DISSERTATION

at

International Institute of Health Management Research, New Delhi

(Mar 15th to Jun 25th, 2022)

CHALLENGES AND LIMITATIONS IN USAGE OF WEARABLE MEDICAL DEVICES IN HEALTHCARE: IDENTIFICATION THROUGH TEXT MINING APPROACH

Report

Submitted by

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ABSTRACT

Medical equipment and devices are an inescapable requirement for providing effective healthcare. Wearable medical devices represents the integration of a machine with healthcare application with a digital solution. Clinical decision support systems, which analyse medical data to assist providers in making clinical decisions at the point of care, have benefited from digital health solutions. The fifth industrial revolution, Industry 5.0, has ushered in a slew of new wireless technologies, many of which have applications in healthcare. These technologies aid in the provision of inputs to issues of geographical access, the facilitation of required medical interventions, the reduction of costs, the education of healthcare consumers, and the promotion of patient empowerment.

Wearable Medical devices which refer to any miniaturized electronic device that can be worn on the body, can be part of clothing or be embedded in accessories worn on body are used to perceive, record, analyse, regulate, and intervene human activities for healthcare purposes in conjunction with technologies for identification, sensing, connection, cloud services, and storage. They have various applications including detection of indications from patient body that can be a laboratory indicators, assist in timely drug administration, give guidance in physical to enable real-time, online, accurate and intelligent detection and analysis of human physiological and pathological information. This information may be used for diagnosis and monitoring by self or by a medical practitioner. These intelligent wearables is also a source of big data in health care that can be used for disease diagnosis and treatment.

Even though there have been wide percolation of wearable devices with advanced technology, reduction in cost however there has not been commensurate increase in their integration into clinical care despite multiple healthcare applications that these devices can be employed to. Some of the identified challenges towards this are requirement standardization of data and interoperability amongst commercially available devices and sensor locations, as also integration of this data into the electronic health record and defined clinical workflow. There are also human centric issues like the acceptance and ability to use the technology, correctly setting up the device , timely charging and calibrating the device etc. Additional issues include potential stigma associated with their use, and quality control issues affecting accuracy of the devices .If the challenges and barriers in adoption wearable devices are identified to subsequently address these challenges that will improve utility and expand the market of these devices.

Although there have been several attempts to review the challenges in usage of wearable devices research through systematic reviews the sheer magnitude of the number of studies published in recent years related to medical devices makes this task particularly challenging. Text mining approaches have been utilized to successfully extract hitherto unknown knowledge hidden in the literature by allowing analyses of large volume of texts through semi-automated processes. The thesis utilises text mining approach to identify challenges and barriers related to use of wearable medical devices with an aim to identify the challenges and limitations in usage of wearable health devices reported in the literature through text-mining approach.

Keywords

Wearable medical devices ; Healthcare; Health monitoring; Chronic disease management; Text mining; Challenges in adopting wearable devices ; Digital health

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The certificate is awarded to

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Dr. Sumesh Kumar

Associate Dean, Academic and Student Affairs

IIHMR, New Delhi

Dr Anandhi Ramachandran

Mentor

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Area of Dissertation:

Attendance:

Objectives achieved:

Deliverables:

Strengths:

Suggestions for Improvement:

Suggestions for Institute (course curriculum, industry interaction, placement, alumni):

Signature of the Officer-in-Charge/ Organisation Mentor (Dissertation)

Date:

Place:

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CHAPTER 1: INTRODUCTION

1.1 Background.

Medical devices are the pre-requisite for effective healthcare. Medical devices are important to achieve Sustainable Development Goals (SDGs) as laid by United Nations which includes universal health coverage and adequate access to essential health- care services amongst other things (1). In today's age and time, all SDGs have a technology component, with internet and data being inherent in them. Technical enablement is essential to achieve Universal Health Coverage. There are many examples towards this. Collection of data for monitoring the spread of data and deciding on preventive measures and counter strategies during Covid-19 pandemic recently being one of them. With solutions being offered by digital health innovations, clinical decision making at point of care has enhanced through medical data being fed through Clinical Decision Support Systems. (1)

Industry 5.0, the fifth industrial revolution, entail a synergy and partnership between machines and human beings, creating customised products thereby adding value towards production in various industries including healthcare (2). Some of the latest developments in wireless technologies have numerous applications in healthcare. These technologies assist in providing inputs towards issues of geographical access , facilitate requisite medical interventions, make it economical, make healthcare consumers aware as also promote patient empowerment (1).

Wearable devices refers to any electronic device usually of small size that can be put on person, can be part of clothing or be embedded in accessories worn on body. Vastly used in fitness, gaming and entertainment industries, there is an increased momentum in healthcare domain These are used in conjunction with technology for identification, sensing, connection, cloud services, and storage to detect, store, evaluate, control, and intervene in human activities to monitor individual's health. It has many uses like assisting in timely drug administration, and analysis of human physiological and pathological data. This information may be used for diagnosis and monitoring by self or by a medical practitioner. These intelligent wearables is also a source of big data in health care that can be used for disease diagnosis and treatment (3). Needless to say, wearable devices can be the mainstay to attain Universal Health Coverage.

Even though there have been wide percolation of wearable devices with advanced technology, reduction in cost however there has not been commensurate increase in their integration into clinical care despite multiple healthcare applications that these devices can be employed to. Some of the identified challenges towards this are requirement standardization of data and interoperability as also integration of existing healthcare ecosystem with data. There are also human centric issues like the acceptance and ability to use the technology, correctly setting up the device , timely charging and calibrating the device etc. Additional issues include potential stigma associated with their use, and quality control issues affecting accuracy of the devices (4)

The global wearable medical devices market size is expected to have CAGR of 26.4 % between 2020 to 2027 reaching USD 195.57 billion by 2027 . The growth has been fuelled by increase chronic diseases and increasing awareness in people about their health and their need to stay fit. This has driven the use of wearable type of medical devices globally. Covid19 had an overall positive effect on demand of wearable devices. One of the reasons was requirement of self-monitoring of Covid 19 symptoms at home. India accounts for 13% of total Asia – Pacific market that is $ 1328.86 millions in 2022. (5). It is evident that if the full potential of wearable medical devices is realised by addressing challenges and limitations in India, it will be instrumental in achieving Universal Health Coverage(6).

1.2 Problem Description

To potentially contribute to universal health coverage in a developing country like India, wearable devices should be adopted by large population in a sustainable manner. However , despite the projected growth in usage of these devices there are still many challenges that are being faced by healthcare professionals and patients which is preventing them to become a defining pillar of healthcare. If these challenges are identified it will not only aid in improving monitoring of chronic diseases but also make them main stay of preventive medicine.

Further, there has been an exponential increase in the number of wearable devices and their design complexity in the last two decades. There have been many studies pertaining to identification of barriers and challenges but most of them are particular to specific devices or constrained to particular geographical region. Also, despite various studies to review the challenges in use of wearable devices research through systematic reviews have been made, the large number of published papers on the subject makes this a daunting task.

With modern text mining approach it is possible extract information and hidden knowledge from available literature by analysing large volume of texts. The purpose of this study is to utilize text mining approach to identify challenges and barriers related to use of wearable medical devices.

1.3. Objective.

The objective of this dissertation is to identify the challenges and limitations in usage of wearable health devices reported in the literature through text-mining approach.

1.4. Outline of the Research Approach.

The research design is descriptive study. The data was collected based on scientific articles published. This dissertation follows the text mining process. The Step 1 was document search and establishment of corpus where in databases of Pubmed and Google Scholar have been used. The Search Terms used are as under :-

(a) Monitoring of health through wearable devices.
(b) Challenges in adopting wearable devices in healthcare.
(c) Barriers in using wearable devices in ambulatory care.
(d) Remote monitoring of patients using wearable devices.

For the purpose of paper, compound queries on the above mentioned strings were done on the undermentioned data bases like Google Scholar and Pubmed databases. All together, these sites form a comprehensive citation based database of peer reviewed research articles.

The selection of articles was done based on the modified version of PRISMA guideline. The inclusion criteria was full text, English only articles, published within last 12 years , while the exclusion criteria involved general description, systematic reviews, books, book chapters, patents. After this the next step was generating and curating the term list. Thereafter the R open source software was used for text mining. Finally, an analysis of the terms to retrieve trends and evaluating the findings was done. For ethical clearance the student review board of IIHMR, Delhi has reviewed and provided waiver for study as it is based on secondary data from published literature.

A set 67 papers published between year 2010 to 2022, were collected through research process. A total of 5 duplicate databases were found and removed being redundant. A total of 62 documents were compiled. Abstracts and meta data were compiled into RIS format required for text mining using Zotero. Further filtration was done to filter the documents with high relevance and a Corpus of 40 documents was created by compiling the discussion of the subject documents to give inputs for more focused analysis of compiled data.

It is mentioned that the data analysed specifically pertains to wearable medical devices. The data does not pertains to generalised term of medical devices.

1.5. Organization of the Thesis

The organization of the thesis is as follows. In Chapter 2, the literature in the area of wearable medical devices and text mining is reviewed. This gives overview of current state of usage of wearable medical devices and the challenges in their usage . Chapter 3 describes the methodology used in detail including usage of open source software R. In Chapter 4, covers the results obtained through text mining process. Chapter 5, covers the discussion on text mining data including thesis conclusion.

CHAPTER 2: LITERATURE REVIEW

Medical wearable devices are now aided by technologies like cheap and global availability of internet connectivity, Internet of Things, Artificial Intelligence, various tools to handle and analyse Big Data Healthcare field has been a game changer for the field of healthcare. Wearable devices refers to any miniaturized electronic device that can be worn on the body, can be part of clothing or be embedded in accessories worn on body. Vastly used in fitness, gaming and entertainment industries, there is an increased momentum in healthcare domain These are used to perceive, record, analyse, regulate, and intervene human activities for healthcare purposes in conjunction with technologies for identification, sensing, connection, cloud services, and storage. Various applications include detection of indications from patient body that can be a laboratory indicators, assist in timely drug administration, give guidance in physical to enable real-time, online, accurate and intelligent detection and analysis of human physiological and pathological information. This information may be used for diagnosis and monitoring by self or by a medical practitioner. These intelligent wearables is also a source of big data in health care that can be used for disease diagnosis and treatment (3). Needless to say, wearable medical devices have the potential to form mainstay of achieving Universal Health Coverage.

Ambulatory monitoring devices enable collecting , collation and analysis of temporal data to assist accurate diagnostics. Popular example of the same is cardiac monitoring device which continuously monitor a patient. With increased reliability, lesser cost and high quality control these devices are increasingly used to monitor patients from the comfort of their homes. There have been many recent developments in the area of ambulatory and remote monitoring solutions based on wearable devices, smartphones, and other ambulatory sensors.(7).

Health wearables enable individuals a direct access to body analytics that support management of different aspects of health. Their use directed to patients of all ages. Not only children to adults are targeted but even unborn babies are being monitored using this technology. Self-tracking is done using devices with specialised software and apps. in flux. There are many players who have classically not been part of healthcare scenario that have entered the fray for wearable medical devices. For example, large internet companies like Nokia, Apple, Samsung, Google and Amazon have taken a leap in field of digital health. Also players in the health arena are convincing patients to engage in self-monitoring through wireless devices. For example, insurance companies are encouraging and rewarding consumer with discounts for healthier lifestyle being monitored by wearable devices (8).

2.1 Overview of Wearable Medical Devices

2.1.1. Characteristics

Wearable medical devices are defined by their wireless mobility, how they interact with user and do they any on-board intelligence, how long do they sustain in their operations, weather the device is durable and its reading is reliable and repeatable and the design that aids wearability in -terms of size, portability and ease of operation by all kinds of patients (3).

2.1.2 Classification of Wearable Devices

One of the way of classifying wearable medical devices is based on the part of the body they are worn in that is on head, limb or torso. Example of head type devices are helmets , patches being placed on head or devices placed in ears. The Limb devices as the name suggests care placed on an arm, legs or feet. Example of these are smart watches or sensors placed in shoes or socks to monitor movement while walking. Similarly, torso worn devices include the ones that are worn on upper body like belts or systems embedded in vests or under garments.

2.1.3. Applications

Applications of Medical devices can be defined by four Ps viz. preventive, predictive, personalized, and participatory medicine (3). Some of the applications are listed below :-

Preventive Healthcare

Examples are devices that can detect a fall and prevent the same, as well as physical activity and interaction monitoring, are among them(9). A language-tracking wearable gadget, for example, could be used to collect data on mother-child communication in order to improve it(10).

There are devices to measure vital parameters like heartbeat, blood pressure, body temperature, etc to give indication of individual health. Further, data like calories burned is prominently used by people looking to lose weight. Latest commercially available devices like Apple watches can detect heart parameters with an ECG(11). Also, devices are able to predict stress, activity levels. Similarly, another applications area is in area of sports where parameters like body movements , repetitions, heart rates of athletes are measured to enhance their performance and reduce injuries.(12)

Mass Health Awareness

Simulators with body sensors, VR equipment and gadgets like google glass in conjunction with advanced Healthcare apps and simulations are being used to increase awareness about health and provide medical education (13).

Managing Patients

Wearable devices are prominently used in ambulatory as well as In-patient care with their ability to detect and diagnoses of medical conditions. There are many point of care devices with are used to monitor vital signs of patients in Hospitals and transmit data continuously through wireless means to monitoring devices. The same is used for monitoring patients with Spinal injuries, Cancer patients and patients suffering with say heart conditions and diabetes to provide continuous or periodic data to Doctors or Patients (14).

Managing Ailments and Diseases.

Wearable devices have major applications in managing chronic diseases like Heart Conditions, Diabetes by monitoring the health related data through sensors and giving indications for interventions when data is not optimum. Similarly, Blood related disorders are being monitored Blood Pressures sensors aided by wireless technology and mHealth apps. This improves adherence of drug schedule and Hypertension control(15)). Another area of application is in management of Diabetes for which wearable devices are being used to give tailor made solutions(16). Example of the same is non- invasive glucose sweat based monitoring through wearable system(17). Applications are there for many other diseases like Autism, where in emotions can be detected and classified and Parkinson’s disease (13).

2.2. India Perspective(16)

The spread of these technologies has been considerably faster in industrialised countries, and it has just lately begun in India. India with its large population in its youth has potential to become one of the biggest markets in coming days. The market which has high component of smartwatches , fitness bands, mHealth applications include well-known brands like Fitbit, Garmin, Omron, Apple, Zephyr, Xiomi, as also some of start-ups like Cardea Labs(6).

Higher economic affluence in society, increased awareness and availability of information, better availability, and changing disease profiles in Indian society are all key drivers of medical device growth. With more evidence that continuous physiological data can be useful in managing chronic diseases and monitoring patients after hospitalisation, an increasing number of medical devices are being converted into wearables in India. Examples of these are Pulse oximeters, devices to monitor Blood Pressure and Glucose and Heart rate. Simultaneously, an effort has been made to deliver patient data to clinicians in a seamless manner. These have huge applications in country like India where there is large burden of Non Communicable Diseases. For example India with large diabetic population have high usage of Continuous Glucose Monitors (CGM) to monitor the glucose level in human bodies as also to timely inject insulin when required. (18).

2.2. Challenges & Barriers

The application of wearables in healthcare is hampered by a slew of obstacles and roadblocks. The challenges range from issues pertaining to security and privacy of the patients – where in there is a fear that third parties might get access to personal data and may use it for commercial use to things like social stigma attached to use of these devices. Other issues are in technological domain where in there are issues of interoperability of various data with existing Healthcare Digital systems, issue of sensitivity and accuracy of sensors placed in the devices, the issues of miniaturisation of sensors or embedding them in clothing to make them unobtrusive for usage. Acceptability of technology and change management amongst the healthcare professionals and the patients is another area of concern.

Other area of concern is issue of inadequate regulation to avoid misuse of devices, ensuring standardisation, regulating correct handling and management of data. The cost of devices and uniformity in quality of sensors which case shadow on accuracy and efficacy of device are areas that need to be addressed. Issue of hardware like ergonomic design, battery life, wireless compatibility and framework for data transfer and storage , safety concerns that need to be incorporated in design phase are some of the factors that is affecting adoption the wearable devices. Further, there have been issues of software compatibility across various platforms, integration with various other technologies like Artificial Intelligence, Big Data Handling, Internet of things, wireless communication and cloud storage that needs consideration.

It is urgent to address many of above mention challenges and do a systematic study into other factors that is affecting the usage of wearable devices and preventing them from realising their potential.

2.4. Text Mining.

Text Mining is a technology which has revolutionised the process of analysis of data from large volume of documents. The fast rise of data, the majority of which is unstructured, has been a feature of the last decade. Data from social media, news columns, websites, transcribed data from video streams, and formal documents like research papers and published articles are all examples of text-heavy data. Unstructured or semi-structured data accounts for around 80% of today's data. The objective is to find patterns and trends in the available huge data to analyse the text documents. The technique of extracting interesting and non-trivial patterns from large amounts of text documents is known as text mining. For mining text for meaningful information for future prediction and decision-making, a range of methodologies and technologies are available. The suitable and appropriate text mining technique is used to increase the speed and reduce the time and effort necessary to retrieve relevant data. (19).

Generic process of text mining performs the following steps(20) (Figure 1)

I. Various sources in varied file formats are browsed and unstructured data is collected. e.g. files in pdf format , data from web pages etc.
II. Next step is Pre-processing. In this cleansing of data is done so the real information can be derived from data. The steps include removing punctuations, numbers, spaces, stopwords which have no real information and

any anomalies, so that data can be processed. Steps like stemming and lemmatisation maybe done here.

III. The corpus is then processed and controlling operations applied to so that data is checked for text analysis and is cleaned further.

IV. Pattern are analysis by information system.

V. Trends , Patterns, various analyses like drawing Histograms and word clouds is done so that valuable and meaning information can be drawn from the vast text.

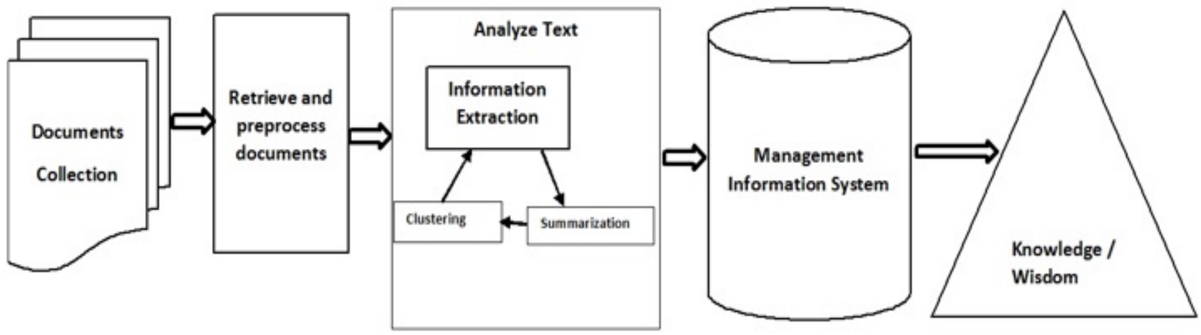

Figure 1:Generic Text Mining Process

CHAPTER 3: METHODOLOGY

3.1. Methodology Overview

Research Design: Descriptive Study

Data Collection Method: Secondary data based on published scientific articles

Approach: This dissertation follows the text mining process and consists of the following steps :-

Step 1:

Document Search and establishment of corpus – For this the databases of Pubmed and Google Scholar have been used.

Search Terms used:

(e) Monitoring of health through wearable devices.

(f) Challenges in adopting wearable devices in healthcare.

(g) Barriers in using wearable devices in ambulatory care.

(h) Remote monitoring of patients using wearable devices.

Step 2: Selection of articles

Modified version of PRISMA guideline has been utilized for retrieving the articles.

Inclusion Criteria : Full text, English only articles, published within last 12 years

Exclusion Criteria: General description, systematic reviews, books, book chapters, patents

Step 3:

Generating and curating the term list

Step 4: Utilising 'R' Language package for text mining.

Step 5: Analyses of the terms to retrieve trends and Evaluating the findings.

Ethical Clearance: The student review board of IIHMR Delhi has reviewed and provided waiver for study as it is based on secondary data from published literature.

3.2. Collection of Data.

A clear strategy was formulated to select the relevant papers for making the thesis a meaningful, robust and comprehensive document. For the purpose of retrieving relevant papers , search strings and keywords were formulated . The keywords include Wearable medical devices ; Healthcare; health monitoring; chronic disease management; Text mining; Challenges in adopting wearable devices ; digital health. The various search strings included -

(i) Monitoring of health through wearable devices.
(j) Challenges in adopting wearable devices in healthcare.
(k) Barriers in using wearable devices in ambulatory care.
(l) Remote monitoring of patients using wearable devices.

Due to limited available information on the subject, an effort was made to mine relevant information from all credible sources , to create a cogent picture of the subject. For the purpose of paper, compound queries on the above mentioned strings were done on the undermentioned data bases like Google Scholar and Pubmed databases. All together, these sites form a comprehensive citation based database of peer reviewed research articles.

As shown in the Prisma diagram at Figure 1, 67 papers published between year 2010 to 2022, were collected through research process. A total of 5 duplicate databases were found and removed being redundant. A total of 62 documents were compiled. Abstracts and meta data were compiled into RIS format required for text mining using Zotero. Further filtration was done to filter the documents with high relevance and a Corpus of 40 documents was created by compiling the discussion of the subject documents to give inputs for more focused analysis of compiled data.

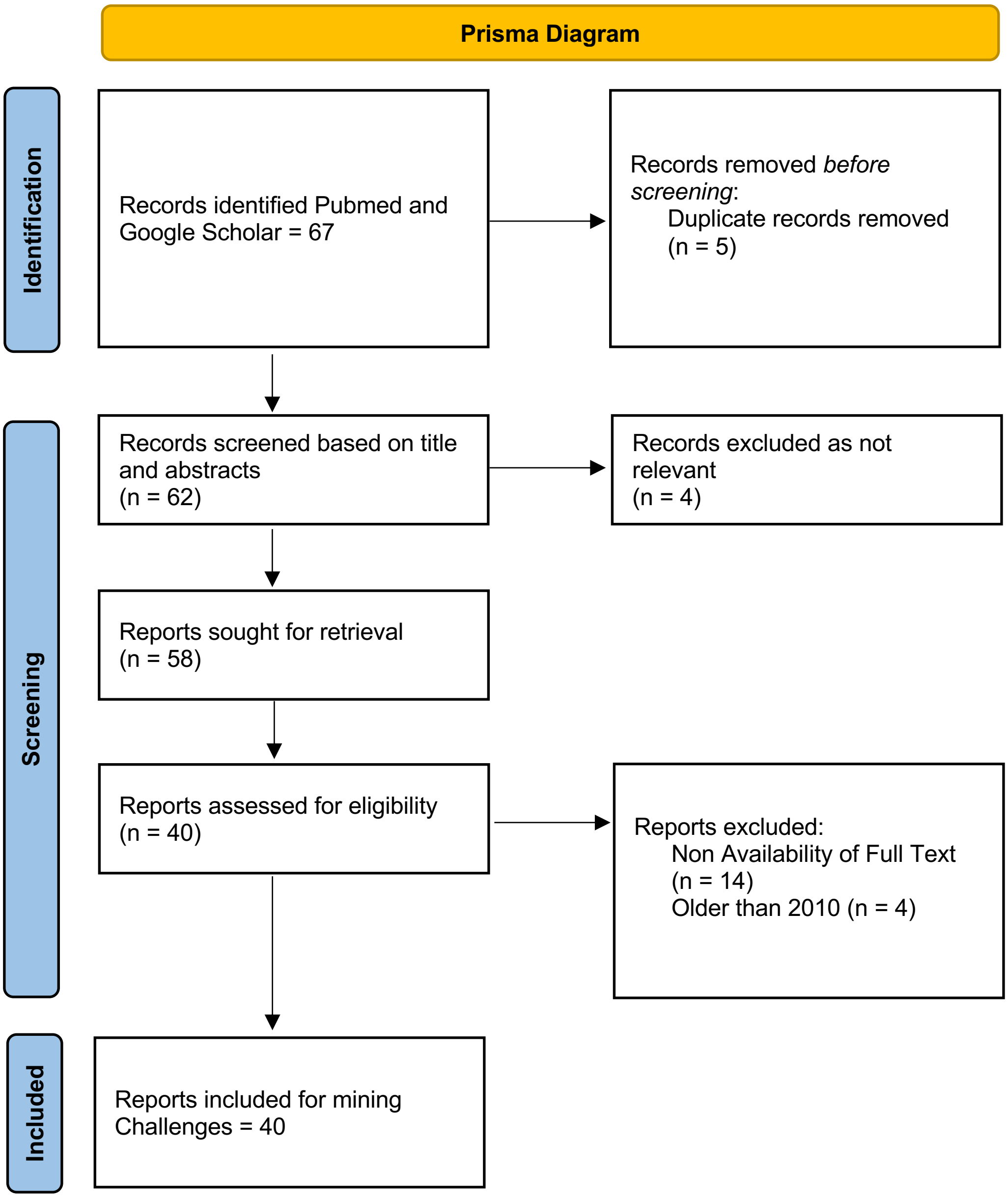

Figure 2: Prisma Diagram

3.3. Text mining with R

One of the process for text mining is open-source software R which has been used to do text mining in this dissertation. There are many iterative and sequential steps in text analysis. Given the unstructured nature of text data, a consistent and repeatable approach is required to assign a set of meaningful quantitative measures to this type of data. This process can be roughly divided into four steps: data selection, data cleaning, information extraction, and analysis of that information. (20)

Text analysis catches and analyses many meanings concealed within the text. In text analysis data is deciphered from Natural Language using computer tools. We look for specified keywords or concepts in a document in quantitative text analysis.

3.3.1. Text extraction

In this first step is to collate the set of documents which we need to analyse and that will serves as the input to R. For this package tm is used in the package. (21)
Package tm is an inbuilt package that can be installed for text mining applications in R that include actions like creating a corpus and pre-processing. Corpus is a core function of tm package which references to the relevant set of documents that are to be text mined. The function is given a file path containing the files to be analysed as input while the output is document which has all these inputs organised in a specific manner.

Function called file.path() tells working directory where all of text documents are stored after which function corpus from the package tm is applied to all of the files in the working directory. After this each file is captured and interpreted as a document and is formatted and defined into a corpus object class that as dictated by the tm package. Once documents are organised in a corpus object, we used writeLines() function to access and read each document in the corpus.

3.3.2. Cleaning and storing text

Once we have defined the Corpus and its contents are accessed it is converted into suitable form for further analysis. Here we use something called as Tokens (a document is seen to be made of a collection of tokens). Tokens are small subparts consisting of words, numbers, punctuation marks, and other symbols found in Corpus. The tokens not having any meaningful information are cleansed so that the unstructured data is now uniform and the irrelevant text not having any information values is removed. For this functions like removePunctuation(),
removeNumbers, removeWords() are used. Thereafter stop words are to be removed however before that whole text is converted to lower case using command
corpus < - tm_map(corpus, tolower)

Finally Stemming is done so that which picks words with common root and converts then to one. For example, after stemming, words such as “challenged”, “challenges”, and “challenging” become “challenge”.
corpus < - tm_map(corpus, stemDocument)

3.3.3. Data structures

Once cleaning is done a Document Term Matrix is created which checks the frequency of words in various documents. All the documents arranged in the row and words arranged in the column and is used in NLP. The command used is dtm < - DocumentTermMatrix(corpus)

Here each row represents a specific document in the collection and each column corresponds to the count of specific terms within that document. It is a vector-space representation of a set of documents.

3.3.4. Data exploration

Once the Data Structure has been defined we analyse the corpus in an exploratory manner to derive meaningful insights into the document. Various things like fining the terms with highest and lowest frequencies or sorting them in order of frequency can be done using various commands. Further correlation between most frequent terms can be found with other words using findAssocs() function in package tm. Various graphical methods like creating a heat map can be used to represent data.

3.3.5. Text analytics

Next analysis both within and between texts is required to be done. Techniques like sentiment analysis, term frequency, Dictionary based text analysis , wordscores are used for the purpose.

3.4 Text Mining Framework

Text-mining was done using open source software R. The broad flow diagram (22)for the same is given below as Figure 2 :-

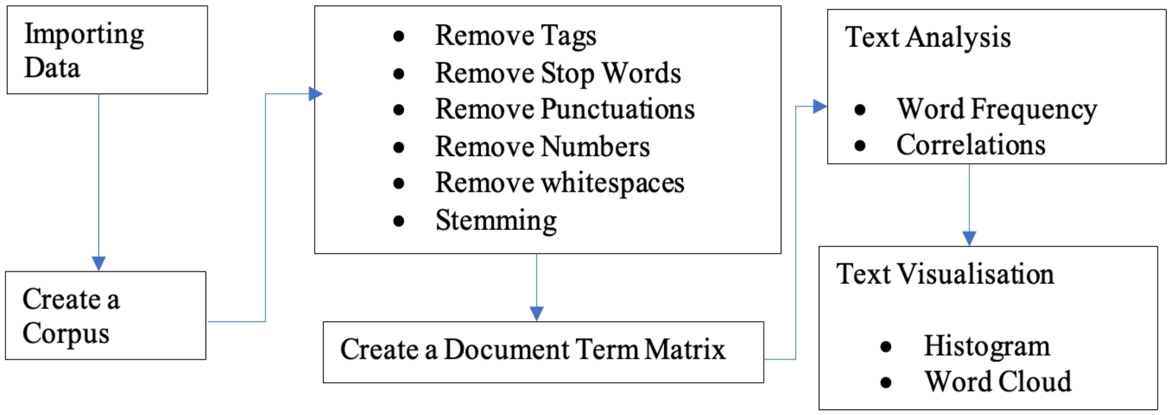

Figure 3: Text Mining Framework

The R Script with explanation is given in Appendix A.

CHAPTER 4: RESULTS

4.1. Output of Data after Pre-processing.

The document was cleaned for unwanted characters, numbers, hyphens, punctuations, stripped of white spaces and Stopwords like ‘in’, ‘and’, ‘the’ etc. Also, customised stopwords like insole, long , crossref, include etc were removed which had no value for text analysis. These were found during iterations, Once the pre-processing was done the output was checked. The screenshot of the same is shown below :-

> writeLines (as.character(docs[[40]]))

```
Console   Terminal ×   Jobs ×
R 4.2.0 · ~/
> Tospace <- content_transformer(function (x, pattern) {return (gsub(pattern, " ",x))})
> docs <- tm_map (docs, Tospace, "-")
> docs <- tm_map(docs, Tospace, ":")
> docs <- tm_map(docs, Tospace, "’")
> docs<- tm_map(docs, Tospace, " _")
> docs <- tm_map(docs, removePunctuation)
> docs <- tm_map(docs, content_transformer(tolower))
> docs <- tm_map(docs, removeNumbers)
> docs <- tm_map(docs , removeWords , stopwords ("english"))
> docs <- tm_map(docs , removeWords , stopwords ("SMART"))
> docs <- tm_map(docs , removeWords , c("torous","day","term","include","due","rate","ppd","time", "’","day","term","due","crossre
f","home" ,"able","based","user","full","free","users","insole","gait","the","long","low","high","this","study"))
> docs <- tm_map(docs , stripWhitespace)
> writeLines (as.character(docs[[40]]))
 tools health coaching challenges opportunities wearable devices enabling tools health coaching poses myriad questions questions tim
ely pertinent line computing healthcare blurred questions arise concern effectiveness wearable devices comparison clinical counterpa
rts effectiveness health coaching programs devices curate scrutiny compared health coaching program supervised healthcare practition
er physical limitations inherent wearable device margin error terms measurements limit devices clinical settings small form factor d
ictated devices health coaching accurate measurements vital success patient coaching program inaccurate measurement device considera
ble disturbances health coaching program normal flow finally concerns forefront design process paradigms – design considerations met
hodologies stimulate inspire advance field computing healthcare challenges wearable devices
```

Figure 4: Output after Corpus Pre-processing

4.2. Iteration 1.

Document Term Matrix. Output is shown as per Figure 5 below :-

```
Console   Terminal ×   Jobs ×
R 4.2.0 · ~/
> inspect(Dtm[1:40,1:3000])
<<DocumentTermMatrix (documents: 40, terms: 3000)>>
Non-/sparse entries: 10815/109185
Sparsity           : 91%
Maximal term length: 20
Weighting          : term frequency (tf)
Sample             :
        Terms
Docs      data device foot individual information monitoring patient sensor system technology
  1.txt     18     43    0          2           4          3       2     12      5          7
  10.txt     3      8    5          1           0          2       0     31      4          5
  19.txt    32      8    0          8           5          3      18      1      2          3
  23.txt    18     19    0          3           6         14       2     15     13         11
  24.txt    26     13    0          1           3          9      16      8      6         11
  25.txt    18     43    0          2           4          3       2     12      5          7
  31.txt    59     69  115         87          38         85       0    242     99          7
  35.txt    18      4    0          2          21         19      76     30      5         38
  4.txt     14     23    0          1           1          3       3      2      4         13
  6.txt     15     27    0          0           7          5       5      5      2         10
> freq<- colSums(as.matrix(Dtm))
> length (freq)
[1] 4906
```

Figure 5: Output DTM as per given Command (Iteration 1)

Length, Most Frequent Terms and Least Frequent terms in this iteration given below as per Figure 5.

```
> freq<- colSums(as.matrix(Dtm))
> length (freq)
[1] 4906
> ordr <- order(freq, decreasing = TRUE)
> freq[head(ordr)]
    sensor     device       data monitoring     system    patient 
       530        477        409        259        202        198 
> freq[tail(ordr)]
    forefront        myriad     paradigms     pertinent practitioner     stimulate 
            1             1             1             1            1             1 
```

Figure 6: Length, Most Frequent & Least Frequent Terms (Iteration1)

Most Frequent Terms with Minimum Frequency of 40 are given below :-

```
> findFreqTerms(Dtm, lowfreq=40)
 [1] "accuracy"     "activities"   "activity"     "analysis"      "applications" "battery"      "body"
 [8] "care"         "challenges"   "clinical"     "cost"          "data"         "design"       "detection"
[15] "developed"    "development"  "device"       "ensure"        "figure"       "future"       "healthcare"
[22] "human"        "important"    "improve"      "individual"    "information"  "life"         "limitations"
[29] "measurements" "monitoring"   "patient"      "physiological" "platforms"    "potential"    "power"
[36] "privacy"      "research"     "sensing"      "sensor"        "signals"      "smart"        "specific"
[43] "studies"      "system"       "technologies" "technology"    "temperature"  "walking"      "wearables"
[50] "addition"     "foot"         "plantar"      "provide"       "quality"      "textile"      "key"
[57] "related"      "concerns"     "participants" "people"        "security"     "parameters"   "text"
[64] "years"        "medline"
```

Figure 7: Most Frequent Terms with Minimum Frequency of 30 (Iteration 1)

Thereafter correlations between most frequently occurring words that is sensor, device, data, monitoring, system and patient was done. As an illustrative example the screenshot of correlation of data is shown below as per Figure 8 below :-

```
> findAssocs(Dtm,"data", 0.7)
$data
         real      obesity      benefit  information        exist     accuracy     proposed      setting      provide
         0.80         0.80         0.79         0.79         0.79         0.78         0.78         0.77         0.77
      ability   individual       larger     purposes    encourage       medium      predict       stroke     activity
         0.77         0.76         0.76         0.76         0.76         0.76         0.76         0.76         0.75
  potentially       create        point   considered        large       reduce        small identification         key
         0.75         0.75         0.75         0.74         0.74         0.74         0.74         0.74         0.74
    generally       showed       stages accelerometer    analyses     critical     analysis    analyzing communication
         0.74         0.74         0.74         0.74         0.74         0.74         0.73         0.73         0.73
    determine       enable     increase       number         step     wireless    frequency       adults       engage
         0.73         0.73         0.73         0.73         0.73         0.73         0.73         0.73         0.73
       entire         fast      general      greater        steps     adequate       modern        sense    difficult
         0.73         0.73         0.73         0.73         0.73         0.73         0.73         0.73         0.72
   electronic       figure     identify      monitor       nature   literature  researchers     reliable    wellbeing
         0.72         0.72         0.72         0.72         0.72         0.72         0.72         0.72         0.72
    continues      diverse   estimating   reflective      improve       result      results     sampling       system
         0.72         0.72         0.72         0.72         0.71         0.71         0.71         0.71         0.71
    improving        major       global  lightweight        older      reduced     exercise    attaining    clearance
         0.71         0.71         0.71         0.71         0.71         0.71         0.71         0.71         0.71
        deter     economic     exposing    extensive     inactive   introduced        light        merit   physically
         0.71         0.71         0.71         0.71         0.71         0.71         0.71         0.71         0.71
 prescription      product       random       reward    summarize       unable       verify     affected    obtaining
         0.71         0.71         0.71         0.71         0.71         0.71         0.71         0.71         0.71
      optimal       serves     decision     estimate     location        smart         worn      dynamic    validated
         0.71         0.71         0.70         0.70         0.70         0.70         0.70         0.70         0.70
          gps      present      subject   indication  incorporate      opposed      running
         0.70         0.70         0.70         0.70         0.70         0.70         0.70
```

Figure 8: Correlation analysis frequent terms(Iteration 1)

Histogram

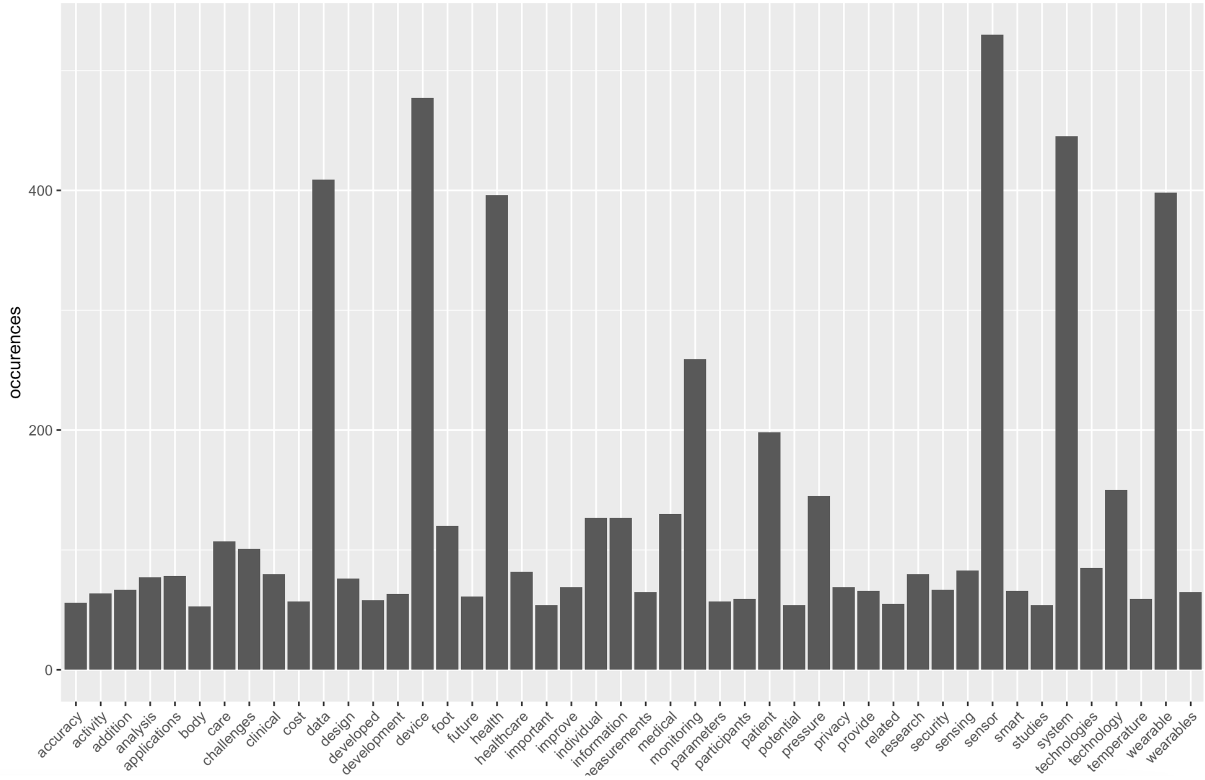

Figure 9: Histogram (Iteration 1)

Word Cloud

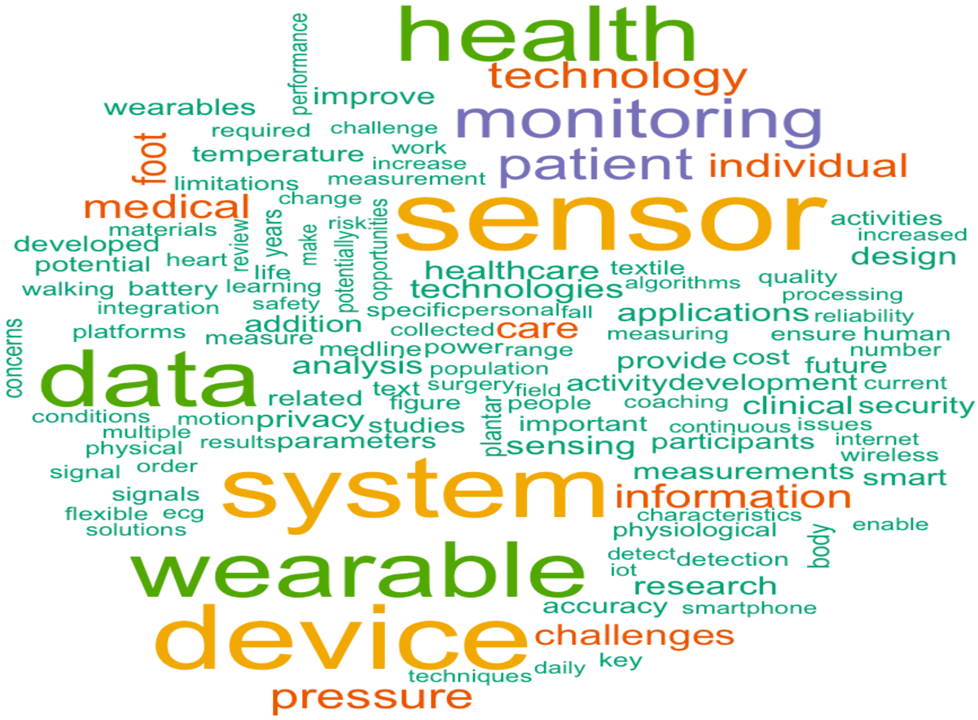

Figure 10: Word Cloud

4.3. Iteration 2

List the most frequent terms with Lower bound specified as second argument. Items which have occurred at least 80 times.

```
> findFreqTerms(Dtm, lowfreq=40)
 [1] "accuracy"      "activities"    "activity"      "analysis"
 [5] "applications"  "battery"       "body"          "care"
 [9] "challenges"    "clinical"      "cost"          "data"
[13] "design"        "detection"     "developed"     "development"
[17] "device"        "ensure"        "figure"        "future"
[21] "health"        "healthcare"    "human"         "important"
[25] "improve"       "individual"    "information"   "life"
[29] "limitations"   "measure"       "measurements"  "medical"
[33] "monitoring"    "patient"       "physiological" "platforms"
[37] "potential"     "power"         "privacy"       "research"
[41] "sensing"       "sensor"        "signals"       "smart"
[45] "specific"      "studies"       "system"        "technologies"
[49] "technology"    "temperature"   "walking"       "wearable"
[53] "wearables"     "addition"      "foot"          "plantar"
[57] "pressure"      "provide"       "quality"       "textile"
[61] "key"           "related"       "concerns"      "participants"
[65] "people"        "security"      "parameters"    "text"
[69] "years"         "medline"
```

Figure 11: Length, Most Frequent , Least Frequent Terms, Frequent terms (Iteration2)

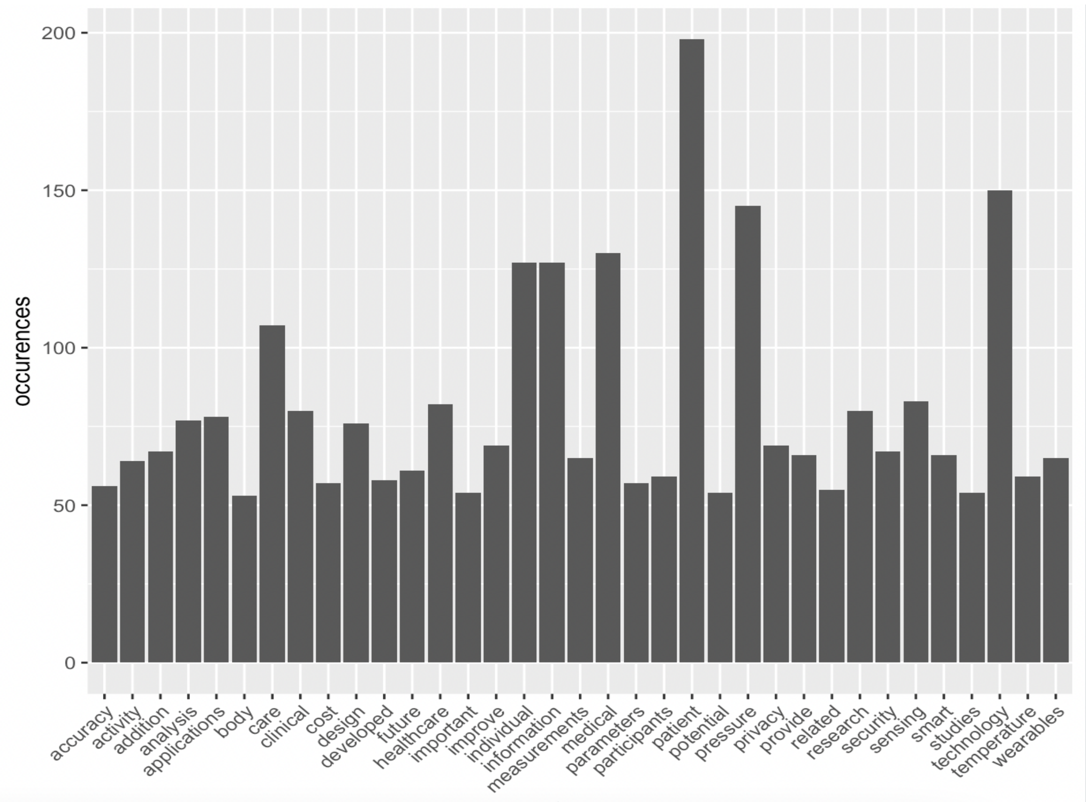

Figure 12: Histogram (Iteration 2)

Figure 13: Word Cloud (Iteration 2)

CHAPTER 5 : DISCUSSION

5.1. Data Interpretation.

There are several indicators that emerge through the text analysis that has been done on the corpus of documents for which the results are shown in the previous chapters. Once the DTM was drawn the most frequent terms which appeared as under as Table 1 :-

Term	Sensor	Device	Data	Monitoring	System	Patient
Frequency	530	477	409	259	202	198

Table 1: List of Most Frequent Terms

These are the identified broad verticals under which issues and challenges can be tabulated. Other frequent terms appearing in the text included following terms as per Table 2 below :-

Accuracy	Activities	Activity	Analysis	Application	Battery
Body	Care	Challenges	Clinical	Cost	Data
Design	Detection	Developed	Device	Ensure	Future
Human	Individual	Information	Limitations	Measurement	Monitoring
Patient	Physiological	Platforms	Potential	Power	Privacy
Research	Sensing	Sensor	Signals	Smart	Specific
Studies	System	Technologies	Temperature	Walking	Wearables
Addition	Quality	Textile	Key	Related	Concerns
Participants	People	Security	Parameters	Text	Years

Table 2: List of Most Frequent Terms (40 Frequency)

Further, the correlation analysis was done with top six frequent terms frequent terms. Some of the keywords emerging having high correlations were as under as per Table 3 below:-

Freq-uent Term	**<u>Relevant Terms with High Correlation (> 0.7)</u>**					
Sensor	Placement	Pressure	Shape	Embed-ded	Accuracy	Customis-able
	Impact	Position	Sensitivity	Communi-cation	Reliable	Expensive
Device	Minitat-urised	Monitored	Record	Regulation	Bulky	Accurate
	Scalable	Wireless	Obtrusive	Smart	Integrated	Worn
Data	Health	Accuracy	Large	Analysis	Commun-ication	Summarise
	GPS	Diverse	Wireless	Monitor	Encourage	purposes
Monito-ring	Measure-ment	Consistency	Analysis	Smart	Accuracy	Customiz-able
	Distant	Diagnoses	Fabric	Insight	Individual	Transmis-sion
System	Parameters	Stability	Accura-cies	Budget	Convergence	Customiz-able
	Deviation	Minimally	Resear-ched	Sensit-ivities	Synchronise	Temporal
Patient	Consent	Replacement	Adopting	Aftercare	Inconvenience	Lifestyle
	Wireless	Reassurance	Expectation	Anonymisation	Interfere	Acceptabi-lity

Table 3: Correlation Table of Most Frequent Terms

Histogram showed highest bars for Terms like Data, Device, Monitoring, Pressure, Sensor, Wearable, Technology and Information. The Word Cloud had biggest terms like health Technology, Monitoring, Patient, Individual, Sensor, Data, Wearability, System , Information and Pressure.

5.2. Identification of Challenges

Based on the most frequent terms the major challenges can be classified under following subheads :-

(a) Data Related.

(b) System Related.

(c) Device and Sensor Related.

(d) Patient Related.

(e) Monitoring and Miscellaneous.

Identified Challenges under each sub-head based on analysis of correlation data, Histograms and Wordcloud is as under :-

I. Data Related

i. Handling Big Data. Since there is continuous stream of data being collected. The data handling, interpretation, analysis comes under domain of Big Data. This entails confluence of technologies like big data, cloud computing, and IoT—the internet of things be fed create a database that is part of medical ecosystem. Using this resource, we can fully the data can be used in fields such as epidemiology, preventive medicine and telemedicine (3). The is a need to explore and analyse the gathered data to get correct insights. Further, high processing limits for computers and storage to store this data needs to be planned. To keep real time updates and recommendation techniques like parallel computing need to come to play. (23)

ii. Risk of data loss. As data is collected by a device and transmitted to a storage device, there will be a loss of data if there is a disconnection due to power outage or internet connectivity. This will result in incorrect health parameters being conveyed. Possible remedy is storing data temporarily in the device through buffering by creating some internal storage. (24).

iii. Security and Communication of Data. One of the major concerns with Data is its security and maintenance of confidentiality. Steps like encryption is the key element of comprehensive data – centric security (13).

iv. Interoperability of data from diverse heterogenous devices. Various kinds of wearable sensors present data in non-standardized , heterogenous data. Integrating this varied data received from the wearable sensors is a big challenge so that meaningful clinical diagnosis and decisions can be made. (25)

v. Data Accuracy Reliability of the data generated by many of the wearable sensors is still a suspect because of non-standardization of hardware and sensors being used in wearable devices (8).

II. System Related.

i. Threat of Excessive Monitoring. Consumer wearable may cause excessive and intrusive monitoring and transmitting of additional personal data that is vulnerable to be used for commercial or nefarious purposes(8).

ii. Security and Ownership. Ownership of data by production agencies and use of the same by third parties is a major concern. Usage of GPS on the devices along with user information like age , sex , health parameters can be exploited for various means in is a cause of concern (26).

iii. Communication of Wireless Means. Most of these devices communicate over wireless means which is vulnerable to hacking and interception of health data (27).

iv. Lack of Regulations . Most of the app market being used as an interface of these devices is un regulated and there are no mandatory provisions to address security and privacy concerns in design of these apps. This leading to many users discarding these apps for privacy concerns (28).

III. Sensor Related.

i. Customisable. Monitoring required may be Continuous of episodic or periodic. The compliance of the same to needs and requirements of different patients is the key. For example heart rhythm irregularities require continuous monitoring while a diabetic monitoring for glucose levels may require periodic monitoring (29).

ii. Embedded into Healthcare Ecosystem Data generated through these sensors cannot be read in isolation and there is need to integrate the same with the existing healthcare ecosystem like EHR and Hospital MIS (30).

iii. Placement. There is requirement and placement of sensors inside the body and subsequent extraction – which might raise issues of size of sensors, power supply issues of sensors and access to sensors for reading of the data (25) .

iv. Sensitivity and Accuracy. The data generated by humans need to picked up faithfully and accurately. The techniques like multi-sensing techniques, specifically in wearable sensors can prevent contamination of data by noise. Periodic accuracy check and self-calibration are the other issues that need to be addressed (3).

IV. Individual/ Patient Related.

i. Convenience. The design of the wearable device needs to such that it fits for purpose and is seamlessly adapted to user movements and lifestyle (31).

ii. Acceptability. There are instances where there is a stigma attached to the usage of wearable devices. Also, many users face technological and behavioural issues accepting these devices. (8).

iii. Consent and Ethical Issues**.** There are issues related to collecting of personal information without proper consent and ethical issues concerning usage of this information by third parties which is preventing adopting of these technologies. (25)

V. Miscellaneous

i. Cost and Health Disparity. The cost of the wearables vary as per brand, region, accessibility to technology. Most of the daily usage wearables which are commercially available are out of reach of many common people. This might result in health disparity with not all segments of the population deriving benefits from these devices (32).

ii. Regulations. Other area of concern is issue of inadequate regulation to avoid misuse of devices, ensuring standardisation, regulating correct handling and management of data. Also there need to be mechanism to verify claims made by manufacturers regarding accuracy and reliability of the devices (33).

iii. Connectivity Issues. Simple, secured and consistent connectivity of the device to enable easy data collection with subsequent transmission of data to a storage and ability to monitor at a medical station along with encryption requirements (24).

iv. Battery Life. Since most of the devices collect data over long period of time, there are concerns about the battery life and their ability to sustain the device of long period of time. Similarly design requirement of the devices to consume minimal power so that they can have extended battery life needs to incorporated during design stage and may raise cost issues (3).

v. Issues related to Wireless Networks. Communications across most of the wearable devices have been on wireless communication network. The various issues including security issues, technological protocol issues , design issues are impediments that need to overcome in these devices (25).

vi. Challenges in Smart Health Applications. The use of off-the-shelf sensors to track health functionality, physiology, and activity can lead to the detection of health hazards. Before biosensor systems with smart healthcare services can be extensively implemented, various technological difficulties must be overcome. Data processing goes from servers or cloud sites to devices, for example, because to a lack of system standards. Security, privacy, and energy efficiency are all issues that must be addressed.(34)

5.3. Conclusion.

Today, a wide range of medical wearable sensors exist that are already transforming the healthcare scene. Wearable devices are being utilised to manage general health and are being used both inside and outside of hospitals to impact healthcare. Remote monitoring with wearable sensors is the buzzword for new techniques to monitor metabolic, cardiovascular, and gastrointestinal disorders; sleep, neurology, movement disorders, and mental health amongst other things. There are still a number of technical and regulatory roadblocks to overcome before wearable sensors can be widely adopted in healthcare.

Way Forward.

To achieve Universal Health Coverage in India the importance of Wearable Medical Devices cannot be over emphasised. The challenges needs to be addressed at four levels viz. at Governmental or Policy level, at Providers level, at the level of Users and finally at the level of Developers, for them to realise their full potential. Some of the recommendations for each level are given below :-

At Policy Level

Governments need to clearly legislate and implement the national standards and laws for data handling, management , protection and punitive measures in case of misuse of data by any of the stake holders (35). There has to be systematic oversight of medical industry clearly mentioning relevant medical responsibilities and rights between doctors and patients.(3)

Most of the devices have high cost component. To enhance usage of these devices and to ensure health equity – government needs to regulate cost of these devices. Also, inventory list of mandatory wearable devices that can be held at various health echelons can be created so that these can be utilised by poorer section of the population. Inclusion of the provision of medical devices in various health insurance schemes can be thought of.

At Developer's Level

Data Security needs to be addressed at the developers level where in multi layered data control and management needs to factored at hardware and software levels. There has to be usage of encryption and authentication technologies by the manufacturer(35).

Manufacturers should provide built-in security to the device such as secure boot, secure chipsets, and functions for secure internal buffer data storage to handle data incase of loss of data stream. Further, integrating wearable medical devices into internet of things is required to be done.

There is a growing requirement to ensure interoperability and intra-operability between various wearable devices and existing systems of HMIS and HER. The developers need to looking into creating third party apps to enable easy communication of data between diverse systems. Also, there has to be a growing partnership between various stake holders in design and development to ensure this critical issue.

Technological advancement in wearable health devices to develop low-consumption and high-integration sensor technology; low-power high-performance battery technology; high processing efficiency medical chip technology; and human-computer interaction technology to improve information accuracy, information processing speed, extend battery life, and user experience (3).

There is a need to increased R&D efforts towards producing sensors with high accuracy and sensitive software to faithfully interpret the data emanated from these. High battery life and wireless communication methods will ensure the efficacy of these devices.

Design of the device should be such so that it is unobtrusive to patient comfort and activity requirement so that data can be collected in passive manner over prolonged periods. Miniaturisation, better ergonomic designs of the devices, long battery lives , better fabric design are key features that need to factored in at the design level.

At Provider's Level

Training in handling of big data needs to be integrated so that dynamic, updated and real-time health related inputs can be drawn from the data collected (35). Utilising of technologies like Artificial intelligence and cloud computing is inescapable incase the full potential of the devices is to be realised.

With plethora of data being collected continuously by wearable devices, getting informed consent from patients is very important. Also, it needs to be clarified what all data is being collected and which all third parties can access the same. Strict in-house checks and balances to ensure that this data is not used in intended way have to be created.

There is a requirement to plan and create training schedules for the health practitioners to so that they are aware of availability , utilisation, integration of these devices along with interpretation of data emanating out of these devices.(36)

At User's Level

The usage of wearable devices have risk of increased emotional burden and distraction for the patients. The issue of technology addiction is something we need to be aware of. At the same time, enhancing user awareness about the benefits and importance of these devices in addition to bringing a social awareness will help create opportunity for increased acceptance of these devices.

There has been inadequate evidence supporting the safety, accuracy, effectiveness of wearable medical devices. The issues is compounded with non-standardised products competing in commercial market, where quality may be compromised to reduce costs. This can be addressed by vetting of wearable technologies through randomized controlled trials with results available in peer-reviewed publications.(37)

Finally, text mining is a potent tool and can be used to effectively browse large amounts of data to derive meaningful insights into any subject. With ever increasing pool of research and big data available on wearable devices the thesis can be a building block into a systematic research to define factors that can enhance usage of wearable medical devices.

Appendix A

R SCRIPT USED WITH EXPLANATION

```
#installing tm package
install.packages("tm")
#loading required package :NLP
library(tm)
#creating a corpus with 40 files in folder corpusA
docs<- Corpus(DirSource('/Users/amitl/Downloads/dissertation/corpusA'))
#inspect a particular document
inspect (docs)
# start pre-processing. Cleaning the data by using Tospace function for removing hyphen,
numbers, symbols like colons, underscores etc. Also, the code ensures that if colon is
removed between two words, they don't join to become one by creating a custom transformer
- content transformer.
Tospace <- content_transformer(function (x, pattern) {return (gsub(pattern, " ",x))})
docs <- tm_map (docs, Tospace, "-")
docs <- tm_map(docs, Tospace, ":")
docs <- tm_map(docs, Tospace, "'")
docs<- tm_map(docs, Tospace, " _")
# Remove Punctuations
docs <- tm_map(docs, removePunctuation)
# Transform the entire corpus to lower case. Required because R is case sensitive.
docs <- tm_map(docs, content_transformer(tolower))
# Remove numbers. As numbers are not of much value in our text analysis.
docs <- tm_map(docs, removeNumbers)
# Remove standard stopwords using "English" and "SMART" dictionaries
docs <- tm_map(docs , removeWords , stopwords ("english"))
docs <- tm_map(docs , removeWords , stopwords ("SMART"))
# Remove standard custom stopwords identified through iterations
docs <- tm_map(docs , removeWords
c("torous","day","term","include","due","rate","ppd","time",
```

```
"’","day","term","due","crossref","home"
,"able","based","user","full","free","users","insole","gait","the","long","low","high","this","st
udy"))
# Strip extraneous white space
docs <- tm_map(docs , stripWhitespace)
# Inspect output
writeLines (as.character(docs[[40]]))
# Install SnowballC package for stemming
install.packages ('SnowballC')
library(SnowballC)
# Stemming the document by removing prefixes and suffixes of similar words – like using,
used, usable
docs <- tm_map(docs, stemDocument)
# once stemming is done certain words might be stemmed with wrong spellings. These can be
corrected by undermentioned function

docs <- tm_map(docs, content_transformer(gsub), pattern = "devices", replacement =
"device")
docs <- tm_map(docs, content_transformer(gsub), pattern = "sensors", replacement =
"sensor")
docs <- tm_map(docs, content_transformer(gsub), pattern = "systems", replacement =
"system")
docs <- tm_map(docs, content_transformer(gsub), pattern = "individuals", replacement =
"individual")
docs <- tm_map(docs, content_transformer(gsub), pattern = "patients", replacement =
"patient")

# Create a Document word matrix to check the frequency of words in various documents. All
the documents arranged in the row and words arranged in the column
Dtm<- DocumentTermMatrix(docs)
#inspect the part of the matrix
inspect(Dtm[1:40,1:3000])
#collapse matrix by summing over columns- this gets total count over all documents for each
term
freq<- colSums(as.matrix(Dtm))
```

```
#length should be total number of terms in the corpus
length (freq)
#sort the frequency of the words in ascending order
ordr <- order(freq, decreasing = TRUE)
#list most frequent words
freq[head(ordr)]
#list least frequent words
freq[tail(ordr)]
#remove words
dtmr<-DocumentTermMatrix(docs, control=list(wordLengths=c(4,20), bounds = list(global =
c(3, 27))))
freq<- colSums(as.matrix(dtmr))
# length should be total number of terms
length(freq)
#create sort order (asc)
freq<- colSums(as.matrix(Dtm))
#create sort order (asc)
ordr <- order(freq, decreasing =TRUE)
#inspect most frequently occurring terms
freq[head(ordr)]
#inspect lease frequently occurring terms
freq [tail (ordr)]
#list the most frequent terms. Lower bound specified as second argument. Items which have
occurred atleast 80 times.
findFreqTerms(Dtm, lowfreq=40)
#find correlations between these frequently occurring words using findAssocs function
findAssocs(Dtm,"data", 0.75)
findAssocs(Dtm,"wearable", 0.6)
findAssocs(Dtm,"challenges",0.65)
findAssocs (Dtm, "healthcare",0.65)
# draw histogram
install.packages("ggplot2")
library(ggplot2)
wf=data.frame(term=names(freq),occurences=freq)
```

```
p <- ggplot(subset(wf, freq >50), aes(term, occurences))
p <- p +geom_bar(stat ="identity")
p <- p+theme(axis.text.x=element_text(angle=45, hjust =1))
p
#draw wordcloud
install.packages ("wordcloud")
library(wordcloud)
#colour palette of Word cloud
install.packages("RColorBrewer")
set.seed(42)
wordcloud(names(freq),freq, min.freq=40, colors=brewer.pal(6,"Dark2"))
```

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