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READINESS OF GENERAL PRACTITIONER AND ALLIED WORKERS IN CLINICAL DATA MANAGEMENT – A CROSS-SECTIONAL STUDY

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ABSTRACT Clinical data management (CDM) is an important process in clinical research, resulting in high-quality, reliable, and statistically sound data from clinical trials. The objective of CDM is to guarantee that conclusions drawn from the investigation are well backed by the information. This article focuses on the forms affected by CDM and provides users with an overview of how to manage information.

Methodology: The study was conducted among health care professionals of the south Indian population. A total sample size of 50 respondents (Doctors, Staff) were included in the study. Data was collected using a validated questionnaire. statistical analysis is done by using the Chi-Square test & correlation coefficient.

Result: There is no relationship between the respondent work encounter within the hospital and an attainable shape of reporting. There could be a relationship between the respondent's work encounter within the hospital and the length of reporting the adverse effects.

KARL PEARSON'S CORRELATION: There is a positive relationship between the awareness of clinical data management in day-to-day practice and clinical data management plays important role in.

Conclusion: To meet the desires, there's a slow move from paper-based to electronic frameworks of information administration. At the same time, CDM experts ought to guarantee the benchmarks for making strides in information quality

KEYWORDS : Clinical data management, general practitioner

INTRODUCTION

Clinical data management (CDM)may be a vital method in clinical analysis that results in the generation of high-quality, reliable, and statistically sound information from clinical trials. It ensures the gathering, integration, and convenience of information at acceptable quality and cost. It also supports the conduct, management, and analysis of studies across the spectrum of clinical research as defined by the National Institutes of Health (NIH)

The goal of CDM is to confirm that conclusions drawn from the analysis are well supported by the info. Achieving this goal protects public health and confidence in marketed medicine.[1,2] CDM could be a relevant and necessary part of a clinical trial. All researchers strive their hands-on CDM activities throughout their research work, wittingly or unwittingly. Without identifying the technical phases, we tend to undertake a number of the processes concerned in CDM throughout our research work.

A good medical record helps both the doctor and his patient. It is very important that the attending physician properly document the treatment of the patient being treated. Keeping medical records has become a science. The key to exemption from most medical malpractice claims is the quality of medical records. One of the challenges in managing clinical data is the willingness of the GP itself. Physically and mentally. When considering a review, these conditions influence the willingness to learn as a diagram of the initiation of clinical data management activities. To do this, you need to provide an answer that actually contributes to the achievement of a particular goal. This article focuses on the forms affected by CDM and provides users with an overview of how to manage information..[2,3,4]

The study aims to study the readiness of general practitioners in clinical data management. Secondary objectives are to evaluate and determine the practicality of collecting data from various sources for the clinical data management, to study the level of general practitioner readiness in the same and where do they fall back, to find the various types and to comply effectively and use it systematically is what makes a proper record and to file adverse drug reactions if any occur and for medicolegal purposes.

METHODOLOGY

This cross-sectional study was conducted among health care professionals of the south Indian population between January to March 2021 and the study was approved by an institutional ethical committee. A total sample size of 50 respondents (Doctors, Staff) were included in the study. Data were collected using a validated questionnaire which includes both rhetorical and closed-ended questions using a survey or personal interview. Statistical analysis is done by using the Chi-Square test & correlation coefficient. SPSS 20.0 was used for result analysis.

RESULTS & DISCUSSION

14% of respondents are 20-30 years, 24% of respondents are between the age group of 31-40 years, 28% of respondents are in the age between 41-50 years and 34% of respondents are between 51-60 years. 54% of respondents are male, 46% of respondents are female.

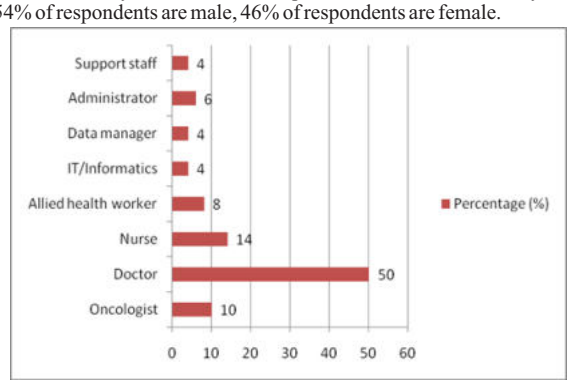

Fig: 1 - Designation

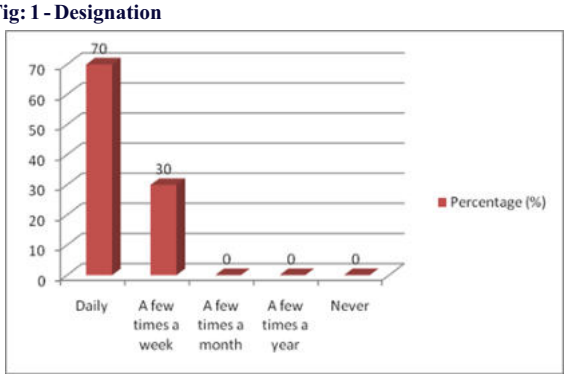

FIG: 2 – Frequency of using computer

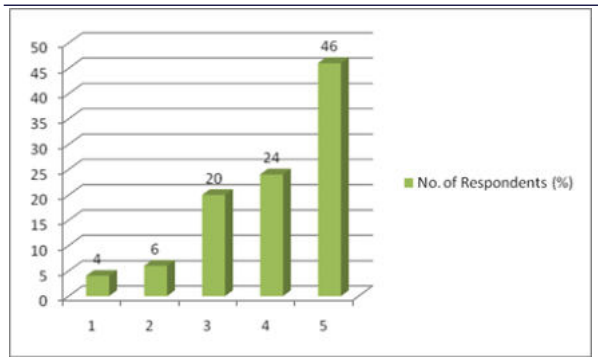

Fig: 3 - Rate of computer skills on a scale of 1 to 5

Table:1- Work Experience In Hospital

S.No	Work Experience In Hospital	No. of Respondents	Percentage (%)
1	1-3 years	8	16
2	3-5 years	10	20
3	5-8 years	12	24
4	8-10 years	15	30
5	Above 10 years	5	10
	Total	50	100

- 94% of respondents said yes, they have experience using clinical data management and 6% of them denied the same.
- 50% of respondents said yes they have received training on clinical data management and 50% of them denied they haven't received training on clinical data management.
- 44% of respondents said briefly they are collecting details from patients and 24% of respondents are said they will collect only the necessary information from patients.
- 48% of respondents said two weeks once they reported adverse effects of patients caused during treatment and 6% of respondents said monthly once they reported adverse effects of patients caused during treatment.

Table: 2 - Duration of reporting adverse side effects of the patient caused during treatment

S. No	Duration of reporting adverse side effects of the patient caused during treatment	No. of Respondents	Percentage (%)
1	Once a week	16	32
2	Two weeks once	24	48
3	Three weeks once	7	14
4	Monthly once	3	6
	Total	50	100

Table:3 - Feasible form of reporting

S. No	Feasible form of reporting	No. of Respondents	Percentage (%)
1	Paper Form	18	36
2	Electronic	27	54
3	Real-Time Scan	5	10
	Total	50	100

100% of respondents said yes, they will check their entry and data validation and none of them are denied.

52% of respondents said they are well aware and criticizing and 14% of respondents said they have no idea about the same.

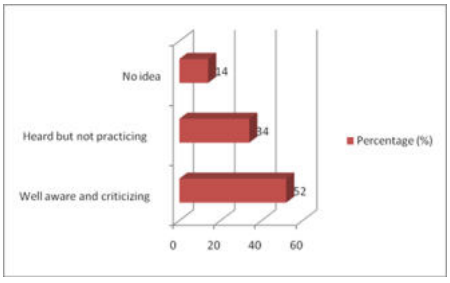

Fig: 4 - Awareness of clinical data management in day to day practice

82% of respondents said yes the collection of clinical data information makes a change in medical field practice and 8% of respondents said they have no idea about the same.

66% of respondents said yes every medical field professional should be taught to collect and update information in the software database for efficiency and 4% of respondents are denied about the same.

100% of respondents said yes they are interested in learning more about clinical data management and none of them are interested in the same.

58% of respondents said hospital plays important role in clinical data management and 4% of respondents said clinics play an important role in the same.

CHI-SQUARE TEST

There is no relationship between the respondent work encounter within the hospital and an attainable shape of reporting There could be a relationship between the respondent's work encounter within the hospital and the length of reporting the adverse effects.

KARL PEARSON'S CORRELATION

There is a positive relationship between the awareness of clinical data management in day-to-day practice and clinical data management plays important role in.[5,6]

CONCLUSION

CDM meets growing demands for speeding up drug development processes and patient records from hospitals and pharmaceutical companies, and establishing quality systems that ensure the generation of high-quality data for accurate patient and drug evaluations from regulators. It has evolved in response.[7,8] To meet expectations, we are gradually moving from paper-based systems for data management to electronic systems.[9]

At the same time, CDM professionals need to ensure standards for improving data quality. CDM as a discipline must be evaluated and standard compliant with the implemented systems and processes. The main challenge from a regulatory perspective is to standardize the data management process across the organization and develop regulations to define the procedures and data standards to follow.

REFERENCES

1. 2https://en.wikipedia.org/wiki/Clinical_data_management
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3326906/#:~:text=Clinical%20Data%20Management%20(CDM)%20is,sound%20data%20from%20clinical%20trials.&text=They%20should%20have%20adequate%20process,quality%20standards%20of%20CDM%20processes.
3. https://www.researchgate.net/publication/43024102_Are_general_practice_networks_'ready'_for_clinical_data_management
4. Sandra Hakiem Afrizal , Achmad Nizar Hidayanto , Putu Wuri Handayani , Meiwita Budiharsana , Tris Eryando (2019) - Narrative Review for Exploring Barriers to Readiness of Electronic Health Record Implementation in Primary Health Care Healthc Inform Res. 2019 Jul;25(3):141-152. doi: 10.4258/hir.2019.25.3.141. Epub 2019 Jul 31
5. Binny Krishnankutty, Shantala Bellary, Naveen Kumar B.R., Latha S. Moodahadu (2012)-Data management in clinical research: An overview-Indian Journal of Pharmacology | April 2012 | Vol 44 | Issue 2 and standards adopted as well as the roles and responsibilities in CDM.
6. Senafekesh Biruk, Tesfahun Yilma, Mulusew Andualem & Binyam Tilahun (2014) Health Professionals' readiness to implement electronic medical record system at three hospitals in Ethiopia: a cross sectional study-BMC Medical Informatics and Decision Making volume 14, Article number: 115 (2014)
7. Jill Kelly,Peter Schattner,Jane Sims (2014)-Are general practice networks-ready' for clinical data management-Reprinted from Australian Family Physician. Dec 2009:Vol. 38, No. 12,
8. Simon de Lusignan, Siaw-Teng Liaw (2011) Key Concepts to Assess the Readiness of Data for International Research: Data Quality, Lineage and Provenance, Extraction and Processing Errors, Traceability, and Curation. Contribution of the IMIA Primary Health Care Informatics Working Group Lusignan on 21 May 2014.imia.schattauer.de on 2011-10-12 | ID: 20631 | IP: 82.8.180.47
9. Sima Ajami, Saeedeh Ketabi, Sakineh Saghaeiannejad Isfahani, Asieh Heidari (2011) Readiness assessment of electronic health records implementation-Acta Inform Med2011 Dec;19(4):224-7. doi: 10.5455/aim.2011.19.224-227