DESIGNING AND EVALUATION OF ELECTRONIC HEALTH RECORD SOFTWARE: ADVERSE DRUG REACTION REPORTING AMONG DIABETES PATIENTS

Saloni Gupta
M. Pharmacy, Department of Pharmacology, Seth G. L. Bihani S. D. College of Technical Education, Sri Ganganagar (Raj.), salonigupta290890@gmail.com.

Sudeep Bhardwaj
Professor, Department of Pharmacology, Seth G. L. Bihani S. D. College of Technical Education, Sri Ganganagar (Raj.), kaka_sudeep@rediffmail.com.

Abstract

The objective of conducting this study is to design and evaluate Electronic Health Record (EHR) software to rationalize its usage of automating the manual day-to-day paper based record system. It was designed by globally reviewing various health record related software systems. The designed EHR software was evaluated by running it in a private hospital under physician specialized in diabetes. Data entry of 200 patients was conducted using EHR software consisting of various key functionalities, for 4 months. 114 Diabetic patients were segregated for Adverse drug reaction (ADR) reporting, which is an important tool of EHR. Data entered was analyzed statistically using ANOVA test, student's t test and chi square, etc. The average no. of males and females were found to be 47.5% and 52.5% respectively out of total. 64.5% patients were aware towards their health depending on follow up visits. A significant difference was observed between patients having BMI 23-25 & 25 kg/m^2. Prescribing pattern of diabetic patients was observed using previous history every month in which maximum no. of patients (57.01%) were observed to be using oral hypoglycemic agents. ADRs were reported & analyzed, an awareness of 95% was found towards ADR by physician. Thus, it may be concluded that electronic health records can successfully be used in management and planning of healthcare facilities and services and the production of health care statistics. Further study is suggested to reveal the precise designing methodology and significance of electronic health record software.

Keywords: *EHR- Electronic Health Record software, diabetes, ADR- Adverse drug reaction, healthcare.*

1. INTRODUCTION

Electronic Health Records (EHRs) are patient's health records which are a soul Source of health information and proves to be an important milestone for hopefully aiding efforts for safeguarding their health, because as medical care gets more and more complex & new information is already overwhelming physician's capacity to treat patients with the latest information, they need new technologies to help them cope [1]. The electronic health record is an important compilation that reflects the entire health history of a patient's health in the digital version which includes documented data on past and present illnesses and treatment written by health care professionals including patient's demographics, medical history, lab tests, etc. [2]. The main feature of the EHR is the incorporation of extra patient information beyond what is presented with a prescription or its history [3].

In an electronic world, it eliminates the need to track down a patient's previous paper records because the current, largely paper-based medical records world, invaluable data is more often than not unavailable at the right time in the hands of the clinical care providers to permit better care which has been possible just with one click of mouse in EHR that paper medical records can't deliver [4]. As a result, many healthcare professionals and administrators want to move from a paper to a paperless environment [5]. Also, there are drawbacks associated with using PATIENT-HELD HEALTH RECORDS (record kept by the patient), however, often outweigh their usefulness.

"If suppose in the future, any Health officials come & ask for records. To get the information from register, it would take time. But by computer (EHR), it can be accessed immediately".

A major boon to healthcare professionals through this EHR software system is that it efficiently saves their time after bringing it into use, but in 2005, Pizziferri et al reported that EHRs may take long time for physicians to use than paper-based systems which is concerned as a barrier in its adoption [6]. Patients will be uniquely identified at all times with a UID number. Today with the vast development of technology in the world responding to the varied and complex needs for interchanging clinical information among healthcare providers to improve the quality of healthcare services seems more practical than any time before for e.g. Personally Controlled Electronic Health Record (PCEHR) in Australia, Canada Health Infoway in Canada aims to accelerate development of EHR, etc. [7], [8]. Highlighting its status in Indian scenario, EHRs are still limited, but progress is being made in a number of instances. Some approaches the country has advanced so far in its development are computerized data management system run by AIIMS, New Delhi, National eHealth Authority (NeHA) for patient's health record standardization, storage and exchange, as part of the government's Digital India programme [9], [10]. This and other national experiences described above clearly highlight that there is a need for upscale such a system to national & international level.

An overview of electronic functionalities of a standard EHR software system is represented in the following Figure 1.

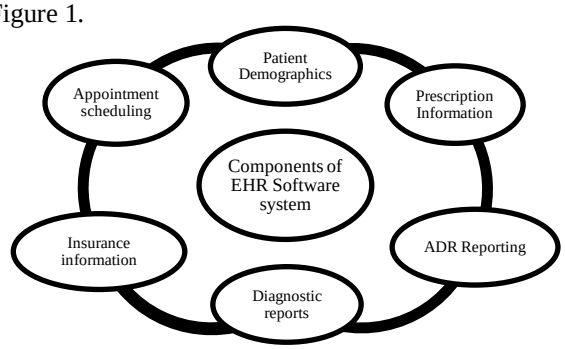

Figure 1. Electronic Functionalities/Key Components of an EHR: An Overview

Additionally, each medicinal product requires adverse drug reactions monitoring to ensure patient safety to prevent or reduce harm to the patients, which need specialized systems so that serious and mild ADRs which tend to go unreported can be successfully reported using EHR [11]. In 2014, Qassim et al reported about tragedy of the Thalidomide disaster which encouraged many countries to establish Pharmacovigilance (PV) systems for detecting ADRs of drugs available in the market [12].

Hsiao et al observed that Physician's use of EHR software has increased from 18% in 2001 to 57% in 2011 and **2 out of 3 people** would consider **switching** to a physician who offers access to medical records through a **secure** Internet connection [13]. Thus, in all regions, today's rapid globalization and the expansion of the healthcare sector is making this service more useful and essential than ever before. Our goal is to become the channel of choice for coordinating Healthcare provider's efforts to safeguard patients everywhere.

2. MATERIALS & METHODS

2.1. Materials

The following are the materials that were used during research work:

- A Laptop/Computer system with webcam.
- Furniture provided for computers.
- The EHR Software installed with a password for its access.

2.1.1. Technology for the development of EHR software system

Based on our experience, these can be broadly divided into software being used and the hardware on which the system is operational. The software can be described in terms of the core database, the user interface and the operating system (OS).

Since the database stores personal information on a large population where they can be identified by names, data security is a vital concern. The hardware and software setup is access controlled with multiple passwords. Antivirus software is installed on the machines [9]. Following are the main requirements for development of technology:

- Technical support: Computer operator/Software developer
- Minimum System Requirements for development of Hardware are:
  Windows XP, 512 MB Ram, .Net Framework 4.0.
- Framework required for the development of EHR software system is given in Table No. 1.

Table No. 1. Framework of EHR software system

Features	Used in Development of Software (EHR)
Operating System	Windows 7
Processor	Intel Core i3 CPU M 350 @ 2.27 GHz, 4 GB RAM
Software Language	.Net Framework 4.0 (Visual studio 2010)
Database	Microsoft Access

2.2 Study design

2.2.1. Search strategy for Literature: [14]

The articles identified from the various search strategies such as Pubmed, Medline, Elsevier, etc. were considered to be academic peer-reviewed articles if they were to be included in our research. Further, they were assessed and had to satisfy the following criteria to be included:

- Written in English,
- Full text available online,
- Focused on hospital-wide EHR implementation,
- Meeting established quality criteria

The Table No. 2. shows an overview of the keywords used for literature review:

Table No. 2. Overview of the search strategy keywords

(1) "Electronic Health Record" + implement + "health care"
(2) "Electronic Patient Record" + implement + hospital
(3) "Electronic Patient Record" + implement + "health care"
(4) "Electronic Medical Record" + implement + hospital

2.2.2. Development of EHR Software System*:*

Designing of EHR

Various software systems were reviewed and based on needs of physician and patients, present software was designed. Various electronic functionalities/key components were designed which are summarized as:

- Login ID
- Patient search window
- Entry of patient information which includes following functionalities:

i. Administrative system components/Patient Demographics
ii. Anthropometric measurements
iii. Diagnostic and Laboratory systems
iv. Clinical/Prescription documentation
v. Adverse drug reaction Reporting (ADR)

2.3. Working/Methodology of data collection in EHR*:*

This EHR software system allows for an entire patient history to be viewed, without the need to track down patients's previous medical record. Before evaluating performance of the EHR software system through its trial run, it is important to be considered that where does the data entry in Electronic Health Record begins?.....

- It begins with the assignment of Unique ID number to each patient electronically at the time of enrollment. This UID is used as a primary key in the database.
- Before data entry, major points were assured related to patient counseling, i.e. the questions asked are clear & understood by the person being interviewed because many patients who come to a hospital or clinic are nervous and may have difficulty with some simple questions. They should be put at ease and be given time to respond. Also, the data collected must be written clearly in the correct form [2].
- Then, the collection of data begins in software through personal patient counselling and data was entered in the manner in which various electronic functionalities (key components of the EHR software system) which are mandatory and are related to each other dynamically and sequentially.
- Data is entered in a standard electronic format, starting with the following pattern:

2.3.1. PATIENT DEMOGRAPHIC DATA

In order to identify patients, their demographic detail, i.e. their personal data is entered. It consists of name, age, sex, gender, date of registration, complete postal address, name of Physician referred by along with the allergy details if any. Figure No. 2. shows the Demographic data of patients.

2.3.2. ANTHROPOMETRIC DATA

This consists of vital signs such as body mass index, blood pressure, blood sugar, pulse rate of patients. These data were measured manually using under mentioned clinical measurement methods and was entered electronically.

- ***Measurement of Body mass index (BMI)***

BMI of all the diabetic patients was recorded. Body weight & height were measured.

BMI was calculated by default in the EHR software as per standard formula kg/m^2 [15]. Patients depending on varying BMI, were divided in following categories: less than 18, 18-20, 20-23, 23-25, more than 25.

- ***Measurement of Blood Pressure (B.P.)***

Blood pressure was measured by the auscultatory method with the use of a stethoscope and a sphygmomanometer. An inflatable cuff was placed around the upper left arm, at the same vertical height as the heart, as per JNC VII Guidelines [16].

- ***Measurement of Blood Glucose***

Blood sugar was measured using glucomeasurement strips with strip method during each patient visit. It was done by using Glucometer (DiabaScan).

- ***Measurement of Pulse rate***

Pulse rate was measured by placing the index and second fingers on patient's inside part of wrist. Fingers were positioned just below the base of the thumb to take the radial pulse at the wrist. Figure No. 3. shows Anthropometric data of patients.

2.3.3. DIAGNOSTIC AND LABORATORY SYSTEMS

Based on clinical measurement and lab. data, values in alphanumeric form were entered in the respective section. This section covers various screening tests such as liver function test (LFT), lipid profile, complete blood count (CBC), thyroid test, etc. Values written on reports were

entered into software along with the attachment of reports in digital format using a webcam. Figure No. 4. shows the Laboratory/Diagnostic data of patients.

2.3.4. CLINICAL / PRESCRIPTION DOCUMENTATION

This functionality is comprised of disorders of the patients along with their duration, complete information about drugs prescribed related to all disorders which covers dose, dosage form, expiry date, therapy date started, batch no., etc. Data was entered in this section from manual prescription along with its attachment in digital format. This is the most important part of a patient's health record. Figure No. 5. shows the Prescription documentation of patient.

2.3.5. ADVERSE DRUG REACTION REPORTING

Adverse drug reaction reporting forms the core of postmarketing surveillance and the identification of unusual patterns of adverse effects has led to the withdrawal or restriction of many medicines since the World Health Organization began the international drug monitoring programme in 1971 [17]. Keeping this in mind, this EHR software here proves to be beneficial for the development of a novel Adverse drug reaction reporting system for reporting unreported ADRs.

In patients having ADR; all drug details, the nature of reaction, the outcome and steps taken for its treatment such as medicine discontinued or changed, is assessed along with type of ADR. ADR reporting was restricted to only patients suffering from Diabetes mellitus as the Physician under whom the research was carried out, was specialized in Diabetes.

Figure No. 6. shows Adverse drug reaction reporting functionality of EHR

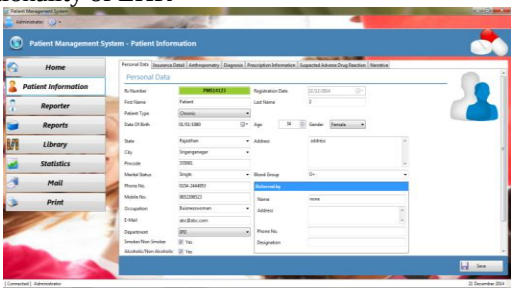

Fig. No. 2. Demographic data of patients

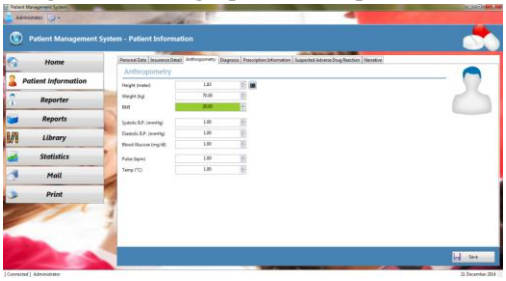

Fig. No. 3. Anthropometric data of patients

Fig. No. 4. Diagnostic/laboratory reports of patients

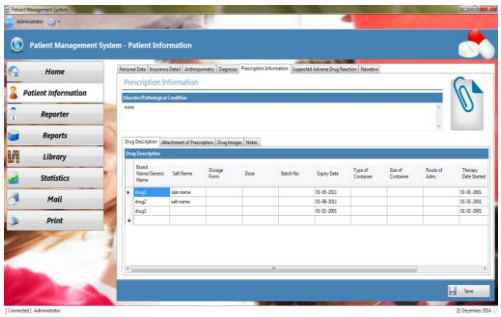

Fig. 5. A patient's Prescription documentation

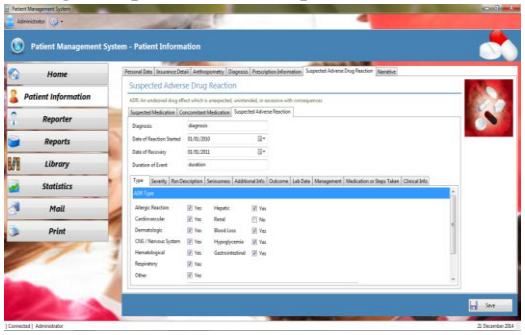

Figure No. 6. Adverse drug reaction reporting of a patient

2.4. Follow up

During the next visit of previously enrolled patients, UID is used to access their health record information electronically. Patients were revisited according to the scheduled appointment. It allows for an entire patient history to be viewed by the physician. Using the previous prescription history, new prescription is prepared by the physician, taking steps to improve health conditions of the patients as well as identifying ADR related to previous prescription pattern.

2.5. Biostatistical interpretation of Quantitative data:

The Results were statistically analysed using the GraphPad and Instat statistical software program. The

results are presented at 95% confidence interval (CI). All data were analyzed by the chi square test, student's t test, ANOVA; P < 0.05 was considered as level of significance.

- ***Chi square test***
- ***Analysis of Variance (ANOVA)***
- ***Student's t test***

3. RESULTS AND DISCUSSION

3.1. RESULTS

3.1.1 Initial trial run of Electronic Health Record for evaluation of its performance:

During the 6 month trial run period, data of a total 200 patients from OPD (Out patient department) entered by one-to-one interaction using Electronic Health record software and reviewed this data further for analysis of the results in which there were 95 males (47.5%) and 105 females (52.5%), shown in Figure No. 7. and baseline clinical parameters are shown in Table No. 2. Each day data of 3-4 patients, including new patient or the patients with follow up was entered in the time duration of about 20-30 minutes for each patient. Prior to data entry, each patient was enrolled with a Unique ID (UID) number. After which the data collection in EHR included entry of information of patient in various Electronic functionalities mentioned above. The Steps followed for data entry of each patient in these functionalities using EHR software are shown in Table No. 3.

Table No. 2. Baseline clinical parameters of total patients

Clinical Parameteres	No. of Patients (N = 200)
Age	48.39±1.074
Male	95 (47.5%)
Female	105 (52.5%)
BMI (Kg/m^2)	26.94±0.380
Smoker	10 (5%)
Non smoker	190 (95%)
Alcoholic	8 (4%)
Non Alcoholic	192 (96%)
Urban	140 (70%)
Rural	60 (30%)

Table No. 3. Various Electronic Functionalities of EHR showing various different health parameters for data entry

Electronic Functionalities	Required Health parameters
Patient Demographics	Name with complete postal address (urban: 70%, rural: 30%), sex, age, allergy status, unhealthy habits like smoking (smoker: 5%, non smoker: 95%), alcohol intake (alcoholic: 4%, nonalcoholic: 96%, physician reference, etc.
Anthropometric data	BMI (height-weight in kg/m^2) (26.94±0.380), B.P., Blood sugar, temperature, pulse rate, etc.
Prescription Information	Disorder diagnosis with duration, medication description as dosage form, salt name, expiry date, etc.
Diagnostic reports	Includes essential health screening, having hematological data, LFT, KFT, lipid profile, thyroid, etc. along with the attachment of reports.

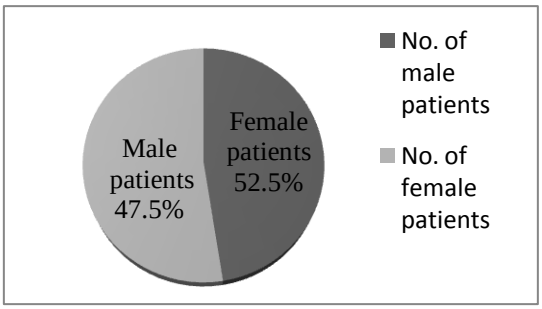

Figure No. 7. Gender wise distribution of total 200 patients

3.1.2 Follow up of enrolled patients

The Patient is scheduled for an appointment on first time data entry as per the directions given by the physician in schedule appointment table. Enrolled patients were reminded by a phone call to their follow up session on the scheduled date. It was identified that not all the patients visited at the scheduled time given by the physician so an exercise to observe the awareness towards their own health was done by identifying patients at high risk as well as low risk.

Awareness

Identification of no. of patients who had followed up and those who hadn't. The present study revealed that 64.5% of the patient population were aware and 35.5% unaware towards their own health. It was also observed that no. of patients were reduced in each follow up visit which directly or indirectly signifies their awareness towards their own health.

Patients at high risk:

High risk refers to patients having disorders which needs regular monitoring such as hypertension, diabetes, pregnancy, CVS related problems, mental disorders, thyroid, etc. Table No. 4. shows the follow up status of patients at high risk. No significant difference was

observed between the patient's awareness related to diabetes and CVS disorders (P = 0.6453, χ^2 = 0.2121, df = 1. Odd ratio = 0.8273, RR = 0.9333).

Patients at low risk:

Low risk refers to patients suffering from some infection, pyrexia, GI discomfort, analgesia, etc. These disorders are treated in a matter of time or depending on drug dose duration and does not long lasts.

Table No. 4. Follow up status of patients at high risk

Disorders	Total no. of Patients	No. of patients with follow up	No. of patients who didn't follow up	Awarenes s	P value	X^2, df	Odd ratio	Relative risk (RR)
Diabetes	114	70 (61.40 %)	44 (38.59 %)	61.40 %	0.6453	0.2121, 1	0.8273	0.9333
CVS related disorders • HT	76	50 (65.78 %)	26 (34.21 %)	65.78 %				
Pregnancy	10	9 (90%)	1(10%)	= or > 90%				

3.1.3. Baseline clinical parameters of Diabetic patients

- ***Comparison of BMI during follow up:*** When BMI was compared using one way ANOVA in 40 regular visited patients, a significant difference was not observed between the various sessions (P > 0.05) (Table No. 5.).

Table No. 5. BMI Comparison during follow up in Diabetic patients

Session I (N=40)	Session II (N=40)	Session III (N=40)	P value
25.688±0.761	25.936±0.799	25.916±0.800	0.969

- ***Comparison of BMI in type II DM patients during follow up***

Maximum no. of patients was observed, using unpaired student's t test, with 23-25 Kg/m^2 group of BMI (10) and above 25 Kg/m^2 BMI (18) in the first session. During follow up, no. of patients increased in Session II with BMI above 25 kg/m^2 (19). A significant difference was observed between patients having BMI 23-25 kg/m^2 (24.14±0.149) and those with above 25 kg/m^2 (29.06±0.98) in session I (P < 0.001). Extremely significant difference was observed between 23-25 kg/m^2 group of patients (23.98±0.202) and those with above 25 BMI (29.31±0.991) in session II (P < 0.0001). In session III, very significant difference was observed between patients with 23-25 BMI (24.06±0.212) group and those with above 25 BMI (29.28±0.985) (P < 0.001).

A Significant difference was observed in each preceding session in BMI, shown in Table No. 6.

Table No. 7 shows comparison of BMI in Type I DM patients during their follow up. Table No. 8. shows comparison of BMI in gestational DM during their follow up.

Table No. 6. BMI Comparison of Type II DM follow up patients in every session

BMI	No. of Patients	I Session	P value	No. of Patients	II Session	P value	No. of Patients	III Session	P value
< 18	1	16.80		1	16.55		1	17.00	
18 to 20	1	18.00		1	18.82		1	18.60	
20 to 23	1	21.85		1	22.47		2	22.16	
23 to 25	10	24.14±0.149	0.0011*	9	23.98±0.202	0.0008***	8	24.06±0.212	0.00024***
> 25	18	29.06±0.98		19	29.31±0.991		19	29.28±0.985	
Total No. of Patients	31			31			31		

* significant, ** very significant, *** extremely significant

Table No. 7. BMI Comparison of Type I DM Follow up patients in every session

BMI	I Session	II Session	III Session
< 18	14.42	14.42	13.94
18 to 20	18.61	18.93	18.28
20 to 23	22.19	21.94	22.15
23 to 25	23.69	23.28	24.04
> 25	26.22	26.80	27.00
Total No. of Patients	7	7	7

Table No. 8. BMI Comparison of Gestational DM Follow up patients in every session

- ***Age wise distribution of Diabetic patients***

Patients were divided into various age groups and were observed maximum no. of them as 35 (30.97%) and 27 (23.89%) in the age group 51-60 yrs and 41-50 yrs respectively, shown in Table No. 9.

Table No. 9. Age group wise division of Patients showing their percentage in each group

Age Groups (Age in yrs)	No. of Patients in each Age Group	Percentage of Patients in each Age Group
1-10	2	1.76 %
11-20	3	2.65 %
21-30	10	8.84 %
31-40	14	12.38 %
41-50	27	23.89 %
51-60	35	30.97 %
61-70	16	14.15 %
71-80	5	4.42 %
81-90	1	0.88 %

3.1.3. ADR Reporting

Before ADR reporting and during the trial run of software system, diabetic patients (114) were segregated and then ADR reporting was initiated. Out of total, 13 had Type I DM (Diabetes mellitus) and 99 had Type II DM & 2 were suffering from Gestational Diabetes. Extremely significant difference was observed among diabetic patients with other disorders and those without any other disorder ($P < 0.0001$, $\chi^2 = 15.96$, df = 1, Odd ratio = 0.078, RR = 0.276).

No. of patients suffering from Diabetes Mellitus with or without other disorders (Table No. 10.):

Type I DM – patients without any other disorder were 11, Type I DM – patients with other disorders were 3

Type II DM – patients without any other disorder were 22, Type II DM – patients with other disorders were 76

Gestational – Patient with the disorder was 1, Gestational – Patient without disorder was 1

Table No. 10. No. of Patients suffering from DM with or without other disorders

BMI	I Session	II Session	III Session
< 18	-	-	-
18 to 20	-	-	-
20 to 23	-	-	-
23 to 25	-	-	-
> 25	27.62	28.03	28.58
Total No. of Patients	2	2	2

No. of Patients / Type of DM	Patients with other disorders	Patients without any other disorder	Total no. of Patients	P value	X^2, df	Odd ratio	Relative ratio
Type 1 DM	3	11	14	P < 0.0001	15.96, 1	0.078	0.276
Type II DM	76	22	98				
Gestational	1	1	2				

- ***Prescription pattern of Diabetes Mellitus:***

Different classes of Anti diabetic therapy were used for the management of Diabetes Type I And Type II. Common classes of anti diabetic therapy with their Prescribed percentage in Type II DM patients are shown in the Table No. 11. and Figure No. 8. Monotherapy and Combination therapy of some common classes of Anti diabetic drugs in Type II DM patients & Type I patients are shown in Table No. 12 & Table no. 13, respectively. Based on no. of patients receiving oral therapy/insulin therapy/Combination therapy of oral & Insulin, they were classified, Figure No. 9. shows percentage of oral hypoglycemic agents and Insulin preperations prescribed.

Table No. 11. Prescribed percentage of common classes of Anti diabetic therapy in Type II DM Patients

BIGUANIDES (Metformin)						%
Metformin Monotherapy (A)	**Metformin Combination Therapy (Fixed dose combination) (B)**				**Both (A & B)**	
14	26				42	74.54%
SULPHONYLUREA (SU) (Glimepiride, Gliclazide, Glipizide, Glibenclamide)						
Monotherapy	**Combination Therapy**					
	Fixed dose combination of SU	Fixed dose combination of SU with another drug	SU with fixed dose combination	Fixed combination of SU with Insulin Therapy	SU with Insulin Therapy	
-	19	23	7	19	2	63.63%
THIAZOLIDINEDIONES [Pioglitazone (PG)]						
Monotherapy	**Combination Therapy**					

	PG along with other Fixed dose combination	PG with other drugs	Fixed dose combination of PG	
-	6	1	1	7.27%
α - GLUCOSIDASE INHIBITORS (Voglibose)				
Monotherapy	**Combination Therapy**			
	Voglibose along with other fixed dose combination	Voglibose with other drugs	Fixed dose combination of Voglibose	
-	2	1	1	3.63%
DPP-IV INHIBITORS (Vidagliptin, Sitagliptin)				
Monotherapy	**Combination Therapy**			
	Along with other fixed dose combination	Fixed dose combination	Fixed dose combination with other drugs	

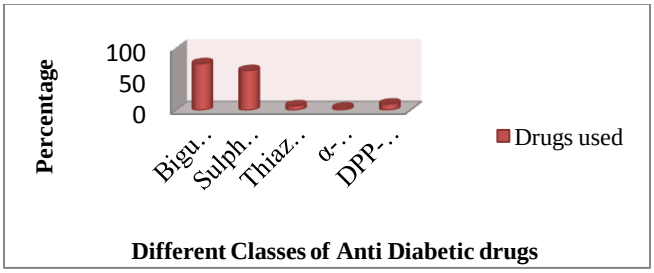

Figure No. 8. Prescribed percentage of common classes of anti diabetic therapy in Type II DM patients

Table No. 12. Monotherapy and Combination therapy of some common classes of Anti diabetic drugs in Type II DM patients

MONOTHERAPY		**COMBINATION THERAPY**	
Classes	**No. of Patients**	**Combinations given to the patients**	**No. of Patients**
Biguanides • Metformin	27	Biguanides + Sulphonylurea • Metformin + Glimepiride • Metformin + Glipizide • Metformin + Glibenclamide • Metfomin + Gliclazide	31 10 9 8
Thiazolidinediones • Pioglitazone	7	Biguanide + DPP-IV Inhibitors • Metfomin + Sitagliptin	8
α- Glucosidase Inhibitors • Voglibose	4	Biguanides + α-Glucosidase Inhibitors • Metformin + Voglibose	2
Sulphonylurea a)Second generation • Glimepiride • Gliclazide • Glipizide	4 3 2	Sulphonylurea + Thiazolidinediones • Glimepiride + Pioglitazone	1
DPP-IV Inhibitors • Sitagliptin • Vidagliptin	1 1	Biguanides + Sulphonylurea + Thiazolidinediones • Metformin + Glimepiride + Pioglitazone	1

Table No. 13. Monotherapy and Combination therapy of some common classes of Anti diabetic drugs in Type I DM patients

MONOTHERAPY		**COMBINATION THERAPY**	
Classes	**No. of Patients**	**Combinations given to the patients**	**No. of Patients**
Insulin Human	2	30% soluble Insulin Aspart, 70% Insulin Aspart crystallized with Protamine	8
Insulin Aspart	3	Insulin 50%, Insulin isophane 50 %	14
Insulin Glargine	6	Human Insulin 25%, Human Isophane 75%	1
Insulin Lispro	1	50% Insulin Lispro Protamine Suspension and 50% Insulin Lispro injection	1

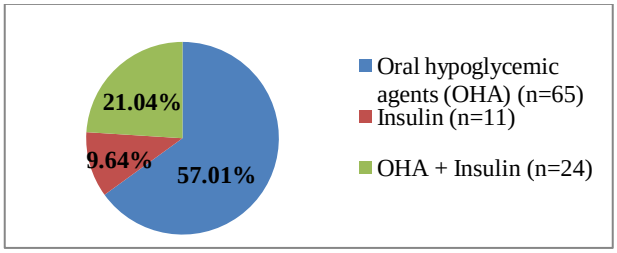

Figure No. 9. Percentage of oral hypoglycemic agents and Insulin preperations prescribed

Prescription pattern among Previously diagnosed/Newly diagnosed patients (Table No. 14.):

- *Previously diagnosed Patients-95*

Patients on Monotherapy- 14, Patients on Combination therapy- 81

From 95 patients, 85.26% were on combination therapy and only 14.74% were on monotherapy so the result of the present study revealed a significant problem of resistivity.

- *Newly diagnosed patients- 13*

Patients on Monotherapy- 8, Patients on Combination therapy- 5

It was observed that newly diagnosed patients were initially prescribed monotherapy, 61.53% were on monotherapy as compared to 38.57% on combination therapy. Table No. 14. shows no. of patients taking mono or combination therapy among previously diagnosed and newly diagnosed. Figure No. 10. shows total no. of patients along with patients on monotherapy as well as combination therapy. Extremely significant difference was observed between patients having monotherapy and those having combination therapy ($P < 0.0001$).

Table No. 14. No. of Patients taking mono or combination therapy among previously and newly diagnosed

Therapy given	Previously diagnosed patients	Newly Diagnosed Patients	P value
Monotherapy	14 (14.74%)	81 (85.26%)	0.0006***
Combination Therapy	8 (61.53%)	5 (38.57%)	

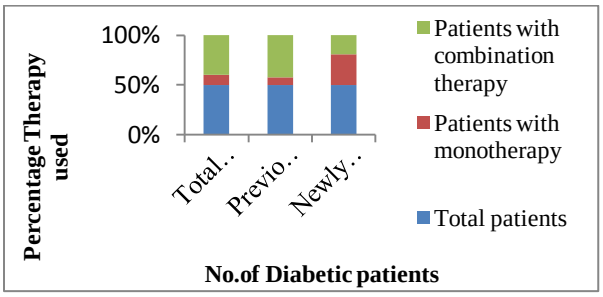

Figure No. 10. No of total diabetic patients along with previously diagnosed and newly diagnosed

ADR Reporting:

ADR reporting is an imp. tool to be used in segregated Diabetic patients (114), out of which females & males were 58 and 56, respectively. Out of total Diabetic patients, 40 of them did follow up or regular visit and ADR reporting was done in their each preceding session. Most frequently observed ADRs in diabetic patients were analysed and were then divided accordingly**.** The proportion of women in the ADR group (62.5%) was slightly but significantly higher than the proportion of men in the ADR group (37.5%). While the proportion of women in the non ADR group (27.19%) was significantly higher than in the ADR group (21.92%). Figure No. 11. shows the percentage awareness among physician towards Adverse drug reaction. No. of patients reported with each ADR are also shown in the following Table No. 15.

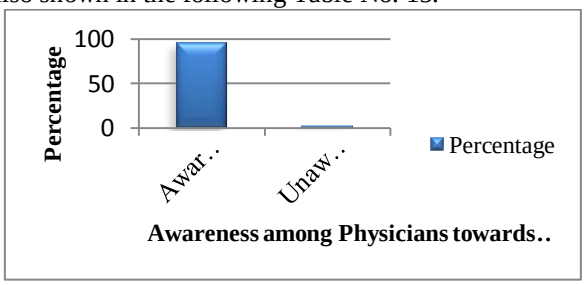

Fig No. 11. Awareness of Physician towards action taken for ADR due to Diabetes

Table No. 15. Reported /Unreported Observed Adverse Drug Reactions

Adverse Drug Reactions	Reported/ Unreported	No. of Patients	Action taken	Percentage Awareness regarding ADRs
Weight gain	Reported	2	The dose of Metformin increased	5% aware
Weight loss	Reported	5	The dose of metformin reduced	12.5% aware
Hypoglycemia	Reported	5	The dose of Insulin reduced	12.5% aware
Gastroesophageal reflux disease	Reported	3	A medicine given to treat GERD	7.5% aware
Muscle pain or Cramping (Including Headache, body ache)	Reported	6	NSAIDs	15% aware
Fast or shallow breathing	Reported	2	No action taken	5% unaware
Sleepiness	Reported	3	A medicine given (Sedative)	7.5% aware
General feeling of Discomfort	Reported	3	A medicine given (Anti anxiety)	7.5% aware
Loss of Appetite	Reported	2	Enzymes	5% aware
Abdominal discomfort	Reported	2	Antibiotic given (levofloxacin)	5% aware

Lower back pain	Reported	2	NSAIDs has given	5% aware
Skin rashes	Reported	2	An antibiotic given (Stafcure LZ)	5% aware
Leg edema	Reported	1	The dose of Insulin increased	2.5% aware
Hyperglycemia (in Pregnancy)	Reported	2	The dose of Insulin increased	5% aware

3.2. DISCUSSION

The analysis of data revealed advantages and limitations of using EHR software system. It was observed that paper prescriptions are missing 25% of the time [18]. Acc. to another study carried out showed, even if the prescription available, specifies are always missing in 13.6% of prescriptions [19]. In many countries during the 1980s, manual medical record systems were replaced by computerized medical information systems (MIS) in which facts concerning healthcare of individual patients are stored and processed on computers and now with progress over the years, the system has developed further which led to replacement of hospital information systems (HIS) with MIS in many countries [2]. The experience of working on such software with a computerized system, resulting in a high service coverage statistics indicate the feasibility and desirability of implementing such a system for strengthening the healthcare system all around [20]. EHR should improve patient safety through many mechanisms:

(1) Improved legibility of clinical notes & Improved access anytime and anywhere,

(2) Reduced duplication,

(3) Clinical decision support that reminds clinicians about patient allergies, correct dosage of drugs, etc.,

(4) Electronic problem summary lists provide diagnoses, allergies and surgeries at a glance [21].

Following discussion meets the above mentioned considerations regarding the use of EHR software system.

During the 6 month trial run period, data of a total 200 patients from OPD (Out patient department) entered by one-to-one interaction using EHR software and reviewed this data further for analysis of the results. Each day data of 3-4 patients, including new patient or the patients with follow up was entered in the time duration of about 20-30 minutes for each patient. Time efficiency is recognized as a factor for facilitator/barrier for EHR implementation [22]. UID was given to each enrolled patient as it is also mentioned in IT standards of India which is used to identify a particular patient in the entire software, also it secures to the direct access to the records of patients. After the enrollment, data entry of each patient was done in different EHR functionalities (Table No. 3.) which includes: a) Patient demographics, i.e. personal details, incorporation of patient age for appropriate prescribing in the elderly and children, allowed the development of an alert with suitable patient sensitivity, incorporation of pregnancy status was utilized for the application of a context-sensitive alert for pregnant women, b) Anthropometric data in which, BMI is an indicator of body fatness in which patients having a BMI between 25-29 are classified as overweight and that above 30 are classified as obese. Patients who are overweight & obese are at increased risk for many diseases & health conditions, including high b.p., cholesterol, Type II DM, etc. c) Prescription Information including diagnosis of the disorder with medication details. EHR software also provides the feature of attachment of the prescription. d) Lab. reports has crucial role in EHR when lab or x-ray results are frequently missing, the implication is that they need to be repeated which adds to this country's staggering healthcare bill [23], [24]. With an EHR, lab results related to any disorder can be entered, retrieved much more rapidly, thus saving time, along with an alert to clinical lab values to the Physician [25]. With EHR, patient could have one health record with all admissions filed in the one record for better patient care [2].

This system is thus used, in which schedule date of appointment is used as a reminder for the next visit of the patient, which will facilitate direct communication with them to enhance overall patient care. Identification of total no. of visits of a patient automatically, it is simply a matter of a few mouse clicks and this feature of the system is useful in finding out awareness among different patients for the concern especially towards patients at high risk status. No significant difference was observed between patient's awareness related to DM and that related to CVS disorders ($P > 0.05$) (Table No. 4.).

BMI has an important correlation with DM. When BMI was compared between the various sessions, no significant difference was observed ($P > 0.05$). But the extremely significant difference was observed between the BMI categories of 23-25 kg/m^2 and those above 25 kg/m^2 in every session, which also seems to be increased in every preceding session. As it already proved in various studies that BMI more than 25 kg/m^2 is an associated risk factor for Diabetes Mellitus [26]. Patients were also counselled for the importance of this factor for the diabetes. It is calculated automatically by the software in which a signal noise (a blinking red dot) is generated by the system for underweight and overweight patients.

In the present study, it was observed that maximum no. of patients were in the age group 41-50 and 51-60 yrs of age. A similar result was also observed by Centers for Disease Control and Prevention that in the age group of 20-44 years, it was estimated about 3.7% people had DM; while in the age group 45-64 years the number increased to 13.7%; and the highest percentage of 26.9% was found in the age group of ≥ 65 years [27]. The reason behind this may be that aging induces decrease insulin sensitivity and decrease in beta cell proliferation capacity.

Extremely significant difference was observed among diabetic patients with other disorders and those without any other disorder ($P < 0.0001$).

Through EHR software, prescription pattern of Anti diabetic therapy was analyzed for all the cases related to Diabetes. And it was observed that significant population was using Biguanides (74.54%), followed by other classes such as sulphonylurea (63.63%), Thiazolidinediones (7.27%), α–glucosidase inhibitors (3.63%), DPP-IV inhibitors (10%) which were less significantly used by the Physician. In both types of Diabetes Mellitus, in Type I DM, 3 patients (2.63%) were only on oral therapy, 4 patients (3.50%) were on Insulin therapy and 2 patients (1.75%) were prescribed with Combination therapy of oral + Insulin therapy. In Type II DM, 62 patients (54.38%) were on oral therapy, 7 patients (6.14%) on Insulin therapy and 22 patients (19.29%) were prescribed with Combination therapy of oral + Insulin therapy, in which mostly used drugs in oral therapy were sulphonylurea or metformin or their FDC. Figure No. 8. shows percentage of oral hypoglycemic agents and Insulin preparations prescribed to the patients. This shows that OHA still dominate the prescribing pattern, but there is a shifting trend towards the use of Insulin preparations in the management of Diabetes Mellitus.

Sulphonylureas (SUs) and thiazolidinediones are commonly used as alternatives when metformin therapy fails [28]. Combination therapy with either SUs or thiazolidinediones and metformin is a common next step if the glycemic target is not attained by monotherapy [29]. When combination therapy for diabete fails to achieve therapeutic targets, insulin therapy will be initiated to provide sufficient amount of insulin for maintaining homeostasis of blood glucose [29].

Different fixed dose combination (FDCs) therapy used in Diabetic patients are shown in Table No. 12. It was observed that in Type II DM patients, most of the FDC were of Biguanides & sulphonylurea class and least used was sulphonylurea + thiazolidinediones. And as in monotherapy, mostly used drug was Metformin from Biguanides class in around 27 patients, which is also reported by a similar study that metformin has been used alone as the first line OHA for Type II diabetes [29]. The reason behind this may be that it reduces hepatic glucose output and promotes peripheral glucose uptake [30] and least used drugs were Sitagliptin, vidagliptin belonging to the class of DPP-IV inhibitors in 2 patients [31]. Although Dipeptidyl peptidase-IV (DPP-IV) inhibitors are the newest class of oral agents for the treatment of type II diabetes, but still less prescribed may be due to its limiting factor, i.e. cost and weak potency but major advantage of this class is the weight neutrality [32].

Significant difference was observed between patients having monotherapy and those having combination therapy ($P < 0.0001$), especially in previously diagnosed diabetic patients which shows initially, treatment is started with monotherapy and later on due to resistivity problem, combination therapy is prescribed. Our results mirror the experience of another study which revealed that in patients with high mean baseline HbA1c of 8.2–8.4%, glycemic control was reached by only 25% of patients treated with metformin monotherapy. Additionally, 3 years into the UKPDS study, half of the patients required combination therapy and by 9 years, 75% of the patients needed combination therapy. This shows combination therapy with established medications is frequently used when adequate glycemic control has not been achieved with monotherapy. The reason behind this can be that monotherapy loses efficacy over time as evidenced by a continued increase in HbA1c [33].

In Type I DM patients, FDC of drugs used are shown in Table No. 13. FDC of Insulin 50% + Insulin Isophane 50% was observed to be used the most i.e. in around 14 patients and least used was FDC of Human Insulin 25% + Human Isophane 75% in 2 patients and Insulin glargine as monotherapy was observed to be used the most in comparison to Human insulin which was used the least in the prescription pattern by the physician.

In this study, all the drugs were prescribed by brand names suggesting popularity of the brands among the physician and influence of pharmaceutical companies on the physician.

Out of total 200 patients enrolled and segregated 114 patients, it was observed that only 40 patients had follow up during the study period. ADRs were reported as described by these 40 patients followed by us in which most of them were reported in the literature.

Known barriers to Adverse drug reaction reporting include the absence of a prompt to initiate reporting, considering that the reaction is already well known and finally the time required to manually fill in adverse reaction forms. The adverse reaction reporting tool has been developed in EHR to help overcome these barriers. Along with ADR reporting data, availability of laboratory and other investigation reports through the use of EHR, improves the ability of the clinicians

reviewing the data to determine whether the medicine is causing the reaction [34]. Significant no. of Unreported/some new ADRs due to anti diabetic therapy were not observed during the study. Features of EHR system towards ADR reporting were discovered by reviewing various ADR reporting forms globally, including forms of CDSCO which are:

- Management done, by the physician,
- Type of ADR i.e. related to which system in the body
- Severity of Adr i.e. mild/moderate/significant, etc.
- Seriousness of the reaction
- The Outcome of the Adr i.e. recovered/death, along with action taken by physician.

ADR reporting in the EHR software thus proves to be useful and can be used as an assessment tool for identifying various adverse events and adverse drug reactions, previously reported and unreported. No. of patients reported with each ADR are also shown in the Table No. 15. Muscle pain, weight loss and hypoglycemia were observed in maximum no. of patients out of whole (40 patients). A similar study also reports weight loss and hypoglycemia as most common adverse effects of Anti diabetic drugs [35].

Action was taken by the physician in reported/unreported ADRs in approx 95% of the patients, which shows the favorable/satisfactory observation and awareness of the physician towards ADR and patient care given in the Table No. 15. For e.g. a 50 year aged male patient previously diagnosed with DM type II for last 3-4 months was prescribed with FDC of Glimepiride and metformin & ADR detected was weight loss and action taken by the physician in his next visit was changed in drugs prescribed i.e. metformin was prescribed to him as monotherapy and in his next visit, improvement in weight loss was discovered. The Figure No. 11. shows the awareness of physician towards ADR reported by the patients. Thus, with the help of EHR software, known and even those which are sometimes overlooked by the physician or unknown ADRs can be reported.

The future challenge is to replicate this system in routine PHCs of state governments so as to enable a full evaluation of its implementation in a routine health system of the government as opposed to a health system run by an institution. In fact, it can be moved further ahead with contemplating the use of this EHR system using web, i.e. web based EHR system. Also, it can be used to provide a platform for convergence of different services related to social sectors [9].

4. CONCLUSION

The Present study was carried out to design and implement Electronic health record (EHR) that tries to automate the manual day-to-day paper based record system. In all regions, today's rapid globalization and the expansion of the healthcare sector is making this service more essential than ever before. But unfortunately, this type of record is not maintained in many healthcare facilities today. And however we have seen that in India and other developing countries this component is weak and therefore there is often a lack of good quality data and inefficient utilization of resources [9]. It was developed with the objective that, it benefits clinicians and healthcare organizations along with patients compliance, they continue to proliferate and improve over time as the practice of community pharmacy expands into greater health services, the potential uses of EHR may broaden. Hence health records are useful in management and planning of healthcare facilities and services and the production of health care statistics. It improved care coordination and communication between various healthcare professionals. The benefit is that every physician will be able to tap into that national biomedical network from his or her desktop computer.

Newer technology, however, such as small wireless devices, EHR manual For Developing Countries notebook computers and mobile phones with data capture capability are also initiating for improvement in status of EHR usability, better fit workflow and speed to make them faster to use. Hence, EHRs won't improve unless we study them, collect data on what went wrong, and importantly resolve to use these data to make the EHR systems better.

In future, the EHR can be coded to enable the retrieval of information on diseases and injuries which is also taking place in most developed countries [2]. It improves care coordination and communication between attending doctors and other healthcare professionals by sharing necessary information with them such as laboratories and specialists and also benefit all the stakeholders who play role in the patient's care.

5. ACKNOWLEDGEMENT

The author is thankful to the Director/Principal, Prof. Sudeep Bhardwaj, Assistant Prof., Seth G. L. Bihani S. D. College of Technical Education, Sri Ganganagar (Raj.), Dhiraj Bansal, Software developer for their favourable gesture and support during entire work.

Conflict of Interest

There is no conflict of interest.

References

[1] Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson. To err is human: building a safer health system [online]. A report of the Institute of Medicine. 1999, Washington, DC: National Academy Press.
Available from http://www.csen.com/err.pdf [Accessed on 27 August 2015].

[2] World Health Organization. Regional Office for the Western Pacific. Medical records manual: a guide for developing countries [online], 2006a.
Available from www.wpro.who.int/publications/PUB_9290610050/en [Accessed on 9 august 2015].

[3] C. Curtain and G. M. Peterson. Review of computerized clinical decision support in community pharmacy. Journal of Clinical Pharmacy and Therapeutics. 2014; 39: 343–348.

[4] EMR Standards Committee. Recommendations On Electronic Medical Records Standards In India [online]. Ministry of Health & Family Welfare, Government of India, 2013.
Available from http://clinicalestablishments.nic.in/WriteReadData/107.pdf [Accessed on 25 August 2015].

[5] World Health Organization. Medical Records Manual: A guide f developing countries [online]. Geneva: WHO, 2006b.

[6] Pizziferri L, Kittler AF, Volk LA, Honour MM, Gupta S, Wang Wang T, Lippincott M, Li Q and Bates DW. Primary care Physician time Utilization before and after Implementation of an Electronic Health Record: A time-motion study. J Biomed Inform. 2005; 38(3): 176-188 (Pubmed).

[7] Jun Xu, Xiangzhu Gao, Golam Sorwar and Peter Croll. Implementation of E-health Record Systems in Australia. The International Technology Management Review. 2013; 3 (2): 92-104.

[8] Aminpour F, Sadoughi F and Ahamdi M. Utilization of open source electronic health record around the world: A systematic Review. J Res Med Sci. 2014; 19(1): 57-64 (pubmed).

[9] Krishnan A, Nongkynrih B, Yadav K, Singh S and Gupta V. Evaluation of computerized health management information system for primary health care in rural India. BMC Health Servic Research. 2010; 10: 310.

[10] Abantika Ghosh. Digital India programme: Govt mulls setting eHealth Authority [online]. The Indian Express, 2015.
Available from http://indianexpress.com/article/india/india-others/digital-india-programme-govt-mulls-setting-up-ehealth-authority/ [Accessed on 29 August 2015].

[11] Guidelines for monitoring and reporting adverse drug reactions (ADRs) [online]. The United public of Tanzania, ministry of health, 2006.
Available from http://apps.who.int/medicinedocs/documents/s18571en/s18571en.pdf [Accessed on 29 August 2015]. .

[12] Sundos Qassim, Zakia Metwaly, Mohammed Shamsain and Yassin Al Hariri. Reporting Adverse Drug Reactions: Evaluation of Knowledge, Attitude and Practice among Community Pharmacists in UAE. IOSR Journal of Pharmacy. 2014; 4(4): 17-23.

[13] Hsiao CJ, Hing E., Socey TC and Cai B. Electronic Health Record Systems and intent to apply for meaningful use incentives among Office-based Physician Practices: United States [online], 2001-2011. Centers for Disease control and Prevention. NCHS data Brief, No. 79. Hyattsville, MD: National Center for Health Statistics, 2011.

[14] Boonstra Albert, Versluis Arie and Vos F J Janita. Implementing eletronic health records in hospitals: a systematic literature review. BMC Health Services Research. 2014; 14: 370.

[15] Snehalatha C, Viswanathan V and Ramachandran A. Cutoff values for normal anthropometric variables in Asian Indian Adults. Diabetes Care. 2003; 26(5): 1380-84.

[16] Chobanian AV and Hill M. National Heart, Lung, and Blood Institute Workshop on Sodium and Blood pressure: A critical review of current scientific evidence. Hypertension. 2000; 35: 858-863.

[17] Update on the Adverse Drug Reaction reporting tool [online]. New Zealand. BPJ Issue 60.
Available from http://www.bpac.org.nz/BPJ/2014/April/reaction.aspx [Accessed on 31 August 2015].

[18] Paul C. Tang, Michael P. Larosa, Carol Newcomb and Susan M. Gorden. Measuring the effects of reminders for outpatient Influenza immunizations at the point of clinical opportunity. Journal of the American Medical Informatics Association. 1999; 6(2): 115-121.

[19] Smith PC, Araya-Guerra R, Bublitz C, Parnes B, Dickinson LM, Van Vorst R, Westfall JM and Pace WD. Missing clinical information during primary care visits. JAMA. 2009; 293(5): 565-71 (Pubmed).

[20] Anantraman V, Mikkelsen T, Khilnani R, Pentland A, Kumar VS and Ohno-Machado L. Open source handheld-based EMR for paramedics working in rural areas. Proc AMIA Symp. 2002; 12-16 (PubMed).

[21] Terhilda Garrido, Laura Jamieson, Yvonne Zhou, Andrew Wiesenthal and Louise Liang. Effect of Electronic Health Records in ambulatory care: retrospective, serial, cross sectional study. Information in Practice. 2005; 330: 1-5.

[22] Poissant L, Pereira J, Tamblyn R and Kawasumi Y. The impact of Electronic Health Records on time efficiency of Physicians and nurses: A systematic Review. Journal of American Medical Informatics Association. 2005; 12(5): 505-516.

[23] Reeve J.F., Tenni P.C. and Peterson G.M. An electronic prompt in dispensing software to promote clinical interventions by community pharmacists: a randomized controlled trial. Br J Clin Pharmacol. 2008; 65(3): 377–385 (Pubmed).

[24] Raebel MA, Carroll NM, Kelleher JA, Chester EA, Berga S and Magid DJ. Randomized trial to improve prescribing safety during pregnancy. J Am Med Inform Assoc. 2007; 14(4): 440–450.

[25] Dr. Robert Hoyt. Benefits of switching to an Electronic health record (EHR) [online]. Health Informatics: a practical guide. (pp. 1-9).
Available from http://www.practicefusion.com/health-informatics-practical-guide/ [Accessed on 31 August 2015].

[26] Narayan K.M.V., Boyle J.P., Thompson T.J., Gregg E.W. and. Williamson D.F. Effect of BMI on lifetime risk for Diabetes in the U.S. Diabetes Care. 2007; 30(6): 1562-1566.

[27] Suastika Ketut, Dwipayana Pande, Semadi MS and Kuswardhani RAT. Age is an important risk factor for Type 2 Diabetes Mellitus and cardiovascular diseases [online], 2012.
Available from http://cdn.intechopen.com/pdfs-wm/41385.pdf [Accessed on 1 September 2015].

[28] DeFronzo RA and Goodman AM. Efficacy of Metformin in Patients with Non-Insulin-Dependent Diabetes Mellitus. The Multicenter Metformin Study Group. N Engl J Med. 1995; 333(9): 541–549.

[29] Martin C. S. Wong, Harry H. X. Wang, Mandy W. M. Kwan, Daisy D. X. Zhang, Kirin Q. L. Liu, Sky W. M. Chan, Carmen K. M. Fan, Brian C. Y. Fong, Shannon T. S. Li and Sian M. Griffiths. Comparative Effectiveness of Dipeptidyl Peptidase-4 (DPP-4) Inhibitors and Human Glucagon-Like Peptide-1 (GLP-

1) Analogue as Add-On Therapies to Sulphonylurea among Diabetes Patients in the Asia-Pacific Region: A Systematic Review. Plos One. 2014; 9(3): 1-8.

[30] Fawziya Alkhalaf, Ashraf T Soliman and Vincenzo De Sanctis. Metformin Use in Adolescents: Old and New Therapeutic Perspectives. J Diabetes Metab. 2014; 5(12): 1-8.

[31] Whittaker Catherine. A review of oral diabetic medication. SA Pharmaceutical Journal. 2010; 77(6): 20-22.

[32] Fowler MJ. Diabetes Treatment, Part 2: Oral Agents for Glycemic Management. Clinical diabetes. 2007; 25(4): 131-134.

[33] Robert G Mosses. Combination Therapy for Patients with Type 2 Diabetes: Repaglinide in Combination with Metformin. Expert Rev Endocrinol Metab. 2010; 5(3): 331-342.

[34] Medsafe. Launch of an electronic adverse reaction reporting tool [online], 2009.
Available from http://www.medsafe.govt.nz/profs/PUArticles/ADR%20Reporting%20Tool-May09.htm [Accessed on 7 august 2015].

[35] Prashant B Mane, Rishikesh V Antre and Rajesh J Oswal. Antidiabetic drugs: An overview. International Journal of Pharmaceutical and Chemical sciences. 2012; 1(1).