



## An Observational Study To Evaluate The Awareness About Therapeutic Drug Monitoring (TDM) Amongst Clinicians

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### Abstract

**Introduction:** Therapeutic drug monitoring (TDM) is the clinical practice of measuring specific drugs at designated intervals to maintain a constant concentration in a patient's bloodstream, thereby optimizing individual dosage regimens. The goal of TDM is to use appropriate concentrations of difficult-to-manage medications to optimize clinical outcomes in patients in various clinical situations.

**Materials and Methods:** A questionnaire containing 20 questions was prepared. Five questions were about awareness of TDM and its availability in the institution and frequency of TDM being done. Few questions were asked about the utility of TDM and its implication in the treatment and prognosis of the patient. Some applied questions were asked which were important to assess the knowledge and awareness of the physicians.

**Result:** 92.2 % of clinicians had a positive attitude for TDM. Despite the fact that most clinicians felt the need and considered this investigation very useful and were even ready to attend seminars related to TDM, but only 40% were aware whether the investigation is available or not in their hospital, and only 46.7 % of them had ever asked the patients to get TDM done. 96% of clinicians said that many patients came with signs of drug toxicity and they were able to diagnose it clinically. 93.3% of them were aware about drugs having narrow therapeutic range but when asked about dose response curve only 70% were able to answer it correctly

**Discussion:** Use of TDM in hospital is much needed for benefit of the patient

**Keywords:** Therapeutic drug monitoring (TDM), prevalence, clinicians, future prospects.

### Introduction:

Therapeutic drug monitoring (TDM) is the clinical practice of measuring specific drugs at designated intervals to maintain a constant concentration in a patient's bloodstream thereby optimizing individual dosage regimens.<sup>1</sup> TDM is a two course sequence that emphasizes the application of pharmacokinetic principles to the individualization of drug regimens. Therapeutic drug monitoring also enables dose adjustment, prevention of adverse drug reactions, and ascertainment of drug adherence, therapeutic nonresponse, or pharmacokinetic drug-drug interactions, as the concentration of the drug correlates with its clinical effect.<sup>2</sup> The science of

TDM introduced a new aspect of clinical practice in the 1960s with the publication of initial pharmacokinetic studies linking mathematical theories to patient outcome.<sup>3</sup> Precision medicine for patient management is achieved by many tools including Therapeutic drug monitoring (TDM).<sup>4</sup>

'Knowledge is of no value unless you put it into your practice'. In case of TDM, knowledge of pharmaceuticals, pharmacokinetics and pharmacodynamics must be applied for the assessment of the efficacy and safety of medicine. TDM is mainly used for drugs with narrow therapeutic index and usually for drugs which are used for long duration in non-critically ill patients.

TDM as a service (an adjunct to patient care) was introduced towards the mid and late 1980s and the last 10 years have seen it grow, along with the growth of separate Clinical Pharmacology departments. The service is being improved each year to include more and more drugs and the number of requests for TDM is increasing. Automation and the availability of technically simple methods have made this service available even in rural areas. Despite this, TDM in several centres remains within the confines of clinical biochemistry departments that provide only the 'measuring' (assay only) and not the 'monitoring' (assay and clinical interpretation) service<sup>5</sup>. The study undertaken is an observational study which aims to interpret the utility and requirement of TDM prescribing amongst physicians and psychiatrists. Despite the utility of TDM, it is one of the lesser prescribed test so through the questionnaire sent to various doctors their inclination and awareness about the test is interpreted.

#### **Materials and Methods:**

**STUDY AREA:** The questionnaire was sent to clinicians of Rajendra Institute of Medical Sciences, Ranchi and various other clinicians who are working in various corporate hospitals of ranchi

**STUDY POPULATION:** Clinicians (mainly general medicine and psychiatrist) were included in the study.

**SAMPLE SIZE:** Questionnaire made on google was sent to around 300 clinicians (mainly general medicine and psychiatrist) individually and on various whatsapp group. Response rate was 96% ie.288 doctors replied to the questionnaire sent to them.

**INCLUSION CRITERIA:** Mostly internal medicine and psychiatrist were shortlisted though the list was sent to some other doctors also. Experience of most doctors who were sent questionnaire was above five years.

**EXCLUSION CRITERIA:** Health care professionals who were not willing to participate / who did not reply to the questionnaire.

#### **Study Procedure:**

#### **QUESTIONNAIRE VALIDATION**

A questionnaire containing 20 questions was prepared. Five questions were about awareness of TDM and its availability in the institution and frequency of TDM being done. Few questions were asked about the utility of TDM and its implication in the treatment and prognosis of the patient. Some applied questions were asked which were important to assess the knowledge and awareness of the physicians. First 10 questions mainly belonged to two categories i.e. closed and leading. These questions were mainly used to check the attitude, interest and practice of physicians for this investigation. Funnelling of last 10 questions were done to assess the knowledge and awareness of the physicians. In this method, questioning is used to funnel the respondent's answers i.e. a series of questions are asked that become restrictive at each step. Funnelling technique is a very useful tactic to find out the maximum amount of information by beginning with open questions and then gradually asking closed questions. Few questions were regarding the utility and some to evaluate the future prospect of this investigation. The credibility of the questionnaire was assessed by a team of four doctors, two professors from the department of psychiatry and two from the department of pharmacology.

#### **Enrollment And Data Collection:**

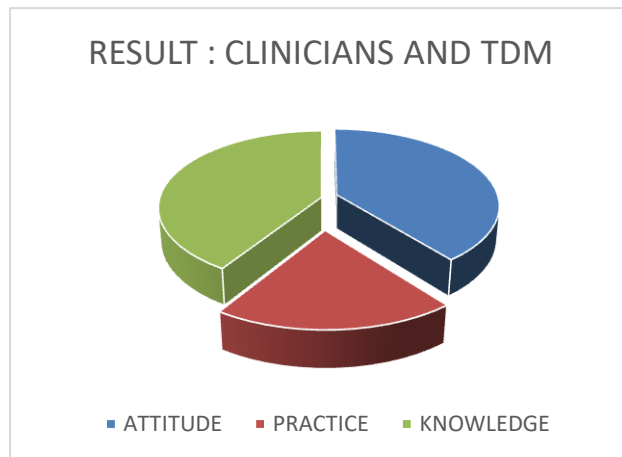
The questionnaire was prepared on google form. This questionnaire was sent to the selected individuals via mail and whats-app by sharing the link, though the questionnaire can be sent to unlimited number of people. Along with the questionnaire, a text explaining the purpose and significance of the study was sent individually to doctors. Any query regarding questionnaire was clarified on phone. The questionnaire had multiple choice questions consisting maximum of four options and the responses were automatically recorded when a participant clicked on any of the choices. Cumulative response for a question was recorded as percentage response for a particular question. Similar response was recorded for all twenty questions and analysed.

**Result:**

WHO says, "Monitoring the results of treatment is an important part of the rational prescribing process." The intent of this article was to assess the availability

of TDM in various hospitals of ranchi, its familiarity amongst clinicians and its future prospect.

Response rate percentage for the questionnaire was 96% i.e. 288 doctors out of 300.

**Attitude:**

92.2 % of clinicians had a positive attitude for TDM. Six questions of the questionnaire were closed questions with emphasis on the outlook of physicians. Direct questions were asked which vividly showed the inclination of the physicians towards the investigation.

**Practice:**

Despite the fact that most clinicians felt the need and considered this investigation very useful and were even ready to attend seminars related to TDM, but only 40% were aware whether the investigation is available or not in their hospital, and only 46.7 % of them had ever asked the patients to get TDM done.

**Knowledge:**

Twelve questions were asked in a funnelling manner to assess the knowledge of clinicians regarding TDM. 96% of clinicians said that many patients came with signs of drug toxicity and they were able to diagnose it clinically. 93.3% of them were aware about drugs having narrow therapeutic range but when asked about dose response curve only 70% were able to answer it correctly. 60 % of doctors said that they prefer to stop the suspected drug causing toxicity despite being aware of the fact that the treatment of the patient is severely affected because there is not much substitute of drugs like lithium available in the market. 73.3% of respondents answered that they are

aware about the therapeutic range of the commonly prescribed drugs, but when further intrigued with implied questions like do you require TDM for anti-diabetic medication, or for understanding drug interaction on an average only 33% of clinicians were able to answer these questions correctly

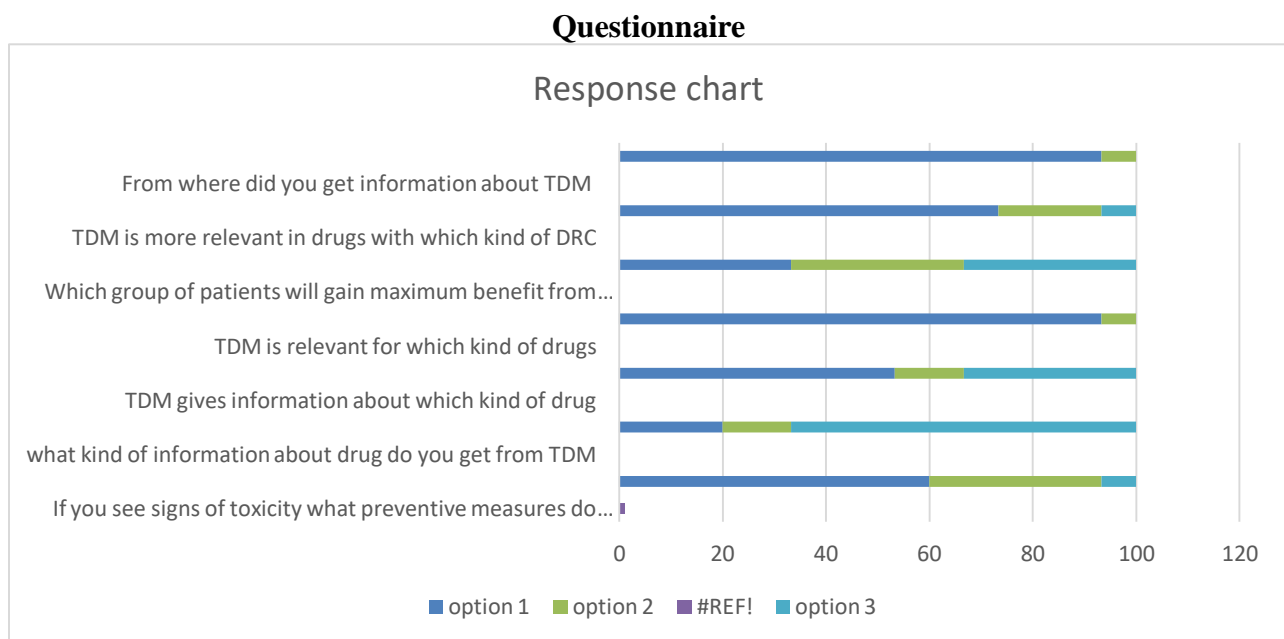
**Discussion:**

The evolution of TDM can be traced through three distinct phases-the 1960s which saw the development of the principles of TDM, the 1970s with automation of laboratory methods and the 1980s when there was widespread expansion of TDM<sup>6</sup>. Therapeutic Drug Monitoring (TDM) was introduced in India in the mid and late 1980s and the last 10 years have seen it grow, together with the growth of separate Clinical Pharmacology departments. The TDM service in the country is broadly of two types: in large teaching hospitals where the service is available through departments of Clinical Pharmacology, and in the private sector, where drug estimations are done by clinical biochemistry departments with minimal interpretation<sup>7</sup>. The service is being improved every year to include more drugs and even the requests for this investigation is increasing. The principles of pharmaco-economics are now being applied in all fields, TDM is one of the effective tool to achieve this.<sup>8</sup> TDM helps to improve patient's response to various life-sustaining drugs and decreases adverse drug reactions. Positive outcomes of TDM like

optimum medication, decreased hospitalisation due to toxicity outweigh the cost of investigation. There is large inter-individual variation in the plasma level achieved at same dose of the drug due to variation in pharmacokinetics of the individual. TDM helps in development of safe and effective individualisations of these medicines. Role of TDM is very well established in drugs like phenytoin, lithium, vancomycin, methotrexate, digoxin, etc. TDM is being widely and very effectively used in hospitals like AIIMS and KEM. Doctors who took part in this

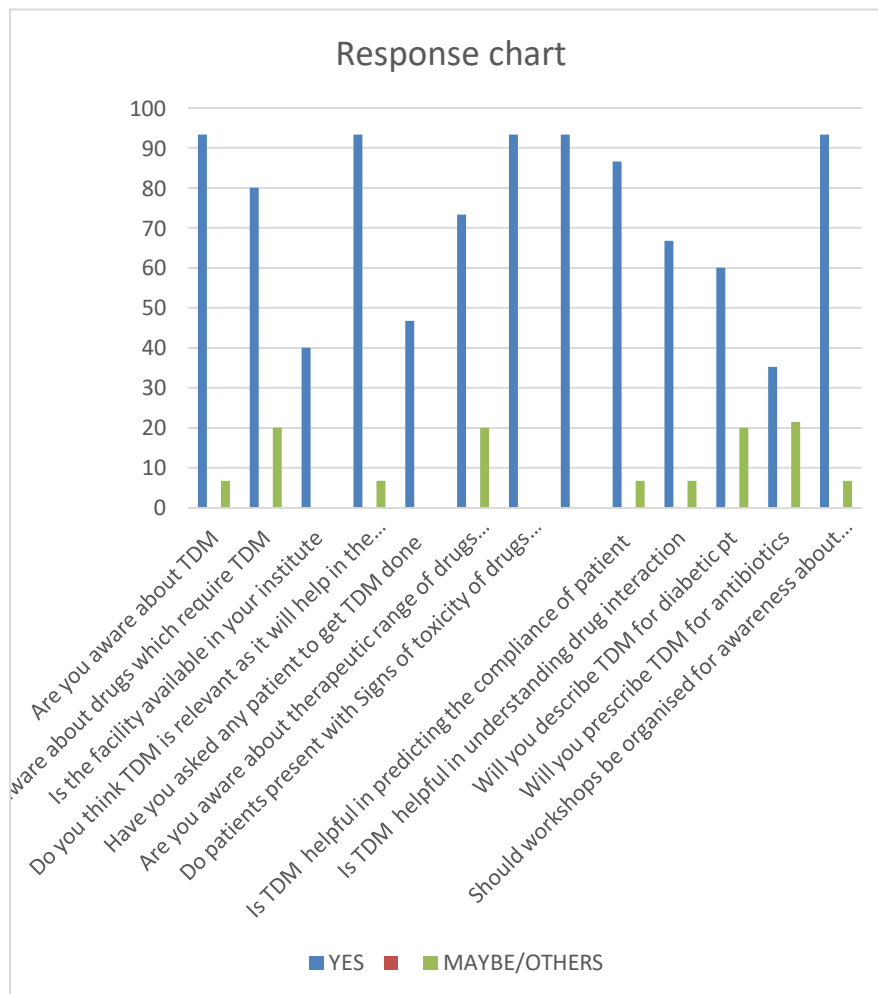
study strongly agree that TDM is very useful investigation and were ready to attend seminars for updated information. Most of the clinicians lacked specialised information and only few recommend this investigation because of lack of proper infrastructure and trained staff. Though use of TDM is low in hospital setups under study but the attitude of the clinicians and positive outlook to use TDM for the benefit of the patients is the silver lining of this study.

**Tables and figures:**



QUESTIONS	YES	NO	MAYBE/OTHERS
Are you aware about TDM	93.3	0	6.7
Are you aware about drugs which require TDM	80	0	20
Is the facility available in your institute	40	60	0
Do you think TDM is relevant as it will help in the prognosis of the patient	93.3	0	6.7
Have you asked any patient to get TDM done	46.7	53.3	0
Are you aware about therapeutic range of drugs oftenly prescribed	73.3	6.7	20
Do patients present with Signs of toxicity of drugs which have been prescribed	93.3	6.7	0
Do you explain the pts the importance of maintaining the dose and time of the drug	93.3	6.7	0

Is TDM helpful in predicting the compliance of patient	86.7	6.6	6.7
Is TDM helpful in understanding drug interaction	66.7	26.7	6.7
Will you describe TDM for diabetic patient	60	20	20
Will you prescribe TDM for antibiotics	35.2	42.9	21.4
Should workshops be organised for awareness about TDM	93.3	0	6.7



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