Annexure
To,
Mr. M. S. Ganachari,
Dept. of Pharmacy, JNMC,
Belgaum

Dear Sir,

The Ethical Committee [Human] for Ph. D. Research Project, KLE University reviewed and discussed your Ph. D. research project titled 'MONITORING DRUG-DRUG INTERACTIONS AND ADVERSE DRUG EVENTS IN PATIENTS ADMITTED IN TERTIARY CARE TEACHING HOSPITAL' on 20th February, 2008.

After discussion and review of your project, the committee approves the project to be conducted in the present form.

The Ethical Committee expects to be informed about the progress of the study with any changes in the protocol and informed consent and asks to be provided a copy of the final report.

Yours faithfully,

[Dr. Swapnil S. Agarwal]  
Member Secretary  
Ethics Committee,  
KLE University,  
Belgaum

[Dr. S. C. Metgud]  
Chairperson  
Ethics Committee,  
KLE University,  
Belgaum

Copy to:
1. The Registrar, KLE University, Belgaum
2. The SO, Vice Chancellor, KLE University, Belgaum
KLE SOCIETY'S
Jawaharlal Nehru Medical College,
Nehru Nagar, Belgaum-590010, (Karnataka).
INSTITUTIONAL ANIMAL ETHICS COMMITTEE.
Phone No. JNMC (0831) 2471350

Sri S.N.Sambrekar
Chairman, IAEC.
IAEC.

Principal,
MM’s College of Pharmacy,
Belgaum

Dr. A. Jagannadha Rao
Dept. of Biochemistry,
IISc, Bangalore

Dr. P. A. Patil
Member-Secretary

Mrs. Hemalatha M. Swamy, Belgaum
Non-scientific Social worker

Dr. (Mrs) S. C. Metgud,
Officer in-charge,
Central Animal House,
JNMC, Belgaum.

Dr. V. S. Shirol,
Professor of Anatomy.
JNMC, Belgaum.

Dr. R. N. Raichur,
Assoc Professor of Physiology,
JNMC, Belgaum.

IAEC Reg. No.: 627/02/a/CPCSEA
Email: drpapatil@yahoo.co.in

MEMBERS:

Dr. V. V. Gobannavar
Veterinarian,
Belgaum.

Pro. A. D. Taranalli.
Scientist,
College of Pharmacy,
Belgaum

Mrs. Hemalatha M. Swamy, Belgaum,
Non-scientific Social worker

Dr. (Mrs) S. C. Metgud,
Officer in-charge,
Central Animal House,
JNMC, Belgaum.

Dr. V. S. Shirol,
Professor of Anatomy.
JNMC, Belgaum.

Dr. R. N. Raichur,
Assoc Professor of Physiology,
JNMC, Belgaum.

CERTIFICATE

This is to Certify that the research project (Ph.D)
“MONITORING DRUG-DRUG INTERACTIONS AND
ADVERSE DRUG EVENTS IN PATIENTS ADMITTED TO
TERTIARY CARE TEACHING HOSPITAL”

Submitted by Mr. M. S. Ganachari has been approved in the
Institutional Animal Ethics Committee meeting held on 23rd

Dr. A. Jagannadha Rao
Member-Secretary, IAEC,
J. N. Medical College,
BELGAUM-10.

Dr. P. A. Patil
Member-Secretary, IAEC,
J. N. Medical College,
BELGAUM-10.
Informed Consent Form

Informed consent for participation in the study—"Monitoring Drug-Drug Interactions and Adverse Drug Events in Patients Admitted to Tertiary Care Teaching Care Hospital" by Department of Pharmacology, J N Medical College, Belgaum, Karnataka through Mr M.S. Ganachari, Professor, K.I. F.S’s College of Pharmacy, Belgaum, Karnataka.

I have understood the procedure of the study as mentioned in the information sheet about the project entitled "Monitoring Drug-Drug Interactions and Adverse Drug Events in Patients Admitted to Tertiary Care Teaching Hospital" which has been explained to me in my language. I have been given sufficient time to consider the matter for my participation/otherwise in the study.

By the information given to me, I understand that:

1. My participation in the study is purely voluntary.
2. I have the right to consent/ not to consent for participation in the study.
3. I can withdraw from the study at any time.
4. By not consenting to participate or by my withdrawal form the study at any point of time. will not affect the treatment I am receiving.
5. The results of the study and my photograph (in part/ full) may be utilized for the scientific publications for further advancement of science, of course without revealing my identity.
6. My personal identity and other information (revealing my identity) will not be disclosed and used for any other purpose.
vii. There are no monetary or other benefits to me for participating in the study.

Having considered the matter, I consent to participate in the study.

<table>
<thead>
<tr>
<th>SUBJECT:</th>
<th>IMPARTIAL WITNESS:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>Name:</td>
</tr>
<tr>
<td>Address:</td>
<td>Address:</td>
</tr>
<tr>
<td>Signature:</td>
<td>Signature:</td>
</tr>
<tr>
<td>Date:</td>
<td>Date:</td>
</tr>
</tbody>
</table>

*CO-INVESTIGATOR (obtaining consent):*

<table>
<thead>
<tr>
<th>Name:</th>
<th>Address:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature:</td>
<td>Date:</td>
</tr>
</tbody>
</table>

(In case when the subject is illiterate, the impartial witness has to explain the contents of the consent form and patient information sheet in patient's language.)
Patient Information Sheet

Information sheet on the study entitled “Monitoring Drug-Drug Interactions and Adverse Drug Events in Patients Admitted to Tertiary Care Teaching Hospital” in KLES Prabhakar Kore Hospital and Medical Research Center by Department of Pharmacology, Jawaharlal Nehru Medical College, Belgaum, Karnataka.

1. Mr. M.S.Ganachari, from Department of Pharmacy Practice, K.L.E.S’s College of Pharmacy, Belgaum, Karnataka carrying out a multicenter study on “Monitoring Drug-Drug Interactions and Adverse Drug Events in Patients Admitted to Tertiary Care Teaching Hospital” under the supervision of Dr. P.A.Patil, Professor and Head, Dept. of Pharmacology, J N Medical College, Belgaum, Karnataka.

2. You are being requested to take part in this research. Your participation in this study helps in assessing the occurrence of adverse drug reactions (side effects) and thus can help to promote the safer use of medications.

3. If you agree to be a part of this study: from the time of your admission, you will be monitored for the occurrence of adverse drug reactions (side effects). They may occur as part of treatment in some patients. If any adverse drug reaction you suffer, additional details regarding the same will be documented in separate forms for the study purpose.

4. This study will not affect your treatment and there is no invasive intervention. You would not be given any special treatment for the study purpose. No special laboratory tests will be done as part of the study.

5. Results of the study may be published in scientific journals for further advancement of science.
6. If needed, your photograph (partly/fully) will be taken and the same may be used for publication purpose, of course, without revealing your identity.

7. Confidentiality will be maintained throughout the study. Your identity will not be disclosed at any time. Data collected will not be used for any purpose other than described above.

8. Your participation in the study will be purely voluntary and you can withdraw from the study at anytime. Such withdrawal will not affect the course of your treatment. If you have any clarifications about the study procedures, please feel free to clarify the same. You may take your own time to consent or otherwise.
अनुमति पत्र

ये अनुमति पत्र है आपके इस स्टडी में हिस्सा लेने के लिये। "मोमेंटरियम डूग, डूग इंटररेक्शन्स ऑफ़ एवरेस्ट डूग इंजीनियरिंग स्टडी और डूग इंजीनियरिंग स्टडी फार्मेंट फॉर मैनेजिंग हॉस्पिटल" जो कि के.एम.डि.एस. प्रभावक कोर्ट के अस्तित्व और अधिकृत रूप में बातचीत करते हैं। या फार्मेंट फॉर मैनेजिंग जे.एस. मेडिकल कॉलेज, जे.एस. मेडिकल कॉलेज, ज्योतिष, जो कि एम.एस. गणेशचारी के डाक की जा रही है।

मैं इस उपयोग को अच्छी तरह से समझा गया है। जो कि मुझे मैंने अपनी भाषा में समझाना चाहिए।

मूर्त आवश्यक साफ़ दिखा गया, मैंने इस उपयोग में हिस्सा लेने के लिये जो सुनचा मुझे दी गयी है, इसके अनुसार

1. मेरे इस प्रयोग का हिस्सा बनना मेरी अनुमति पर ही आधारित है।
2. मूड़े अधिकार है इस स्टडी को अनुमति देने को और न देने को।
3. मैं इस प्रयोग से कभी भी निर्णय सकता हूँ।
4. मैं इस स्टडी को अनुमति न देने से, मेरे इलाज को कौई प्रभाव नहीं है।
5. इस प्रयोग के परिपालन और मेरा कोई प्रयोग इस स्टडी के स्टडी स्टडी के प्रयोग स्टेटस के लिए हस्ताक्षर किया जा सकता है।
6. मेरी निजी प्रत्याशा को किसी भी समय प्रस्तुत नहीं किया जानेगा।
7. इस स्टडी से मुझे कोई भी अवधिक सहयोग नहीं मिलेगा।

मैं इस प्रयोग को समझते हूँ इस अपना निर्णय लेता हूँ।

मृत्यु: विटामिन:

हस्ताक्षर: हस्ताक्षर:

दिनांक: दिनांक:

सूचना: अगर मृत्यु अनुमति है तो, ती सार्वजनिक को मृत्यु की भाषा में समझाना है।

एम.एस. गणेशचारी, हे सार्वजनिक के.एम.डि. कॉलेज ऑफ़ फार्मेंट, वेंट्री
सूचना पत्र

मरीज सूचना पत्र

सूचना पत्र इस स्टूडी पर आधारित है “मोनिटरिंग गुण, इंटरक्रॉस्क ओर्डर अहस्य गुण इंटररोटिस्क होने वाला ” जो कि के.एल.इ.ए.स. प्रभावकर कोरे अस्पताल और ओषधीय संस्थापन केंद्र में, कार्यालयावासी विभाग, जेएन. मेडिकल कॉलेज, बेंगलाम, कर्नाटक, के द्वारा की गई रही है।

1. भी एम.एस. रायचरा, फार्मासीटालि विभाग, जेएन. मेडिकल कॉलेज, बेंगलाम, कर्नाटक, से इस स्टूडी की शुरुआत कर रहा है । यह स्टूडी डॉ. पार्टील प्रोफेसर ओर्डर हेड, फार्मासीटालि विभाग, जेएन. मेडिकल कॉलेज बेंगलाम, कर्नाटक, की सहायता से की जा रही है।

2. आप से किस्मत के अभिलाष श्रावन से जैसा हानिकारक है कि इस स्टूडी का हिस्सा बनने। आपके इस स्टूडी में हिस्सा लेने से हम ओषधिय के बुरे प्रभावों के बारे में जानकारी मिलेगी और इस से आपको बुरे प्रभावों (ओषधिय) को रोकने में सहायता मिलेगी।

3. अगर आप इस स्टूडी का हिस्सा बनने के लिए वैकल्पिक हैं, तो आपके दाखिले के समय से आपको ओषधिय के बुरे प्रभावों के लिए आपको मोनिटर किया जायेगा। कुछ मरीजों में ओषधिय का बुरे प्रभाव होता है। अगर आप में कोई बुरे प्रभाव होता है, तो आपसे नूह के मेडिकल सूचना को अध्यन के लिए लिखा जायेगा।

4. ये स्टूडी आपके इलाज को कोई नुकसान नहीं करेगी, इस स्टूडी के तहत आपको कोई नया इलाज भी नहीं किया जायेगा। कोई प्रयोगशाला परीक्षा भी नहीं दी जायेगी।

5. इस स्टूडी के परिचारकों को साइटिक जरूरत में परीक्षा भी किया जा सकता है।

6. अगर आपस्वावश्यकता पड़ते हैं, आपका प्रोटोकॉल भी लिखा जायेगा।

7. आपकी पहचान को प्रत्येक नहीं किया जायेगा।

8. आपके इस स्टूडी का इलाज बनना का विचार आपका अपना है। आप किसी भी स्थान स्टूडी को छोड़ सकते हैं। जब आपके इलाज को कोई नुकसान नहीं करेगा। अगर आपको अब भी कोई शंका है तो आप को पूरी आश्वासन है अपने विचारों को बचाने की। आप इस विषय पर विचार करें।

8
भाषिती असल्याचे समस्ती पत्र

जवाहरलल नेहरू मंडिकल कॉलेज वेळागांवर, कर्नाटक, प्रमाण कोणे बुधकाळीन अभ्यासामध्ये सहभागासाठी माहिती असल्याचे समस्ती पत्र प्रभावर कोणे इतिहास व वैज्ञानिक संशोधन केंद्र, औषधीय रसायन शास्त्र विभागात अर्ध पवित्र अभ्याससंबंधी माहिती येथे "औषध्य-औषध्यसंबंधी परस्पर क्रिया आणि औषध्यांच्या प्रतिकूल परिवर्तन यांची तृतीय श्रेणी अभ्यास रुग्णालयमध्ये देखें.

माहिती खालील म्हणजेच प्रामाण्यमय विविध कार्यस्थलातील आणि औषध्यांच्या प्रतिकूल परिवर्तन यांची तृतीय श्रेणी अभ्यास रुग्णालयमध्ये देखें.

माहिती प्रमाणे म्हणजेच पावती करणे आहे.

1. या अभ्यासात माझ्या सहभागात स्वेच्छेने आहे.

2. या अभ्यासात सहभागात घेण्याची मी समस्ती देखे/ न देखें माझ्या अधिकारात आहे.

3. या अभ्यासातुन मी केवळ माझ्यांच्या माध्यमातून घेऊन शकतो/शकती.

4. समस्ती न देखे अथवा या अभ्यासातुन देखे तर मी कुट्झाही निर्विवाद परिवर्तन भेट असलेल्या उपचारांतर होणार नाही.

5. या अभ्यासाचा निश्चयत्व व माझ्या फॉलो (अर्ध/पुर्ण) पुढील वैज्ञानिक संशोधन साठी वापरला जावे शकतो. त्याच प्रमाणे वैज्ञानिक प्रगतिशील, माझी ओळख पटु न देला वापरला जाऊ शकती.

6. माझी वैचारिक ओळख आणि उवाचेत माहिती ( माझी ओळख दर्शविणाऱ्या) ही केवळ माझ्याचे, कुठेही दुसरे-या क्रियान्वयनी साबधानी वापर नये.

7. या अभ्यासाचे भाग प्रेमाने म्हणजे माझ्या अर्थिक व इतर क्रियान्वयनाची समर्थनी दिल्या जाणार नाहीत.
हे सर्व मूर्त विचार येजन, मी या अभ्यासात भाग घेण्याची समस्ती देत आहे।

<table>
<thead>
<tr>
<th>क्रमांकाठी</th>
<th>निर्दिष्ट साक्षीदायकाठी</th>
</tr>
</thead>
<tbody>
<tr>
<td>नाव :</td>
<td>नाव :</td>
</tr>
<tr>
<td>पत्ता :</td>
<td>पत्ता :</td>
</tr>
<tr>
<td>सही :</td>
<td>सही :</td>
</tr>
<tr>
<td>तारीख :</td>
<td>जर सण निर्धार असल्यास निर्दिष्ट साक्षीदायकांने परीक्षी समस्ती मजकूर हा सणास समजेल अशा भाषेत सांगावे।</td>
</tr>
</tbody>
</table>

सह संशोधक (अनुमति घेणारे)

नाव : श्री. एम. एस. गणापती, प्राकीर्ष, के.एस.ए. कॉलेज ऑफ़ कार्यमालिके, वेळगाव

पत्ता : डिपार्टमेंट ऑफ़ कार्मिकोलाजी, जे.एन. मेडिकल कॉलेज, वेळगाव, कर्नाटक

सही:

तारीख :
हन्नाचे माहिती पत्तूँ

जवाहरलल नेहरू मेडिकल कॉलेज बेंगलूर, कर्नाटक, भारत में अनेक संस्थाओं के तरकके पुर्वी अध्यासकारके 'भारती' पत्र "आळळा--अध्यासमंत्रिम परस्पर क्रिया आणि अध्यासार्थक प्रतिकूल परिणाम याची तृणी श्रेणी अध्यास पर्यायवळ शक्तिल देखील देखरेख."

1. मी, एम. एस. गणाचारी, आळळा विभाग, जे.एन. मेडिकल कॉलेज, बेंगलूर, पुर्वी शिक्षका अमर्गत "आळळा--आळळा अध्यासमंत्रिम परस्पर क्रिया आणि अध्यासार्थक प्रतिकूल परिणाम याची तृणी श्रेणी अध्यास पर्यायवळ शक्तिल देखील देखरेख. हा बुढ़कंठदी अध्यास हानी चेतन आहे. मी हा अध्यास, डॉ. पी.पी. पादील, प्रो. व विपण आळळा रसायनशास्त्र, जे.एन. मेडिकल कॉलेज, बेंगलूर, कर्नाटक शाही देखील देखरेखी खाली करत आहे.

2. आळळा विनेती कर्याचार येते की, आणण या संशोधनात्मक अध्याससंग्रह भाग चालवा, जे.पे क्रमान आळळा आळळा अध्यायांमध्ये धीरजत दुर्योगिण दोरात याची पदविकरण कर्याचार पदत होईल आणि चाहुण आळळा अध्यास सुरक्षित आळळा उपचार पदविकरण चालवणा मिळतेल.

3. जर तुझी या अध्यास क्रमान भाग चेतनास इच्छुक असल; तर प्रवेशाच्या वेळेपासून तुझी आळळा विनेती कर्याचार दुर्योगिण होतात याच्या पदविकरणच्या असल. जे काही रुग्णांमध्ये आळळा पदविकरण भाग महजून आढळत. जर तुझीला एखादा आळळा दुर्योगिण व्यतीत असेल तर त्या वर्तनी अधिक माहिती वेळजिंना पॉर्मिंडीही अध्यास सर्वित नोंदवली जाघाल.

4. वा अध्यासाचा तुम्हाचा इलाजात्तक कुटकल्यांशी तुम्ही दुर्योगिण होणार नाही आणि कुटीली चिकित्सक प्रयोग नसलेला. तुम्हाच्या चाल अध्याससाठी कुटीली विशेष अध्यासपासर केला जाऊन नाही. अध्यास क्रमान एक भाग महजून प्रयोगशाळेत कोणत्याही विशेष चाहचत्या चेतना जाऊन वहीं.

5. वा अध्यासाचे निष्कर्ष वैज्ञानिक प्रतिक्रिया विज्ञानाच्या ग्रामीणसाठी प्रसिद्ध केलेला जात शक्तिल.

6. जर आयुर्विकाःच्या भागात तुम्ही कोटो (अर्थांत पूर्ण) घेतले जातील आणि ते प्रसिद्धसाठी वडपले जाऊ शक्तिल, निष्कर्ष, तुमच्या ओठखऱ न पट्ट देता.
7. अभ्यास ऋण पूर्ण होई परेैंत गुपला संखली जाईल. तुम्ही ओळख कशीही कुठेही उच्चेरी केली जोणार नाही. एकत्रिी केलेली माहिती वा कारणालेल्ये दुसरं-तर कोणत्याही कारणांसाठी वापरली जाणार नाही.

8. तुम्ही सहभाष या अभ्यासांसाठी स्वेच्छेने असेल आणि या अभ्यासांकडे मधून तुमच्या सहभाष तुम्ही केंद्राही काहून पेहुऱ शकला. आणि या भाषा कुठमाही विपरीत परिणाम तुम्ही उपचारांवर होणार नाही. परंतु तुम्हाला या अभ्यास बहुत कुठलेही स्पष्टीकरण हवे असल्यास मोकद्दमातील बिच्छाम. तुम्ही अनुमति द्यावी किंवा नाही हे उद्देश्यास राखला चा तेलं पेहुऱ शकला.
1. ಕೆ. ಬಾರಿ ಡಿ. ವಿ. ರಾಜು ಕೇಂದ್ರದ ಕನ್ನಡ ಸಾಹಿತ್ಯ ಸಂಸ್ಥೆಯ ಮೇಲೆ ಸಾಧನ ವ್ಯವಹಾರದಲ್ಲಿ ಸಾಧನಾಂಶ ವ್ಯವಹಾರದಲ್ಲಿ ತೆಗೆದುಕೊಂಡರು. "ಕೆ. ಬಾರಿ ಡಿ. ವಿ. ರಾಜು ಕೇಂದ್ರದ ಕನ್ನಡ ಸಾಹಿತ್ಯ ಸಂಸ್ಥೆಯ ಮೇಲೆ ಸಾಧನಾಂಶ ವ್ಯವಹಾರದಲ್ಲಿ ತೆಗೆದುಕೊಂಡರು.

2. ಕೆ. ಕೆ. ಬಾರಿ ಡಿ. ವಿ. ರಾಜು ಕೇಂದ್ರದ ಕನ್ನಡ ಸಾಹಿತ್ಯ ಸಂಸ್ಥೆಯ ಮೇಲೆ ಸಾಧನಾಂಶ ವ್ಯವಹಾರದಲ್ಲಿ ತೆಗೆದುಕೊಂಡರು.

3. ಕೆ. ಬಾರಿ ಡಿ. ವಿ. ರಾಜು ಕೇಂದ್ರದ ಕನ್ನಡ ಸಾಹಿತ್ಯ ಸಂಸ್ಥೆಯ ಮೇಲೆ ಸಾಧನಾಂಶ ವ್ಯವಹಾರದಲ್ಲಿ ತೆಗೆದುಕೊಂಡರು.

4. ಕೆ. ಬಾರಿ ಡಿ. ವಿ. ರಾಜು ಕೇಂದ್ರದ ಕನ್ನಡ ಸಾಹಿತ್ಯ ಸಂಸ್ಥೆಯ ಮೇಲೆ ಸಾಧನಾಂಶ ವ್ಯವಹಾರದಲ್ಲಿ ತೆಗೆದುಕೊಂಡರು.

5. ಕೆ. ಬಾರಿ ಡಿ. ವಿ. ರಾಜು ಕೇಂದ್ರದ ಕನ್ನಡ ಸಾಹಿತ್ಯ ಸಂಸ್ಥೆಯ ಮೇಲೆ ಸಾಧನಾಂಶ ವ್ಯವಹಾರದಲ್ಲಿ ತೆಗೆದುಕೊಂಡರು.

6. ಕೆ. ಬಾರಿ ಡಿ. ವಿ. ರಾಜು ಕೇಂದ್ರದ ಕನ್ನಡ ಸಾಹಿತ್ಯ ಸಂಸ್ಥೆಯ ಮೇಲೆ ಸಾಧನಾಂಶ ವ್ಯವಹಾರದಲ್ಲಿ ತೆಗೆದುಕೊಂಡರು.

7. ಕೆ. ಬಾರಿ ಡಿ. ವಿ. ರಾಜು ಕೇಂದ್ರದ ಕನ್ನಡ ಸಾಹಿತ್ಯ ಸಂಸ್ಥೆಯ ಮೇಲೆ ಸಾಧನಾಂಶ ವ್ಯವಹಾರದಲ್ಲಿ ತೆಗೆದುಕೊಂಡರು.

8. ಕೆ. ಬಾರಿ ಡಿ. ವಿ. ರಾಜು ಕೇಂದ್ರದ ಕನ್ನಡ ಸಾಹಿತ್ಯ ಸಂಸ್ಠೆಯ ಮೇಲೆ ಸಾಧನಾಂಶ ವ್ಯವಹಾರದಲ್ಲಿ ತೆಗೆದುಕೊಂಡರು.
<table>
<thead>
<tr>
<th>ವಿಷಯ:</th>
<th>ಶ್ರೇಣಿ ಸಂಶೋಧನಾ (ಮರಣಸೂಚಿಗಳು)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ವಿಷಯ:</td>
<td>ರೇಖೆ</td>
</tr>
<tr>
<td>ವಿಷಯ:</td>
<td>ಸೂಚನೆ</td>
</tr>
<tr>
<td>ವಿಷಯ:</td>
<td>ಕಾರ್ಯಸಂಸ್ಥೆ</td>
</tr>
</tbody>
</table>

ಆರಂಭ ವಿಷಯ: ಕಾರ್ಯಸಂಸ್ಥೆಯಾದಾಗ ವಿಷಯವನ್ನು ಮಾರ್ಗಾಗಿ ಸಹಾಯ ಸೇವೆಯನ್ನು ನೀಡುವ ಸಮಯದ ವಿದ್ಯಾತ್ಮಕ ವಿಜ್ಞಾನ ಸಂಶೋಧನೆಯನ್ನು ನೀಡಬೇಕು. ಅತ್ಯಂತ ಸುಮಾರು ಸ್ವಲ್ಪ ಕಾಲ ಸಮಯದಲ್ಲಿ ಮೀಮಾಂಸೆಯನ್ನು ಹಚ್ಚಲು ಮಾರ್ಗಾಗಿ ಸಹಾಯ ಸೇವೆಯನ್ನು ನೀಡಲು ವಿಶಾಲವಾಗುತ್ತದೆ.
To your kind attention..................
Please report all Suspected Adverse Drug Reactions (ADRs)

PATIENT SAFETY IS A MAJOR CONCERN

Report ADRs through:
• **ADR drop box - yellow card system (at nursing station)**
• Telephone: 0831-2470400
• E-mail: pharmacovigilance.kle@gmail.com

For further information, please contact: Mr. M.S. Ganachari
GUIDELINES ON ADR AND ITS REPORTING

KLES DR. PRABHAKAR KORE HOSPITAL

"IF YOU SUSPECT AN ADR...
DO NOT ASSUME SOMEONE ELSE
WILL REPORT IT!"

ADR REPORTING FORM
The aim of this study is to create awareness regarding ADRs, increase reporting of ADRs and increase the opportunities to review drug selection and prescribing practices which affects patient outcome.

PREAMBLE:
India has more than half a million qualified doctors and 15,000 hospitals having bed strength of 6,24,000. It is the fourth largest producer of pharmaceuticals in the world. It is emerging as an important Clinical trial hub in the world. Many new drugs are being introduced in our country quite frequently. India being the second most populated country has over one billion potential drug consumers, and no amount of pre-clinical and clinical data is sufficient to ensure the complete safety of a drug. Therefore, under this scenario there is a need for a vibrant pharmacovigilance system in the country to protect the population from the potential harm that may be caused by some of these new drugs. In India, general practitioners, with a large outpatient base tend to be among the first ones to use the drugs entering the market; hence they are in the best position to detect the adverse drug reactions associated with drugs.

(Source: National Pharmacovigilance Protocol, Ministry of Health & Family Welfare, Govt. of India)

IMPORTANCE OF ADR REPORTING:
The JAMA study reported that, in 1994, adverse drug reactions were between the fourth and sixth leading cause of death in the United States.
More recently, a study published in the New England Journal of Medicine found that one in four patients is plagued by side effects from prescription medications. "It's a problem that is common, in many cases the impact could be prevented or reduced, and it has a large impact on patients," said Tejal Gandhi, lead author of the study and an internist at Brigham & Women's Hospital in Boston.

Of the patients who experienced side effects (out of over 1,200 patients), 13% were serious (internal bleeding, low blood pressure, etc.). Another 39% were preventable or potentially treatable, such as a patient accidentally receiving a drug he or she is allergic to.

In an editorial about the study, William Tierney of the Indiana University School of Medicine said, "They found that adverse drug events were fairly frequent and usually mild, although potentially serious, and preventable events were more frequent than any patient or clinician would like (or should be willing) to accept."

Out of the cases that were preventable:

- Patients received the wrong drug 45% of the time.
- Patients received the wrong dose 10% of the time.
- Patients were told to take the drug too frequently 10% of the time.

If measures aren't taken to keep mistakes like those from happening, Tierney says the outlook is dim.
"... Given the increasing number of powerful drugs available to care for the aging population, the problem will only get worse," he said.

Other studies have also found that adverse drug reactions represent a serious risk to Americans.

**ADR reporting in India:**

Peripheral Pharmacovigilance Centres will forward case report forms to the Regional Pharmacovigilance Centres, where the causality analysis is carried out and the information is forwarded to the Zonal Pharmacovigilance Centres. Finally the data is statistically analysed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.

**DRUG THERAPY:**

The purpose of using drugs is to relieve symptoms, treat infection, reduce the risk of future disease, and destroy selected cells such as in the chemotherapeutic treatment of cancer.

When more than one drug is useful, physicians should select the one that is most effective and least hazardous. Every drug has multiple actions; it will affect organs and systems beyond those to which it is specifically targeted. Some patients may also experience idiosyncratic effects as well as allergic reactions to certain drugs. Unnecessary drug use also increases the possibility of drug interactions that may interfere with drug effectiveness and precipitate toxicity.
HOW TO SUSPECT AN ADR?

A symptom that:

• Appears soon after a new drug is started
• Appears after a dosage increase
• Disappears when the drug is stopped
• Reappears when a drug is restarted (do not deliberately rechallenge!)

What questions should be asked if you suspect an ADR?

• Does the patient have a history of other drug-induced problems?
• Does the patient take more than one drug?
• Could an interaction of drug be causing the ADR?
• When did the reaction or symptoms begin?
• Have any of the clinical measurements or lab results recently become abnormal?
• Does the patient have any medical problems that could be causing the symptoms?
• Timings are useful
• Some diseases predispose patients to ADRs
• Long term medication is unlikely to cause new problems
<table>
<thead>
<tr>
<th>CAUSALITY ASSESSMENT OF ADR: WHO scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERTAIN</td>
</tr>
<tr>
<td>PROBABLE/LIKELY</td>
</tr>
<tr>
<td>POSSIBLE</td>
</tr>
<tr>
<td>UNLIKELY</td>
</tr>
<tr>
<td>CONDITIONAL/UNCLASSIFIED</td>
</tr>
<tr>
<td>UNASSESSABLE/UNCLASSIFIABLE</td>
</tr>
</tbody>
</table>
Level of Description of reaction severity

Level 1
An ADR occurred but required no change in treatment with the suspected drug.

Level 2
The ADR required that treatment with the suspected drug be held, discontinued or otherwise changed. No antidote or other treatment required. No increase of LOS (Length of Stay)

Level 3
The ADR required that treatment with the suspected drug be held, discontinued or otherwise changed, AND/OR antidote or other treatment required. No increase of LOS (Length of Stay)

Level 4
a) Any level 3 ADR that increases LOS by at least one day
b) The ADR is the reason for admission

Level 5
Any level 4 ADR which requires intensive medical care.

Level 6
The adverse reaction caused permanent harm to the patient

Level 7
The adverse reaction either directly or indirectly led to the death of the patient

HOW TO REPORT AN ADR?

What should be reported?

* For "new" drugs - report all suspected reactions, including minor ones. (In many countries drugs are still considered "new" up to five years after marketing authorization); For established or well-known drugs - report all serious or unexpected (unusual) suspected ADRs;
• Report if an increased frequency of a given reaction is observed;
• Report all suspected ADRs associated with drug-drug, drug-food or drug-food supplements (including herbal and complementary products) interactions;
• Report ADRs in special fields of interest such as drug abuse and drug use in pregnancy and during locality.
• Report when suspected ADRs are associated with drug withdrawals;
• Report ADRs occurring from overdose or medication error;
• Report when there is a lack of efficacy or when suspected pharmaceutical defects are observed.

**ADR Forms:**

Local ADR Forms (CRF) are made available at nursing stations or by request on phone to extension 1768 from Department of Clinical Pharmacy G+4.

**What to fill in ADR forms:**

<table>
<thead>
<tr>
<th>Patient details</th>
<th>Patient Initials, Age, Gender, Weight, Department, Unit, I.P. / O.P. No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reaction Date</td>
<td>Date of reaction started, Date of recovery, Description of the reaction</td>
</tr>
<tr>
<td>Suspected</td>
<td>Name of medications (brand, generic), Date of the Drug started, Date of drug stopped, Indication for the use, Route and frequency.</td>
</tr>
</tbody>
</table>

• Dechallenge and rechallenge information
• Relevant laboratory data, other relevant history
• Reporter’s information like Name, Contact No; Sign, Date
**NARANJO'S SCALE FOR ASSESSMENT OF ADR:**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Don't know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are there previous conclusion reports on this reaction?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Did the adverse event appear after the suspect drug was administered?</td>
<td>+2</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>Did the AR improve when the drug was discontinued or a specific antagonist was administered?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Did the AR reappear when drug was readministered?</td>
<td>+2</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>Are there alternate causes [other than the drug] that could solely have caused the reaction?</td>
<td>-1</td>
<td>+2</td>
<td>0</td>
</tr>
<tr>
<td>Did the reaction reappear when a placebo was given?</td>
<td>-1</td>
<td>+1</td>
<td>0</td>
</tr>
<tr>
<td>Was the drug detected in the blood [or other fluids] in a concentration known to be toxic?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Did the patient have a similar reaction to the same or similar drugs in any previous exposure?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Was the adverse event confirmed by objective evidence?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**SCORING FOR NARANJO’s ALGORITHM**
- +9 = definite ADR
- 5-8 = probable ADR
- 1-4 = possible ADR
- 0 = doubtful ADR
In order to reduce or prevent drug-related mortality and morbidity, one must efficiently take steps to minimize ADR. This can be done by developing certain strategies like provision of Patient Alert Cards.

**SOME DOs:**

- Ensure that the medicine ordered is the medicine received and actually taken by the patient at the dose advised;
- Verify that the onset of the suspected ADR was after the drug was taken, not before and discuss carefully the observation made by the patient;
- Determine the time interval between the beginning of drug treatment and the onset of the event;
- Evaluate the suspected ADR after discontinuing the drugs or reducing the dose and monitor the patient's status. If appropriate, restart the drug treatment and monitor recurrence of any adverse events.
- Analyze the alternative causes (other than the drug) that could on their own have caused the reaction;
- As a health professional, use relevant up-to-date literature and personal experience on drugs and their ADRs and verify if there are previous conclusive reports on this reaction. The National Pharmacovigilance Centre and Drug Information Centres are very important resources for obtaining information on ADR. The manufacturer of the drug can also be a resource to consult;
• Report any suspected ADR to the person nominated for ADR reporting in the hospital or directly to the National ADR Centre.

Detection
• Identify triggers that signal an investigation by the pharmacist. Examples include emergency box usage, abrupt discontinuation of a drug, multiple patients with similar unwanted symptoms on the same drug therapy, and the use of any drug used to treat a symptom rather than a disease, e.g., corticosteroids, epinephrine, antihistamines.

• Provide information to other health care professionals to better identify ADRs, e.g., list of common ADRs by therapeutic category.

Assessment
• Review reports of suspected ADRs and differentiate between obvious medication errors and suspected ADRs.
• Use a validated algorithm to determine the probability that the event is drug related (remaining suspected ADR reports).
• Categorize severity using Hartwig’s scale.
• Track ADRs for patterns and incidence.
• Interact with other health professionals as appropriate.
• Monitor medicines as used in everyday practice to identify previously unrecognized adverse effects or changes in the patterns of their adverse effects.
• Assess the risks and benefits of medicines in order to determine what action, if any, is necessary to improve their safe use providing information to users to optimize safe and effective use of medicines.

• Monitor the impact of any action taken

Risk reduction strategies

Improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions;

• Improve public health and safety in relation to the use of medicines;

• Detect problems related to the use of medicines and communicate the findings in a timely manner;

• Contribute to the assessment of benefit, harm, effectiveness and risk of medicines, leading to the prevention of harm and maximization of benefit;

• Encourage the safe, rational and more effective (including cost-effective) use of Medicines.

• Educate staff (physician, nurses, etc.) and encourage compliance with the ADR reporting program. Include the importance of ADR reporting, identified trends, common signs and detection tips.

• Develop prospective review systems for reducing ADRs, e.g., target drug projects, residents on high risk medications (warfarin, NSAIDs, etc.), residents on >5 medications, and routine monitoring of abnormal laboratory values and high-risk patients.
Adverse drug reactions are an inevitable risks associated with the use of modern medicines. Careful attention to dosage is necessary, taking into account factors such as proper selection of drug, correct titration of dose, proper route and frequency, careful watch on lab investigations, close monitoring of the patient. Genetic status should be taken into account in the few cases where this is appropriate, and it is now possible to genotype individuals, using recombinant DNA methods, for some of the known polymorphisms.
Remember "All health-care professionals have a responsibility to inform colleagues about clinically important adverse drug reactions that they detect, even if a well-recognised or causal link is uncertain."


Developed by:
Department of Pharmacology
J. N. Medical College,
Nehru Nagar, Belgaum.
Extn. No. 1768
PERFORMA OF THERAPEUTIC EVALUATION FOR SUSPECTING ADVERSE DRUG EVENTS AND INTERACTIONS

<table>
<thead>
<tr>
<th>Name:</th>
<th>Presenting complaints:</th>
</tr>
</thead>
<tbody>
<tr>
<td>IP no.:</td>
<td></td>
</tr>
<tr>
<td>Gender: M/F</td>
<td></td>
</tr>
<tr>
<td>Age:</td>
<td>Weight:</td>
</tr>
<tr>
<td>Date of admission:</td>
<td></td>
</tr>
<tr>
<td>Past medical history:</td>
<td>Past medication history:</td>
</tr>
<tr>
<td>Diagnosis Provisional/Final</td>
<td></td>
</tr>
</tbody>
</table>

**Current medications:**

<table>
<thead>
<tr>
<th>Dose, Frequency, route</th>
<th>Date started</th>
<th>Date stopped</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**INVESTIGATIONS**

| Radiology: | |
| Special Investigations: | |
Laboratory data:

<table>
<thead>
<tr>
<th>Biochemical (Serum)</th>
<th>Date</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na⁺ (130-145 mEq/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>K⁺ (3-5 mEq/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cr (0.5-1.4 mg/dL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urea (10-45 mg/dL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ca²⁺ (8.1-10.4 mg/dL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PO₄ (2.5-4.8 mg/dL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCO₃ (24-36 mEq/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cl (98-106 mg/dL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gluc (60-160 mg/dL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uric acid (2.4-7 mg/dL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBAIC (6-8 %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bili. Total (0.2-1 mg/dL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bili. Direct (0.2-1 mg/dL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AST (5-40 IU/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALT (5-40 IU/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total protein (6-8 gm/dL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albumin (3.5-5 gm/dL)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Hematology

<table>
<thead>
<tr>
<th>TC</th>
<th>WBC (4-11x 10⁹)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>DC</td>
<td>Neutrophils (40-70%)</td>
</tr>
</tbody>
</table>
|    | Eosinophils (1-6%)
|    | Lymphocytes (20-40%)
|    | Monocytes (2-10%)
|    | Basophils (0-1%)
| RBC M (4.5-6.5x 10¹²) | F (3.8-5.8x 10¹²)
| ESR M (1-15 mm/hr)    | F (1-20 mm/hr)
| CK MB (<25 U/L)       |               |
| CPK (25-175 IU/L)     |               |
| Lipid Profile:        |               |
| LDL                    |               |
| VLDL                   |               |
Performa for documenting suspected Adverse Drug events & interactions

Note: Please return or inform the Dept. of Clinical Pharmacy, G+4.

DOCUMENTING DRUG-DRUG INTERACTION

IP. NO—— Gender—— Age—— Ward——

Bed No.— Weight——

Reaction Description——

Suspected Drug/s:

Remarks:

Reporter Name——

Signature ——— Date——
WHO PROBABILITY SCALE

**Certain**
- Event of laboratory test abnormality, with plausible time relationship to drug intake
- Cannot be explained by disease or other drugs
- Response to withdrawal plausible (pharmacologically, pathologically)
- Event definitive pharmacologically or phenomenologically (an objective and specific medical disorder or a recognized pharmacological phenomenon)
- Rechallenge (if necessary)

**Unassessable/ unclassifiable**
- A report suggesting an adverse reaction
- Cannot be judged because of insufficient or contradictory information
- Report cannot be supplemented or verified

**Probable**
- Event or lab test abnormality, with reasonable time relationship to drug intake
- Unlikely to be attributed to disease or other drugs
- Response to withdrawal clinically reasonable
- Rechallenge not necessary

**Unlikely**
- Event or laboratory test abnormality with a time to drug that makes a relationship improbable (but not impossible)
- Diseases or other drugs provide plausible explanations

**Possible**
- Event or laboratory test abnormality, with reasonable time relationship to drug intake
- Could also be explained by disease or other drugs

**Conditional/ Unclassified**
- Event or laboratory test abnormality
- More data for proper assessment

**Causality Categories**
- Certain
- Probable
- Possible
- Unassessable/ Unclassifiable
- Unlikely
- Conditional/ Unclassified
DRUG INTERACTION PROBABILITY SCALE

Directions:
- Circle the appropriate answer for each question, and add up the total score.
- Object drug = Drug affected by the interaction. Precipitant drug = Drug that causes the interaction.
- Use the Unknown (Unk) or Not Applicable (NA) category if (a) you do not have the information or (b) the question is not applicable (eg, no dechallenge; dose not changed, etc.).

<table>
<thead>
<tr>
<th>Serial Number</th>
<th>Questions</th>
<th>Yes</th>
<th>No</th>
<th>Unk or NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Are there previous credible reports of this interaction in humans?</td>
<td>+1</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>Is the observed interaction consistent with the known interactive properties of precipitant drug?</td>
<td>+1</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>Is the observed interaction consistent with the known interactive properties of object drug?</td>
<td>+1</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>Is the event consistent with the known or reasonable time course of the interaction (onset and/or offset)?</td>
<td>+1</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td>Did the interaction remit upon dechallenge of the precipitant drug with no change in the object drug? (if no dechallenge, use Unknown or NA and skip Question 6)</td>
<td>+1</td>
<td>-2</td>
<td>0</td>
</tr>
<tr>
<td>6</td>
<td>Did the interaction reappear when the precipitant drug was readministered in the presence of continued use of object drug?</td>
<td>+2</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>7</td>
<td>Are there reasonable alternative causes for the event?</td>
<td>-1</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>8</td>
<td>Was the object drug detected in the blood or other fluids in concentrations consistent with the proposed interaction?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>9</td>
<td>Was the drug interaction confirmed by any objective evidence consistent with the effects on the object drug (other than drug concentrations from question 8)?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>10</td>
<td>Was the interaction greater when the precipitant drug dose was increased or less when the precipitant drug dose was decreased?</td>
<td>-1</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

*Consider clinical conditions, other interacting drugs, lack of adherence, risk factors (eg, age, inappropriate doses of object drug). A ‘NO’ answer presumes that enough information was presented so that one would expect any alternative causes to be mentioned. When in doubt, use ‘Unk’ or ‘NA’ designation.

Total score from the above table defines the final category as:
- Highly Probable (>8), Probable (5 to 8), Possible (2 to 4) and Doubtful (<2)
NARANJO'S ADVERSE DRUG WITHDRAWAL EVENT CAUSALITY ALGORITHM

The total score calculated from this table defines the category as:
Definite (≥9); Probable (5 to 8); Possible (1 to 4) and Doubtful (≤0).

<table>
<thead>
<tr>
<th>Serial Number</th>
<th>Questions</th>
<th>Yes</th>
<th>No</th>
<th>Unknown or Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Are there previous conclusive reports on this reaction?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2.</td>
<td>Did the adverse event appear after the suspected drug was withdrawn?</td>
<td>+2</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>3.</td>
<td>Did the adverse reaction improve when the drug was readministered?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4.</td>
<td>Did the adverse reaction reappear when the drug was rewithdrawn?</td>
<td>+2</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>5.</td>
<td>Are there alternative causes (other than the drug) that could solely have caused the reaction?</td>
<td>-1</td>
<td>+2</td>
<td>0</td>
</tr>
<tr>
<td>6.</td>
<td>Did the reaction reappear when a placebo was withdrawn?</td>
<td>-1</td>
<td>+1</td>
<td>0</td>
</tr>
<tr>
<td>7.</td>
<td>Did the patient previously use the drug chronically?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>8.</td>
<td>Was the reaction less severe when the dose was increased, or more severe when the dose was decreased?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>9.</td>
<td>Did the patient have a similar reaction to the same or similar drugs in any previous exposure?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>10.</td>
<td>Was the adverse event confirmed by objective evidence?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
CRITERIA FOR DETERMINING PREVENTABILITY OF AN ADVERSE DRUG EVENT
(Modified Shumock and Thornton criteria)

SECTION A
Answering "yes" to one or more of the following implies that an ADE is DEFINITELY preventable.

1. Was there a history of allergy or previous events to the drug?
2. Was the drug involved inappropriate for the patient's clinical condition? or was the drug appropriate for the patient's clinical condition not prescribed?
3. Was the dose, route, or frequency of administration inappropriate for the patient's age, weight, or disease state?
4. Was a toxic serum drug concentration (or laboratory monitoring test) documented? or was the serum drug concentration at sub therapeutic levels?
5. Was there a known treatment for the adverse drug event?

If answers are all negative to the above, then proceed to Section B.

SECTION B
Answering "yes" to one or more of the following implies that an ADE is PROBABLY preventable.

1. Was required therapeutic drug monitoring or other necessary laboratory tests not performed?
2. Was a drug interaction involved in the ADE?
3. Was poor compliance involved in the ADE?
4. Were preventative measures not prescribed or administered to the patient?

If answers are all negative to the above, then proceed to Section C.

SECTION C
ADE is NOT PREVENTABLE
ADE SEVERITY ASSESSMENT SCALE
(Modified Hartwig et al., scale)

Mild:

Level 1: The ADE requires no change in treatment with the suspected drug.

OR

Level 2: The ADE requires that the suspected drug be withheld, discontinued, or otherwise changed. No antidote or other treatment is required, and there is no increase in length of hospital stay.

Moderate:

Level 3: The ADE requires that the suspected drug be withheld, discontinued, or otherwise changed, and/or an antidote or other treatment is required. There is no increase in length of hospital stay.

OR

Level 4(a): Any level 3 ADE that increases length of hospital stay by at least one day.

OR

Level 4(b): The ADE is the reason for admission.

Severe:

Level 5: Any level 4 ADE that requires intensive medical care.

OR

Level 6: The ADE causes permanent harm to the patient.

OR

Level 7: The ADE either directly or indirectly leads to the death of the patient.
Adverse Drug Reaction Questionnaire

1. Do you experience ADRs in your day to day practice?
   - Yes [ ]
   - No [ ]

2. If you experience ADRs in your practice what do you do?
   a) Corrective treatment or drug therapy [ ]
   b) Dechallenge the suspected drug [ ]

3. Have you ever reported ADR that you came across?
   - Yes [ ]
   - No [ ]
   If Yes,
   a) How do you report?
      - Verbal [ ]
      - Written [ ]
      - Presenting in medical conference [ ]
   b) To whom/where?
      - Colleagues [ ]
      - Pharmacist [ ]
      - Pharmacovigilance group [ ]
   c) How frequently?

If No,

a) Why?
   - No time [ ]
   - Not interested/ not important [ ]
   - Does not affect the patient care [ ]
   - Not aware where to report [ ]

4. Are you interested to know more about the global reporting systems?
   - Yes [ ]
   - No [ ]
**ADR feedback data form**

1. Common source of knowledge of ADR
   - Books
   - Package inserts
   - Colleagues
   - Journals
   - Internet
   - Medical sales representative

2. Barriers in ADR reporting
   - Lack of awareness
   - Lack of resources
   - Apprehension
   - Lack of Patient feedback
   - Lack of incentive
   - Lack of assistance [paramedical staff]
   - Busy Schedule
   - Non availability of ADR reporting forms

**Your suggestions to improve ADR reporting**

7. Inclusion of pharmacovigilance in UG&PG curriculum
   - Yes
   - No

8. ADR reporting cells be established in all tertiary hospitals?
   - Yes
   - No

10. Effective method to improve reporting in India
    - Compulsory reporting
    - Inventives
    - Prescription monitoring
    - Legal compulsion to report

25
### Awareness Regarding ADR Related Issues

**General ADR and ADR reporting awareness**

1. **Definition**
   - Yes [ ]
   - No [ ]

2. **Grading of ADR**
   - Yes [ ]
   - No [ ]

3. Are you aware of relationship between ADR and
   - Patients Characteristics
     - Yes [ ]
     - No [ ]
   - Prescription errors
     - Yes [ ]
     - No [ ]
   - Patient education
     - Yes [ ]
     - No [ ]

**ADR reporting awareness**

1. Information included to report ADR
   - Yes [ ]
   - No [ ]

2. Do you think awareness of ADR will improve reporting
   - Yes [ ]
   - No [ ]

3. Are you aware of
   - ADR grading based on causality
     - Yes [ ]
     - No [ ]
   - Recently drug withdrawn
     - Yes [ ]
     - No [ ]
   - Information included in reporting ADR.
     - Yes [ ]
     - No [ ]