient oxygen supply to the body causes hypoxia. Anemic patients have also lower oxygen saturation level in the blood (Tamura et al.,2014). As the PPG (Dias et al 2017) is popular to detect the oxygen saturation level but several noninvasive techniques has been also introduced that can be applied to wearable devices. An independent wearable device for this purpose has also been introduced (Sola et al.,2006).
7. Blood Glucose: Blood glucose level is a parameter that indicates the patient is diabetic or not. The constant decreasing or increasing level of blood glucose levels can cause several organ damage in human body such as lever, kidney etc. The monitoring of blood glucose level plays a vital role to prevent such fatal organ damage condition for the patient. A constant higher glucose level causes heart attack also. Various invasive methods of measuring blood glucose levels are available in the market and now a day the noninvasive techniques are also developed for continuous blood glucose monitoring. Medtronic continuous glucose monitoring (MGM) is an example of invasive device that monitors continuous blood glucose level, it sends the data wirelessly to a wearable insulin pump that releases insulin into the body (Medtronic 2017). Dexcom G4 platinum is also a device that measure your blood glucose level and information will be given to a mobile device (Dexcom, 2017)
8. Sweat rate or skin conductivity: Sweat rate is normally not used for detecting any disease in clinical applications but it can be used to analyze human behavior. When human body sweats it releases a moisture that changes the electrical conductivity of the skin. A skin galvanic response (GSR) can measure the quantity of sweat. In (Leehoon et al.,2014; Nikolic-Popovic and Goubran.,2011) skin sweat rate and heart rate variability parameters are used to detect mental states. Human sweat contains sodium, calcium, ammonium etc. so the rate of release of such compounds can also correlated with the physiological condition of the person/patient. In (Bandodkar and Wang,2014) physical stress measured by sweat rate of the military persons
9. Body temperature: Body temperature is a parameter that can be checked by most of the medical professionals primarily when the patient feels any abnormality. Human body can lose functioning due to high temperature. Blood circulation, heart rate and metabolic rate are the parameters that affects the skin temperature (Popovic et al., 2014). Except these external environmental factors such as air flow, humidity etc. are also the factors that affect the body temperature (Buller et al,2010). In (Webb et al.,2014) a wearable temperature detection system has been proposed.
10. Body movements: Motion sensors are commonly used for rehabilitation, to analyze how a particular task is completed by patient. Except these body postures, muscle activities can also be monitored with the help of motion sensors. Athlete performance improvement, fatigue detection due to wrong body movement are also the applications of such monitoring. Arm movement (Buckley et al.,2017) timing is analyzed during basketball through. Accelerometers are used for the measurement of acceleration in 3D space. For the more accurate monitoring gyroscope and magnetometers can also embedded in wearable sensors (] Mohammed andTashev.,2017). With the help of these parameters the various states of human body can be monitored.

**Data Processing**

Data processing is the next step after the acquisition of data by the sensors.it is the conversion of raw data to machine readable format. Data processing involves further steps:

1. Preprocessing: The raw data acquired by the sensors contains noise, various artifacts and other sensor error related issues. A/D conversion, unusual data removal (Sow et al., 2013; Lara and Labrador., 2013) and noise removal are some common benefits of preprocessing of raw data in healthcare system. ECG preprocessing (Apiletti, et al.,2009) has been done that involves filtering and other statistical tools. Power spectral density (Hu et al., 2008) and fast Fourier transforms are used to remove frequency noise. A low pass filtering (Frantzidis et al.,2010) is used to remove the artifacts from the acquired signal. Data normalization and synchronization has been done with the help of preprocessing when the data is taken from the sensors. Sometimes the data acquired may be unreliable and massive so the preprocessing step required.
2. Feature Extraction/Selection: The main objective of feature extraction is to find the main characteristics of the acquired data set (Guyon et al.,2006). The acquired data have different in complexity and magnitude so the feature extraction process can differentiate the data and helps to find the common pattern of the data that is helpful to make decisions (Bellos et al.,2010). Several classifiers are also used for this purpose (Mao et al,2012). Features extraction can be done in time domain or in frequency domain. In sensor data acquisition the time domain feature extraction is common that includes basic waveform characteristic analysis, other statistical parameters such as mean, variance etc.(Apiletti et el.,2019; Singh et al,2011). Frequency domain analysis is also beneficial and used frequently now a day. Power spectral density, filtering, spectral energy comparison (Gialelis et al.,2012) can be done with the help of frequency domain analysis. Data classifiers such as support vector mechanism (SVM) (Cortes and Vapnik, 1995) neural networks (Paliwal and Kumar., 2009) are used for the classification of data. Except these various classification/selection methods are available.
3. Storage or Transmission of Data: The monitoring of the patient is the final step in WHM system, it can be done inside the hospital or outside the hospital environment. A daily activity monitoring (Pantelopoulos and Bourbakis,2010) been proposed. The vital information can be provided to the patient itself or transmitted to the doctor or medical professional that can take immediate action at the critical condition of the patient. This vital signal can also be transmitted to an ambulance or any relative of the patient. These vital signal can be recorded and saved for the further analysis of medical professional. A micro SD card or a hard disk is used for the storage of data. Using the internet and mobile networks any one can be monitored inside hospital or inside/outside home. WHM system provides a normal life to the patient while being monitored for medical status. (Custodio et al., 2010) Proposed a system that provides a real time monitoring for elderly peoples. The vital signs transmitted by the various communication methods. Various wireless communication protocols viz Zigbee, Wi-Fi, Bluetooth etc. are available for data communication purpose. The table below shows different wireless communication protocols, their limitations and other parameters.

**2.1.4 Mobile Health Monitoring**

Information technology, as a powerful tool, is the most important factor in increasing the efficiency and effectiveness of organizations. Various industries in order to maintain their existence in the current competitive environment and promotion of their outcomes have taken effective steps toward the use of these technologies. The health care industry is no exception from this rule. Different countries consider the information technology to promote the development of health information and health system outcomes with regard to the importance of care industry, direct and indirect impacts on various aspects of community development (Safdari and Mohammadzadeh., 2011)

Advent of mobile devices with capabilities of caring handy and easy is one of the modern effects of IT that application of them is growing especially in the industrial sector. Some of the mobile devices include cell phones, smart phones (mobile phones processing capabilities, storage, and intelligence communications), and personal digital assistants (PDA). These devices are equipped with communication capabilities such as the ability to connect through GSM/GPRS, Wireless LAN, and Bluetooth networks; hence their utilization will provide comfort for their users

Using mobile devices seems inevitable because the health industry is facing challenges such as resource constraints like focusing resources on specific areas, for example, in large cities (Kahn et al., 2011), rising health care costs, the need for immediate access to various health care data types such as audio, video, text for early detection and treatment of patients, especially in emergency situations, and difficult in rural areas, and increasing remote aid in telemedicine and home care (tan., 2009).

The use of mobile health programs is very interesting due to numerous benefits; however, using these tools is still having many challenges. One of the approaches that significantly helps to reduce barriers is survey of advantages and obstacles of mobile devices usage. Studies of opportunities and strengthening them and identifying problems help to design proper planning and a roadmap for promoting the achievements of mobile health systems.

**Chronic disease management: necessity of mobile Health approach**

In most countries, chronic diseases lead to high health care costs and reduced productivity of people in society (Engelgau et al., 2011). Diabetes is a common chronic disease in nearly all countries (Zhang et al.,2010) and one of the most common metabolic diseases with an increasing incidence. More than 15% of national health budget is dedicated to diabetic care (World Health Organization.,2011). Diabetes as a hidden disease causes many complications such as various types of heart disease, nephropathy, retinopathy, and so on, thus imposing direct and indirect high costs to society. In Iran, diabetes complications contributed to 53% of the aggregate excess direct costs of diabetes (Esteghamati et al.,2011).

The quality of diabetic care improves, on one hand, if patient monitoring is done according to the nutrition program and physician orders that are placed with high quality (McAndrew et al.,2013). On the other hand, fast and accurate diagnosis due to continuous monitoring through information communication technology (ICT) devices leads to prevent the death of diabetic patients (Paré et al,2010). Telemedicine as a main tool to remote health care delivery and home care has advantages such as real-time access to health information (tan., 2009; Barjis et al.,2013). reducing medical errors (Skolnik.,2011) and increasing coordination and cooperation among health care teams (Safdari and Mohammadzadeh., 2011), reducing travel of patients and their families in remote area (Finn and Bria.,2011), and useful education tool for patients, their families, and health care providers (Toledo et al.,2012).Therefore, this technology has a very important role in decreasing costs and taking appropriate management actions especially in diabetes management and other chronic disease (Khoumbati et al.,2009; Safdari and Mohammadzadeh, 2012)The use of innovative technologies such as mobiles to enjoy the most advantages of telemedicine is necessary. Mobile health systems can be a good option for health care industry because of reducing delay and error in patient treatment, avoiding test duplication, providing remote and timely access of health care professionals to organizational database and patient information especially in the emergency situations

**Mobile Health opportunities in patient monitoring**

In this study, electronic chronic disease management systems based on mobile technology were divided into two types: agent-based systems and non-agent-based systems. Some electronic health system based on agent that studied in this research are:

Integrated mobile information system (IMIS) in Sweden through mobile network communication platform provides the possibility of self-treatment and home care supervision for the diabetic patient. This system has six databases (Safdari and Mohammadzadeh., 2011) database for patients including all necessary information about diabetic health care centers, medical journals, dietary, food habits, etc.; (Kahn et al., 2011) database for care providers containing whole information about physicians, home care services; (Tan 2009) tools or instrument base including all aiding functions for implementation health care such as visit reserve, alarms, monitor; (Bøne et al.,2007) community network include all relevant actors like diabetes centers, consultation, and so on links to each other; (World Health Organization.,2013) database for laws, rules, and norms applied in health care including all legal and cultural documents about health care therefore can help with privacy, security, and quality of services; and (Pawar et al.,2013) database for labor division in health care that determines who (health care provider) and what to do, this ensures to provide all the different patient needs (Shaheen et al..2013; Zhang et al.,2013; Bellazzi et al.,2001)

M2DM Telemedicine Service system in European Commission with the aim of presenting correct knowledge to correct people at correct time. Two types of agents are used in the M2DM: (Safdari and Mohammadzadeh., 2011) communication server that is responsible for communication between different user terminals and (Kahn et al., 2011) application server that is responsible for data analysis and processing. The architecture of this system includes multi-access server, common database management system (DBMS), multi-access organizer, communication server agent, and application server agent. The overall goal of M2DM is increasing quality of care through improving communication between patient and health care providers (Hernando et al.,2013; Jones et al.,2010)

**Also other non-agent and useful e-health system survey in this section are:**

Personal Health Monitor (PHM), University of Sydney, Australia, uses PHM with focus on e-health services based on mobile devices at local level for monitoring patient in various situations therapeutic. Architecture of PHM comprises BAN devices, sensor front end, mobile base unit, back end (Leijdekkers and Gay 2008; Jones et al.,2008)

Mobile Health and Body Area Network [BAN], most of the European countries use this system for remote patient monitoring and provide appropriate care to patients. A consortium of 14 European countries was set up to implement the health system project (Otto et al.,2009) This project has been implemented in four countries: Spain, the Netherlands, Sweden, and Germany for different groups of patients, including home care and trauma, where the patient is located in an outdoor center. It aims to improve patients’ quality of life and freedom in their daily activities and complete mobility. BAN devices, sensor front end, mobile base unit, and back end are the architecture elements (Leijdekkers and Gay 2008).

In 2009, the first virtual diabetes clinic in Iran was inaugurated at Tehran University of Medical Sciences with common database, multi-access server architecture, and organizer server is discussed in this chapter (Annicchiarico et al,2008)

**Mobile Health challenges in patient monitoring**

Although mobile Health technology has a key role in health care systems, yet its uptake has faced with general and specific challenges. Some problems in general dimension include organizational challenges like organizational culture, support of high-level management; technological barriers such as lack of ICT and mobile infrastructure (Cresswell and Sheikh ,2012)human challenges, for example, lack of trained and skilled personnel at health care centers in this field (Khoumbati et al.,2010), user attitudes, technology acceptance (Hardiker and Grant.,2010; Taniar 2009), user characteristics like age, economic, social, and educational status (Taniar 2009); and threats to confidentiality and privacy, legal, ethical, and administrative barriers, costs of system implementation and maintenance (Khoumbati et al.,2010), dependence on IT , the cost of updating, costly modern systems , sufficient investment, delays in implementation and providing electronic devices and software . Some barriers from specific aspects also include problems in interoperability between other health systems and information technology tools, poor and inappropriate design and implementation , effect on face-to-face communication between health care providers and patient, causes omission of human relationship and the negative effects of technology on relationships between individuals and social processes, designing of mHealth services content , failure to meet targets, virtual information control medical errors due to malfunctioning of system fault documentation like data manipulation and rewriting, misrepresentation, and violation of patients’ legal rights. Difficulties related to telecommunication industry such as reliability, sustainability of connections, sudden interruptions of telecommunication networks device and sensor type that can be used, type of data and language presentation, scalability in terms of data rate, power and energy consumption; antenna design, quality of service, energy efficiency wearable devices weight, type of devices that used for patient monitoring that sometimes lead to problem in data processing, accuracy of gathering information depends on where data were collected, and user training to use wearable system.

**2.1.5 Remote Health Monitoring**

[Remote patient monitoring](https://mhealthintelligence.com/features/rpm-101-what-is-remote-patient-monitoring-its-benefits-and-uses) (RPM) is a subcategory of homecare [telehealth](https://mhealthintelligence.com/features/telehealth-snapshot-use-cases-policies-hybrid-care) that allows patients to use mobile medical devices and technology to gather patient-generated health data ([PGHD](https://www.techtarget.com/searchhealthit/definition/patient-generated-health-data-PGHD)) and send it to healthcare professionals. Common physiological data that can be collected with RPM programs include vital signs, weight, blood pressure and heart rate. Once collected, patient data is sent to a physician’s office by using a special telehealth computer system or software application that can be installed on a computer, [smartphone](https://www.techtarget.com/searchmobilecomputing/definition/smartphone) or [tablet](https://www.techtarget.com/searchmobilecomputing/definition/tablet-PC).

RPM is frequently used to help patients that require chronic, post-discharge or senior care. By connecting high-risk patients with remote monitoring, it can notify healthcare organizations of potential health issues or keep track of patient data between visits. Additionally, RPM could be used by businesses that want to record workmen’s compensation cases, making sure employees are on the right path to return to work.

Remote patient monitoring (RPM) though by no means a new care modality is evolving rapidly, spurred by the constraints of the COVID-19 pandemic and the corresponding regulatory push to expand access to care. In its simplest form, [**RPM involves the use**](https://www.healthit.gov/topic/health-it-health-care-settings/telemedicine-and-telehealth#:~:text=Remote%20patient%20monitoring%20(RPM)%3A,usually%20at%20a%20different%20time.) of connected electronic tools to record personal health and medical data in one location that is reviewed by a provider at a different location. The data may or may not be viewed as soon as it is transmitted. Increasingly, health systems are leveraging RPM to care for patients suffering from a myriad of conditions, including diabetes, hypertension, and COVID-19. In addition, regulatory changes enacted by the Centers for Medicare and Medicaid Services have bolstered this trend, indicating that RPM is becoming an important part of care delivery.RPM can be used to treat both chronic and acute conditions, enabling clinicians to keep tabs on patient’s in-between clinic visits or when in-person care is not possible. For chronic care, in particular, RPM enables clinicians to observe patients in near real-time, gather necessary data, and make adjustments to improve care outcomes. This type of continuous tracking is helpful [for patients with ongoing care needs](https://telehealth.hhs.gov/providers/preparing-patients-for-telehealth/telehealth-and-remote-patient-monitoring/), such as those with diabetes, heart conditions, asthma, hypertension, mental illness, and, more recently, [long COVID](https://www.cdc.gov/flu/symptoms/flu-vs-covid19.htm#:~:text=Long%20COVID%20is%20a%20range,they%20had%20no%20symptoms.), that is, the long-lasting symptoms following COVID-19 infection and recovery. RPM programs employ the use of various types of devices, like weight scales, pulse oximeters, blood glucose meters, blood pressure monitors, heart monitors, and even specialized monitors for dementia and Parkinson's disease. Another category of RPM devices that can be used to track patients' health over the long term are wearables. These can range from more consumer-facing devices like smartwatches to continuous blood glucose monitors. Wearables especially appear to be in demand, with [**Deloitte predicting that**](https://www2.deloitte.com/cn/en/pages/technology-media-and-telecommunications/articles/pr-tmt-predictions-2022.html) 320 million consumer health and wellness wearable devices will ship worldwide in 2022. That figure could jump to 440 million units shipped by 2024. But RPM is not just useful for managing long-term diseases — it can be used for more urgent and acute conditions as well. Increasingly, healthcare organizations are setting up hospital-at-home programs that enable treatment for higher acuity conditions at home. These [**programs can provide a**](https://www.aha.org/system/files/media/file/2020/12/issue-brief-creating-value-by-bringing-hospital-care-home_0.pdf) wide array of services, including diagnostics like echocardiograms and X-rays, treatments such as oxygen therapy and intravenous fluids, as well as pharmacy and skilled nursing services. Though hospital-at-home programs involve in-person care, they are supported by continual monitoring of biometrics by a care team and telehealth visits. Further, remote patient monitoring can be used to track patient recovery once they have been discharged to their homes post-surgery. For example, the University of California Los Angeles Health System [**has a post-surgery RPM program**](https://www.uclahealth.org/telehealth/remote-patient-monitoring) for heart procedure patients. As part of the program, patients provide an array of biometric data like heart rate, blood pressure, and blood oxygen levels to their care team using devices provided in a kit. The team can track this data to ensure the patient is recovering as expected.

The delivery of healthcare through electronic communication, or [telehealth](https://psnet.ahrq.gov/primer/telehealth-and-patient-safety), has changed greatly since its introduction. Over the years, [telehealth has rapidly evolved](https://psnet.ahrq.gov/issue/telehealth) with the continued advancement in available technology and the innovations by the healthcare community in identifying new uses and applications for technology. The implementation of electronic health records (EHRs) and expanded access to the internet and medical devices have enabled healthcare to move outside of traditional clinical settings and into a patient’s home.

[Remote patient monitoring](https://telehealth.hhs.gov/providers/preparing-patients-for-telehealth/telehealth-and-remote-patient-monitoring/) (RPM) is a type of telehealth in which healthcare providers monitor patients outside the traditional care setting using digital medical devices, such as weight scales, blood pressure monitors, pulse oximeters, and blood glucose meters. The data collected from these devices are then electronically transferred to providers for care management. Automated feedback and workflows can be built into data collection, and out-of-range values or concerning readings can be flagged. Historically, RPM has been used to measure symptoms of chronic conditions, such as cardiac diseases, diabetes, and asthma. Patients may have experienced this through wearable devices, like Holter monitors that can measure heart rhythms, to remotely detect heart conditions and monitor cardiovascular diseases (MacKinnon and Brittain 2020) The American Heart Association recommends remote monitoring of vital signs for hypertension patients given the evidence and large number of research studies showing the benefits of RPM. These benefits include patient engagement in their medical care, patient adherence to their treatment plan, and the ability to expand physician reach and easily provide care to patients without the need for patients to travel for in-person visits (Omboni et al.,2020)

A 2017 study by the GAO (U.S. Government Accountability Office) showed that RPM was commonly reported by provider associations and patient associations as a significant factor that improved or maintained the quality of care, which further encouraged its use and implementation. Additional studies have shown benefits of remote patient monitoring in managing diseases such as chronic obstructive pulmonary disease (COPD) and congestive heart failure (CHF), resulting in fewer emergency department visits, hospital readmission avoidance, and reduced hospital length of stay (Taylor et al.,2020; Tomasic et al.,2018)

Throughout the COVID-19 public health emergency (PHE), the [use of telehealth has been considered an effective patient safety mechanism](https://psnet.ahrq.gov/perspective/telehealth-and-patient-safety-during-covid-19-response) to limit potential patient exposure to infected patients by replacing in-person visits with telehealth visits and using virtual processes when possible. Like other forms of telehealth and telemedicine, [RPM implementation has increased](https://psnet.ahrq.gov/issue/remote-patient-monitoring-during-covid-19-unexpected-patient-safety-benefit) and evolved quickly during the course of the PHE. In addition to increasing their use of RPM for chronic conditions, many organizations began monitoring for acute conditions and have developed programs to monitor affected patients for COVID symptoms outside the hospital setting (Shah and Schulman 2021; Tabacof et al.,2022]. These programs were aimed at reducing the burden on hospitals at times of increased hospital utilization and detecting any change in status of patients. One emergency department provided patients with pulse oximeters and thermometers upon discharge, monitored patients daily, and escalated patients for further care in case of worsening symptoms (Aalam et al.,2021). Program infrastructure is paramount in ensuring patient safety, including team composition, patient selection, and device management and data collection processes. Organizations must understand the volume of data that will be transferred to systems and decide how the data will be integrated into its EHRs. Appropriate staff are needed to train patients and provide technical support, monitor data, or respond to abnormal values. Successful programs stated that having internal or external dedicated staff to monitor patient status and provide direct communication to patients is an important part of the RPM infrastructure (Patel et al., 2022). Because RPM processes rely on biometric data transferred by the patient, another risk for clinical misdiagnosis is that patients may not use medical devices appropriately or follow data collection protocols. To support the correct use of devices according to guidelines and avoid false values, organizations should create a strong patient education system that includes feedback to patients. Education should include setting clear expectations with patients about how abnormal values will be managed by clinicians and what would be considered an emergency for the patient to respond to independently (Tabacof et al.,2022)

Although RPM has substantial benefits to both the health system and patients, there are still barriers to implementing and expanding its use to a broader audience. While telehealth has the promise of providing healthcare access in areas where in-person care may be difficult to obtain, its implementation is limited by technological infrastructure barriers, including lack of access to the internet or inadequate cellular data to support video-based care or frequent connectivity. Digital literacy and lack of knowledge, skills, or confidence to use digital tools can also be barriers to use. These barriers are often found among people who already experience health inequities, such as those living in rural areas, people of some racial or ethnic minorities, people with lower socioeconomic status, and people with limited health literacy and English proficiency (Nouri et al.,2020) Programs by the [Federal Communications Commission](https://www.fcc.gov/connecting-americans-health-care) and at the [Office for the Advancement of Telehealth at the Health Resources & Services Administration](https://www.hrsa.gov/rural-health/topics/telehealth) aim to expand access to telehealth and fund more services. Further action is still needed at the state and federal levels to increase access to broadband internet. At the health system level, several actions can be taken to address access issues, such as providing phone-based care and check-ins when possible and providing devices to patients free of charge. By understanding their patient populations and their needs, and by creating person-centered care that accounts for inequities and linguistic differences, organizations could more rapidly spread RPM(Wardlow et al.,2022)

An additional challenge in implementing RPM is billing and payment. The lack of coverage of services and lower reimbursement rates disincentivize organizations from expanding and implementing programs due to upfront costs. The cost-effectiveness of providing RPM can vary by types of monitoring, by diseases monitored, and by the setting in which monitoring is occurring (such as an integrated delivery network, accountable care organization, or large health system Prior to the PHE, the Centers for Medicare & Medicaid Services (CMS) implemented new billing codes and expanded coverage of RPM. At the onset of the PHE, CMS further expanded coverage by introducing [waivers and flexibilities](https://www.cms.gov/coronavirus-waivers) for providing telehealth services. Some requirements were relaxed by these waivers, including the need for existing physician–patient relationships and minimum requirements for time spent monitoring In a study completed in early 2022, many physicians across different care settings acknowledged the benefits to the workforce and care provided to patients but stated the primary reason for adopting or failing to adopt telehealth services was related to cost. Physicians interviewed shared that cost-reimbursement challenges, like the lack of payment parity with providing in-hospital services or that reimbursements covered only a small fraction of the actual cost of services, hindered overall telehealth implementation.

##### **Patient Safety Considerations for RPM Implementation**

[Patient safety concerns](https://psnet.ahrq.gov/primer/telehealth-and-patient-safety) when implementing RPM include the risk of clinical misdiagnosis or failure to identify when patients need attention from providers. In both these cases, developing robust processes and clear guidelines for providers will help mitigate the risk of patient safety issues. When designing the program, organizations must develop clear protocols for identifying appropriate patients to use RPM and have escalation protocols so that patients with abnormal results are appropriately referred for higher levels of care or have their symptoms managed. Understanding each individual patient’s typical disposition and variability is important as well. Ideally, thresholds for flagging abnormal results should be individualized for each patient [9]

**Clinical Evidence Backing RPM Use**

Research backing the clinical benefits of RPM has been available for well over a decade, with a study published back in 2005 showing that hospital-at-home care resulted in patients having a shorter length of stay — 3.2 days versus 4.9 days — and fewer complications. Since then, clinical evidence has only grown, especially in the last two years spurred by the COVID-19 pandemic. Just last year, a study published in JAMA Open Network found that hospital-at-home interventions that include at least one home visit from a nurse or physician may be a promising substitute to in-hospital care, especially for chronic diseases patients. Further, RPM was used across the country to monitor COVID-19 patients at home as hospitals struggled to keep beds open for those who became critically ill. Rochester, Minnesota-based Mayo Clinic published a study in npj Digital Medicine in 2021 that showed low rates of emergency department visits and hospitalization for COVID-19 patients enrolled in an RPM program. The ER visit rate was 11.4 percent, the hospitalization rate was 9.4 percent within 30 days of enrollment, and the 30-day mortality rate was 0.4 percent, according to the study. Similarly, a Kaiser Permanente study revealed that of 13,055 patients enrolled in its COVID-19 Home Monitoring program between April 2020 and February 2021, 95.5 percent recovered and completed the program, 10.6 percent were admitted to the hospital, and 0.2 percent died. Not only is RPM linked to enhanced or similar outcomes as in-hospital care for high-acuity conditions, but also long-term chronic conditions, like type 2 diabetes. A study out of the St. Joseph's/Candler (SJ/C) health system in Savannah, Georgia, published last October, shows that people with diabetes who received care via RPM and telehealth during the pandemic saw their A1C levels drop, with 2 percent and 2.2 percent reductions at three and six months, respectively. Another organization, Huntsman Cancer Institute at the University of Utah, studied its adult oncology hospital-at-home program and found that during the first 30 days of enrollment, patients in the program were 58 percent less likely to be admitted for an unplanned hospital stay, and those who were admitted to the hospital had a shorter length of stay. Research organizations that provide funding are also pouring millions into studies focused on the use of RPM for neurodegenerative diseases like Alzheimer's. In addition, there is research backing the use of RPM for post-surgery care and rehabilitation. One study, published in 2020, touted a fourfold reduction in re-hospitalizations among knee and hip replacement patients who used RPM tools at home rather than participate in a rehab program in person. And just last year, a study published in the British Medical Association trade journal showed that while an RPM program didn't significantly affect the mortality or re-hospitalization rate for non-elective surgery patients, it did significantly reduce pain and was linked with a significant increase in detection and correction of medication errors.

**The non-clinical benefits of the modality**

RPM's benefits are not limited to clinical improvements alone. The care modality can also help break down hurdles related to social determinants of health, that is, social factors that negatively affect health. One major socioeconomic hurdle that holds people back from seeking care is transportation. In fact, 3.6 million people in the US do not obtain medical care due to transportation barriers, according to the [American Hospital Association](https://www.aha.org/ahahret-guides/2017-11-15-social-determinants-health-series-transportation-and-role-hospitals). Transportation issues include lack of access to vehicles, broken infrastructure, long distances, and lengthy times to reach services, as well as transportation costs. "Inherently, we all know that remote patient monitoring can eliminate that [transportation] barrier as we are meeting patients where they are," said Julie Henry, chief operating officer of digital medicine at New Orleans-based Ochsner Health at an [mHealthIntelligence webcast](https://vimeo.com/640331352) last year. "Access to a provider…through technology and digital reach and telephonic intervention or secure texting and chatting can be that touchpoint rather than [patients] having to go into bricks and mortar." The additional touchpoints enabled via RPM also provide health systems with more information about their patients' lives, allowing clinical teams to make adjustments to treatment plans in accordance with social determinants of health.

Not only is RPM beneficial for patients facing socioeconomic hurdles to care, but it also offers several advantages to healthcare providers. One key advantage is the potential for cost savings. For example, Deaconess Health in Evansville, Indiana, saw its 30-day readmission rate drop by half after [implementing an RPM program](https://mhealthintelligence.com/news/deaconess-health-finds-success-in-tailoring-telehealth-to-specific-patients), translating into savings of $500,000 in costs associated with readmission, including penalties. Another is the care modality's hand in freeing up space in hospital facilities for severely ill patients. South Shore Health in Weymouth, Massachusetts, combined RPM with mobile health strategies to manage patient care outside the hospital. "We are a health system that frequently functions at high capacity," said Kelly Lannutti, DO, director of clinical transformation and co-medical director of mobile integrated health for South Shore Health, at Xtelligent Healthcare Media's [RPM Virtual Summit last year](https://vimeo.com/575327722). "Our hospital is frequently at a 100 percent capacity or more. So for us, it really makes sense to move patients to alternate care settings where possible."

2.2 **Diagnosing System**

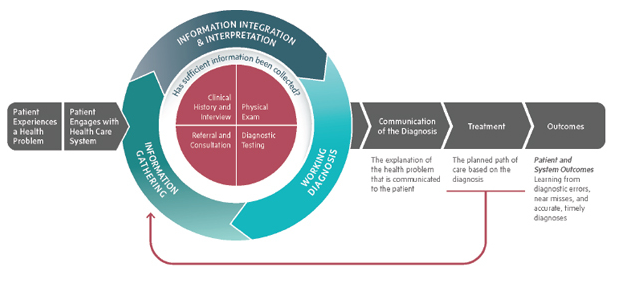
Medical diagnosis  is the process of determining which [disease](https://en.wikipedia.org/wiki/Disease) or condition explains a person's [symptoms](https://en.wikipedia.org/wiki/Symptom) and [signs](https://en.wikipedia.org/wiki/Medical_sign). It is most often referred to as diagnosis with the [medical](https://en.wikipedia.org/wiki/Medicine) context being implicit. The information required for diagnosis is typically collected from a [history](https://en.wikipedia.org/wiki/Medical_history) and [physical examination](https://en.wikipedia.org/wiki/Physical_examination) of the person seeking medical care. Often, one or more diagnostic procedures, such as [medical tests](https://en.wikipedia.org/wiki/Medical_test), are also done during the process. Sometimes the [posthumous diagnosis](https://en.wikipedia.org/wiki/Posthumous_diagnosis) is considered a kind of medical diagnosis.

Diagnosis is often challenging because many signs and symptoms are [nonspecific](https://en.wikipedia.org/wiki/Sensitivity_and_specificity). For example, redness of the [skin](https://en.wikipedia.org/wiki/Skin) ([erythema](https://en.wikipedia.org/wiki/Erythema)), by itself, is a sign of many disorders and thus does not tell the healthcare professional what is wrong. Thus [differential diagnosis](https://en.wikipedia.org/wiki/Differential_diagnosis), in which several possible explanations are compared and contrasted, must be performed. This involves the [correlation](https://en.wikipedia.org/wiki/Correlation) of various pieces of information followed by the recognition and differentiation of patterns. Occasionally the process is made easy by a sign or symptom (or a group of several) that is [pathognomonic](https://en.wikipedia.org/wiki/Pathognomonic). Diagnosis is a major component of the [procedure of a doctor's visit](https://en.wikipedia.org/wiki/Doctor%27s_visit#Procedure). From the point of view of [statistics](https://en.wikipedia.org/wiki/Statistics), the diagnostic procedure involves [classification tests](https://en.wikipedia.org/wiki/Classification_test).

Diagnosis has been described as both a process and a classification scheme, or a “pre-existing set of categories agreed upon by the medical profession to designate a specific condition” ([Jutel, 2009](https://www.ncbi.nlm.nih.gov/books/NBK338593/)).[1](https://www.ncbi.nlm.nih.gov/books/NBK338593/) When a diagnosis is accurate and made in a timely manner, a patient has the best opportunity for a positive health outcome because clinical decision making will be tailored to a correct understanding of the patient's health problem ([Holmboe and Durning, 2014](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). In addition, public policy decisions are often influenced by diagnostic information, such as setting payment policies, resource allocation decisions, and research priorities ([Jutel, 2009](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Rosenberg, 2002](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [WHO, 2012](https://www.ncbi.nlm.nih.gov/books/NBK338593/)).

**Overview of the Diagnostic Process**

To help frame and organize its work, the committee developed a conceptual model to illustrate the diagnostic process (see fig 2.3). The committee concluded that the diagnostic process is a complex, patient-centered, collaborative activity that involves information gathering and clinical reasoning with the goal of determining a patient's health problem. This process occurs over time, within the context of a larger health care work system that influences the diagnostic process . The committee's depiction of the diagnostic process draws on an adaptation of a decision-making model that describes the cyclical process of information gathering, information integration and interpretation, and forming a working diagnosis ([Parasuraman et al., 2000](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Sarter, 2014](https://www.ncbi.nlm.nih.gov/books/NBK338593/))



### FIGURE 2.3The committee's conceptualization of the diagnostic process

### The diagnostic process proceeds as follows: First, a patient experiences a health problem. The patient is likely the first person to consider his or her symptoms and may choose at this point to engage with the health care system. Once a patient seeks health care, there is an iterative process of information gathering, information integration and interpretation, and determining a working diagnosis. Performing a clinical history and interview, conducting a physical exam, performing diagnostic testing, and referring or consulting with other clinicians are all ways of accumulating information that may be relevant to understanding a patient's health problem. The information-gathering approaches can be employed at different times, and diagnostic information can be obtained in different orders. The continuous process of information gathering, integration, and interpretation involves hypothesis generation and updating prior probabilities as more information is learned. Communication among health care professionals, the patient, and the patient's family members is critical in this cycle of information gathering, integration, and interpretation.

### The working diagnosis may be either a list of potential diagnoses (a differential diagnosis) or a single potential diagnosis. Typically, clinicians will consider more than one diagnostic hypothesis or possibility as an explanation of the patient's symptoms and will refine this list as further information is obtained in the diagnostic process. The working diagnosis should be shared with the patient, including an explanation of the degree of uncertainty associated with a working diagnosis. Each time there is a revision to the working diagnosis, this information should be communicated to the patient. As the diagnostic process proceeds, a fairly broad list of potential diagnoses may be narrowed into fewer potential options, a process referred to as diagnostic modification and refinement (Kassirer et al., 2010). As the list becomes narrowed to one or two possibilities, diagnostic refinement of the working diagnosis becomes diagnostic verification, in which the lead diagnosis is checked for its adequacy in explaining the signs and symptoms, its coherency with the patient's context (physiology, risk factors), and whether a single diagnosis is appropriate. When considering invasive or risky diagnostic testing or treatment options, the diagnostic verification step is particularly important so that a patient is not exposed to these risks without a reasonable chance that the testing or treatment options will be informative and will likely improve patient outcomes.

### Throughout the diagnostic process, there is an ongoing assessment of whether sufficient information has been collected. If the diagnostic team members are not satisfied that the necessary information has been collected to explain the patient's health problem or that the information available is not consistent with a diagnosis, then the process of information gathering, information integration and interpretation, and developing a working diagnosis continues. When the diagnostic team members judge that they have arrived at an accurate and timely explanation of the patient's health problem, they communicate that explanation to the patient as the diagnosis.

### It is important to note that clinicians do not need to obtain diagnostic certainty prior to initiating treatment; the goal of information gathering in the diagnostic process is to reduce diagnostic uncertainty enough to make optimal decisions for subsequent care (Kassirer, 1989; see section on diagnostic uncertainty). In addition, the provision of treatment can also inform and refine a working diagnosis, which is indicated by the feedback loop from treatment into the information-gathering step of the diagnostic process. This also illustrates the need for clinicians to diagnose health problems that may arise during treatment.

### The committee identified four types of information-gathering activities in the diagnostic process: taking a clinical history and interview; performing a physical exam; obtaining diagnostic testing; and sending a patient for referrals or consultations. The diagnostic process is intended to be broadly applicable, including the provision of mental health care. These information-gathering processes are discussed in further detail below.

### Clinical History and Interview

### Acquiring a clinical history and interviewing a patient provides important information for determining a diagnosis and also establishes a solid foundation for the relationship between a clinician and the patient. A common maxim in medicine attributed to William Osler is: “Just listen to your patient, he is telling you the diagnosis” (Gandhi, 2000). An appointment begins with an interview of the patient, when a clinician compiles a patient's medical history or verifies that the details of the patient's history already contained in the patient's medical record are accurate. A patient's clinical history includes documentation of the current concern, past medical history, family history, social history, and other relevant information, such as current medications (prescription and over-the-counter) and dietary supplements.

### The process of acquiring a clinical history and interviewing a patient requires effective communication, active listening skills, and tailoring communication to the patient based on the patient's needs, values, and preferences. The National Institute on Aging, in guidance for conducting a clinical history and interview, suggests that clinicians should avoid interrupting, demonstrate empathy, and establish a rapport with patients (NIA, 2008). Clinicians need to know when to ask more detailed questions and how to create a safe environment for patients to share sensitive information about their health and symptoms. Obtaining a history can be challenging in some cases: For example, in working with older adults with memory loss, with children, or with individuals whose health problems limit communication or reliable self-reporting. In these cases it may be necessary to include family members or caregivers in the history-taking process. The time pressures often involved in clinical appointments also contribute to challenges in the clinical history and interview. Limited time for clinical visits, partially attributed to payment policies, may lead to an incomplete picture of a patient's relevant history and current signs and symptoms.

### There are growing concerns that traditional “bedside evaluation” skills (history, interview, and physical exam) have received less attention due the large growth in diagnostic testing in medicine. Verghese and colleagues noted that these methods were once the primary tools for diagnosis and clinical evaluation, but “the recent explosion of imaging and laboratory testing has inverted the diagnostic paradigm. [Clinicians] often bypass the bedside evaluation for immediate testing” (Verghese et al., 2011). The interview has been called a clinician's most versatile diagnostic and therapeutic tool, and the clinical history provides direction for subsequent information-gathering activities in the diagnostic process (Lichstein, 1990). An accurate history facilitates a more productive and efficient physical exam and the appropriate utilization of diagnostic testing (Lichstein, 1990). Indeed, Kassirer concluded: “Diagnosis remains fundamentally dependent on a personal interaction of a [clinician] with a patient, the sufficiency of communication between them, the accuracy of the patient's history and physical examination, and the cognitive energy necessary to synthesize a vast array of information” (Kassirer, 2014).

### Physical Exam

The physical exam is a hands-on observational examination of the patient. First, a clinician observes a patient's demeanor, complexion, posture, level of distress, and other signs that may contribute to an understanding of the health problem ([Davies and Rees, 2010](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). If the clinician has seen the patient before, these observations can be weighed against previous interactions with the patient. A physical exam may include an analysis of many parts of the body, not just those suspected to be involved in the patient's current complaint. A careful physical exam can help a clinician refine the next steps in the diagnostic process, can prevent unnecessary diagnostic testing, and can aid in building trust with the patient ([Verghese, 2011](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). There is no universally agreed upon physical examination checklist; myriad versions exist online and in textbooks.

Due to the growing emphasis on diagnostic testing, there are concerns that physical exam skills have been underemphasized in current health care professional education and training ([Kassirer, 2014](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Kugler and Verghese, 2010](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). For example, Kugler and Verghese have asserted that there is a high degree in variability in the way that trainees elicit physical signs and that residency programs have not done enough to evaluate and improve physical exam techniques. Physicians at Stanford have developed the “Stanford 25,” a list of physical diagnostic maneuvers that are very technique-dependent ([Verghese and Horwitz, 2009](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). Educators observe students and residents performing these 25 maneuvers to ensure that trainees are able to elicit the physical signs reliably ([Stanford Medicine 25 Team, 2015](https://www.ncbi.nlm.nih.gov/books/NBK338593/))

### Diagnostic Testing

Over the past 100 years, diagnostic testing has become a critical feature of standard medical practice ([Berger, 1999](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [European Society of Radiology, 2010](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). Diagnostic testing may occur in successive rounds of information gathering, integration, and interpretation, as each round of information refines the working diagnosis. In many cases, diagnostic testing can identify a condition before it is clinically apparent; for example, coronary artery disease can be identified by an imaging study indicating the presence of coronary artery blockage even in the absence of symptoms.

The primary emphasis of this section focuses on laboratory medicine, anatomic pathology, and medical imaging. However, there are many important forms of diagnostic testing that extend beyond these fields, and the committee's conceptual model is intended to be broadly applicable. Aditional forms of diagnostic testing include, for example, screening tools used in making mental health diagnoses ([SAMHSA and HRSA, 2015](https://www.ncbi.nlm.nih.gov/books/NBK338593/)), sleep apnea testing, neurocognitive assessment, and vision and hearing testing.

Although it was developed specifically for laboratory medicine, the brain-to-brain loop model is useful for describing the general process of diagnostic testing ([Lundberg, 1981](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Plebani et al., 2011](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). The model includes nine steps: test selection and ordering, sample collection, patient identification, sample transportation, sample preparation, sample analysis, result reporting, result interpretation, and clinical action ([Lundberg, 1981](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). These steps occur during five phases of diagnostic testing: prepre-analytic, pre-analytic, analytic, post-analytic, and post-post-analytic phases. Errors related to diagnostic testing can occur in any of these five phases, but the analytic phase is the least susceptible to errors ([Eichbaum et al., 2012](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Epner et al., 2013](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Laposata, 2010](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Nichols and Rauch, 2013](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Stratton, 2011](https://www.ncbi.nlm.nih.gov/books/NBK338593/)).

The pre-pre-analytic phase, which involves clinician test selection and ordering, has been identified as a key point of vulnerability in the work process due to the large number and variety of available tests, which makes it difficult for nonspecialist clinicians to accurately select the correct test or series of tests ([Hickner et al., 2014](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Laposata and Dighe, 2007](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). The pre-analytic phase involves sample collection, patient identification, sample transportation, and sample preparation. During the analytic phase, the specimen is tested, examined, or both. Adequate performance in this phase depends on the correct execution of a chemical analysis or morphological examination ([Hollensead et al., 2004](https://www.ncbi.nlm.nih.gov/books/NBK338593/)), and the contribution to diagnostic errors at this step is small. The post-analytic phase includes the generation of results, reporting, interpretation, and follow-up. Ensuring accurate and timely reporting from the laboratory to the ordering clinician and patient is central to this phase. During the post-post-analytic phase, the ordering clinician, sometimes in consultation with pathologists, incorporates the test results into the patient's clinical context, considers the probability of a particular diagnosis in light of the test results, and considers the harms and benefits of future tests and treatments, given the newly acquired information. Possible factors contributing to failure in this phase include an incorrect interpretation of the test result by the ordering clinician or pathologist and the failure by the ordering clinician to act on the test results: for example, not ordering a follow-up test or not providing treatment consistent with the test results ([Hickner et al., 2014](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Laposata and Dighe, 2007](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Plebani and Lippi, 2011](https://www.ncbi.nlm.nih.gov/books/NBK338593/)).

The medical imaging work process parallels the work process described for pathology. There is a pre-pre-analytic phase (the selection and ordering of medical imaging), a pre-analytic phase (preparing the patient for imaging), an analytic phase (image acquisition and analysis), a post-analytic phase (the imaging results are interpreted and reported to the ordering clinician or the patient), and a post-post-analytic phase (the integration of results into the patient context and further action). The relevant differences between the medical imaging and pathology processes include the nature of the examination and the methods and technology used to interpret the results.

#### **Laboratory Medicine and Anatomic Pathology**

In 2008 a Centers for Disease Control and Prevention (CDC) report described pathology as an “essential element of the health care system,” stating that pathology is “integral to many clinical decisions, providing physicians, nurses, and other health care providers with often pivotal information for the prevention, diagnosis, treatment, and management of disease” ([CDC, 2008](https://www.ncbi.nlm.nih.gov/books/NBK338593/), p. 19). Primary care clinicians order laboratory tests in slightly less than one third of patient visits ([CDC, 2010](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Hickner et al., 2014](https://www.ncbi.nlm.nih.gov/books/NBK338593/)), and direct-to-patient testing is becoming increasingly prevalent ([CDC, 2008](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). There are now thousands of molecular diagnostic tests available, and this number is expected to increase as the mechanisms of disease at the molecular level are better understood ([CDC, 2008](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Johansen Taber et al., 2014](https://www.ncbi.nlm.nih.gov/books/NBK338593/)) .

The task of selecting the appropriate diagnostic testing is challenging for clinicians, in part because of the sheer volume of choices. For example, [Hickner and colleagues (2014)](https://www.ncbi.nlm.nih.gov/books/NBK338593/) found that primary care clinicians report uncertainty in ordering laboratory medicine tests in approximately 15 percent of diagnostic encounters. Choosing the appropriate test requires understanding the patient's history and current signs and symptoms, as well as having a sufficient suspicion or pre-test probability of a disease or condition (see section on probabilistic reasoning) ([Pauker and Kassirer, 1975](https://www.ncbi.nlm.nih.gov/books/NBK338593/), [1980](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Sox, 1986](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). The likelihood of disease is inherently uncertain in this step; for instance, the clinician's patient population may not reflect epidemiological data, and the patient's history can be incomplete or otherwise complicated. Advances in molecular diagnostic technologies and new diagnostic tests have introduced another layer of complexity. Many clinicians are struggling to keep up with the growing availability of such tests and have uncertainty about the best application of these tests in screening, diagnosis, and treatment ([IOM, 2015a](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Johansen Taber et al., 2014](https://www.ncbi.nlm.nih.gov/books/NBK338593/)).

Diagnostic tests have “operating parameters,” including sensitivity and specificity that are particular to the diagnostic test for a specific disorder (see section on probabilistic reasoning). Even if a test is performed correctly, there is a chance for a false positive or false negative result. Test interpretation involves reviewing numerical or qualitative (yes or no) results and combining those results with patient history, symptoms, and pretest disease likelihood. Test interpretation needs to be patient-specific and to consider information learned during the physical exam and the clinical history and interview. Several studies have highlighted test interpretation errors, such as the misinterpretation of a false positive human immunodeficiency virus (HIV) screening test for a low-risk patient as indicative of HIV infection ([Gigerenzer, 2013](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Kleinman et al., 1998](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). In addition, test performance may only be characterized in a limited patient population, leading to challenges with generalizability ([Whiting et al., 2004](https://www.ncbi.nlm.nih.gov/books/NBK338593/)).

The laboratories that conduct diagnostic testing are some of the most regulated and inspected areas in health care. Some of the relevant entities include The Joint Commission and other accreditors, the federal government, and various other organizations, such as the College of American Pathologists (CAP) and the American Society for Clinical Pathology. There are many ways in which quality is assessed. Examples include proficiency testing of clinical laboratory assays and pathologists (e.g., Pap smear proficiency testing), many of which are regulated under the Clinical Laboratory Improvement Amendments, and inter-laboratory comparison programs (e.g., CAP's Q-Probes, Q-Monitors, and Q-Tracks programs).

#### Medical Imaging

Medical imaging plays a critical role in establishing the diagnoses for innumerable conditions and it is used routinely in nearly every branch of medicine. The advancement of imaging technologies has improved the ability of clinicians to detect, diagnose, and treat conditions while also allowing patients to avoid more invasive procedures ([European Society of Radiology, 2010](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Gunderman, 2005](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). For many conditions (e.g., brain tumors), imaging is the only noninvasive diagnostic method available. The appropriate choice of imaging modality depends on the disease, organ, and specific clinical questions to be addressed. Computed tomography (CT) and magnetic resonance imaging (MRI) are first-line methods for assessing conditions of the central and peripheral nervous system, while for musculoskeletal and a variety of other conditions, X-ray and ultrasound are often employed first because of their relatively low cost and ready availability, with CT and MRI being reserved as problem-solving modalities. CT procedures are frequently used to assess and diagnose cancer, circulatory system diseases and conditions, inflammatory diseases, and head and internal organ injuries. A majority of MRI procedures are performed on the spine, brain, and musculoskeletal system, although usage for the breast, prostate, abdominal, and pelvic regions is rising ([IMV, 2014](https://www.ncbi.nlm.nih.gov/books/NBK338593/)).

Medical imaging is characterized not just by the increasingly precise anatomic detail it offers but also by an increasing capacity to illuminate biology. For example, magnetic resonance spectroscopic imaging has allowed the assessment of metabolism, and a growing number of other MRI sequences are offering information about functional characteristics, such as blood perfusion or water diffusion. In addition, several new tracers for molecular imaging with PET (typically as PET/CT) have recently been approved for clinical use, and more are undergoing clinical trials, while PET/MRI was recently introduced to the clinical setting. Functional and molecular imaging data may be assessed qualitatively, quantitatively, or both. Although other forms of diagnostic testing can identify a wide array of molecular markers, molecular imaging is unique in its capacity to noninvasively show the locations of molecular processes in patients, and it is expected to play a critical role in advancing precision medicine, particularly for cancers, which often demonstrate both intra- and intertumoral biological heterogeneity ([Hricak, 2011](https://www.ncbi.nlm.nih.gov/books/NBK338593/)).

The growing body of medical knowledge, the variety of imaging options available, and the regular increases in the amounts and kinds of data that can be captured with imaging present tremendous challenges for radiologists, as no individual can be expected to achieve competency in all of the imaging modalities. General radiologists continue to be essential in certain clinical settings, but extended training and sub-specialization are often necessary for optimal, clinically relevant image interpretation, as is involvement in multidisciplinary disease management teams. Furthermore, the use of structured reporting templates tailored to specific examinations can help to increase the clarity, thoroughness, and clinical relevance of image interpretation ([Schwartz et al., 2011](https://www.ncbi.nlm.nih.gov/books/NBK338593/)).

Like other forms of diagnostic testing, medical imaging has limitations. Some studies have found that between 20 and 50 percent of all advanced imaging results fail to provide information that improves patient outcome, although these studies do not account for the value of negative imaging results in influencing decisions about patient management ([Hendee et al., 2010](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). Imaging may fail to provide useful information because of modality sensitivity and specificity parameters; for example, the spatial resolution of an MRI may not be high enough to detect very small abnormalities. Inadequate patient education and preparation for an imaging test can also lead to suboptimal imaging quality that results in diagnostic error.

Perceptual or cognitive errors made by radiologists are a source of diagnostic error ([Berlin, 2014](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Krupinski et al., 2012](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). In addition, incomplete or incorrect patient information, as well as insufficient sharing of patient information, may lead to the use of an inadequate imaging protocol, an incorrect interpretation of imaging results, or the selection of an inappropriate imaging test by a referring clinician. Referring clinicians often struggle with selecting the appropriate imaging test, in part because of the large number of available imaging options and gaps in the teaching of radiology in medical schools. Although consensus-based guidelines (e.g., the various “appropriateness criteria” published by the American College of Radiology [ACR]) are available to help select imaging tests for many conditions, these guidelines are often not followed. The use of clinical decision support systems at the point of care as well as direct consultations with radiologists have been proposed by the ACR as methods for improving imaging test selection ([Allen and Thorwarth, 2014](https://www.ncbi.nlm.nih.gov/books/NBK338593/)).

There are several mechanisms for ensuring the quality of medical imaging. The Mammography Quality Standards Act (MQSA)—overseen by the Food and Drug Administration—was the first government-mandated accreditation program for any type of medical facility; it was focused on X-ray imaging for breast cancer. MQSA provides a general framework for ensuring national quality standards in facilities that perform screening mammography ([IOM, 2005](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). MQSA requires all personnel at facilities to meet initial qualifications, to demonstrate continued experience, and to complete continuing education. MQSA addresses protocol selection, image acquisition, interpretation and report generation, and the communication of results and recommendations. In addition, it provides facilities with data on diagnostic performance that can be used for benchmarking, self-monitoring, and improvement. MQSA has decreased the variability in mammography performed across the United States and improved the quality of care ([Allen and Thorwarth, 2014](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). However, the ACR noted that MQSA is complex and specified in great detail, which makes it inflexible, leading to administrative burdens and the need for extensive training of staff for implementation ([Allen and Thorwarth, 2014](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). It also focuses on only one medical imaging modality in one disease area; thus, it does not address newer screening technologies ([IOM, 2005](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). In addition, the Medicare Improvements for Patients and Providers Act (MIPPA)[3](https://www.ncbi.nlm.nih.gov/books/NBK338593/) requires that private outpatient facilities that perform CT, MRI, breast MRI, nuclear medicine, and PET exams be accredited. The requirements include personnel qualifications, image quality, equipment performance, safety standards, and quality assurance and quality control ([ACR, 2015a](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). There are four CMS-designated accreditation organizations for medical imaging: ACR, the Intersocietal Accreditation Commission, The Joint Commission, and RadSite ([CMS, 2015a](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). MIPPA also mandated that, beginning in 2017, ordering clinicians will be required to consult appropriateness criteria to order advanced medical imaging procedures, and the act called for a demonstration project evaluating clinician compliance with appropriateness criteria ([Timbie et al., 2014](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). In addition to these mandated activities, societies such as ACR and the Radiological Society of North America (RSNA) provide quality improvement programs and resources ([ACR, 2015b](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [RSNA, 2015](https://www.ncbi.nlm.nih.gov/books/NBK338593/)).

### Referral and Consultation

Clinicians may refer to or consult with other clinicians (formally or informally) to seek additional expertise about a patient's health problem. The consult may help to confirm or reject the working diagnosis or may provide information on potential treatment options. If a patient's health problem is outside a clinician's area of expertise, he or she can refer the patient to a clinician who holds more suitable expertise. Clinicians can also recommend that the patient seek a second opinion from another clinician to verify their impressions of an uncertain diagnosis or if they believe that this would be helpful to the patient. Many groups raise awareness that patients can obtain a second opinion on their own ([AMA, 1996](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [CMS, 2015c](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [PAF, 2012](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). Diagnostic consultations can also be arranged through the use of integrated practice units or diagnostic management teams ([Govern, 2013](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Porter, 2010](https://www.ncbi.nlm.nih.gov/books/NBK338593/);

**Important Consideration in the Diagnostic Process**

The committee elaborated on several aspects of the diagnostic process which are discussed below, including

1. Diagnostic uncertainty
2. Time
3. Population trends
4. Diverse populations and health disparities
5. Mental health

### Diagnostic Uncertainty

One of the complexities in the diagnostic process is the inherent uncertainty in diagnosis. As noted in the committee's conceptual model of the diagnostic process, an overarching question throughout the process is whether sufficient information has been collected to make a diagnosis. This does not mean that a diagnosis needs to be absolutely certain in order to initiate treatment. Kassirer concluded that:

Absolute certainty in diagnosis is unattainable, no matter how much information we gather, how many observations we make, or how many tests we perform. A diagnosis is a hypothesis about the nature of a patient's illness, one that is derived from observations by the use of inference. As the inferential process unfolds, our confidence as [clinicians] in a given diagnosis is enhanced by the gathering of data that either favor it or argue against competing hypotheses. Our task is not to attain certainty, but rather to reduce the level of diagnostic uncertainty enough to make optimal therapeutic decisions. ([Kassirer, 1989](https://www.ncbi.nlm.nih.gov/books/NBK338593/), p. 1489)

Thus, the probability of disease does not have to be equal to one (diagnostic certainty) in order for treatment to be justified ([Pauker and Kassirer, 1980](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). The decision to begin treatment based on a working diagnosis is informed by: (1) the degree of certainty about the diagnosis; (2) the harms and benefits of treatment; and (3) the harms and benefits of further information-gathering activities, including the impact of delaying treatment.

The risks associated with diagnostic testing are important considerations when conducting information-gathering activities in the diagnostic process. While underuse of diagnostic testing has been a long-standing concern, overly aggressive diagnostic strategies have recently been recognized for their risks ([Zhi et al., 2013](https://www.ncbi.nlm.nih.gov/books/NBK338593/)) (see [Chapter 3](https://www.ncbi.nlm.nih.gov/books/n/nap21794/ch3/)). Overuse of diagnostic testing has been partially attributed to clinicians' fear of missing something important and intolerance of diagnostic uncertainty: “I am far more concerned about doing too little than doing too much. It's the scan, the test, the operation that I should have done that sticks with me—sometimes for years. . . . By contrast, I can't remember anyone I sent for an unnecessary CT scan or operated on for questionable reasons a decade ago” ([Gawande, 2015](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). However, there is growing recognition that overly aggressive diagnostic pursuits are putting patients at greater risk for harm, and they are not improving diagnostic certainty ([Kassirer, 1989](https://www.ncbi.nlm.nih.gov/books/NBK338593/); [Welch, 2015](https://www.ncbi.nlm.nih.gov/books/NBK338593/)).

When considering diagnostic testing options, the harm from the procedure itself needs to be weighed against the potential information that could be gained. For some patients, the risk of invasive diagnostic testing may be inappropriate due to the risk of mortality or morbidity from the test itself (such as cardiac catheterization or invasive biopsies). In addition, the risk for harm needs to take into account the cascade of diagnostic testing and treatment decisions that could stem from a diagnostic test result. Included in these assessments are the potential for false positives and ambiguous or slightly abnormal test results that lead to further diagnostic testing or unnecessary treatment.

There are some cases in which treatment is initiated even though there is limited certainty in a working diagnosis. For example, an individual who has been exposed to a tick bite or HIV may be treated with prophylactic antibiotics or antivirals, because the risk of treatment may be felt to be smaller than the risk of harm from tick-borne diseases or HIV infection. Clinicians sometimes employ empiric treatment strategies—or the provision of treatment with a very uncertain diagnosis—and use a patient's response to treatment as an information-gathering activity to help arrive at a working diagnosis. However, it is important to note that response rates to treatment can be highly variable, and the failure to respond to treatment does not necessarily reflect that a diagnosis is incorrect. Nor does improvement in the patient's condition necessarily validate that the treatment conferred this benefit and, therefore, that the empirically tested diagnosis was in fact correct. A treatment that is beneficial for some patients might not be beneficial for others with the same condition ([Kent and Hayward, 2007](https://www.ncbi.nlm.nih.gov/books/NBK338593/)), hence the interest in precision medicine, which is hoped to better tailor therapy to maximize efficacy and minimize toxicity ([Jameson and Longo, 2015](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). In addition, there are isolated cases where the morbidity and the mortality of a diagnostic procedure and the likelihood of disease is sufficiently high that significant therapy has been given empirically. [Moroff and Pauker (1983)](https://www.ncbi.nlm.nih.gov/books/NBK338593/) described a decision analysis in which a 90-year-old practicing lawyer with a new 1.5 centimeter lung nodule was deemed to have a sufficiently high risk for mortality from lung biopsy and high likelihood of malignancy that the radiation oncologists felt comfortable treating the patient empirically for suspected lung cancer.

### Time

Of major importance in the diagnostic process is the element of time. Most diseases evolve over time, and there can be a delay between the onset of disease and the onset of a patient's symptoms; time can also elapse before a patient's symptoms are recognized as a specific diagnosis ([Zwaan and Singh, 2015](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). Some diagnoses can be determined in a very short time frame, while months may elapse before other diagnoses can be made. This is partially due to the growing recognition of the variability and complexity of disease presentation. Similar symptoms may be related to a number of different diagnoses, and symptoms may evolve in different ways as a disease progresses; for example, a disease affecting multiple organs may initially involve symptoms or signs from a single organ. The thousands of different diseases and health conditions do not present in thousands of unique ways; there are only a finite number of symptoms with which a patient may present. At the outset, it can be very difficult to determine which particular diagnosis is indicated by a particular combination of symptoms, especially if symptoms are nonspecific, such as fatigue. Diseases may also present atypically, with an unusual and unexpected constellation of symptoms ([Emmett, 1998](https://www.ncbi.nlm.nih.gov/books/NBK338593/)).

Adding to the complexity of the time-dependent nature of the diagnostic process are the numerous settings of care in which diagnosis occurs and the potential involvement of multiple settings of care within a single diagnostic process. Henriksen and Brady noted that this process—for patients, their families, and clinicians alike—can often feel like “a disjointed journey across confusing terrain, aided or impeded by different agents, with no destination in sight and few landmarks along the way” ([Henriksen and Brady, 2013](https://www.ncbi.nlm.nih.gov/books/NBK338593/), p. ii2).

Some diagnoses may be more important to establish immediately than others. These include diagnoses that can lead to significant patient harm if not recognized, diagnosed, and treated early, such as anthrax, aortic dissection, and pulmonary embolism. Sometimes making a timely diagnosis relies on the fast recognition of symptoms outside of the health care setting (e.g., public awareness of stroke symptoms can help improve the speed of receiving medical help and increase the chances of a better recovery) ([National Stroke Association, 2015](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). In these cases, the benefit of treating the disease promptly can greatly exceed the potential harm from unnecessary treatment. Consequently, the threshold for ordering diagnostic testing or for initiating treatment becomes quite low for such health problems ([Pauker and Kassirer, 1975](https://www.ncbi.nlm.nih.gov/books/NBK338593/), [1980](https://www.ncbi.nlm.nih.gov/books/NBK338593/)). In other cases, the potential harm from rapidly and unnecessarily treating a diagnosed condition can lead to a more conservative (or higher-threshold) approach in the diagnostic process.

**Population Trends**

Population trends, such as the aging of the population, are adding significant complexity to the diagnostic process and require clinicians to consider such complicating factors in diagnosis as comorbidity, polypharmacy and attendant medication side effects, as well as disease and medication interactions (IOM, 2008, 2013). Diagnosis can be especially challenging in older patients because classic presentations of disease are less common in older adults (Jarrett et al., 1995). For example, infections such as pneumonia or urinary tract infections often do not present in older patients with fever, cough, and pain but rather with symptoms such as lethargy, incontinence, loss of appetite, or disruption of cognitive function (Mouton et al., 2001). Acute myocardial infarction (MI) may present with fatigue and confusion rather than with typical symptoms such as chest pain or radiating arm pain (Bayer et al., 1986; Qureshi et al., 2000; Rich, 2006). Sensory limitations in older adults, such as hearing and vision impairments, can also contribute to challenges in making diagnoses (Campbell et al., 1999). Physical illnesses often present with a change in cognitive status in older individuals without dementia (Mouton et al., 2001). In older adults with mild to moderate dementia, such illnesses can manifest with worsening cognition. Older patients who have multiple comorbidities, medications, or cognitive and functional impairments are more likely to have atypical disease presentations, which may increase the risk of experiencing diagnostic errors (Gray-Miceli, 2008).

**Diverse Populations and Health Disparities**

Communicating with diverse populations can also contribute to the complexity of the diagnostic process. Language, health literacy, and cultural barriers can affect clinician–patient encounters and increase the potential for challenges in the diagnostic process (Flores, 2006; IOM, 2003; The Joint Commission, 2007). There are indications that biases influence diagnosis; one well-known example is the differential referral of patients for cardiac catheterization by race and gender (Schulman et al., 1999). In addition, women are more likely than men to experience a missed diagnosis of heart attack, a situation that has been partly attributed to real and perceived gender biases, but which may also be the result of physiologic differences, as women have a higher likelihood of presenting with atypical symptoms, including abdominal pain, shortness of breath, and congestive heart failure (Pope et al., 2000).

**Mental Health**

Mental health diagnoses can be particularly challenging. Mental health diagnoses rely on the Diagnostic and Statistical Manual of Mental Disorders (DSM); each diagnosis in the DSM includes a set of diagnostic criteria that indicate the type and length of symptoms that need to be present, as well as the symptoms, disorders, and conditions that cannot be present, in order to be considered for a particular diagnosis (APA, 2015). Compared to physical diagnoses, many mental health diagnoses rely on patient reports and observation; there are few biological tests that are used in such diagnoses (Pincus, 2014). A key challenge can be distinguishing physical diagnoses from mental health diagnoses; sometimes physical conditions manifest as psychiatric ones, and vice versa (Croskerry, 2003a; Hope et al., 2014; Pincus, 2014; Reeves et al., 2010). In addition, there are concerns about missing psychiatric diagnoses, as well as overtreatment concerns (Bor, 2015; Meyer and Meyer, 2009; Pincus, 2014). For example, clinician biases toward older adults can contribute to missed diagnoses of depression, because it may be perceived that older adults are likely to be depressed, lethargic, or have little interest in interactions. Patients with mental health–related symptoms may also be more vulnerable to diagnostic errors, a situation that is attributed partly to clinician biases; for example, clinicians may disregard symptoms in patients with previous diagnoses of mental illness or substance abuse and attribute new physical symptoms to a psychological cause (Croskerry, 2003a). Individuals with health problems that are difficult to diagnose or those who have chronic pain may also be more likely to receive psychiatric diagnoses erroneously.

Clinical Reasoning and Diagnosis

Accurate, timely, and patient-centered diagnosis relies on proficiency in clinical reasoning, which is often regarded as the clinician's quintessential competency. Clinical reasoning is “the cognitive process that is necessary to evaluate and manage a patient's medical problems” (Barrows, 1980, p. 19). Understanding the clinical reasoning process and the factors that can impact it are important to improving diagnosis, given that clinical reasoning processes contribute to diagnostic errors (Croskerry, 2003a; Graber, 2005). Health care professionals involved in the diagnostic process have an obligation and ethical responsibility to employ clinical reasoning skills: “As an expanding body of scholarship further elucidates the causes of medical error, including the considerable extent to which medical errors, particularly in diagnostics, may be attributable to cognitive sources, insufficient progress in systematically evaluating and implementing suggested strategies for improving critical thinking skills and medical judgment is of mounting concern” (Stark and Fins, 2014, p. 386). Clinical reasoning occurs within clinicians' minds (facilitated or impeded by the work system) and involves judgment under uncertainty, with a consideration of possible diagnoses that might explain symptoms and signs, the harms and benefits of diagnostic testing and treatment for each of those diagnoses, and patient preferences and values.

The current understanding of clinical reasoning is based on the dual process theory, a widely accepted paradigm of decision making. The dual process theory integrates analytical and non-analytical models of decision making (see Box 2-4). Analytical models (slow system 2) involve a conscious, deliberate process guided by critical thinking (Kahneman, 2011). Nonanalytical models (fast system 1) involve unconscious, intuitive, and automatic pattern recognition (Kahneman, 2011).

### Diagnostic criteria

The term diagnostic criteria designates the specific combination of [signs and symptoms](https://en.wikipedia.org/wiki/Signs_and_symptoms), and test results that the [clinician](https://en.wikipedia.org/wiki/Clinician) uses to attempt to determine the correct diagnosis.

Some examples of diagnostic criteria, also known as [clinical case definitions](https://en.wikipedia.org/wiki/Clinical_case_definition), are:

* [Amsterdam criteria](https://en.wikipedia.org/wiki/Amsterdam_criteria) for [hereditary nonpolyposis colorectal cancer](https://en.wikipedia.org/wiki/Hereditary_nonpolyposis_colorectal_cancer)
* [McDonald criteria](https://en.wikipedia.org/wiki/McDonald_criteria) for [multiple sclerosis](https://en.wikipedia.org/wiki/Multiple_sclerosis)
* [ACR criteria for systemic lupus erythematosus](https://en.wikipedia.org/wiki/Systemic_lupus_erythematosus#Diagnostic_criteria)
* [Centor criteria](https://en.wikipedia.org/wiki/Centor_criteria) for [strep throat](https://en.wikipedia.org/wiki/Streptococcal_pharyngitis)

### 2.2. 1 Clinical decision support system

### A clinical decision support system (CDSS) is a [health information technology](https://en.wikipedia.org/wiki/Health_information_technology) that provides clinicians, staff, patients, and other individuals with knowledge and person-specific information to help health and health care. CDSS encompasses a variety of tools to enhance decision-making in the clinical workflow. These tools include computerized alerts and reminders to care providers and patients, clinical guidelines, condition-specific order sets, focused patient data reports and summaries, documentation templates, diagnostic support, and contextually relevant reference information, among other tools. CDSSs constitute a major topic in [artificial intelligence in medicine](https://en.wikipedia.org/wiki/Artificial_intelligence_in_medicine).

The main purpose of modern CDSS is to assist clinicians at the point of care. (Berner,2007)This means that clinicians interact with a CDSS to help to analyze and reach a [diagnosis](https://en.wikipedia.org/wiki/Diagnosis_(medical)) based on patient data for different diseases.

In the early days, CDSSs were conceived to make decisions for the clinician literally. The clinician would input the information and wait for the CDSS to output the "right" choice, and the clinician would simply act on that output. However, the modern methodology of using CDSSs to assist means that the clinician interacts with the CDSS, utilizing both their knowledge and the CDSS's, better to analyze the patient's data than either human or CDSS could make on their own. Typically, a CDSS makes suggestions for the clinician to review, and the clinician is expected to pick out useful information from the presented results and discount erroneous CDSS suggestions.

The two main types of CDSS are knowledge-based and non-knowledge-based (Berner,2007)

An example of how a clinician might use a clinical decision support system is a diagnosis decision support system (DDSS). DDSS requests some of the patients' data and, in response, proposes a set of appropriate diagnoses. The physician then takes the output of the DDSS and determines which diagnoses might be relevant and which are not, (Berner,2007) and, if necessary, orders further tests to narrow down the diagnosis.

Another example of a CDSS would be a [case-based reasoning](https://en.wikipedia.org/wiki/Case-based_reasoning) (CBR) system.( Khussainova et al.,2015).A CBR system might use previous case data to help determine the appropriate amount of beams and the optimal beam angles for use in [radiotherapy](https://en.wikipedia.org/wiki/Radiotherapy) for brain cancer patients; medical physicists and oncologists would then review the recommended treatment plan to determine its viability.

Another important classification of a CDSS is based on the timing of its use. Physicians use these systems at the point of care to help them as they are dealing with a patient, with the timing of use being either pre-diagnosis, during diagnosis, or post-diagnosis. Pre-diagnosis CDSS systems help the physician prepare the diagnoses. CDSSs help review and filter the physician's preliminary diagnostic choices to improve outcomes. Post-diagnosis CDSS systems are used to mine data to derive connections between patients and their past medical history and clinical research to [predict future events](https://en.wikipedia.org/wiki/Predictive_medicine). (Berner,2007) As of 2012, it has been claimed that decision support will begin to replace clinicians in common tasks in the future.  Khosla and Vinod 2012

Another approach, used by the [National Health Service](https://en.wikipedia.org/wiki/National_Health_Service) in England, is to use a DDSS to [triage](https://en.wikipedia.org/wiki/Triage) medical conditions out of hours by suggesting a suitable next step to the patient (e.g. call an [ambulance](https://en.wikipedia.org/wiki/Ambulance), or see a [general practitioner](https://en.wikipedia.org/wiki/General_Practitioner) on the next working day). The suggestion, which may be disregarded by either the patient or the phone operative if common sense or caution suggests otherwise, is based on the known information and an implicit conclusion about what the *worst-case* diagnosis is likely to be; it is not always revealed to the patient because it might well be incorrect and is not based on a medically-trained person's opinion - it is only used for initial triage purposes.

### Clinical challenges

Much effort has been put forth by many medical institutions and software companies to produce viable CDSSs to support all aspects of clinical tasks. However, with the complexity of clinical workflows and the demands on staff time high, care must be taken by the institution deploying the support system to ensure that the system becomes an integral part of the clinical workflow. Some CDSSs have met with varying amounts of success, while others have suffered from common problems preventing or reducing successful adoption and acceptance.

Two sectors of the healthcare domain in which CDSSs have had a large impact are the pharmacy and billing sectors. Commonly used pharmacy and prescription-ordering systems now perform batch-based checking orders for negative drug interactions and report warnings to the ordering professional. Another sector of success for CDSS is in billing and claims filing. Since many hospitals rely on [Medicare](https://en.wikipedia.org/wiki/Medicare_(United_States)) reimbursements to stay in operation, systems have been created to help examine both a proposed treatment plan and the current rules of Medicare to suggest a plan that attempts to address both the care of the patient and the financial needs of the institution

Other CDSSs that are aimed at diagnostic tasks have found success, but are often very limited in deployment and scope. The Leeds Abdominal Pain System went operational in 1971 for the University of Leeds hospital. It was reported to have produced a correct diagnosis in 91.8% of cases, compared to the clinicians' success rate of 79.6%.

Despite the wide range of efforts by institutions to produce and use these systems, widespread adoption and acceptance have still not yet been achieved for most offerings. One large roadblock to acceptance has historically been workflow integration. A tendency to focus only on the functional decision-making core of the CDSS existed, causing a deficiency in planning how the clinician will use the product in situ. CDSSs were stand-alone applications, requiring the clinician to cease working on their current system, switch to the CDSS, input the necessary data (even if it had already been inputted into another system), and examine the results produced. The additional steps break the flow from the clinician's perspective and cost precious time.

### Technical challenges and barriers to implementation

Clinical decision support systems face steep technical challenges in a number of areas. Biological systems are profoundly complicated, and a clinical decision may utilize an enormous range of potentially relevant data. For example, an electronic [evidence-based medicine](https://en.wikipedia.org/wiki/Evidence-based_medicine) system may potentially consider a patient's symptoms, medical history, [family history](https://en.wikipedia.org/wiki/Family_history_(medicine)) and [genetics](https://en.wikipedia.org/wiki/Genetics), as well as historical and geographical trends of disease occurrence, and published clinical data on therapeutic effectiveness when recommending a patient's course of treatment.

Clinically, a large deterrent to CDSS acceptance is workflow integration.

While it has been shown that clinicians require explanations of Machine Learning-Based CDSS, in order to able to understand and trust their suggestions, (Tonekaboni et al.,2019*)*  there is an overall distinct lack of application of [explainable Artificial Intelligence](https://en.wikipedia.org/wiki/Explainable_artificial_intelligence) in the context of CDSS, (Khalifa, and Zabani, (2016*)*thus adding another barrier to the adoption of these systems. Another source of contention with many medical support systems is that they produce a massive number of alerts. When systems produce a high volume of warnings (especially those that do not require escalation), besides the annoyance, clinicians may pay less attention to warnings, causing potentially critical alerts to be missed. This phenomenon is called alert fatigue. (Khalifa, and Zabani, (2016*)*

### 2.2.2 Combining with electronic health records

### Implementing EHRs was an inevitable challenge. This challenge is because it is a relatively uncharted area, and there are many issues and complications during the implementation phase of an EHR. This can be seen in the numerous studies that have been undertaken. However, challenges in implementing electronic health records (EHRs) have received some attention. Still, less is known about transitioning from legacy EHRs to newer systems. ( Zandieh et al., 2008) EHRs are a way to capture and utilize real-time data to provide high-quality patient care, ensuring efficiency and effective use of time and resources. Incorporating EHR and CDSS together into the process of medicine has the potential to change the way medicine has been taught and practiced.( Berner et al., 2007) It has been said that "the highest level of EHR is a CDSS”. (Rothman et al,2012) Since "clinical decision support systems (CDSS) are computer systems designed to impact clinician decision making about individual patients at the point in time that these decisions are made”, .( Berner et al., 2007) it is clear that it would be beneficial to have a fully integrated CDSS and EHR. Even though the benefits can be seen, fully implementing a CDSS integrated with an EHR has historically required significant planning by the healthcare facility/organization for the CDSS to be successful and effective. The success and effectiveness can be measured by the increased patient care being delivered and reduced adverse events occurring. In addition, there would be a saving of time and resources and benefits in terms of autonomy and financial benefits to the healthcare facility/organization. (Sambasivan et al.,2012)

### 2.3 Review of Literature

### IoT has been used in certain significant medical science research projects to track patients' health. The following is an outline of the works related to this field.

### Muhammad et al., 2023 proposed an intelligent health monitoring and diagnosis system based on the internet of things and fuzzy logic for cardiac arrhythmia COVID-19 patients. The methodology used was artificial intelligence tools divided into two parts: (i) IoT-based health monitoring; and (ii) fuzzy logic-based medical diagnosis. The intelligent diagnosis of heart conditions and IoT-based health surveillance by doctors is offered to critical COVID-19 patients or isolated in remote locations. Sensors, cloud storage, as well as a global system for mobile texts and emails for communication with doctors in case of emergency are employed in their proposal. Their implemented system favors remote areas and isolated critical patients. This system utilizes an intelligent algorithm that employs an ECG signal pre-processed by moving through six digital filters. Then, based on the processed results, features are computed and assessed. The intelligent fuzzy system can make an autonomous diagnosis and has enough information to avoid human intervention. The algorithm is trained using ECG data from the MIT-BIH database and achieves high accuracy. In real-time validation, the fuzzy algorithm obtained almost 100% accuracy for all experiments. One of the drawback is that is they did characterize their work and they did not integrate live location, GSM messages, and an email to the doctors during emergency conditions

**Damin,2022** proposed Internet of things-based health monitoring system for early detection of cardiovascular events during COVID-19 pandemic. The method used was Internet of things (IoT) and health monitoring sensors which help to improve the medical care systems by enabling latency-sensitive surveillance and computing of large amounts of patients’ data. The major challenge being faced currently in this problem is its limited scalability and late detection of cardiovascular events in IoT-based computing environments. Experimental results showed that the proposed method was able to detect cardiovascular events with better performance (95.30% average sensitivity and 95.94% mean prediction values).

**Liang et al., 2021** proposed Toward real-time and efficient cardiovascular monitoring for COVID-19 patients by 5G-enabled wearable medical devices: a deep learning approach. Real-time cardiovascular disease monitoring based on wearable medical devices may effectively reduce COVID-19 mortality rates. However, due to technical limitations, there are three main issues. First, the traditional wireless communication technology for wearable medical devices is difficult to satisfy the real-time requirements fully. They employ 5G to send and receive data from wearable medical devices. Secondly, Flink streaming data processing framework is applied to access electrocardiogram data. Finally, they use convolutional neural networks and long short-term memory networks model to obtain automatically predict the COVID-19 patient's cardiovascular health. Theoretical analysis and experimental results show that our proposal can well solve the above issues and improve the prediction accuracy of cardiovascular disease to 99.29%.

**Neha et al.,** 2023 proposed Diagnostic Concordance of Telemedicine as Compared with Face-to-Face Care in Primary Health Care Clinics in Rural India: Randomized Crossover Trial. With the COVID-19 pandemic, there was an increase and scaling up of provider-to-provider telemedicine programs that connect frontline health providers such as nurses and community health workers at primary care clinics with remote doctors at tertiary facilities to facilitate consultations for rural patients. They conducted a diagnostic concordance study using a randomized crossover study design with 104 patients at 10 telemedicine primary care clinics. Patients reporting to 10 telemedicine primary care clinics were randomly assigned to first receive an in-person doctor consultation (59/104, 56.7%) or to first receive a health worker-assisted telemedicine consultation (45/104, 43.3%). The 2 groups were then switched, with the first group undergoing a telemedicine consultation following the in-person consultation and the second group receiving an in-person consultation after the teleconsultation. The in-person doctor and remote doctor were blinded to the diagnosis and management plan of the other. The diagnosis and treatment plan of in-person doctors was considered the gold standard. they use of a digital assistant to facilitate the consultation resulted in increased adherence to evidence-based care protocols. The findings reflect that telemedicine can be a safe and acceptable alternative mode of care especially in remote rural settings when in-person care is not accessible. Telemedicine has advantages. for the potential gains for improved health care-seeking behavior for patients, reduced costs for the patient, and improved health system efficiency by reducing overcrowding at tertiary health facilities.

**Manogaran et al.,2018** proposed A new architecture of Internet of Things and big data ecosystem for secured smart healthcare monitoring and alerting system. The architecture they use consists of two main sub architectures, namely, Meta Fog-Redirection (MF-R) and Grouping and Choosing (GC) architecture. MF-R architecture uses big data technologies such as Apache Pig and Apache HBase for collection and storage of the sensor data (big data) generated from different sensor devices. The proposed GC architecture is used for securing integration of fog computing with cloud computing.  his architecture also uses key management service and data categorization function (Sensitive, Critical and Normal) for providing security services. The framework also uses MapReduce based prediction model to predict the heart diseases. Performance evaluation parameters such as throughput, sensitivity, accuracy, and f-measure are calculated to prove the efficiency of the proposed architecture as well as the prediction model. They did not characterize the work.

**Awotunde et al.,2022** proposed Internet of Things with Wearable Devices and Artificial Intelligence for Elderly Uninterrupted Healthcare Monitoring Systems. they use of IoT-based systems can be used to leverage these challenges. The combination of IoT-wearable devices enabled by Artificial Intelligence can be used to solve some of these problems by monitoring elderly persons remotely and allowing them to conduct their day-to-day activities without any fear. Therefore, this paper proposed IoT-wearable enabled AI to remotely monitor elderly persons in real-time. Various wearable sensors were used to capture elderly physiological signs, the IoT-based cloud database was used to store the captured data, and the AI model was to process the data for effective decision-making. The health status of the elderly gets to the healthcare workers in real-time, thus enabling them to give precautionary advice to save lives. The system will also reduce the workload of medical personnel by monitoring elderly persons in real-time and remotely.

**Rifat et al., 2022** proposed an Internet of Things based Social Distance Monitoring System in Covid19. This study follows the qualitative-experimental methodology as this proposed system can be implemented on the wearable device, which will help the users to maintain social distancing in real-time. The main goal of our proposed system is to monitor the human presence and ensure proper social distancing. Once they have integrated this architecture into a wearable device, it is time to build the software and flesh out our notion. However, they suggested method may readily mitigate this danger by informing the user of his surroundings. This system can be implemented on wearable devices to get real-time notifications if someone gets too close to them. Thus, social distancing can be effectively maintained in this manner. Additionally, this technology may be easily deployed at a low cost, making it mass manufactured and affordable to the public

**Moghadas et al.,(2020)** proposed An IoT patient monitoring based on fog computing and data mining: Cardiac arrhythmia usecase. The method use to proposed for remote monitoring of patients’ health systems and detecting case arrhythmia using fog computing and data mining technologies. In contrast to earlier models that analyze data on the cloud side, the aim is to provide services close to users to improve QoS and reduce latency. In addition, in an emergency, for example, when a patient has a heart attack, the alert system automatically alerts the patient or physician. An effective system was proposed for monitoring the health of patients. This system is based on fog computing and data mining for patients with arrhythmias. Fog technology is utilized for patient information instead of being transmitted to the cloud thereby optimizing data transmission delays. In the proposed system, the Arduino uno and the AD8232 sensor module were utilized for launching the web service from Raspberry Pi (there are common devices of IoT), which enabled receiving.

**Mahboob et al.,2022** proposed Disease Diagnosis System Using IoT Empowered with Fuzzy Inference System. Their work demonstrates an integrated view of deploying smart disease diagnosis using the Internet of Things (IoT) empowered by the fuzzy inference system (FIS) to diagnose various diseases. The Fuzzy System is one of the best systems to diagnose medical conditions because every disease diagnosis involves many uncertainties, and fuzzy logic is the best way to handle uncertainties. Our proposed system differentiates new cases provided symptoms of the disease. Generally, it becomes a time-sensitive task to discriminate symptomatic disease. The proposed system consists of two cloud computing aspects. The first step defines the training phase, and the second step determines the validation phase. The training phase comprises three levels: the sensory layer, the data-preprocessing layer, and the final layer is the application layer. The Sensory layer comprises input parameters Fever, Cough, Headache, Respiratory Rate, Flu, Blood Pressure, Vomiting, and Diarrhea that assemble and bring the input values through IOT in the database. Because of the wireless communication of data, the data can be noisy and incomplete according to raw data type. After the sensory layer, the critical layer comes. Noise and Null values are handled by using the Normalization and Moving Average technique. Data is transferred to the application layer after preprocessing. Application is categorized into two layers: Prediction and Performance layer.

**Fatima et al, 2020** proposed Disease Diagnosis System Using IOT Empowered with Fuzzy Inference System. The proposed system can track symptoms smartly to diagnose diseases through IoT and FIS smartly and efficiently. Different coefficients have been employed to predict and compute the identified disease’s severity for each sign of disease. The proposed system consists of two cloud computing aspects, as shown. The first step defines the training phase, and the second step determines the validation phase. The training phase comprises three levels: the sensory layer, the data-preprocessing layer, and the final layer is the application layer. The Sensory layer comprises input parameters Fever, Cough, Headache, Respiratory Rate, Flu, Blood Pressure, Vomiting, and Diarrhea that assemble and bring the input values through IoT in the database. Because of the wireless communication of data, the data can be noisy and incomplete according to raw data type. After the sensory layer, the critical layer comes. Noise and Null values are handled by using the Normalization and Moving Average technique. Data is transferred to the application layer after preprocessing. Application is categorised into two layers: Prediction and Performance layer.

**Tamilselvi et al., 2020** proposed IoT based health monitoring system. With the increase in use of wearable sensors and the smart phones, these remote health care monitoring has evolved in such a pace. IoT monitoring of health helps in preventing the spread of disease as well as to get a proper diagnosis of the state of health, even if the doctor is at far distance. We are going to monitor constantly the patient’s heartbeat, body temperature, fall down and other basic parameters of the room. We proposed a nonstop checking and control instrument to screen the patient condition and store the patient information’s in Thingspeak server utilizing Wi-Fi Module based remote correspondence. The project uses an Arduino Board, Temperature sensor, Humidity sensor, Vibration sensor, Heart beat Sensor. The sensor modules will work one after the other in a specific time interval. The DHT 11 sensor will measure the surrounding temperature and humidity level. These measured data are communicated to the Arduino board. The Arduino board is connected with a wifi module to transmit the data to the thingpeak server. The second sensor LM35 sensor measures the body temperature and then it will have sent to the Arduino board. Next heartbeat sensor will measure the BPM and the measured value is given to the Arduino board. Similarly, the vibration sensor will detect the vibration or acceleration and it will be communicated to the Arduino. All the measured values are transmitted to the Thingspeak cloud server and the graphical representation of the measurement can be seen in the Thingpseak channel. Also if any abnormalities happened, Thinsgpeak will send sms to the concern doctor.

**Gregoski et al. (2012**) introduced a smartphone-based heart rate monitoring system. The system used a mobile light and camera to track finger blood flow and calculated blood flow-based cardiac output. The developed system described an integrated device that wirelessly transmitted a person’s pulse to a computer, empowering people to test their heart rate by merely looking at their phones instead of using hands each time. This is an excellent design but it is not feasible if continuous heart monitoring is needed. HRs were collected simultaneously from 14 subjects, ages 20 to 58, healthy or with clinical conditions, using the 3 devices during 5-minute periods while at rest, reading aloud under observation, and playing a video game. Correlation between the 3 devices was determined, and Bland-Altman plots for all possible pairs of devices across all conditions assessed agreement. Across conditions, all device pairs showed high correlations. Bland-Altman plots further revealed the Droid as a valid measure for HR acquisition. Across all conditions, the Droid compared to ECG, 95% of the data points (differences between devices) fell within the limits of agreement.

**Lei et al., (2021)** proposed **A Detailed Research on Human Health Monitoring System Based on Internet of Things.** The technological advent in smart sensing devices and the Internet has provided practical solutions in various sectors of networking, public and private sector industries, and government organizations worldwide. Their study intends to combine the Internet of Things (IoT) technology with health monitoring to make it personalized and timely through allowing the interconnection between the devices. Their work is aimed at exploring various wearable health monitoring modules that people wear to monitor heart rate, blood pressure, pulse, body temperature, and physiological information. The information is acquired using the wireless sensor to create a health monitoring system. The data is integrated using the Internet of Things for processing, connecting, and computing to achieve real-time monitoring. The temperature of three people measured by the temperature thermometer is 36.4, 36.7, and 36.5 (°C), respectively, and the average acquired by the monitoring system of the three people is 36.5, 36.4, and 36.5 (°C), respectively, indicating that the system demonstrated relatively accurate and stable testability. The user’s ECG is displayed clearly and conveniently using the ECG acquisition system. The pulse rate of the three people tested by the system is 78, 78, and 79 (times/min), respectively, similar to the medical pulse meter results. The physiological information acquired using the semantic recognition, matching system, and character matching system is relatively accurate. It concludes that the human health monitoring system based on the Internet of Things can provide people with daily health management, instrumental in heightening health service quality and level.

**Rezaeibagha and Mu (2018)** proposed Practical and secure telemedicine systems for user mobility. The application of wireless devices has led to a significant improvement in the quality delivery of care in telemedicine systems. Patients who live in a remote area are able to communicate with the healthcare provider and benefit from the doctor consultations. However, it has been a challenge to provide a secure telemedicine system, which captures users (patients and doctors) mobility and patient privacy. In this work, we present several secure protocols for telemedicine systems, which ensure the secure communication between patients and doctors who are located in different geographical locations. Their protocols are the first of this kind featured with confidentiality of patient information, mutual authentication, patient anonymity, data integrity, freshness of communication, and mobility. Their protocols are based on symmetric-key schemes and capture all desirable security requirements in order to better serve our objectives of research for secure telemedicine services; therefore, they are very efficient in implementation. A comparison with related works shows that our work contributes first comprehensive solution to capture user mobility and patient privacy for telemedicine systems.

**2.4 Research Gap**

There has been a rise in global demand for intelligent health surveillance and diagnosis systems for patients with critical health conditions, particularly those with severe heart diseases. Sophisticated measurement tools are used in hospitals worldwide to identify serious heart conditions. Previous researchers have work on real time monitoring and diagnosis of various heart disease. One of the drawback of these research was it does not provide the live location, GSM messages, and an email to the doctors during emergency conditions

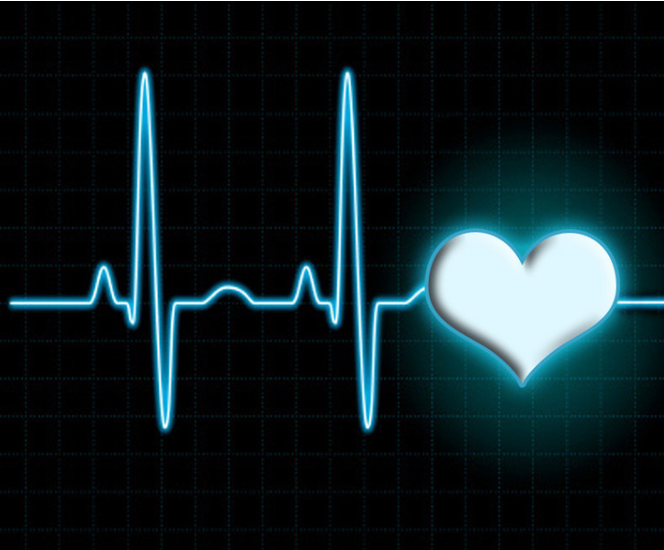
**Chapter Three**

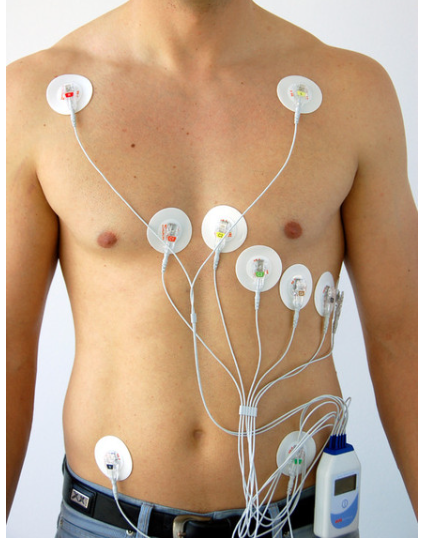
**Methodology**

**3.1 Introduction**

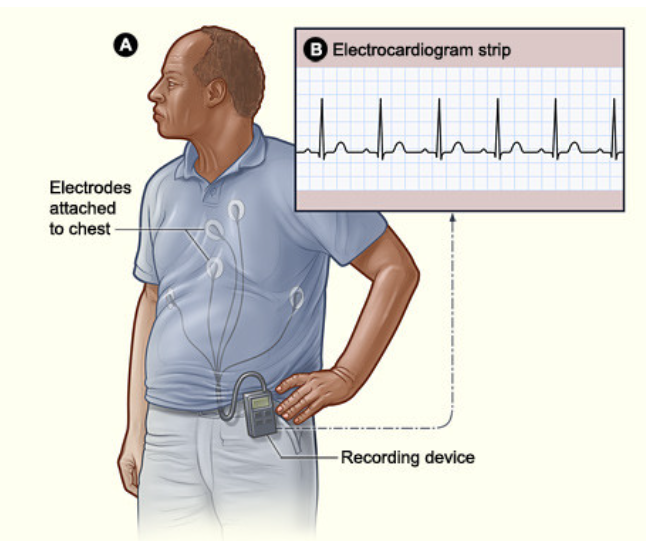
The method that will be use to achieve the overall goal of the dissertation will be as follow, to characterize the problem of monitoring and diagnosis of Cardiac arrhythmias in healthcare system. Here, the clinical assessment of atrial arrhythmias will be carried out. This will help to identify the symptoms. The tendency to use the characteristic of the symptoms to detect the atrial arrhythmias. to study how a doctor, carry out the diagnosis. A smart device will be developing that will monitor and diagnose a patient suffering Cardiac arrhythmias remotely. The device that will provide the live location, GSM messages, and an email to the doctors during emergency conditions. A machine learning model based on the developing smart device that will help the clinic to make a decision will be developed. This help to validate the developing device and model with existing system in monitoring Cardiac arrhythmias

**3.2 Characterize the problem of monitoring and diagnosis of arrhythmias in healthcare system.**

Arrhythmia is a cardiac condition characterized by an irregular heart rhythm that hinders the proper circulation of blood, posing a severe risk to individuals’ lives. Globally, arrhythmias are recognized as a significant health concern, accounting for nearly 12 percent of all deaths. As a result, there has been a growing focus on utilizing artificial intelligence for the detection and classification of abnormal heartbeats. In recent years, self-operated heartbeat detection research has gained popularity due to its cost-effectiveness and potential for expediting therapy for individuals at risk of arrhythmias. However, building an efficient automatic heartbeat monitoring approach for arrhythmia identification and classification comes with several significant challenges. These challenges include addressing issues related to data quality, determining the range for heart rate segmentation, managing data imbalance difficulties, handling intra- and inter-patient variations, distinguishing supraventricular irregular heartbeats from regular heartbeats, and ensuring model interpretability. A study called with an Electrocardiogram / 24hr Holter Monitor, A Holter monitor is a small, wearable device that records the heart's rhythm. It's used to detect or determine the risk of irregular heartbeats (arrhythmias). A Holter monitor test may be done if a traditional electrocardiogram (ECG or EKG) doesn't provide enough details about the heart's condition. If the irregular heartbeats are infrequent, a longer-term monitor called an event recorder may be needed. Doctors use Holter to detect and study many heart problems, such as [heart attacks](http://www.nhlbi.nih.gov/health/health-topics/topics/heartattack/), arrhythmias (ah-RITH-me-ahs), and heart failure. The test's results also can suggest other disorders that affect heart function



1. ECG monitor result (b) Holter(ECG) device monitor



(c)

Fig 3.1 |(a),(b) and (c) Holter device and result sample

An ambulatory electrocardiogram (EKG or ECG) records the electrical activity of your heart while you do your usual activities. (Ambulatory means that you are able to walk.) Ambulatory monitors are referred to by several names, including ambulatory electrocardiogram, ambulatory EKG, Holter monitoring, 24-hour EKG, or cardiac event monitoring. Many heart problems become noticeable only during activity, such as exercise, eating, sex, stress, bowel movements, or even sleeping. A continuous 24-hour recording is more likely to detect any abnormal heartbeats that occur during these activities. Many people have irregular heartbeats (arrhythmias) from time to time. The importance of irregular heartbeats depends on the type of pattern they produce, how often they occur, how long they last, and whether they occur at the same time you have symptoms. Because arrhythmias can occur off and on, it may be hard to record an arrhythmia while you are in the doctor's office.

**3.3 Development of the device using AD8232 ECG Sensor Module that will display the result of the reading on an OLED Screen**

**3.31 Hardware requirements**

1. **AD8232 ECG** Sensor Module
2. **ESP32 Development Board**
3. OLED Screen
4. 5 V DC Source
5. Male and female Header Pins
6. Connecting Wires
7. Perspex Sheet
8. Drilling Tools
9. Soldering Iron and Soft Solder
10. Hot Gun
11. Candle Gum
12. Veroboard and Breadboard

**3.32 Software requirements**

The software implementation of the project uses the source code attached at the Appendix of this work. The coding was done in Arduino IDE (Integrated Development Environment) using C++ Programming Language, after which it was tested, debugged, and then uploaded into the ESP32 Development Board. The Arduino Integrated Development Environment - or Arduino Software (IDE) - contains a text editor for writing code, a message area, a text console, a toolbar with buttons for common functions and a series of menus. This Arduino IDE is supported by Windows 10

* 1. **Hardware Description of Hardware Requirement**

**AD8232 ECG** Sensor Module

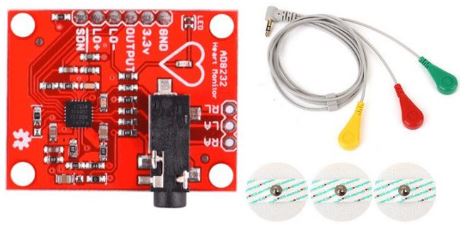


Figure 3.2: AD8232 ECG Sensor Module

AD8232 ECG Sensor Module is a cost-effective board used to measure the electrical activity of the heart. This electrical activity can be charted as an ECG or Electrocardiogram and output as an analog reading. ECGs can be extremely noisy, the AD8232 Single Lead Heart Rate Monitor acts as an op-amp to help obtain a clear signal from the PR and QT Intervals easily.

The AD8232 is an integrated signal conditioning block for ECG and other bio-potential measurement applications. It is designed to extract, amplify, and filter small bio-potential signals in the presence of noisy conditions, such as those created by motion or remote electrode placement.

The AD8232 module breaks out nine connections from the IC that you can solder pins, wires, or other connectors to. SDN, LO+, LO-, OUTPUT, 3.3V, GND provide essential pins for operating this monitor with an ESP32, or other development board. Also provided on this board are RA (Right Arm), LA (Left Arm), and RL (Right Leg) pins to attach and use your own custom sensors. Additionally, there is an LED indicator light that will pulsate to the rhythm of a heartbeat.

This **AD8232 ECG** Sensor Module has its OUTPUT and VCC pins connected to pin A0 and 3.3 V pin of the ESP32 respectively, since the sensor is 3.3 V enabled. Its GND pin is connected to the GND pin of the Arduino Nano. The LO+ and the LO- of the sensor are connected to the digital pins D10 and D11 of the ESP32 respectively.

**ESP32 Development Board**

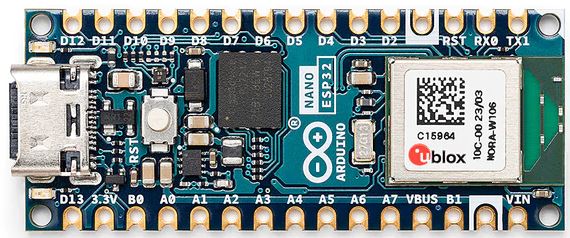


Figure 3.3: ESP32 Development Board

ESP32 is a series of low-cost, low-power [system on a chip](https://en.wikipedia.org/wiki/System_on_a_chip) [microcontrollers](https://en.wikipedia.org/wiki/Microcontroller) with integrated [Wi-Fi](https://en.wikipedia.org/wiki/Wi-Fi) and dual-mode [Bluetooth](https://en.wikipedia.org/wiki/Bluetooth). The ESP32 series employs either a [Tensilica](https://en.wikipedia.org/wiki/Tensilica) Xtensa LX6 microprocessor in both dual-core and [single-core](https://en.wikipedia.org/wiki/Single-core) variations, Xtensa LX7 dual-core microprocessor or a [single-core](https://en.wikipedia.org/wiki/Single-core) [RISC-V](https://en.wikipedia.org/wiki/RISC-V) microprocessor, and includes built-in antenna switches, [RF](https://en.wikipedia.org/wiki/Radio_frequency) [balun](https://en.wikipedia.org/wiki/Balun), power amplifier, low-noise receive amplifier, filters, and power-management modules. ESP32 is created and developed by [EspressIf Systems](https://en.wikipedia.org/wiki/Espressif_Systems), a Chinese company based in Shanghai, and is manufactured by [TSMC](https://en.wikipedia.org/wiki/TSMC) using their 40 nm process. It is a successor to the [ESP8266](https://en.wikipedia.org/wiki/ESP8266) microcontroller. The ESP32 Development Board was used in this dissertation as a Microcontroller to coordinate and regulate the activities of the components that made up the system, and also provides the internet connection used to connect to the Ubidots Server. It also processes the information obtained by the AD8232 ECG Sensor Module, and upload it over the internet through the help of Ubidots IoT Online Platform. The code was written in Arduino IDE, which can be downloaded from the official Arduino website, arduino.cc. The language used in the coding was C++. After writing the code, the code was debugged and verified, before it was uploaded into the ESP32 by using a mini-USB Cable after successfully installed all the required Libraries. The ESP32 was powered through a 5 V rechargeable DC supply through its Vin pin and GND pin to make it a stand-alone system.

**OLED Screen**



Figure 3.4: OLED Screen

The acronym 'OLED' stands for Organic Light-Emitting Diode - a technology that uses LEDs in which the light is produced by organic molecules. We have interfaced an OLED display screen to the ESP32 in order to be able to visualize the output of the system since the output is completely graphical. This OLED display was connected to the ESP32 through the use of I2C (Inter-Integrated Circuit). The benefit of using I2C is that we do not have to use any of the digital pins of the ESP32 when interfacing the OLED display screen to it, and this makes the connection very easy, save the digital pins and reduce the number of lines and complexity of the coding. However, the use of I2C increases the cost of this dissertation

Three different Libraries were used in programming this OLED display screen. These Libraries are:

1. Adafruit\_GFX.h - A library that provides common syntax and set of graphics functions for all of our LCD and OLED displays and LED matrices
2. Adafruit\_SSD1306 - A driver library, which handles display communication, memory mapping, and low-level drawing routines.
3. Wire.h – A library that allows you to communicate with I2C devices, a feature that is present on all Arduino boards. I2C is a very common protocol, primarily used for reading/sending data to/from external I2C components.

Organic LEDs are used to create what are considered to be the world's best display panels. When connecting the OLED to the ESP32, the SDA and the SCL pins of the OLED screen were connected to the analog pins A4 and A5 respectively. The Vcc and GND pins of the OLED display screen were also connected to the ESP32 3.3 V and GND pins.

**5 V DC Source**

****

**Figure 3.5 5v DC source**

5V power supplies (or 5VDC power supplies) are one of the most common power supplies in use today. In general, a 5VDC output is obtained from a 50VAC or 240VAC input using a combination of transformers, diodes and transistors. 5V power supplies can be of two types: 5V regulated power supplies, and 5V unregulated power supplies.5V regulated power supplies come in three styles: Switching regulated AC to DC, Linear regulated AC to DC, and Switching regulated DC to DC.

Switching regulated 5VDC power supplies, sometimes referred to as SMPS power supplies, switchers, or switched mode power supplies, regulate the 5VDC output voltage using a complex high frequency switching technique that employs pulse width modulation and feedback. Acopian switching regulated power supplies also employ extensive EMI filtering and shielding to attenuate both common and differential mode noise conducted to the line and load. Galvanic isolation is standard in our 5VDC switchers, affording our users input to output and output to ground isolation for maximum versatility. Acopian switching regulated power supplies are highly efficient, small and lightweight, and are available in both AC-DC single and wide-adjust output and DC-DC configurations. Our Low Profile wide adjust output switchers can be voltage or current regulated and are externally programmable.

Linear regulated 5VDC power supplies regulate the output using a dissipative regulating circuit. They are extremely stable, have very low ripple, and have no switching frequencies to produce EMI. Galvanic isolation is standard in our 5VDC linears, affording our users input to output and output to ground isolation for maximum versatility. Acopian linear regulated power supplies are available AC to DC single and wide adjust outputs.Unregulated 5VDC power supplies are basic power supplies with an AC input and an unregulated 5VDC output. The output voltage changes with the input voltage and load. These power supplies are inexpensive and extremely reliable.

**Male and female Header Pins**

****

**Fig 3.6 Header pins**

A pin header (or simply header) is a form of [electrical connector](https://en.wikipedia.org/wiki/Electrical_connector). A male pin header consists of one or more rows of metal pins molded into a plastic base, often 2.54 mm (0.1 in) apart, though available in many spacings. Male pin headers are cost-effective due to their simplicity. The female counterparts are sometimes known as female socket headers, though there are numerous naming variations of [male and female connectors](https://en.wikipedia.org/wiki/Gender_of_connectors_and_fasteners). Historically, headers have sometimes been called "[Berg connectors](https://en.wikipedia.org/wiki/Berg_connector)" or "DuPont" connectors, but headers are manufactured by many companies

**Connecting Wires**

****

**Figure 3.7 connecting wires**

Often, when building electronics projects, little thought is given thought is given to the connecting wire. While it is possible to "get away with" almost anything for many projects, it is sometimes necessary to connect the various electronics components using the right wire. For example it is often useful to use coloured connecting wire to indicate such items as electronics wire used for connecting the supplies, signals, and grounds. In this way it is easier to identify the different signals and lines and this reduces the possibility of errors. In addition to this it is sometimes necessary to have connecting wire of a particular size to ensure the connections are made in the right manner. If the wire is too thick it may not be easy to accommodate in some situations, whereas thicker wire may be needed for higher currents of physical strength or robustness in other situations

**Perspex Sheet**



**Figure 3.8 Perspex Sheet**

The brand perspex uses a material called Polymethyl Methacrylate (PMMA), an acrylic. This acrylic material is also referred to as acrylic glass, plexiglass and various other trade names such as Sheet Plastics, all of which use this transparent thermoplastic material.

**Drilling Tools**

****

**Figure 3.9 drilling tools**

A drill is a tool used for making round holes or driving fasteners. It is fitted with a bit, either a drill or driver chuck. Hand-operated types are dramatically decreasing in popularity and cordless battery-powered ones proliferating due to increased efficiency and ease of use.

**Soldering Iron and Soft Solder**

****

**Figure 3.10a Soldering Iron**

****

**Figure 3.10b soft solder**

Soldering Irons and Soft Solder Tools from Rings & Things - Great for all your low-temperature jewelry-making needs!

1. Use soldering irons with *soft solder*, such as StayBrite, Choice, or SILVERGLEEM, and use a flux designed for soft soldering (such as LACO BRITE).
2. Soldering irons do not get hot enough for *hard solders* such as copper and the hard/medium/easy grades of silver solder. (Use a [torch](https://rings-things.com/jewelry-making-tools-and-supplies/jewelry-soldering-tools-and-supplies/jewelry-soldering-tools) for soldering sterling silver or fusing fine silver.)

Soft solder is a low-temperature tin-based solder, perfect for making glass frame pendants, repairing costume jewelry, and soldering pin backs or barrette backs onto metal jewelry when you want a connection more permanent than glue.

**Hot Gun**



**Figure 3.11 Hot gun**

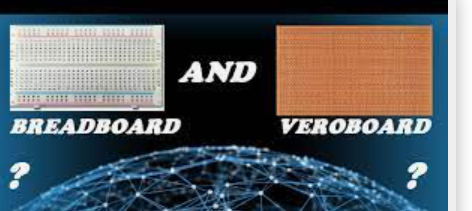
The gun uses a continuous-duty heating element to melt the plastic glue, which the user pushes through the gun either with a mechanical trigger mechanism on the gun, or with direct finger pressure. The glue squeezed out of the heated nozzle is initially hot enough to burn and even blister skin

**Candle Gum**

****

**Figure 3.12 candle Gum**

**Veroboard and Breadboard**

****

**Figure 3.13 Veroboard and Breadboard**

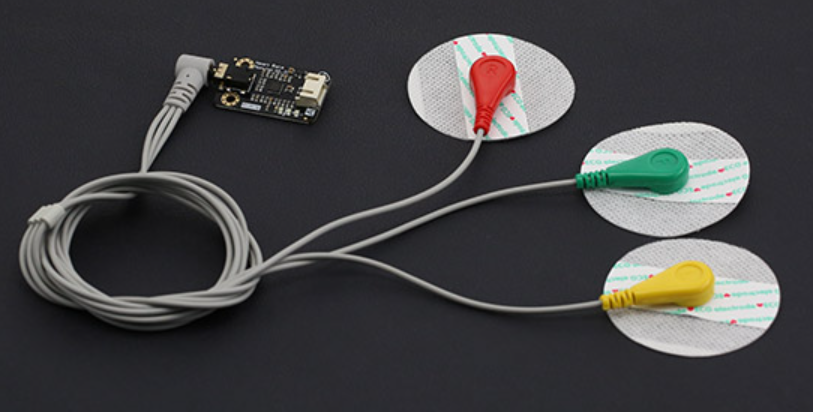
A breadboard is a tool we use all the time when making any circuit prototype. It is like a go-to tool when it comes to building physical circuits. A breadboard is a very basic tool in electronics used to make circuit prototypes, test out circuits, compare the real-time results to simulation one, build a part of a system, and test it independently.

A veroboard is a fundamental tool when it comes to PCB prototyping. It is mostly used by students and beginner level electronics enthusiasts.It has copper traces and comes in various shapes and sizes. Other than size, veroboards have two special categories:

1. Shorted copper strip board
2. Open copper strip board

Breadboard and Veroboard are both basic and fundamental tools when it come to electronic circuits. We use a breadboard for circuit prototyping and use Veroboard for the PCB prototyping. Both have their advantages and drawbacks. Breadboard uses a solderless approach that makes it user friendly and reusable. While with Veroboard we make clean PCBs to verify results before taking the next manufacturing step. With Veroboard, we have to be very careful as it is hard to make changes with boards. However, they provide less parasitic losses when compared to breadboards. In summary, the difference between breadboard and Veroboard is that we use one for circuit prototyping and the other for PCB prototyping. It is not like which one is better. It totally depends on what you want to design, i.e., the design goal.

**ECG Probes**

****

The Disposable ECG electrode is used for ECG or other biopotential measurements. It is composed of 12 adhesive electrodes, using nonwoven fabric material - a kind of breathable paper - cotton or PE and foam with medical hypoallergenic adhesive. This ECG electrode has a high viscosity, so it can adhere to your skin directly. The snap-on connector can be pushed on or removed from the electrode lead easily. It can be used as spare part for the Arduino Analog Heart Rate (ECG) Monitor Sensor. For ECG electrode placement, please check the Heart Rate (ECG) sensor

**Casing/Chassis**

We have used Perspex sheet to form a square-like container of length 10 centimeter to house the entire components in order to protect them from moisture and dust. The components were glued into this Perspex box with candle gum through the use of Hot Gun. We have used some sets of Drilling Instruments to create holes on this Perspex box so that these components can fit properly into it. The testing results shows that the system can effectively measure **ECG status of the user** in **BPM** (Beat Per Minute) when he places the probes correctly on his body, and subsequently upload the values on Ubidots IoT Server, where it is visible to anyone with access, especially his doctor. It also displays the plots on the OLED screen that serves as our output. Majority of the components used in this project were bought from Jumia Online Stores, Konga Online Stores, and Fine Brothers Electronics, Enugu

**3.4 Bill of Engineering Management (BME)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **S/N** | **Name of Equipment** | **Quantity** | **Price per unit cost** | **Total price** |
| **1** | **AD8232 ECG** Sensor Module | **1** |  |  |
| **2** | **ESP32 Development Board** | **1** |  |  |
| **3** | OLED Screen | **1** |  |  |
| **4** | 5 V DC Source | **1** |  |  |
| **5** | Male and female Header Pins | **2** |  |  |
| **6** | Connecting Wires | **2** |  |  |
| **8** | Perspex Sheet | **1** |  |  |
| **9** | Drilling Tools | **1** |  |  |
| **10** | Soldering Iron and Soft Solder | **1** |  |  |
| **11** | Hot Gun | **1** |  |  |
| **12** | Candle Gum | **1** |  |  |
| **13** | Veroboard and Breadboard | **1** |  |  |
| **14** | **Casing/Chassis** |  |  |  |
| **15** | **ECG Probes** | **1** |  |  |
|  | | |  |  |

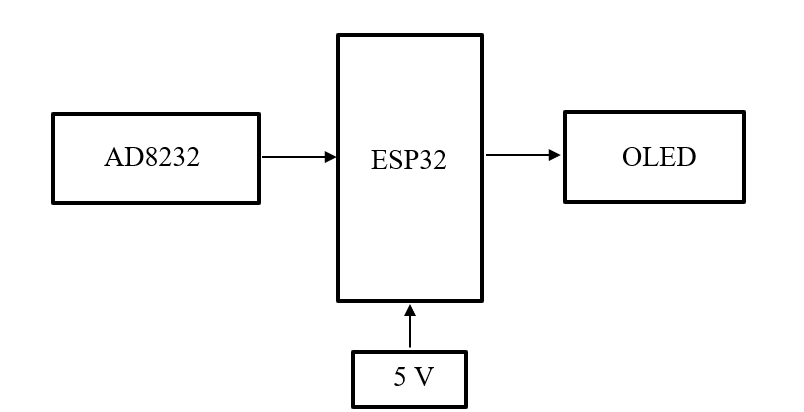
**3.5 Design Architecture**

In this dissertation, “IoT Based ECG Monitoring System” uses **AD8232 ECG Sensor Module interfaced with ESP32 Development Board** to monitor the ECG status of an individual and displays it on Ubidots IoT Online Platform. Here, the ultimate aim is to design an easy-to-use system that will assist the patient in monitoring the electrical signals of his heart and determine the irregular pattern, otherwise known as ECG in BPM entirely on his own, without the assistance of medical personnel and also establish a virtual contact between the patient and his doctor.

In designing this system, the work took into account the fact that heart diseases are becoming big issue for the last few decades, and many people die because of certain health problems that are associated with heart issues. Thus, heart disease cannot be taken lightly. By analyzing or monitoring the ECG signal at the initial stage, this disease can be prevented.

The ESP32 serves as a Microcontroller that control and coordinates the activities of all the components used in this system as well as providing the internet connection. The whole system was contained inside a Perspex container to protect it from moisture and dust. An analog switch was used to ON and OFF the system to safe the battery life. The system is powered by a 5 V rechargeable DC source. The simulation was done in both Proteus and Multism simulation software

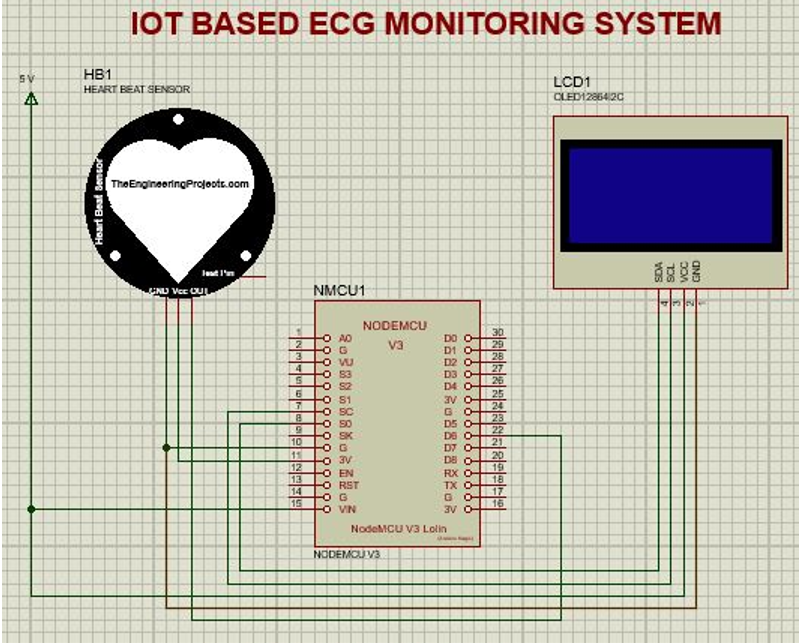
**3.6 Block diagram of the system**

****

**Figure 3.14: Block Diagram of the System**

From the block diagram shown in figure 3.14 above, the ESP32 serves as the Microcontroller, which control and coordinates the activities of the **AD8232 ECG** Sensor Module and the OLED screen connected to it. We have powered this ESP32 from an external 5 V DC source through its Vin pin

**3.7 Circuit Diagram of the System**

****

**3.15 Circuit Diagram of the Proposed device**

From the circuit diagram shown in figure 3.15 above, the ESP32 Development Board serves as the Microcontroller, which control and coordinates the activities of the **AD8232 ECG** Sensor Module, OLED Module and also provide internet access through its inbuilt Wi-Fi property. We have powered this ESP32 from an external 5 V DC source through its Vin pin. The **AD8232 ECG** Sensor Module has its OUT and VCC pins connected to pin D4 and 3.3 V pin of the ESP32 respectively, since the sensor is 3.3 V enabled. We have connected an I2C (Inter-Integrated Circuit) Module to the OLED screen as this will reduce the number of connections from 12 to 4, although increase the cost of the project. The OLED has its SDA (Serial Data) and SCL (Serial Clock) connected to pins A4 and A5 of the ESP32 respectively, while its Vcc pin is connected to the external 5 V DC source. The GND of **AD8232 ECG** Sensor Module and the GND of the OLED screen are tied together and connected to the GND pin of the ESP32. The purpose of this common GND (Ground) connection is to provide a common reference Ground voltage. Without this common reference Ground, the system will never work properly

### Chapter Four

**Implementation and Results**

An analog switch was attached to the back of the system to ON and OFF it. When the system is ON, it takes about 2 seconds to power. After this 2 second, the user places the probes on his body to have his ECG read and display on the screen. The user is expected to place the red probe on the right arm, the yellow probe on the left arm and green probe on the center of the heart to obtained accurate reading of the sensor. However, the positions can be altered based on convenience and the length of the probe.

**Reference**

A. Rahaman, M. M. Islam, M. R. Islam, M. S. Sadi, S. Nooruddin, Developing IoT based smart health monitoring systems: a review, Rev. Intell. Artif., 33 (2019), 435–440. <https://doi.org/10.18280/ria.330605>

Ahrens, T. The most important vital signs are not being measured. Aust. Crit Care 2008, 21, 3–5

Annicchiarico R, Cortés U, Urdiales C. Agent Technology and e-Health. Switzerland: Birkhäuser Verlag; 2008. p: 141–148.

Aalam AA, Hood C, Donelan C, Rutenberg A, Kane EM, Sikka N. Remote patient monitoring for ED discharges in the COVID-19 pandemic. *Emerg Med J*. 2021;38(3):229-231. doi:10.1136/emermed-2020-210022

A. R. Al-Ali, I. A. Zualkernan, M. Rashid, R. Gupta, M. Alikarar, A smart home energy management system using IoT and big data analytics approach, IEEE Trans. Consum. Electron., 63 (2017), 426–434. <https://doi.org/10.1109/TCE.2017.015014>

Apiletti, D.; Baralis, E.; Bruno, G.; Cerquitelli, T. Real-time analysis of physiological data to support medical applications. Trans. Info. Tech. Biomed. 2009, 13, 313–321

Awotunde J. Bamidele**,** Sunday Adeola Ajagbe**,** Hector Florez **“Internet of Things with Wearable Devices and Artificial Intelligence for Elderly Uninterrupted Healthcare Monitoring Systems”** October 2022DOI:10.1007/978-3-031-19647-8\_20In book: Applied Informatics (pp.278-291)

A. Zanella, N. Bui, A. Castellani, L. Vangelista, M. Zorzi, Internet of things for smart cities, IEEE Internet Things J., 1 (2014), 22–32. <https://doi.org/10.1109/JIOT.2014.2306328>

G. Mois, S. Folea, T. Sanislav, Analysis of three IoT-based wireless sensors for environmental monitoring, IEEE Trans. Instrum. Meas., 66 (2017), 2056–2064. <https://doi.org/10.1109/TIM.2017.2677619>

B. Chen, J. Wan, L. Shu, P. Li, M. Mukherjee, B. Yin, Smart factory of industry 4.0: key technologies, application case, and challenges, IEEE Access, 6 (2018), 6505–6519. https://doi.org/10.1109/ ACCESS.2017.2783682

Bandodkar, A.J.;Wang, J. Non-invasive wearable electrochemical sensors: A review. Trends Biotechnol. 2014, 32, 363–371

Berner, Eta S., ed. Clinical Decision Support Systems. New York, NY: Springer, 2007.

Bellos, C.C.; Papadopoulos, A.; Rosso, R.; Fotiadis, D.I. Extraction and Analysis of Features Acquired By Wearable Sensors Network. In Proceedings of 10th IEEE International Conference on Information Technology and Applications in Biomedicine, Corfu, Greece, 3–5 November 2010; pp. 1–4.

Bandodkar, A.J.;Wang, J. Non-invasive wearable electrochemical sensors: A review. Trends Biotechnol. 2014,32, 363–371. [CrossRef] [PubMed]

Begum, Shahina; Ahmed, Mobyen Uddin; Funk, Peter; Xiong, Ning; Folke, Mia (July 2011). ["Case-based reasoning systems in the health sciences: a survey of recent trends and developments"](https://zenodo.org/record/3435685). IEEE Transactions on Systems, Man, and Cybernetics - Part C: Applications and Reviews. **41** (4): 421–434. [doi](https://en.wikipedia.org/wiki/Doi_(identifier)):[10.1109/TSMCC.2010.2071862](https://doi.org/10.1109%2FTSMCC.2010.2071862). [S2CID](https://en.wikipedia.org/wiki/S2CID_(identifier)) [22441650](https://api.semanticscholar.org/CorpusID:22441650).

Buckley, C.; Reilly, M.A.O.; Whelan, D.; Farrell, A.V.; Clark, L.; Longo, V.; Gilchrist, M.D.; Caulfield, B. Binary Classification of Running Fatigue using a Single Inertial Measurement Unit. In Proceedings of the 14th Annual Body Sensor Networks Conference, Eindhoven, The Netherlands, 9–12 May 2017; pp. 197–201.

Bellazzi R, Carson ER, Cobelli C, Hernando E, Gomez EJ, Nabih-Kamel-Boulos M, Rendschmidt T, Roudsari V, et al. Merging Telemedicine With Knowledge Management: The M2DM Project. Published in: Engineering in Medicine and Biology Society. Proceedings of the 23rd Annual International Conference of the IEEE, Volume 4, 2001. p: 4117–4120. doi:10.1109/IEMBS.2001.1019762.

Buller, M.J.; Tharion,W.J.; Hoyt, R.W.; Jenkins, O.C. Estimation of human internal temperature from wearable physiological sensors. In Proceedings of the Twenty-Second Innovative Applications of Artificial Intelligence Conference (IAAI-10), Atlanta, GA, USA, 11–15 July 2010.

Busia K. Medical provision in Africa -- past and present. Phytother Res.2005; 19: 919-23. DOI: 10.1002/ptr.1775.

Bøne E, Hasvold P, Henriksen E, Strandenæs T. Risk analysis of information security in a mobile instant messaging and presence system for healthcare. International Journal of Medical Informatics 2007.76:677–687. doi: <http://dx.doi.org/10.1016/j.ijmedinf.2006.06.002>

World Health Organization. mHealth New horizons for health through mobile technologies. 2011. ISBN 978 92 4 156425 0. Available from: http://www.who.int/goe/publications/goe\_mhealth\_web.pdf [Accessed: 5 June 2013]

Badgujar SB, Patel VV, Bandivdekar AH. Foeniculum vulgare Mill: a review of its botany, phytochemistry, pharmacology, contemporary application, and toxicology. Biomed Res Int. 2014;2014:842674-06. DOI:10.1155/2014/842674.

Chalupsky MR, Craddock KM, Schivo M, Kuhn BT. Remote patient monitoring in the management of chronic obstructive pulmonary disease. *J Investig Med*. 2022;70(8):1681-1689. doi:10.1136/jim-2022-002430

Chan, M.; Esteve, D.; Fourniols, J.Y.; Escriba, C.; Campo, E. Smart wearable systems: Current status and future challenges. Artif. Intell. Med. 2012, 56, 137–156.

Cortes, C.; Vapnik, V. Support-vector networks. Mach. Learn. 1995, 20, 273–297.

Custodio, V.; Herrera, F.J.; Lopez, G.; Moreno, J.I. A review on architectures and communications technologies for wearable health-monitoring systems. Sensors 2012, 12, 13907–13946. [CrossRef] [PubMed]

Dawit A, Ahadu A. Medicinal plants and enigmatic health practices of northern Ethiopia [Internet]. 1993. Available from: https:// agris.fao.org/agris-search/search. do?recordID=XF2015013726

D. Raskovic, T. Martin, and E. Jovanov, “Medical monitoring applications for wearable computing,” Comput. J., vol. 47, pp. 495–504, Apr.2004

D.I., Arredondo Waldmeyer, M.T., Eds.; Springer: Berlin, Germany, 2012; Volume 83, pp. 256–263.

Dias, D.; Ferreira, N.; Cunha, J.P.S. Vital Logger: An adaptable wearable physiology and body-area ambiance data logger for mobile applications. In Proceedings of the 2017 IEEE 14th International Conference on Wearable and Implantable Body Sensor Networks (BSN), Eindhoven, The Netherlands, 9–12 May 2017; pp. 71–74.

Dexcom, I. Dexcom G4 Platinum. Available online: http://www.dexcom.com/pt-PT (accessed on 7 July 2017).

Dami S. Internet of things-based health monitoring system for early detection of cardiovascular events during COVID-19 pandemic. World J Clin Cases 2022; 10(26): 9207-9218 [PMID: [36159404](http://www.ncbi.nlm.nih.gov/pubmed/36159404) DOI: [10.12998/wjcc.v10.i26.9207](https://dx.doi.org/10.12998/wjcc.v10.i26.9207)

Elliott, M.C.A. Critical care: The eight vital signs of patient monitoring. Br. J. Nurs. 2012, 21, 621–625

Engelgau M, Rosenhouse S, El-Saharty S, Mahal A. The economic effect of noncommunicable diseases on households and nations: a review of existing evidence. Journal of Health Communication: International Perspectives 2011.16(2):75–81. doi:10.1080/10810730.2011.601394

F. Rezaeibagha and Y. Mu, “Practical and secure telemedicine systems for user mobility,” *Journal of Biomedical Informatics*, vol. 78, pp. 24–32, 2018.View at: [Publisher Site](https://doi.org/10.1016/j.jbi.2017.12.011) | [Google Scholar](https://scholar.google.com/scholar_lookup?title=Practical%20and%20secure%20telemedicine%20systems%20for%20user%20mobility&author=F.%20Rezaeibagha&author=Y.%20Mu&publication_year=2018)

Frantzidis, C.A.; Bratsas, C.; Klados, M.A.; Konstantinidis, E.; Lithari, C.D.; Vivas, A.B.; Papadelis, C.L.; Kaldoudi, E.; Pappas, C.; Bamidis, P.D. On the classification of emotional biosignals evoked while viewing affective pictures: An integrated datamining-based approach for healthcare applications. Trans. Inf. Tech. Biomed. 2010, 14, 309–318

Guyon, I.; Gunn, S.; Nikravesh, M.; Zadeh, L.A. Feature Extraction: Foundations and Applications (Studies in Fuzziness and Soft Computing); Springer: Secaucus, NJ, USA, 2006

Gregoski MJ, Mueller M, Vertegel A, Shaporev A, Jackson BB, Frenzel RM, Sprehn SM, Treiber FA. Development and validation of a smartphone heart rate acquisition application for health promotion and wellness telehealth applications. *Int J Telemed Appl.*2012;2012:1–7. doi: 10.1155/2012/696324. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3261476/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/22272197)] [[CrossRef](https://doi.org/10.1155%2F2012%2F696324)] [[Google Scholar](https://scholar.google.com/scholar_lookup?journal=Int+J+Telemed+Appl&title=Development+and+validation+of+a+smartphone+heart+rate+acquisition+application+for+health+promotion+and+wellness+telehealth+applications&author=MJ+Gregoski&author=M+Mueller&author=A+Vertegel&author=A+Shaporev&author=BB+Jackson&volume=2012&publication_year=2012&pages=1-7&doi=10.1155/2012/696324&)]

Gialelis, J.; Chondros, P.; Karadimas, D.; Dima, S.; Serpanos, D. Identifying Chronic Disease Complications Utilizing State of the Art Data Fusion Methodologies and Signal Processing Algorithms. In Wireless Mobile Communication and Healthcare; Nikita, K.S., Lin, J.C., Fotiadis,

Hardiker NR, Grant MJ. Factors that influence public engagement with eHealth: a literature review. International Journal of Medical Informatics 2011.80(1):1–12. doi:10.1016/j.ijmedinf.2010.10.017.

H. Nakasaki, T. Mitomi, T. Noto, K. Ogoshi, H. Hanaue, Y. Tanaka, H. Makuuchi,H. Clausen, S.I. Hakomori, Mosaicism in the expression of tumor-associated carbohydrate antigens in human colonic and gastric cancers, Cancer Res. 49 (13) (1989) 3662–3669

Hu, F.; Jiang, M.; Celentano, L.; Xiao, Y. Robust medical ad hoc sensor networks (MASN) with wavelet-based ECG data mining. Ad Hoc Netw. 2008, 6, 986–1012

Halteren Aart V, Bults R, Wac K, Konstantas D, Widya I, Dokovsky N, Koprinkov G, Jones V, Herzog R. Mobile patient monitoring: the MobiHealth system. Journal on Information Technology in Healthcare 2004.2(5):365–373. ISSN 1479-649X.

Hernando M E, Garsia A, Javiar Perdices F, Torralba V, Gomez E J. del Pozo F. Multi agent architecture for the provision of intelligent telemedicine services in diabetes management. Available from: http://cyber.felk.cvut.cz/EUNITE03-BIO/pdf/EHernando.pdf [Accessed 4 July 2013]

1Seoane, F.; Mohino-Herranz, I.; Ferreira, J.; Alvarez, L.; Buendia, R.; Ayllon, D.; Llerena, C.; Gil-Pita, R.Wearable biomedical measurement systems for assessment of mental stress of combatants in real time.Sensors 2014, 14, 7120–7141.

Jones V, Gay V, Leijdekkers P. Body Sensor Networks for Mobile Health Monitoring: Experience in Europe and Australia. Accepted for 4th International Conference on Digital Society, ICDS 2010, February 10–16, 2010, ICDS '10. Fourth International Conference on. Netherlands: Digital Society; 2010

James PB, Wardle J, Steel A, Adams J. Traditional, complementary and alternative medicine use in SubSaharan Africa: a systematic review. BMJ Global Health. 2018;3: e000895-13. DOI:10.1136/bmjgh-2018-000895.

J.R. Millan, F. Renkens, J. Mourino, W. Gerstner, Noninvasive brain-actuated control of a mobile robot by human EE", IEEE Trans. Biomed. Eng. 51 (6) (2004) 1026–1033

Jones M, Bults G, Konstantas D, Vierhout P. Healthcare PANs: Personal Area Networks for trauma care and home care, Proceedings Fourth International Symposium on Wireless Personal Multimedia Communications. [WPMC], Sept. 9–12, 2001, Aalborg, Denmark. 2001. Available from: http://wpmc01.org/, ISBN 87-988568-0-4

Khosla, Vinod (4 December 2012). ["Technology will replace 80% of what doctors do"](https://web.archive.org/web/20130328173118/http:/tech.fortune.cnn.com/2012/12/04/technology-doctors-khosla/). CNN. Archived from [the original](http://tech.fortune.cnn.com/2012/12/04/technology-doctors-khosla/) on 28 March 2013. Retrieved 25 April 2013.

Kahn GJ, Yang SJ, Kahn SJ. 'Mobile' health needs and opportunities in developing countries. Health Affairs 2010.29(2):252–258. doi:10.1377/hlthaff.2009.0965.

Krehel, M.; Wolf, M.; Boesel, L.F.; Rossi, R.M.; Bona, G.L.; Scherer, L.J. Development of a luminous textile for reflective pulse oximetry measurements. Biomed. Opt. Express 2014, 5, 2537–2547

Khoumbati K, Dwivedi Y, Srivastava A, Lal B. Handbook of Research on Advances in Health Informatics and Electronic Healthcare Applications: Global Adoption and Impact of Information Communication Technologies. Hershey. New York: Medical Information Science Reference; 2010. p: 91, 10, 156.

 Khussainova, Gulmira; Petrovic, Sanja; Jagannathan, Rupa (2015). ["Retrieval with clustering in a case-based reasoning system for radiotherapy treatment planning"](https://doi.org/10.1088%2F1742-6596%2F616%2F1%2F012013). Journal of Physics: Conference Series. 616 (1): 012013. [Bibcode](https://en.wikipedia.org/wiki/Bibcode_(identifier)):[2015JPhCS.616a2013K](https://ui.adsabs.harvard.edu/abs/2015JPhCS.616a2013K). [doi](https://en.wikipedia.org/wiki/Doi_(identifier)):[10.1088/1742-6596/616/1/012013](https://doi.org/10.1088%2F1742-6596%2F616%2F1%2F012013). [ISSN](https://en.wikipedia.org/wiki/ISSN_(identifier)) [1742-6596](https://www.worldcat.org/issn/1742-6596).

**K. Perumal, M. Manohar, A survey on internet of things: case studies, applications, and future directions, in Internet of Things: Novel Advances and Envisioned Applications, Springer, Cham, (2017), 281–297.** [**https://doi.org/10.1007/978-3-319-53472-5\_14**](https://doi.org/10.1007/978-3-319-53472-5_14)

Leijdekkers P, Gay V. A Self-Test to Detect a Heart Attack Using a Mobile Phone and Wearable Sensors. 21st IEEE International Symposium on Computer-Based Medical Systems; 2008. p: 93-98. ISBN: 978-0-7695-3165-

[**Liang Tan**](https://pubmed.ncbi.nlm.nih.gov/?term=Tan+L&cauthor_id=34248288)**,**[**Keping Yu**](https://pubmed.ncbi.nlm.nih.gov/?term=Yu+K&cauthor_id=34248288)**,**[**Ali Kashif Bashir**](https://pubmed.ncbi.nlm.nih.gov/?term=Bashir+AK&cauthor_id=34248288)**,**[**Xiaofan Cheng**](https://pubmed.ncbi.nlm.nih.gov/?term=Cheng+X&cauthor_id=34248288)**,**[**Fangpeng Ming**](https://pubmed.ncbi.nlm.nih.gov/?term=Ming+F&cauthor_id=34248288)**,**[**Liang Zhao**](https://pubmed.ncbi.nlm.nih.gov/?term=Zhao+L&cauthor_id=34248288)**, Xiaokang Zhou “Toward real-time and efficient cardiovascular monitoring for COVID-19 patients by 5G-enabled wearable medical devices: a deep learning approach”**

Neural Comput Appl. 2023;35(19):13921-13934. doi: 10.1007/s00521-021-06219-9. Epub 2021 Jul 4.

Luo, N.; Ding, J.; Zhao, N.; Leung, B.H.K.; Poon, C.C.Y. Mobile Health: Design of Flexible and StretchableElectrophysiological Sensors for Wearable Healthcare Systems. In Proceedings of the 2014 11th InternationalConference on Wearable and Implantable Body Sensor Networks, Zurich, Switzerland, 16–19 June 2014; pp. 87–91.

Leehoon, K.; Sungjun, K.; Sangwon, S.; Kwangsuk, P. Highly wearable galvanic skin response sensor using flexible and conductive polymer foam. In Proceedings of the 2014 36th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC), Chicago, IL, USA, 26– 30 August 2014; pp. 6631–6634.

Lara, O.D.; Labrador, M.A. A survey on ambient-assisted living tools for older adults. IEEE Commun. Surv. Tutor. 2013, 15, 1192–1209.

Lei Ru**,Bin Zhang,**Jing Duan,Guo Ru,Ashutosh Sharma,Gaurav Dhiman, Gurjot Singh Gaba, Emad Sami Jaha, and**Mehedi Masu “A Detailed Research on Human Health Monitoring System Based on Internet of Things” Research Article | Open Access, Volume 2021 | Article ID 5592454 |** <https://doi.org/10.1155/2021/5592454>

Lukowicz, P.; Anliker, U.; Ward, J.; Troster, G.; Hirt, E.; Neufelt, C. AMON: A wearable medical computer for high risk patients. In Proceedings of the Sixth International Symposium onWearable Computers, Seattle, WA, USA, 10 October 2002; pp. 133–134. IHS Technology. World Market for Telehealth—2014 Edition; IHS Markit: London, UK, 2014.

M. Ayaz, M. Ammad-Uddin, Z. Sharif, A. Mansour, E. H. M. Aggoune, Internet-of-things (IoT)- based smart agriculture: toward making the felds talk, IEEE Access, 7 (2019), 129551–129583. <https://doi.org/10.1109/ACCESS.2019.2932609>

[Muhammad Zia Rahman](https://pubmed.ncbi.nlm.nih.gov/?term=Rahman+MZ&cauthor_id=36716687), [Muhammad Azeem Akbar](https://pubmed.ncbi.nlm.nih.gov/?term=Akbar+MA&cauthor_id=36716687), [Víctor Leiva](https://pubmed.ncbi.nlm.nih.gov/?term=Leiva+V&cauthor_id=36716687), [Abdullah Tahir](https://pubmed.ncbi.nlm.nih.gov/?term=Tahir+A&cauthor_id=36716687), [Muhammad Tanveer Riaz](https://pubmed.ncbi.nlm.nih.gov/?term=Riaz+MT&cauthor_id=36716687), [Carlos Martin-Barreiro](https://pubmed.ncbi.nlm.nih.gov/?term=Martin-Barreiro+C&cauthor_id=36716687) “An intelligent health monitoring and diagnosis system based on the internet of things and fuzzy logic for cardiac arrhythmia COVID-19 patients” Comput Biol Med. 2023 Mar:154:106583. doi: 10.1016/j.compbiomed.2023.106583. Epub 2023 Jan 24. PMID: 36716687 PMCID: PMC9883984 DOI: 10.1016/j.compbiomed.2023.106583.

M. Hasan, M. M. Islam, M. I. I. Zarif, M. M. A. Hashem, Attack and anomaly detection in IoT sensors in IoT sites using machine learning approaches, Internet Things, 7 (2019), 100059. <https://doi.org/10.1016/j.iot.2019.100059>

Manogaran G, Varatharajan R, Daphne Lopez, Kumar P.M, Sundarasekar R, Thota C. A new architecture of Internet of Things and big data ecosystem for secured smart healthcare monitoring and alerting system. Published in Elsevier BV 2018.DOI: 10.1016/j.future.2017.10.045.Volume: 82

Megha Chavan, Dr. S.A. Khoje, Prof. Prajakta Pardeshi and Prof. Manasvi Patil “Study of Health Monitoring System” Proceedings of the Second International Conference on Intelligent Computing and Control Systems (ICICCS 2018) IEEE Xplore Compliant Part Number: CFP18K74-ART; ISBN:978-1-5386-2842-3

Marco Di Rienzo, G.P.; Brambilla, G.; Ferratini, M.; Castiglioni, P. MagIC System: A New Textile-Based Wearable Device for Biological Signal Monitoring. Applicability in Daily Life and Clinical Setting. In Proceedings of the 2005 IEEE, Engineering in Medicine and Biology 27th Annual Conference 2005, Shangai, China, 1–4 September 2005; pp. 7167–7169

Medtronic MiniMed, I. Continuous Glucose Monitoring. Available online: https://www.medtronicdiabetes.com (accessed on 7 July 2017)

M. Ayaz, M. Ammad-Uddin, Z. Sharif, A. Mansour, E. H. M. Aggoune, Internet-of-things (IoT)- based smart agriculture: toward making the felds talk, IEEE Access, 7 (2019), 129551–129583. <https://doi.org/10.1109/ACCESS.2019.2932609>

Mao, Y.; Chen,W.; Chen, Y.; Lu, C.; Kollef, M.; Bailey, T. An Integrated Data Mining Approach to Real-Time Clinical Monitoring and Deterioration Warning. In Proceedings of the 18th ACM SIGKDD International Conference on Knowledge Discovery and Data Mining, Beijing, China, 16–18 August 2012; pp. 1140–1148.

Mohammed, S.; Tashev, I. Unsupervised Deep Representation Learning to Remove Motion Artifacts in Free-mode Body Sensor Networks. In Proceedings of the 14th Annual Body Sensor Networks Conference, Eindhoven, The Netherlands, 9–12 May 2017; pp. 182–188.

MacKinnon GE, Brittain EL. Mobile Health Technologies in Cardiopulmonary Disease. *Chest*. 2020;157(3):654-664. doi:10.1016/j.chest.2019.10.015

[Neha Verma](https://pubmed.ncbi.nlm.nih.gov/?term=Verma+N&cauthor_id=37130015), [Bimal Buch](https://pubmed.ncbi.nlm.nih.gov/?term=Buch+B&cauthor_id=37130015), [Radha Taralekar](https://pubmed.ncbi.nlm.nih.gov/?term=Taralekar+R&cauthor_id=37130015), Soumyadipta Acharya “Diagnostic Concordance of Telemedicine as Compared With Face-to-Face Care in Primary Health Care Clinics in Rural India: Randomized Crossover Trial” PMID: 37130015 PMCID: PMC10337309 DOI: 10.2196/42775. . 2023 Jun 23:7:e42775. doi: 10.2196/42775

Nikolic-Popovic, J.; Goubran, R. Measuring heart rate, breathing rate and skin conductance during exercise. In Proceedings of the 2011 IEEE InternationalWorkshop on the Medical Measurements and Applications Proceedings (MeMeA), Bari, Italy, 30–31 May 2011; pp. 507–511.

Nouri S, Khoong EC, Lyles CR, Karliner L. Addressing equity in telemedicine for chronic disease management during the COVID-19 pandemic. *Innov Care Deliv.*2020.doi:10.1056/CAT.20.0123

Omboni S, McManus RJ, Bosworth HB, et al. Evidence and recommendations on the use of telemedicine for the management of arterial hypertension: an international expert position paper. *Hypertension*. 2020;76(5):1368-1383. doi:10.1161/HYPERTENSIONAHA.120.15873

Otto C, Milenkovic A, Sanders C, Jovanov E.System Architecture of a wireless body area sensor network for ubiquitous health monitoring. Journal of Mobile Multimedia 2006.1(4):307–326.

Oresko JJ, Jin Zhanpeng, Cheng Jun, Huang Shimeng, Sun Yuwen, Duschl H, Cheng AC. A wearable smartphone-based platform for real-time cardiovascular disease detection via electrocardiogram processing. IEEE Trans Inf Technol Biomed . 2010;14:734–40.

PriyankaKakria, N.K.Tripathi, and Peerapong Kitipawang” A RealTime Health Monitoring System for Remote Cardiac Patients Using Smartphone and Wearable Sensors” nternational Journal of Telemedicine and Applications, Volume 2015 (2015), Article ID373474,11pages

WHO. Legal Status of Traditional Medicine and Complementary/ Alternative Medicine: World Wide Review. Geneva [Internet]. 2001. Available from : https://apps.who.int/ iris/handle/10665/42452.

Paliwal, M.; Kumar, U.A. Neural networks and statistical techniques: A review of applications. Expert. Syst. Appl. 2009, 36, 2–17.

Pantelopoulos, A.; Bourbakis, N.G. A Survey on Wearable Sensor-Based Systems for Health Monitoring and Prognosis. IEEE Trans. Syst. Man Cybern. Part C Appl. Rev. 2010, 40, 1– 12. [CrossRef]

Patel H, Hassell A, Cyriacks B, Fisher B, Tonelli W, Davis C. Building a real-time remote patient monitoring patient safety program for COVID-19 patients. *Am J Med Qual*. 2022;37(4):342-347. doi:10.1097/JMQ.0000000000000046

Pantelopoulos, A.; Bourbakis, N.G. A Survey on Wearable Sensor-Based Systems for Health Monitoring and Prognosis. IEEE Trans. Syst. Man Cybern. Part C Appl. Rev. 2010, 40, 1– 12. [CrossRef]

Pawar P, Jones V, van Beijnum BJ, Hermens H. A framework for the comparison of mobile patient monitoring systems. Journal of Biomedical Informatics 2012.45(3):544–556. doi: 10.1016/j.jbi.2012.02.007.

Popovic, Z.; Momenroodaki, P.; Scheeler, R. Toward wearable wireless thermometers for internal body temperature measurements. IEEE Commun. Mag. 2014, 52, 118–125

P. Bonato, “Advances in wearable technology and applications in physical medicine and rehabilitation,” J. NeuroEng. Rehabil., vol. 2, p. 2, Feb.2005

P. Bonato, “Wearable sensors/systems and their impact on biomedical engineering,” IEEE Eng. Med. Biol. Mag., vol. 22, no. 3, pp. 18–20, May/Jun. 2003

Peyman., Dehghani Soufi, Mahsa. Samad-Soltani, Taha. Shams Vahdati, Samad. Rezaei-Hachesu. Decision support system for triage management: A hybrid approach using rule-based reasoning and fuzzy logic. [OCLC](https://en.wikipedia.org/wiki/OCLC_(identifier)) [1051933713](https://www.worldcat.org/oclc/1051933713).

Rahman, M. Z., Akbar, M. A., Leiva, V., Tahir, A., Riaz, M. T., & Martin-Barreiro, C. (2023). An intelligent health monitoring and diagnosis system based on the internet of things and fuzzy logic for cardiac arrhythmia COVID-19 patients. Computers in Biology and Medicine, 154, Article 106583. <https://doi.org/10.1016/j.compbiomed.2023.106583>

Rifat-Ibn-Alam, Nyme Ahmed, Syed Nafiul Shefat and Dr. Md Taimur Ahad “An Internet of Things based Social Distance Monitoring System in Covid19” Int. J. Advanced Networking and Applications Volume: 13 Issue: 05 Pages: 5128-5133(2022) ISSN: 0975-0290

Soumen Kanrar Prasenjit Kumar Mandal” E-health monitoring system enhancement with Gaussiann mixture model” Springer Science Business Media New York 2016.

Sola, J.; Castoldi, S.; Chetelat, O. SpO2 Sensor Embedded in a Finger Ring: Desing and implementation. In Proceedings of the 2006 International Conference of the IEEE Engineering in Medicine and Biology Society, New York, NY, USA, 30 August–3 September 2006; pp. 4495–4498

Singh, R.R.; Conjeti, S.; Banerjee, R. An Approach for RealTime Stress-Trend Detection Using Physiological Signals in Wearable Computing Systems for Automotive Drivers. In Proceedings of the 14th International IEEE Conference on Intelligent Transportation Systems, Washington, DC, USA, 5–7 October 2011; pp. 1477–1482.

Sow, D.; Turaga, D.; Schmidt, M. Mining of Sensor Data in Healthcare: A Survey. In Managing and Mining Sensor Data; Aggarwal, C.C., Ed.; Springer: Berlin, Germany, 2013; pp. 459– 504.

Sambasivan, Murali; Pouyan Esmaeilzadeh; Naresh Kumar; Hossein Nezakati (2012). "Intention to adopt clinical decision support systems in a developing country: effect of Physician's perceived professional autonomy, involvement and belief: a cross-sectional study". BMC Medical Informatics and Decision Making. 12: 142–150. doi:10.1186/1472-6947-12-142. PMC 3519751. PMID 23216866.

Shaheen A, Ahmad Khan W. Intelligent Decision Support System in Diabetic eHealth Care From the perspective of Elders. [Master Thesis]. Computer Science. Blekinge Institute of Technology. Sweden. 2009. Available from: http://www.bth.se/fou/cuppsats.nsf/all/89449be91369ee27c12575d60071c747/$file/Master\_thesis\_asma.pdf [Accessed 4 July 2013]

Saritha, C.; Sukanya, V.; Murthy, Y.N. ECG Signal Analysis UsingWavelet Transforms. Bulg. J. Phys. 2008, 35,68–77

Seoane, F.; Mohino-Herranz, I.; Ferreira, J.; Alvarez, L.; Buendia, R.; Ayllon, D.; Llerena, C.; Gil-Pita, R.Wearable biomedical measurement systems for assessment of mental stress of combatants in real time. Sensors 2014, 14, 7120–7141.

Safdari R, Mohammadzadeh N. Multi-agent systems and health information management. In 2nd eHospital and Telemedicine Conference. Tehran University of Medical Sciences. Tehran. Iran. 2011.

Shah BR, Schulman K. Do not let a good crisis go to waste: health care’s path forward with virtual care. *Innov Care Deliv.* 2021. doi:10.1056/CAT.20.0693

S. M. R. Islam, D. Kwak, M. D. H. Kabir, M. Hossain, K. S. Kwak, The internet of things for health care: a comprehensive survey, IEEE Acces, 3 (2015), 678–708. <https://doi.org/10.1109/ACCESS.2015.2437951>

Tabacof L, Wood J, Mohammadi N, et al. Remote patient monitoring identifies the need for triage in patients with acute COVID-19 infection. *Telemed e-Health*. 2022;28(4):495-500. doi:10.1089/tmj.2021.0101

Tomasic I, Tomasic N, Trobec R, Krpan M, Kelava T. Continuous remote monitoring of COPD patients-justification and explanation of the requirements and a survey of the available technologies. *Med Biol Eng Comput*. 2018;56(4):547-569. doi:10.1007/s11517-018-1798-z

Taylor ML, Thomas EE, Snoswell CL, Smith AC, Caffery LJ. Does remote patient monitoring reduce acute care use? A systematic review. *BMJ Open*. 2021;11(3):e040232. doi:10.1136/bmjopen-2020-040232

Talha Mahboob Alam, Kamran Shaukat, Adel Khelifi, Wasim Ahmad Khan, Hafiz Muhammad Ehtisham Raza, Muhammad Idrees, Suhuai Luo and Ibrahim A. Hameed “Disease Diagnosis System Using IoT Empowered with Fuzzy Inference System” Computers, Materials & Continua DOI:10.32604/cmc.2022.020344 images Article

Tonekaboni, Sana; Joshi, Shalmali; McCradden, Melissa D.; Goldenberg, Anna (28 October 2019). ["What Clinicians Want: Contextualizing Explainable Machine Learning for Clinical End Use"](https://proceedings.mlr.press/v106/tonekaboni19a.html). Machine Learning for Healthcare Conference. PMLR: 359–380. [arXiv](https://en.wikipedia.org/wiki/ArXiv_(identifier)):[1905.05134](https://arxiv.org/abs/1905.05134).

Tamilselvi, V., Sribalaji, S., Vigneshwaran, P., Vinu, P. and GeethaRamani, J., 2020, March. IoT based health monitoring system. In 2020 6th International conference on advanced computing and communication systems (ICACCS) (pp. 386-389). IEEE

Tamura, T.; Maeda, Y.; Sekine, M.; Yoshida, M. Wearable Photoplethysmographic Sensors—Past and Present. Electronics 2014, 3, 282–302.

Turner, J.R.; Viera, A.J.; Shimbo, D. Ambulatory blood pressure monitoring in clinical practice: A review. Am. J. Med. 2015, 128, 14–20.

Tan J. Medical Informatics: Concepts, Methodologies, Tools, and Applications, Volume 1, Chapter 7.5. Securing Mobile Data Computing in Healthcare, Hershey, New York. 2009. p: 1930.

T. Lin, H. Rivano, F. Le Mouël, A survey of smart parking solutions, IEEE Trans. Intell. Transp. Syst., 18 (2017), 3229–3253. <https://doi.org/10.1109/TITS.2017.2685143>

U. Anliker, J. Beutel, M. Dyer, R. Enzler, P. Lukowicz, L. Thiele, and G. Tr¨oster, “A systematic approach to the design of distributed wearable systems,” IEEE Trans. Comput., vol. 53, no. 8, pp. 1017–1033, Aug.2004

V. P. Rachim and W. Y. Chung, "Wearable Noncontact Arm band for Mobile ECG Monitoring System," in IEEE Transactions on Biomedical Circuits and Systems, vol. 10,no.6, pp.1112- 1118,Dec.2016.

Wardlow L, Leff B, Biese K, et al. Development of telehealth principles and guidelines for older adults: a modified Delphi approach. *J Am Geriatr Soc*. 2022. doi:10.1111/jgs.18123

WHO. Traditional Medicine [Internet]. 2003. Available from: https:// apps.who.int/gb/archive/pdf\_files/ WHA56/ea5618.pdf

Webb, R.C.; Bonifas, A.P.; Behnaz, A.; Zhang, Y.; Yu, K.J.; Cheng, H.; Shi, M.; Bian, Z.; Liu,

Z.; Kim, Y.S.; et al. Ultrathin conformal devices for precise and continuous thermal characterization of human skin. Nat. Mater. 2013, 12, 938–944.

WHO. Traditional Medicine [Internet]. 2020. Available from: http:// www.emro.who.int/health-topics/ traditional-medicine/introduction.html.

World Health Organization. Global status report on non communicable diseases 2010. World Health Organization 2011 Reprinted 2011. ISBN 978 92 4 156422 9. ISBN 978 92 4 068645 8 (PDF). Available from: http://www.who.int/nmh/publications/ncd\_report\_full\_en.pdf [Accessed 30 June 2013].

Xu, P.J.; Zhang, H.; Tao, X.M. Textile-structured electrodes for electrocardiogram. Text. Prog. 2008, 40,183–213.

Xiao-Fei, T.; Yuan-Ting, Z.; Poon, C.C.Y.; Bonato, P. Wearable Medical Systems for p-Health. IEEE Rev. Biomed. Eng. 2008, 1, 62–74.

Xu, P.J.; Zhang, H.; Tao, X.M. Textile-structured electrodes for electrocardiogram. Text. Prog. 2008, 40, 183–213

Xiao-Fei, T.; Yuan-Ting, Z.; Poon, C.C.Y.; Bonato, P. Wearable Medical Systems for p-Health. IEEE Rev. Biomed. Eng. 2008, 1, 62–74

Yilmaz, T.; Foster, R.; Hao, Y. Detecting vital signs with wearable wireless sensors. Sensors 2010, 10, 10837–10862

Zandieh, Stephanie O.; Kahyun Yoon-Flannery; Gilad J. Kuperman; Daniel J. Langsam; Daniel Hyman; Rainu Kaushal (2008). "Challenges to EHR Implementation in Electronic- Versus Paper-based Office Practices". Journal of Global Information Management. 23 (6): 755–761. doi:10.1007/s11606-008-0573-5. PMC 2517887. PMID 18369679

Zhang P. Multi-agent Systems in Diabetic Health Care. Blekinge Institute of Technology Licentiate Series. Issue 5. Karlskrona: Blekinge Institute of Technology. ISBN: 91-7295-060-9. 2005. Available from: http://www.bth.se/fou/forskinfo.nsf/all/07625d65f3f89ee6c1256fef00220c36?OpenDocument [Accessed 4 July 2013].

Zhang P, Zhang X, Brown J, Vistisen D, Sicree R, Shaw J, Nichols G. Global healthcare expenditure on diabetes for 2010 and 2030. Diabetes Research and Clinical Practice 2010.87(3):293–301. doi:10.1016/j.diabres.2010.01.026

* AAFP (American Academy of Family Physicians). About the AAFP proficiency testing program. 2015. [May 15, 2015]. [www​.aafp.org/practice-management​/labs/about.html](http://www.aafp.org/practice-management/labs/about.html).
* ACMG (American College of Medical Genetics and Genomics) Board of Directors. Points to consider in the clinical application in genomic sequencing. Genetics in Medicine. 2012;14(8):759–761. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/22863877)]
* ACR (American College of Radiology). Accreditation. 2015a. [May 22, 2015]. [www​.acr.org/quality-safety/accreditation](http://www.acr.org/quality-safety/accreditation).
* ACR. Quality & safety. 2015b. [May 22, 2015]. [www​.acr.org/Quality-Safety](http://www.acr.org/Quality-Safety).
* Allen B, Thorwarth WT. Comments from the American College of Radiology. Washington, DC: 2014. (Input submitted to the Committee on Diagnostic Error in Health Care, November 5 and December 29, 2014).
* Alper B, Hand JA, Elliott SG, Kinkade S, Hauan MJ, Onion DK, Sklar BM. How much effort is needed to keep up with the literature relevant for primary care? Journal of the Medical Library Association. 2004;92(4):429–437. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC521514/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/15494758)]
* AMA (American Medical Association). AMA code of ethics. 1996. [March 22, 2015]. [www​.ama-assn.org/ama​/pub/physician-resources​/medical-ethics/code-medical-ethics​/opinion8041.page](http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8041.page).
* APA (American Psychiatric Association). DSM. 2015. [May 13, 2015]. [www​.psychiatry.org/practice/dsm](http://www.psychiatry.org/practice/dsm).
* ASCP (American Society for Clinical Pathology). Patient access to test results. 2014. [March 16, 2015]. [www​.ascp.org/Advocacy​/Patient-Access-to-Test-Results.html](http://www.ascp.org/Advocacy/Patient-Access-to-Test-Results.html).
* AvaMedDx. Introduction to molecular diagnostics: The essentials of diagnostics series. 2013. [May 22, 2015]. [http://advameddx​.org​/download/files/AdvaMedDx​\_DxInsights\_FINAL(2).pdf](http://advameddx.org/download/files/AdvaMedDx_DxInsights_FINAL(2).pdf).
* Azar HA. Significance of the Reed-Sternberg cell. Human Pathology. 1975;6(4):479–484. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/1150223)]
* Barrows HS. Problem-based learning: An approach to medical education. New York: Springer; 1980.
* Barrows HS, Norman GR, Neufeld VR, Feightner JW. The clinical reasoning of randomly selected physicians in general medical practice. Clinical & Investigative Medicine. 1982;5(1):49–55. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/7116714)]
* Bayer AJ, Chadha JS, Farag RR, Pathy MS. Changing presentation of myocardial infarction with increasing old age. Journal of the American Geriatrics Society. 1986;34(4):263–266. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/3950299)]
* Berger D. A brief history of medical diagnosis and the birth of the clinical laboratory. Part 4—Fraud and abuse, managed-care, and lab consolidation. Medical Laboratory Observer. 1999;31(12):38–42. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/11184281)]
* Berlin L. Radiologic errors, past, present and future. Diagnosis. 2014;1(1):79–84. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/29539959)]
* Berner ES, Graber ML. Overconfidence as a cause of diagnostic error in medicine. The American Journal of Medicine. 2008;121(5):S2–S23. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/18440350)]
* Bhatt DL, Roe MT, Peterson ED, Li Y, Chen AY, Harrington RA, Greenbaum AB, Berger PB, Cannon CP, Cohen DJ, Gibson CM, Saucedo JF, Kleiman NS, Hochman JS, Boden WE, Brindis RG, Peacock WF, Smith SC Jr., Pollack CV Jr., Gibler WB, Ohman EM. CRUSADE Investigators. Utilization of early invasive management strategies for high-risk patients with non-ST-segment elevation acute coronary syndromes: Results from the CRUSADE Quality Improvement Initiative. JAMA. 2004;292(17):2096–2104. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/15523070)]
* Blanchette I, Richards A. The influence of affect on higher level cognition: A review of research on interpretation, judgement, decision making and reasoning. Cognition and Emotion. 2009;24(4):561–595.
* Bluth EI, Truong H, Bansal S. The 2014 ACR Commission on Human Resources Workforce Survey. Journal of the American College of Radiology. 2014;11(10):948–952. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/25131824)]
* Bor JS. Among the elderly, many mental illnesses go undiagnosed. Health Affairs (Millwood). 2015;34(5):727–731. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/25941272)]
* Bordage G, Zacks R. The structure of medical knowledge in the memories of medical students and general practitioners: categories and prototypes. Medical Education. 1984;18(6):406–416. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/6503748)]
* Boshuizen HPA, Schmidt HG. Clinical reasoning in the health professions. Higgs J, Jones M, Loftus S, Christensen N, editors. Oxford: Butterworth Heinemann/Elsevier; 2008. pp. 113–121. (The development of clinical reasoning expertise; Implications for teaching).
* Boyd CM, Darer J, Boult C, Fried LP, Boult L, Wu AW. Clinical practice guidelines and quality of care for older patients with multiple comorbid diseases: Implications for pay for performance. JAMA. 2005;294(6):716–724. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/16091574)]
* Brozek JL, Akl EA, Jaeschke R, Lang DM, Bossuyt P, Glasziou P, Helfand M, Ueffing E, Alonso-Coello P, Meerpohl J, Phillips B, Horvath AR, Bousquet J, Guyatt GH, Schunemann HJ, Group GW. Grading quality of evidence and strength of recommendations in clinical practice guidelines: Part 2 of 3. The GRADE approach to grading quality of evidence about diagnostic tests and strategies. Allergy. 2009;64(8):1109–1116. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/19489757)]
* Byrnes JP, Miller DC, Schafer WD. Gender differences in risk taking: A meta-analysis. Psychological Bulletin. 1999;125(3):367.
* Campbell VA, Crews JE, Moriarty DG, Zack MM, Blackman DK. Surveillance for sensory impairment, activity limitation, and health-related quality of life among older adults—United States, 1993-1997. Morbidity and Mortality Weekly Report. 1999;48(SS08):131–156. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/10634273)]
* CAP (College of American Pathologists). Guide to CAP proficiency testing/external quality assurance for international participants. 2013. [May 15, 2015]. [www​.cap.org/apps/docs​/proficiency\_testing​/cap\_proficiency\_testing\_guide.pdf](http://www.cap.org/apps/docs/proficiency_testing/cap_proficiency_testing_guide.pdf).
* CAP. Proficiency testing. 2015. [May 15, 2015]. [www​.cap.org/web/home​/lab/proficiency-testing?\_adf​.ctrlstate=146u5nip6d​\_4&\_afrLoop​=77333689866130](http://www.cap.org/web/home/lab/proficiency-testing?_adf.ctrlstate=146u5nip6d_4&_afrLoop=77333689866130).
* Carayon P, Schoofs Hundt A, Karsh BT, Gurses AP, Alvarado CJ, Smith M, Flatley Brennan P. Work system design for patient safety: The SEIPS model. Quality & Safety in Health Care. 2006;15(Suppl 1):i50–i58. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2464868/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/17142610)]
* Carayon P, Wetterneck TB, Rivera-Rodriguez AJ, Hundt AS, Hoonakker P, Holden R, Gurses AP. Human factors systems approach to healthcare quality and patient safety. Applied Ergonomics. 2014;45(1):14–25. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3795965/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/23845724)]
* CDC (Centers for Disease Control and Prevention). Laboratory medicine: A national status report. Church, VA: The Lewin Group; Falls. 2008.
* CDC. National hospital ambulatory medical care survey. Hyattsville, MD: Ambulatory and Hospital Care Statistics Branch, National Center for Health Statistics; 2010.
* CDC. Clinical Laboratory Improvement Amendments (CLIA). 2014. [May 15, 2015]. [www​.cdc.gov/clia](http://www.cdc.gov/clia).
* Centor RM, Witherspoon JM, Dalton HP, Brody CE, Link K. The diagnosis of strep throat in adults in the emergency room. Medical decision making: an international journal of the Society for Medical Decision Making. 1980;1(3):239–246. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/6763125)]
* Chassin MR, Kosecoff J, Solomon DH, Brook RH. How coronary angiography is used: Clinical determinants of appropriateness. JAMA. 1987;258(18):2543–2547. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/3312657)]
* CMS (Centers for Medicare & Medicaid Services). Accreditation organizations/exempt states. 2014. [November 3, 2015]. [www​.cms.gov/Regulations-and-Guidance​/Legislation​/CLIA/Downloads/AOList.pdf](http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOList.pdf).
* CMS. Advanced diagnostic imaging accreditation. 2015a. [May 22, 2015]. [www​.cms.gov/Medicare​/Provider-Enrollment-and-Certification​/MedicareProviderSupEnroll​/AdvancedDiagnosticImagingAccreditation.html](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/AdvancedDiagnosticImagingAccreditation.html).
* CMS. Clinical Laboratory Improvement Amendments (CLIA). 2015b. [May 15, 2015]. [www​.cms.gov/Regulations-and-Guidance​/Legislation/CLIA/index​.html?redirect=/clia](http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia).
* CMS. Getting a second opinion before surgery. 2015c. [March 30, 2015]. [www​.medicare.gov/what-medicarecovers​/part-b​/second-opinions-before-surgery.html](http://www.medicare.gov/what-medicarecovers/part-b/second-opinions-before-surgery.html).
* Cosmides L, Tooby J. Are humans good intuitive statisticians after all? Rethinking some conclusions from the literature on judgment under uncertainty. Cognition. 1996;58(1):1–73.
* Croskerry P. The feedback sanction. Academic Emergency Medicine. 2000;7(11):1232–1238. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/11073471)]
* Croskerry P. The Importance of cognitive errors in diagnosis and strategies to minimize them. Academic Medicine. 2003a;78(8):775–780. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/12915363)]
* Croskerry P. Cognitive forcing strategies in clinical decisionmaking. Annals of Emergency Medicine. 2003b;41(1):110–120. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/12514691)]
* Croskerry P. Clinical cognition and diagnostic error: Applications of a dual process model of reasoning. Advances in Health Sciences Education. 2009a;14(Suppl 1):27–35. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/19669918)]
* Croskerry P. A universal model of diagnostic reasoning. Academic Medicine. 2009b;84(8):1022–1028. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/19638766)]
* Croskerry P, Musson D. Patient Safety in Emergency Medicine. Croskerry P, Cosby KS, Schenkel SM, Wears RL, editors. Philadelphia, PA: Lippincott, Williams & Wilkins; 2009. pp. 269–276. (Individual factors in patient safety).
* Croskerry P, Norman G. Overconfidence in clinical decision making. American Journal of Medicine. 2008;121(5 Suppl):S24–S29. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/18440351)]
* Croskerry P, Abbass AA, Wu AW. How doctors feel: affective issues in patients' safety. Lancet. 2008;372(9645):1205–1206. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/19094942)]
* Croskerry P, Abbass AA, Wu AW. Emotional influences in patient safety. Journal of Patient Safety. 2010;6(4):199–205. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/21500605)]
* Croskerry P, Singhal G, Mamede S. Cognitive debiasing 1: Origins of bias and theory of debiasing. BMJ Quality and Safety. 2013;22(Suppl 2):ii58–ii64. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3786658/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/23882089)]
* Davies RH, Rees B. Include “eyeballing” the patient. BMJ. 2010;340(c291) [[PubMed](https://pubmed.ncbi.nlm.nih.gov/20085978)]
* Eichbaum Q, Booth GS, Young PS, editors; Laposata M, editor. Transfusion medicine: Quality in laboratory diagnosis. New York: Demos Medical Publishing; 2012.
* Elstein AS, Bordage G. Professional judgment: A reader in clinical decision making. Dowie J, Elstein A, editors. New York: Cambridge University Press; 1988. pp. 109–129. (Psychology of clinical reasoning).
* Elstein AS, Schwartz A. Clinical problem solving and diagnostic decision making: Selective review of the cognitive literature. BMJ. 2002;324(7339):729–732. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1122649/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/11909793)]
* Elstein AS, Shulman L, Sprafka S. Medical problem solving: An analysis of clinical reasoning. Cambridge, MA: Harvard University Press; 1978.
* Elstein AS, Shulman LS, Sprafka SA. Medical problem solving: A ten-year retrospective. Evaluation & the Health Professions. 1990;13(1):5–36.
* Ely JW, Graber ML, Croskerry P. Checklists to reduce diagnostic errors. Academic Medicine. 2011;86(3):307–313. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/21248608)]
* Emmett KR. Nonspecific and atypical presentation of disease in the older patient. Geriatrics. 1998;53(2):50–52. 58-60. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/9484285)]
* Epner PL, Gans JE, Graber ML. When diagnostic testing leads to harm: A new outcomes-based approach for laboratory medicine. BMJ Quality and Safety. 2013;22(Suppl 2):ii6–ii10. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3786651/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/23955467)]
* European Society of Radiology. The future role of radiology in healthcare. Insights into Imaging. 2010;1(1):2–11. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3259353/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/22347897)]
* Eva KW. The aging physician: Changes in cognitive processing and their impact on medical practice. Academic Medicine. 2002;77(10 Suppl):S1–S6. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/12377689)]
* Eva KW, Cunnington JPW. The difficulty with experience: Does practice increase susceptibility to premature closure? Journal of Continuing Education in the Health Professions. 2006;26(3):192–198. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/16986144)]
* Eva K, Link C, Lutfey K, McKinlay J. Swapping horses midstream: Factors related to physicians changing their minds about a diagnosis. Academic Medicine. 2010;85:1112–1117. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3701113/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/20592506)]
* Evans JP, Watson MS. Genetic testing and FDA regulation: Overregulation threatens the emergence of genomic medicine. JAMA. 2015;313(7):669–670. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/25560537)]
* Evans JSBT, Stanovich KE. Dual-process theories of higher cognition: Advancing the debate. Perspectives on Psychological Science. 2013;8(3):223–241. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/26172965)]
* FDA (Food and Drug Administration). In vitro diagnostics. 2014a. [May 15, 2015]. [www​.fda.gov/MedicalDevices​/ProductsandMedicalProcedures​/InVitroDiagnostics​/default.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm).
* FDA. Laboratory developed tests. 2014b. [May 15, 2015]. [www​.fda.gov/MedicalDevices​/ProductsandMedicalProcedures​/InVitroDiagnostics​/ucm407296.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm407296.htm).
* Ferket BS, Genders TS, Colkesen EB, Visser JJ, Spronk S, Steyerberg EW, Hunink MG. Systematic review of guidelines on imaging of asymptomatic coronary artery disease. Journal of the American College of Cardiology. 2011;57(15):1591–1600. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/21474039)]
* Fitch K, Bernstein SJ, Aguilar MD, Burnand B, LaCalle JR, Lazaro P, Loo Mvh, McDonnell J, Vader J, Kahan JP. The RAND/UCLA appropriateness method user 's manual. 2001. [May 13, 2015]. [www​.rand.org/pubs/monograph\_reports​/MR1269](http://www.rand.org/pubs/monograph_reports/MR1269).
* Flores G. Language barriers to health care in the United States. New England Journal of Medicine. 2006;355(3):229–231. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/16855260)]
* Frommer D, Morris J, Sherlock S, Abrams J, Newman S. Kayser-Fleischer-like rings in patients without Wilson's disease. Gastroenterology. 1977;72(6):1331–1335. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/558126)]
* Gandhi JS. Re: William Osler: A life in medicine: Book review. BMJ. 2000;321:1087.
* Gawande A. Overkill. The New Yorker. 2015 May 11; [July 13, 2015]; [www​.newyorker.com/magazine​/2015/05/11/overkill-atul-gawande](http://www.newyorker.com/magazine/2015/05/11/overkill-atul-gawande).
* Gigerenzer G. Adaptive thinking: Rationality in the real world. New York: Oxford University Press; 2000.
* Gigerenzer G. HIV screening: Helping clinicians make sense of test results to patients. BMJ. 2013;347:f5151. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/23965510)]
* Gigerenzer G, Edwards A. Simple tools for understanding risks: From innumeracy to insight. BMJ. 2003;327(7417):741–744. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC200816/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/14512488)]
* Gigerenzer G, Goldstein DG. Reasoning the fast and frugal way: Models of bounded rationality. Psychology Review. 1996;103:650–669. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/8888650)]
* Gittell JH, Seidner R, Wimbush J. A relational model of how high-performance work systems work. Organization Science. 2010;21(2):490–506.
* Goodman SN. Toward evidence-based medical statistics. 1: The P value fallacy. Annals of Internal Medicine. 1999;130(12):995–1004. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/10383371)]
* Gopalakrishna G, Mustafa RA, Davenport C, Scholten RJPM, Hyde C, Brozek J, Schunemann HJ, Bossuyt PMM, Leeflang MMG, Langendam MW. Applying Grading of Recommendations Assessment, Development and Evaluation (GRADE) to diagnostic tests was challenging but doable. Journal of Clinical Epidemiology. 2014;67(7):760–768. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/24725643)]
* Govern P. Diagnostic management efforts thrive on teamwork. Vanderbilt University Medical Center Reporter. 2013 March 7; [February 11, 2015]; [http://news​.vanderbilt​.edu/2013/03/diagnosticmanagement-efforts-thrive-on-teamwork](http://news.vanderbilt.edu/2013/03/diagnosticmanagement-efforts-thrive-on-teamwork).
* Graber ML. Diagnostic error in internal medicine. Archives of Internal Medicine. 2005;165(13):1493–1499. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/16009864)]
* Gray-Miceli D. Modification of assessment and atypical presentation in older adults with complex illness. New York: The John A. Hartford Foundation Institute for Geriatric Nursing; 2008.
* Grimes DA, Schulz KF. Refining clinical diagnosis with likelihood ratios. Lancet. 2005;365(9469):1500–1505. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/15850636)]
* Griner PF, Mayewski RJ, Mushlin AI, Greenland P. Selection and interpretation of diagnostic tests and procedures: Principles and applications. Annals of Internal Medicine. 1981;94(4 Pt 2):557–592. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/6452080)]
* Groen GJ, Patel VL. Medical problem-solving: Some questionable assumptions. Medical Education. 1985;19(2):95–100. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/3982318)]
* Gunderman RB. The medical community's changing vision of the patient: The importance of radiology. Radiology. 2005;234(2):339–342. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/15670989)]
* Han PK, Klabunde CN, Breen N, Yuan G, Grauman A, Davis WW, Taplin SH. Multiple clinical practice guidelines for breast and cervical cancer screening: perceptions of U.S. primary care physicians. Medical Care. 2011;49(2):139–148. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4207297/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/21206294)]
* Hendee WR, Becker GJ, Borgstede JP, Bosma J, Casarella WJ, Erickson BA, Maynard CD, Thrall JH, Wallner PE. Addressing overutilization in medical imaging. Radiology. 2010;257(1):240–245. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/20736333)]
* Henriksen K, Brady J. The pursuit of better diagnostic performance: A human factors perspective. BMJ Quality and Safety. 2013;22(Suppl 2):ii1–ii5. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3786636/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/23704082)]
* HFAP (Healthcare Facilities Accreditation Program). Notice of HFAP approval by CMS. 2015. [May 15, 2015]. [www​.hfap.org/AccreditationPrograms​/LabsCMS.aspx](http://www.hfap.org/AccreditationPrograms/LabsCMS.aspx).
* Hickner J, Thompson PJ, Wilkinson T, Epner P, Shaheen M, Pollock AM, Lee J, Duke CC, Jackson BR, Taylor JR. Primary care physicians' challenges in ordering clinical laboratory tests and interpreting results. Journal of the American Board of Family Medicine. 2014;27(2):268–274. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/24610189)]
* Hoffman KA, Aitken LM, Duffield C. A comparison of novice and expert nurses' cue collection during clinical decision-making: Verbal protocol analysis. International Journal of Nursing Studies. 2009;46(10):1335–1344. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/19555954)]
* Hollensead SC, Lockwood WB, Elin RJ. Errors in pathology and laboratory medicine: Consequences and prevention. Journal of Surgical Oncology. 2004;88(3):161–181. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/15562462)]
* Holmboe ES, Durning SJ. Assessing clinical reasoning: Moving from in vitro to in vivo. Diagnosis. 2014;1(1):111–117. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/29539977)]
* Hope C, Estrada N, Weir C, Teng CC, Damal K, Sauer BC. Documentation of delirium in the VA electronic health record. BMC Research Notes. 2014;7:208. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3985575/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/24708799)]
* Hricak H. Oncologic imaging: A guiding hand of personalized cancer care. Radiology. 2011;259(3):633–640. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/21493796)]
* Hsu J, Brozek JL, Terracciano L, Kreis J, Compalati E, Stein AT, Fiocchi A, Schunemann HJ. Application of GRADE: Making evidence-based recommendations about diagnostic tests in clinical practice guidelines. Implementation Science. 2011;6:62. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3126717/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/21663655)]
* IMV. Ready for replacement? New IMV survey finds aging MRI scanner installed base. 2014. [May 3, 2015]. [www​.imvinfo.com/user​/documents/content\_documents​/abt\_prs/2014​\_02\_03\_16\_51\_22\_809​\_IMV\_MR\_Outlook\_Press\_Release\_Jan\_2014​.pdf](http://www.imvinfo.com/user/documents/content_documents/abt_prs/2014_02_03_16_51_22_809_IMV_MR_Outlook_Press_Release_Jan_2014.pdf).
* IOM (Institute of Medicine). Clinical practice guidelines: Directions for a new program. Washington, DC: National Academy Press; 1990. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/25144032)]
* IOM. Medicare laboratory payment policy: Now and in the future. Washington, DC: National Academy Press; 2000. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/25057735)]
* IOM. Unequal treatment: Confronting racial and ethnic disparties in health care. Washington, DC: The National Academies Press; 2003. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/25032386)]
* IOM. Improving breast imaging quality standards. Washington, DC: The National Academies Press; 2005.
* IOM. Cancer biomarkers: The promises and challenges of improving detection and treatment. Washington, DC: The National Academies Press; 2007.
* IOM. Retooling for an aging America: Building the health care workforce. Washington, DC: The National Academies Press; 2008. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/25009893)]
* IOM. Evaluation of biomarkers and surrogate endpoints in chronic disease. Washington, DC: The National Academies Press; 2010. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/25032382)]
* IOM. Clinical practice guidelines we can trust. Washington, DC: The National Academies Press; 2011a. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/24983061)]
* IOM. Finding what works in health care: Standards for systematic reviews. Washington, DC: The National Academies Press; 2011b. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/24983062)]
* IOM. Evolution of translational omics: Lessons learned and the path forward. Washington, DC: The National Academies Press; 2012. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/24872966)]
* IOM. Best care at lower cost: The path to continuously learning health care in America. Washington, DC: The National Academies Press; 2013a. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/24901184)]
* IOM. Delivering high-quality cancer care: Charting a new course for a system in crisis. Washington, DC: The National Academies Press; 2013b. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/24872984)]
* IOM. Improving genetics education in graduate and continuing health professional education: Workshop summary. Washington, DC: The National Academies Press; 2015a. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/25674655)]
* IOM. Policy issues in the clinical development and use of biomarkers for molecularly targeted therapies. 2015b. [May 22, 2015]. [www​.iom.edu/Activities​/Research/BiomarkersforMolecularlyTargetedTherapies.aspx](http://www.iom.edu/Activities/Research/BiomarkersforMolecularlyTargetedTherapies.aspx).
* Jameson JL, Longo DL. Precision medicine—Personalized, problematic, and promising. New England Journal of Medicine. 2015;372(23):2229–2234. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/26014593)]
* Jarrett PG, Rockwood K, Carver D, Stolee P, Cosway S. Illness presentation in elderly patients. Archives of Internal Medicine. 1995;155(10):1060–1064. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/7748049)]
* Johansen Taber KA, Dickinson BD, Wilson M. The promise and challenges of next-generation genome sequencing for clinical care. JAMA Internal Medicine. 2014;174(2):275–280. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/24217348)]
* Johnson-Laird PN, Oatley K. Basic emotions, rationality, and folk theory. Cognition & Emotion. 1992;6(3-4):201–223.
* The Joint Commission. “What did the doctor say?” Improving health literacy to protect patient safety. 2007. [May 11, 2015]. [www​.jointcommission.org​/What\_Did\_the\_Doctor\_Say/default.aspx](http://www.jointcommission.org/What_Did_the_Doctor_Say/default.aspx).
* The Joint Commission. Eligibility for laboratory accreditation. 2015. [May 15, 2015]. [www​.jointcommission.org​/eligibility\_for\_laboratory​\_accreditation/default.aspx](http://www.jointcommission.org/eligibility_for_laboratory_accreditation/default.aspx).
* Jutel A. Sociology of diagnosis: A preliminary review. Sociology of Health and Illness. 2009;31(2):278–299. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/19220801)]
* Kahn JM, Gould MK, Krishnan JA, Wilson KC, Au DH, Cooke CR, Douglas IS, Feemster LC, Mularski RA, Slatore CG, Wiener RS. An official American thoracic society workshop report: Developing performance measures from clinical practice guidelines. Annals of the American Thoracic Society. 2014;11(4):S186–S195. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5469393/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/24828810)]
* Kahneman D. Thinking, fast and slow. New York: Farrar, Straus and Giroux; 2011.
* Kahneman D, Klein G. Conditions for intuitive expertise: A failure to disagree. American Psychologist. 2009;64(6):515–526. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/19739881)]
* Kanwisher N, Yovel G. The fusiform face area: A cortical region specialized for the perception of faces. Philosophical Transactions of the Royal Society B: Biological Sciences. 2006;361(1476):2109–2128. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1857737/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/17118927)]
* Kassirer JP. Our stubborn quest for diagnostic certainty. A cause of excessive testing. New England Journal of Medicine. 1989;320(22):1489–1491. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/2497349)]
* Kassirer JP. Teaching clinical reasoning: Case-based and coached. Academic Medicine. 2010;85(7):1118–1124. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/20603909)]
* Kassirer JP. Imperatives, expediency, and the new diagnosis. Diagnosis. 2014;1(1):11–12. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/29539968)]
* Kassirer JP, Wong J, Kopelman R. Learning clinical reasoning. Baltimore: Williams & Wilkins; 2010.
* Kent DM, Hayward RA. Limitations of applying summary results of clinical trials to individual patients: The need for risk stratification. JAMA. 2007;298(10):1209–1212. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/17848656)]
* Klein G. Sources of power: How people make decisions. Cambridge, MA: MIT Press; 1998.
* Kleinman S, Busch MP, Hall L, Thomson R, Glynn S, Gallahan D, Ownby HE, Williams AE. False-positive HIV-1 test results in a low-risk screening setting of voluntary blood donation: Retrovirus Epidemiology Donor Study. JAMA. 1998;280(12):1080–1085. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/9757856)]
* Korf BR, Rehm HL. New approaches to molecular diagnosis. JAMA. 2013;309(14):1511–1521. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/23571590)]
* Kosecoff J, Chassin MR, Fink A, Flynn MF, McCloskey L, Genovese BJ, Oken C, Solomon DH, Brook RH. Obtaining clinical data on the appropriateness of medical care in community practice. JAMA. 1987;258(18):2538–2542. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/3312656)]
* Kostopoulou O, Rosen A, Round T, Wright E, Douiri A, Delaney B. Early diagnostic suggestions improve accuracy of GPs: A randomised controlled trial using computer-simulated patients. British Journal of General Practice. 2015;65(630):e49–e54. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4276007/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/25548316)]
* Krupinski EA, Berbaum KS, Caldwell RT, Schartz KM, Madsen MT, Kramer DJ. Do long radiology workdays affect nodule detection in dynamic CT interpretation? Journal of the American College of Radiology. 2012;9(3):191–198. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3296477/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/22386166)]
* Kugler J, Verghese A. The physical exam and other forms of fiction. Journal of General Internal Medicine. 2010;25(8):756–757. [[PMC free article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2896585/)] [[PubMed](https://pubmed.ncbi.nlm.nih.gov/20502975)]
* Laposata M. Coagulation disorders: Quality in laboratory diagnosis. New York: Demos Medical Publishing; 2010.