BHARATI VIDYAPEETH UNIVERSITY MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE

CLINICAL AUDIT - SAFE AND EFFECTIVE ANTICOAGULATION WITH WARFARIN

TITLE: To ensure safe and effective anticoagulation with Warfarin in Bharati Vidyapeeth University Medical College Hospital & Research Centre, Pune within one-year time period.

REASON FOR CHOICE OF AUDIT

Warfarin is used as an oral anticoagulant in conditions like deep vein thrombosis, pulmonary embolism, to prevent stroke in patients who have atrial fibrillation, valvular heart disease or artificial valves.

In this University teaching hospital, Quality team found many incident reports of bleeding due to increased INR in patients on anticoagulation therapy with Warfarin. After analysis it was found that most of these patients were unaware about side effects of anticoagulation therapy and drug-drug / food-drug interactions. This led to wrong dietary lifestyle culminating in complications like mild to severe bleeding episodes.

There was a challenging situation in these patients on anticoagulation therapy with warfarin to prevent bleeding episodes which are at times life threatening adverse events. Hence to ensure safety in anticoagulation with Warfarin, the team of a Pharmacologist, Clinical Pharmacist along with Quality manager decided to conduct a clinical audit to improve high alert medication safety with warfarin.

CRITERIA

With reference to British National Formulary SIGN Guideline No. 36, hospital should ensure that:-

(i) Patients should have rational indication for Warfarin recorded

(ii) Patients should have the anticipated adverse drug reaction of warfarin if any recorded.

(iii) Action should be taken within 24hrs of recognition of adverse drug reaction to warfarin

(iv) Patients should check their INR at prescribed intervals as per the physician advice or not.

(v) Patients should have proper education on warfarin regarding drug-drug and drug-food interactions.

STANDARDS:

Based on above criteria, measurable standards were set as follows:-

(i) 100% Patients should have rational indication for Warfarin recorded

(ii) Have the adverse drug reactions or deranged INR of patients on warfarin recorded (Past/present/follow up)

(iii) In 100% cases, action is taken within 24 hrs after recognition of adverse drug reaction to warfarin

(iv) At least 90% patients check their INR at prescribed intervals by physician

(v) At least 90% patients are educated regarding drug-drug and drug-food interactions of the medication

	Process	**Outcome**	**Outcome**	**Process**	**Outcome**
Criteria	Patient should have the indication for Warfarin recorded	Has the patient developed adverse drug reaction or deranged INR when on warfarin (Past/present/follow up)	As ADR recognized, action taken by hospital within 24 hours.	Patient should have their INR checked as prescribed intervals by physician	Patient education given on Medication
Benchmark	100%		100%	90%	90%

PREPARATION AND PLANNING:

To initiate the process of clinical audit, a proposal form for clinical audit was submitted to the Clinical Audit Committee of the hospital. After getting approval from this committee, audit criteria and standards were defined. To measure the standards, data collection checklist was formulated in the form of patient interview with consent form. Before implementation of this clinical audit, training of Clinical pharmacist was conducted on audit process and medication related information like dose, indication, adverse drug reactions, drug-drug and food-drug interactions along with management of these aspects. It was decided that data will be collected on daily basis for in-patients and analysis to be done on monthly basis. The data to be then presented in Clinical audit committee meeting for further improvement. Ethics committee approval was taken on Clinical audit (Ethics committee approval letter no:BVDUMC/IEC/21 dated on 25th Jan 2018

AUDIT FORM ALONG WITH CONSENT FORM: Annexure 1.

TYPE OF AUDIT: Active Audit

AUDIT COMMENCED ON: 15th April 2018

STANDARD REFERENCES: 1) British National Formulary sign guidelines- No- 36

STUDY AREA - Bharati Vidyapeeth University Medical College Hospital and Research Centre, Pune

STUDY DESIGN- Hospital based prospective study

STUDY POPULATION- All IPD patients started with Tab. Warfarin.

NAME OF THE AUDITOR **:** Team of Clinical Pharmacists, Quality Assurance Department

ANALYSIS WI LL BE DONE BY **:** Dr. Priti Dhande, Member Secretary DTC, Professor in Pharmacology,

: Dr. Sushila Kawade, Manager Quality Assurance, Quality Assurance Department

METHODOLOGY:

All patients care areas were distributed amongst team of Clinical Pharmacists. Clinical pharmacists took their clinical rounds to identify patients on anticoagulation with warfarin. These patients were included in the clinical audit. Patient's consent was taken for the involvement in the study in local language and their case files were reviewed for rationality of indication for warfarin, correct dose, duration of therapy whether mentioned or not, drug-drug and food-drug interactions if any, prescribed intervals for checking INR and adverse drug reactions if encountered. Then patients were interviewed for knowledge about the medication (warfarin), drug-drug and food-drug interactions, prescribed intervals for checking INR and adverse drug reactions with the drug. All this information was noted down in the data collection checklist form for individual patient.

Monthly data analysis was carried out. After analysis, necessary corrective actions & preventive actions were taken to improve the safe and effective anticoagulation with warfarin.

INCLUSION AND EXCLUSION CRITERIA

Inclusion: i) In-patients started on Tablet Warfarin for anticoagulation

ii) Patients giving consent for inclusion in the audit

Exclusion: OPD Patients prescribed warfarin therapy

DATA COLLECTION:

After initial data collection, a gap analysis was done in the month of April-May 2018 to know the baseline situation of the clinical audit standards. Based on these findings, interventions were planned to improvise these standards and analysis continued monthly. This data was clubbed together for further months and presented quarterly in Clinical audit committee meetings.

Patient consent

I Mr/Mrs/Ms: _____ has been told by the Dr _____ about the study "Safe and Effective Anticoagulation with warfarin" and after participation in study my data will be kept confidential. I don't mind to share my data for the above mentioned study purpose. I am giving my consent for involvement in this study.

Sign of Patient: _____ Name of Patient: _____ Date and Time: _____

रुग्ण संमती पत्र

मी श्री./श्रीमती. _____ मला डॉक्टर _____ यांनी "वॉरफेरीन या औषधाच्या सुरक्षित वापरा बाबत" या संशोधना बाबत सर्व माहिती दिली आहे व माझी माहिति गोपनिय ठेवली जाईल. मी संमती देतो/ देते कि, वरील संशोधनाबद्दल माझी माहिती वापरण्यास माझी हरकत नाही.

रुग्णाची सही :_____रुग्णाचे नाव:- _____

दिनांक व वेळ :- _____

Checklist for Clinical Audit: Safe and Effective Anticoagulation with warfarin

Date of Audit: ...../……../…… Time: …… Ward:…… Department: …… Unit: ..... Bed No: ..... Weight : ……kg Height: ……cm Contact No. of patient/relative: ……..	Patient details : PRN No. : …… IPD No. :……. Age: ……. Gender: ……. Diagnosis: …… ……..
Patient Medical History: ……	
Patient INR Details:	

Date									
INR									

a) Does the patient have Indication for Warfarin prescription? ○ Yes ○ No
Specify :
……

b) Patient is on Warfarin since how many days/months? Ans: ……

c) Has patient developed adverse drug reaction or deranged INR when on Warfarin? ○ Yes No
Past:
……..

Present:
……

Follow-up:
……

d) Is there any Drug-drug interaction with warfarin? ○ Yes No
……
……

e) Frequency of INR checking as per the Physician? ……..

f) Whether patient following the Frequency of INR checking? ○ Yes No
If Yes, Note down the INR:_____

If No, Reason behind delay:_____

g) Dose adjusted according to INR? ○ Yes No

h) Does the patient know about Warfarin Medicine? ○ Yes No

i) Patient Medication Information Leaflet given to patient? ○ Yes No

j) Instruction related to symptoms of warfarin ADR given to Patient? ○ Yes No

k) Diet related information given to patient? ○ Yes No

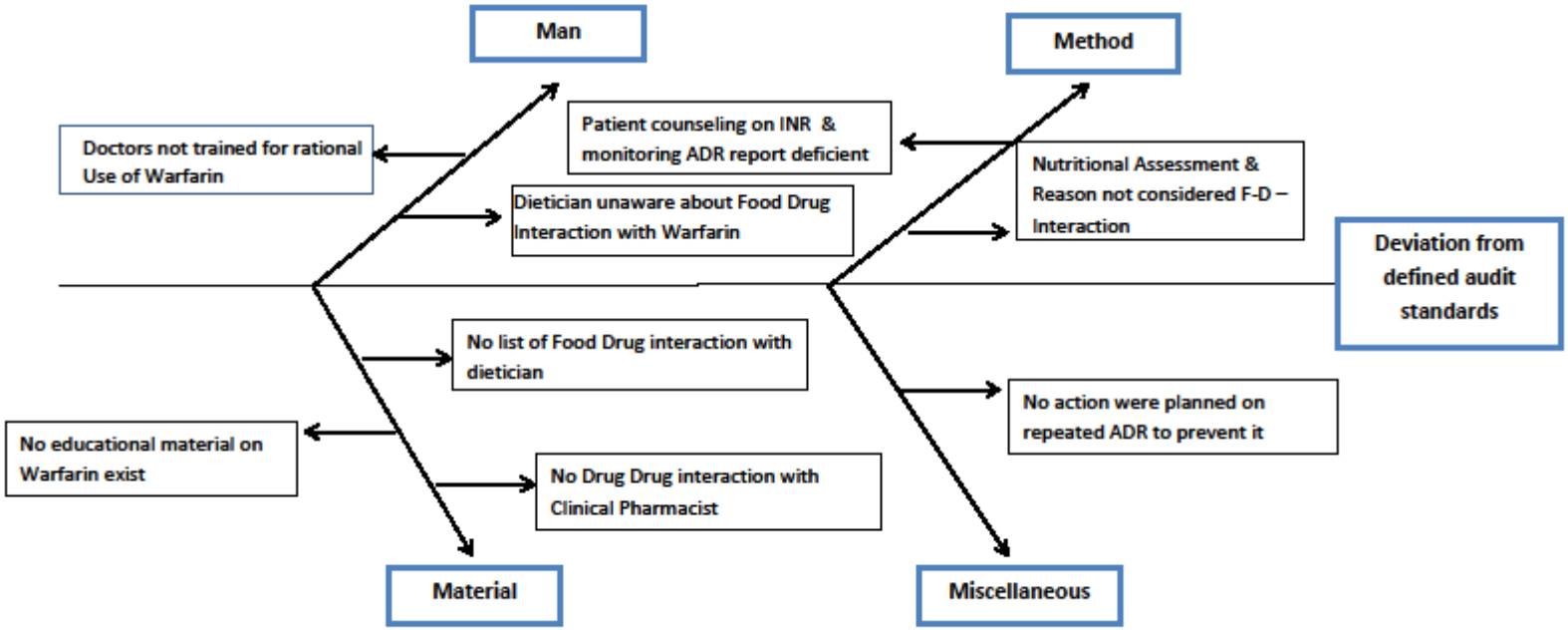
l) Follow-up details:
INR Follow-up:…… Clinical Follow-up:……

Sign of Auditor : Name of Auditor:

FINDINGS:

	Process	Outcome	Outcome	Process	Outcome
Criteria	Patient should have the indication for Warfarin recorded	Has the patient developed adverse drug reaction or deranged INR when on warfarin (Past/present/follow up)	Were ADRs recognized, action taken by hospital within 24 hours.	Patient should have their INR checked as prescribed intervals by physician	Patient education given on Medication
Benchmark	100%		100%	90%	90%
Gap analysis April to 14th May 2018	100%	30.8%	76.9%	53.8%	61.5%

Tool used for analysis was Cause and Effect diagram (Fish-Bone).

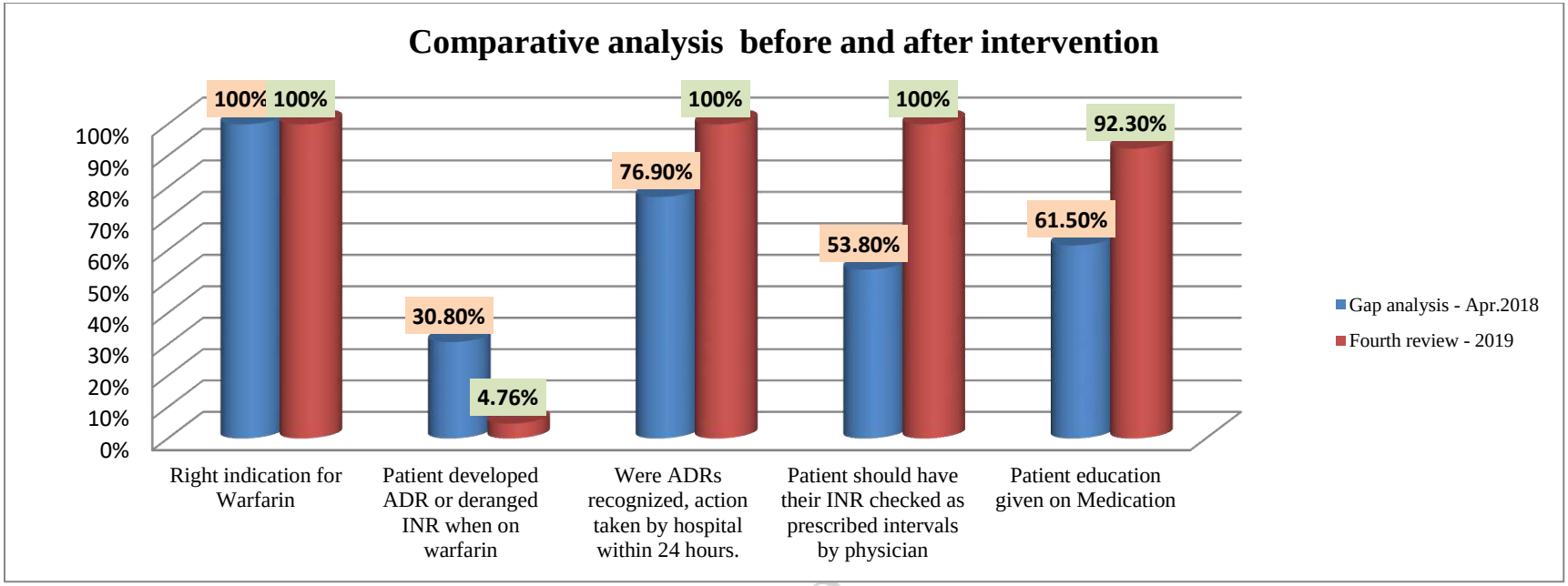


RECOMMENDATIONS

Sr. no.	Observation	Action plan	Responsibility
1	Clinicians not fully aware about rational use of warfarin	Training of clinicians and residents	Pharmacologist
2	Dietician unaware about food-drug interaction with warfarin	To make food-drug interaction list & train Dieticians	Pharmacologist
3	Patient counselling on INR monitoring and ADR reporting found deficient	To provide counselling to patients based on the leaflet To strengthen clinical pharmacy department by establishing Clinical Pharmacy & Pharmacovigilance department	Clinical Pharmacists and Clinicians
4	No structured patient educational material available in hospital	To prepare bilingual patient education leaflet on Warfarin	Clinical Pharmacists
5	Consideration to drug-drug interactions not done by Clinician while prescribing warfarin.	To make list of drug–drug interactions & train Clinicians	Pharmacologist
6	Preventive action on repeated adverse drug reactions to warfarin not existing	To improve clinician awareness about stringent monitoring of INR to prevent harm to the patient	Pharmacologist

FOLLOW UP & EVALUATION OF CHANGE:

	Process	Outcome	Outcome	Process	Outcome
Criteria	Right indication for Warfarin	Adverse drug reaction or deranged INR when on warfarin	ADRs recognized & action taken within 24 hours	Patient checking INR at prescribed intervals	Patient education on Medication
Benchmark	100%		100%	90%	90%
Gap analysis April to May 2018	100%	30.8%	76.9%	53.8%	61.5%
Second Review May to July 2018	100%	8.3%	94.2%	91.6%	87.5%
Third review July to Nov 2018	100%	12.1%	100%	93.8%	91.2%
Fourth review Dec 2018 to April 2019	100%	4.76%	100%	100%	92.3%



IMPACT OF AUDIT:

- Because of above actions and interventions like establishment of separate Clinical Pharmacy & Pharmacovigilance department, improved awareness on drug-drug and food-drug interactions and patient education leaflet introduction, a dramatic improvement was observed in the standards set for this clinical audit.
- Increase in adherence of INR checking from 76.9% to 100 % patients
- Patient's awareness about warfarin medication was found increased from 61.5% to 100%

To check sustainability of the improvement found in this clinical audit, a surprise audit will be done by Quality Assurance department and Clinical Pharmacists in the 1st quarter of 2020.

CONCLUSION:

Marked improvement was observed in the patients' awareness on drug-drug and food-drug interactions as well as INR monitoring, ADR reporting by clinicians and clinical intervention to prevent harm to the patient. During nutritional assessment, dieticians are providing information to patients about food-drug interactions.

As a policy decision, bilingual warfarin education leaflets are given to all patients on warfarin therapy by clinicians. Patient counseling done by clinical pharmacists during their clinical rounds.

Dr. Sushila Kawade
Manager Quality Assurance

Dr. Priti Dhande
Professor, Dept of Pharmacology

Bharati Vidyapeeth University Medical College Hospital Research Centre, Pune
वॉरफेरीन रुग्ण माहिती पत्रक

वॉरफेरीन हे औषध रक्ताची गाठ तयार होऊ देत नाही आणि झालेली रक्ताची गाठ मोठी होऊ देत नाही.

वॉरफेरीन हे औषध रोज संध्याकाळी ६ वाजता न विसरता घेणे

तुम्ही किती गोळ्या घ्यायचा आणि पुढची तपासणी कधी करायची, हे तुम्हाला तुमचे डॉक्टर सांगतील.

जर खालील लक्षणे आढळली तर तुमच्या डॉक्टरचा सल्ला घ्या

अनैयमित रक्तस्राव, त्रीव्र वेदना, ताप येणे, उलटी होणे, संडास विघडणे, इन्फेक्शन (संसर्ग) होणे

Bharati Vidyapeeth University Medical College Hospital Research Centre, Pune
वॉरफेरीन रुग्ण माहिती पत्रक

योग्य मात्रा (डोस) = योग्य INR (आयएन आर)

वॉरफेरीनच्या सोबत इतर औषध घेतली तर वॉरफेरीनचा गुणावर फरक पडू शकतो. या संदर्भात डॉक्टर आणि क्लिनिकल फार्मासिस्ट चा सल्ला घ्या.

Contact: 7798889616/9096143077

इतर माहिती -:

वॉरफेरीन घेण्याची वेळ :-_____

रक्ताची चाचणी नियमित करणे :-_____

रक्ताची INR मात्रा डॉक्टरांना कळवा आणि डॉक्टरांनाचा सल्ला घ्या.

औषधाची सांगेतलेली मात्रा पुढच्या तपासणी पर्यंत चालू ठेवा.

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Patient education leaflet