



INDIAN COUNCIL OF MEDICAL RESEARCH
V Ramalingaswami Bhawan, Ansari Nagar
New Delhi

Developing a Web Based Module for Capturing Acute Coronary Events in Hospitals

New Delhi , India

16th and 17th October 2006

WORKSHOP REPORT

**Developing a Web Based Module for
Capturing Acute Coronary Events in Hospitals**

(Supported by WHO, India, Country Office)

New Delhi , India

16th and 17th October 2006

Report Prepared by

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Division of Non-Communicable Diseases
INDIAN COUNCIL OF MEDICAL RESEARCH
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Acknowledgement

Indian Council of Medical Research, in its efforts to understand the characteristics of acute coronary event patients in India and improve the cardiac care in the country, organized a Workshop on “**Developing a Web Based Module for Capturing Acute Coronary Events in Hospitals**” from 16th to 17th October 2006 at New Delhi; with financial support of WHO Country Office.

Every workshop requires the dedication of many individuals who contribute their time and efforts to enable the workshop to take place. I express my special thanks to WHO, especially, Dr Cherian Varghese and Dr Kavita Venkatraman for their support in carrying out this activity.

I express my deep gratitude to Dr R Tandon and Dr D Prabhakaran for their unstinted guidance in planning various sessions of the workshop. I also express my sincere thanks to Dr LM Nath for immense contribution in streamlining and conducting the overall proceedings of the workshop.

I convey my gratitude to Professor KK Talwar for taking out his precious time to deliver the Chief Guest’s Address.

The chairpersons of the individual sessions and the rapporteurs were instrumental in capturing the information which flowed throughout the presentations and the discussions and I express my sincere thanks to them. Of course, the workshop would not have been possible without the participants listed in Annexure, whose presence is deeply acknowledged.

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Finally, gratitude is due to all persons from the staff of Division of NCD, especially Mr PK Chawla, too numerous to mention, that helped to make the Workshop a success.

(Dr Meenakshi Sharma)
Senior Research Officer, ICMR

1. INTRODUCTION

1.1 Background

The spectrum of diseases in India is changing from one of communicable diseases and perinatal and nutritional disorders to one of predominantly non-communicable diseases including cardiovascular diseases, diabetes, cancer and chronic obstructive pulmonary disease. The changes in the economic, social and demographic determinants of health are responsible for the observed changes in disease pattern. The increased threat of adult chronic diseases is in a backdrop of unabashed crisis of infectious diseases and environmental degradation. Few cross sectional studies from different parts of India have also shown a rising trend in prevalence of coronary artery disease (from 1% in 1960 to 10.5% in 1998) in urban India as well as in rural areas (a two fold increase). According to the Atlas of Heart Diseases, India had more than 1.5 million deaths due to coronary heart disease in 2002 which was the highest in the world. With the “greying of India”, it is anticipated that the mortalities due to CVDs will double from 1985 to 2015. However, of particular concern to developing countries like India is not only the high burden of CVDs, but also the effects of CVD on the productive workforce aged 35-65 years. For example, heart diseases are arising in Indians 5 to 10 years earlier than in other ethnic groups around the world. According to the INTERHEART study the median age for first presentation of acute MI in South Asian (Bangladesh, India, Nepal, Pakistan, Sri Lanka) population is 53 years whereas that in Western Europe, China and Hongkong is 63 years. Although more number of males is affected than females by acute coronary syndrome, distinct gender differences exist in terms of presentation of symptoms, validity of diagnostic tests, drug side effects, and complications.

Cardiovascular diseases have a profound adverse economic impact on individuals and societies and their threat on the already overburdened health care system is perceivable. It is therefore crucial to have timely and comprehensive information on the ongoing coronary artery disease burden in India. This will help in developing cost effective strategies to reduce the burden of ACS and (b) optimal management strategies to reduce mortality due to ACS.

A Workshop for developing a web based module for capturing Acute Coronary Events (ACE) in hospital was convened on October 16th -17th 2006 to evolve a study design for undertaking a large multicentric web based prospective study in India. The participants

of the one and a half day workshop included cardiologists from public and private hospitals, teaching hospitals, biostatisticians, representatives from WHO, Cardiology Society of India, members with IT experience from National Informatics Centre, National Institute of Health and Family Welfare (NIHFW), Ministry of Health and Family Welfare (MH&FW) and Indian Council of Medical Research (ICMR), thus covering a breadth of expertise and stakeholders with interest in this topic (See list of participants at Annexure 1). This document is based on the presentations at the workshop and subsequent discussions by the two working groups – “Hospital Surveillance Systems for Acute Coronary Syndrome (Data Needs and Formats)” and “IT Aspects (Connectivity, Data Transfer, Web Based Data Analysis and Reporting)”.

1.2 Objectives

The main objectives of the workshop were to share experiences, identify strengths and weaknesses and take decision on the strategy for addressing the issue of acute coronary events. The specific objectives were as follows:

1. To identify the opportunities for capturing acute coronary events in hospitals
2. To recommend a study design for undertaking large multicentric prospective study on acute coronary event patients

2. INAUGURAL SESSION (CHIEF GUEST'S ADDRESS)

Available Data and Needs for Undertaking Registry of Acute Coronary Syndrome in India. Dr KK Talwar, Director, Prof & Head Cardiology, PGIMER, Chandigarh.

It has been estimated that coronary artery disease (CAD) will be the number one killer in India by 2020 though there is lower prevalence of conventional risk factors. Data on acute coronary syndrome (ACS) from India is sparse. Acute coronary events (ACE) including ST segment elevation myocardial infarction (STEMI), Non ST segment elevation myocardial infarction (NSTEMI) and unstable angina (UA) are major causes of emergency hospital admissions. In USA, 1.7 million ACS patients are admitted every year and one fourth of these cases are STEMI cases. One third of the STEMI cases are non-fatal. Half of the deaths are within first hour of admission. In developed countries there has been a declining trend in mortality since 1960s. The three phases of management of STEMI were clinical observation phase, coronary care unit phase and reperfusion era. There are several limitations to current therapy in STEMI. Randomized trials have reported short term mortality in the range of 6.5 to 7.0%, whereas that in community studies is between 15 to 20%. Advanced age is an important determinant of mortality, reluctance to use life saving drug therapy and higher threshold for intervention.

The Algorithm for STEMI developed by American Heart Association (AHA) was presented. In case of NSTEMI, the short term mortality in USA has been reported to be 1.7% at 30 days. The occurrence of MI was 5.1% at 30 days for both types of AMI. The indicators for NSTEMI and UA are advanced age, diabetes mellitus, Braunwald class II, III or B, ST depression >0.05 mV, T wave inversion >0.3 mV and elevated cardiac enzymes. Dr Talwar also discussed the algorithm for lower risk patients with unstable angina. Data on ACEs in India is not available. There is a need for addressing this issue through both population and hospital based registries.

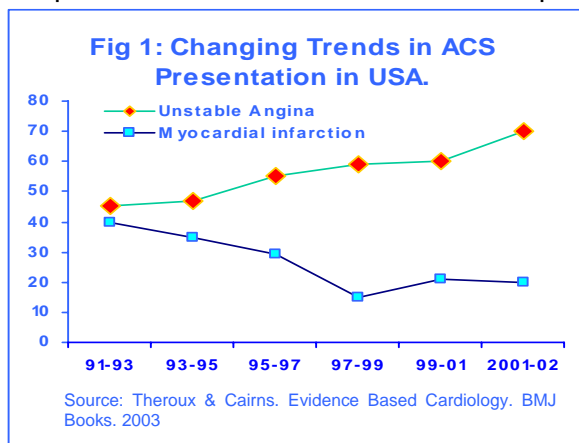
3. TECHNICAL PRESENTATIONS

3.1 Scientific Session I: Addressing a Sustainable Approach for Capturing Acute Coronary Syndrome

Chairperson : Dr R Tandon

3.1.1 *What can we learn from global ACS registries?* - Dr D Prabhakaran, Additional Professor, Department of Cardiology, AIIMS, New Delhi

The differences between clinical trial and registry were emphasized. Clinical trials are by their very nature selective and patients known to be at very high risk are often excluded. The issues which need to be addressed by hospital based ACS registry include pre-hospital, in-hospital, on-discharge and other long-term issues. Globally ENACT, GRACE, MONICA, NRMI, Euro Heart Survey, OASIS 1 and 2, PRAIS-UK are some of the registries which have collected information on STEMI, UA and NSTEMI. Other registries which emerged as off-shoot of clinical trials are RIKS-HIA, GUSTO IIB, PURSUIT, OPUS- TIMI 16, Symphony, PRISM- PLUS, OPTIMAAL, In-TIME, etc. ACS registries can provide information on trends in the epidemiology of ACS, practice patterns, regional



variations, and quality of care issues as well as develop hypothesis. The trends in ACS presentation are shifting from MI to unstable angina in US (Figure 1). However, admissions of less sick patients are not the only cause of reduction in case fatality. A drastic decline in 28-day post MI death (from 18% in 1978-81 to around 10% in 1990-

93) has also been observed in Spain. NRMI 1,2,3 observed an increase in usage of aspirin, oral beta blockers, ACE inhibitor, IV beta blockers and antiplatelet agents with a decline in use of unfractionated heparin, calcium blockers and lidocaine from 1994-99. Registries like Global Registry of Acute Coronary Events (GRACE) observed differences in in-hospital therapy depending on the hospital location. Percentage of patients receiving Gp IIb/IIIa and percutaneous coronary intervention (PCI) was higher in USA as compared to Australia, Canada, New Zealand, Europe, Argentina and Brazil. The latter countries however used low molecular weight heparin in a larger percentage of patients.

Oasis registry reported practice patterns of UA/NSTEMI management in developed and developing countries. Nitrates were used preferentially in developing countries whereas more number of patients went for angiography by 7 days, heparin IV and calcium channel blocker (CCB) in developed countries. The CREATE, GRACE and NRMI registries observed a mortality rate between 7.8 to 9.4% in STEMI cases, whereas the percentage of patients undergoing PCI/CABG were between 17 to 27%. The data provided by the registries are useful in international comparison of outcomes in ACS patients. Among the countries participating in the Oasis I registry, the mean age of presentation for Indians was 57.3 years as compared to average of 64.9 years. The percentage of MI caused deaths was higher in Indian (15%) as compared to China (6.9%). Adherence to beta blockers fell from 62% after 3 months of the event to 46% after one year. In case of patients eligible for thrombolytic therapy/ PCI, this was administered more often in younger patients (<65years). Similar was the case for GpIIb/IIIa inhibitor. Age related differences in patterns of use of medications, catheterization, therapeutic revascularization and clinical outcomes were also observed by these registries. The use of lipid lowering drugs and angiography declined in older patients. Gender inequality was visible in lower usage of preventive drug treatment. Recording of symptom to door and door to needle/balloon time helps not only in improving clinical management but also suggests a need for generating community awareness for recognizing early symptoms of ACS. Dr Prabhakaran also highlighted the impact of ACS registries on undertaking quality improvement initiatives. A study carried in Trichur in Kerala in secondary hospitals pointed to improvement of management after initiation of study. Globally registries have been useful in increasing awareness, improving knowledge, modifying practice patterns, identifying specific risk factors, developing and assessing algorithms of affordable clinical care for ACS.

3.1.2 National Surveillance Systems – Opportunities for Acute Coronary Events Surveillance. Dr Bela Shah, Sr DDG, Division of Non Communicable Diseases, ICMR

ICMR and WHO have assisted several NCD risk factor surveillance activities including development of Sentinel Health Monitoring Centers in India [WHOSTEP wise approach 1 and 2]. The WHO STEPS approach was adapted for conducting a survey of NCD risk factors in the selected sample of urban, rural and peri-urban population aged between 15 to 64 years and included males and females. The study was done at 6 sites across

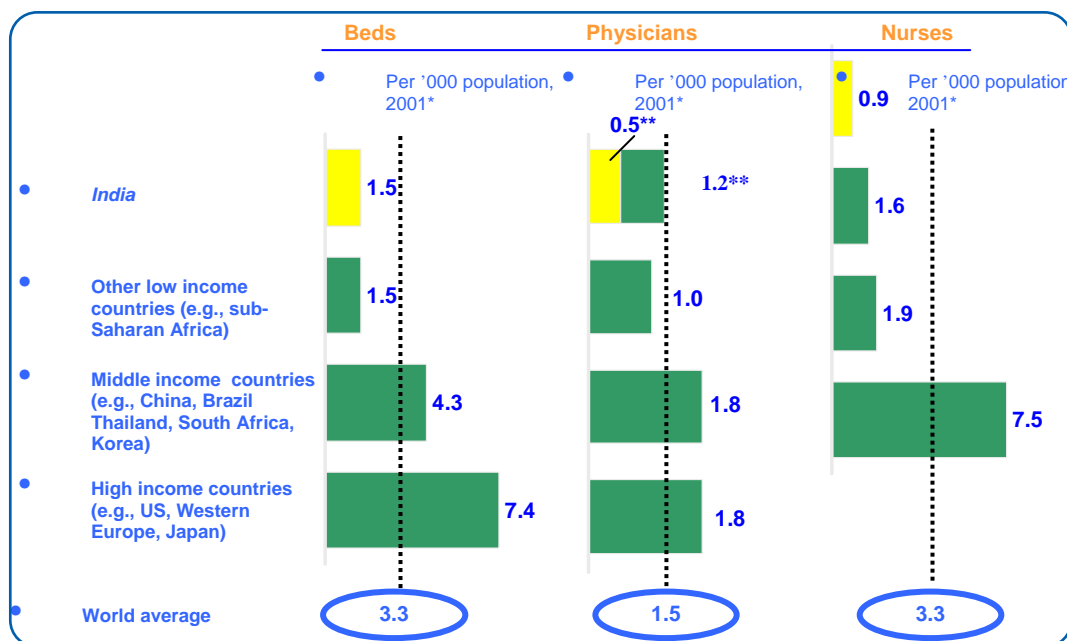
the country, viz. Ballabgarh, Chennai, Dibrugarh, Delhi, Nagpur, and Trivandrum. During 2002–2003, data on behavioral and physical measurements, risk factors including tobacco and alcohol consumption, diet, physical activity, weight, height, blood pressure and waist circumference was collected. The data was collected in 42,000 individuals in five decadal age groups (15-24, 25-34, 45-54, 55-64 yrs), and 250 persons were recruited in each age and sex category. Current usage of smoking tobacco was observed in 22.5% to 36% of males, while it was negligible in females. Use of smokeless tobacco was lower across all centers, but women reported a higher usage. Current consumption of alcohol in men ranged from 75-95% across various populations, whereas 28- 50% of women in rural and slum areas of Dibrugarh and peri-urban areas of Trivandrum reported high consumption of alcohol. The consumption of fruits and vegetables was low across all centers in both sexes. Physical inactivity was observed in 25-90% of study subjects. Another common observation in all centres was higher mean BMI and waist circumference in urban females as against their male counterparts. Hypertension was more frequently observed in urban men and women (17-45%), with lower mean values in females as compared to men.

An exploratory study into the determinants and community perception and barriers for NCD risk factors was also conducted using WHOSTEP wise approach 1. The study was carried out in urban area of Dilshad Garden and slums of Sunder Nagri, Delhi. The determinants of risk factors in urban population included individualistic attitude and life-style mechanical comforts, fast- food culture, sedentary life style etc., whereas that in the slum population were adulteration of food, vegetables commodities of daily use and unhygienic environment, pollution etc. Barriers for modifications in urban area were busy life style, working spouse, lack of time, middle class urban culture, lack of motivation and lack of will-power etc. whereas in slum area, it was poverty, lack of awareness and education, peer group pressure, social environment, unemployment, etc. ICMR-WHO studies have shown the feasibility of advocacy and partnerships between public and private sector and acceptability at government level. Centralized training, close monitoring in response, pro-activeness and supervision is required for enhancing the quality of data. Uniformity of protocol, sensitivities, timeline, funding are essential features of the wider network. Budgetary provision for undertaking quality assurance measures (centralized training, site visits, correspondence etc.) need to be increased.

3.1.3 Public Private Partnerships for Developing Web Based Acute Coronary Events Data - Dr RR Kasliwal, Director, Non-Invasive Cardiology, ESCORTS Heart Instt. of Research Centre, New Delhi

India was a signatory to the Alma – Ata declaration, 1978 to attain the global objective of “Health for all by 2000 AD”. But we are far from reaching that vision.

Figure 2: Comparison of health services in low, middle and high income countries with India

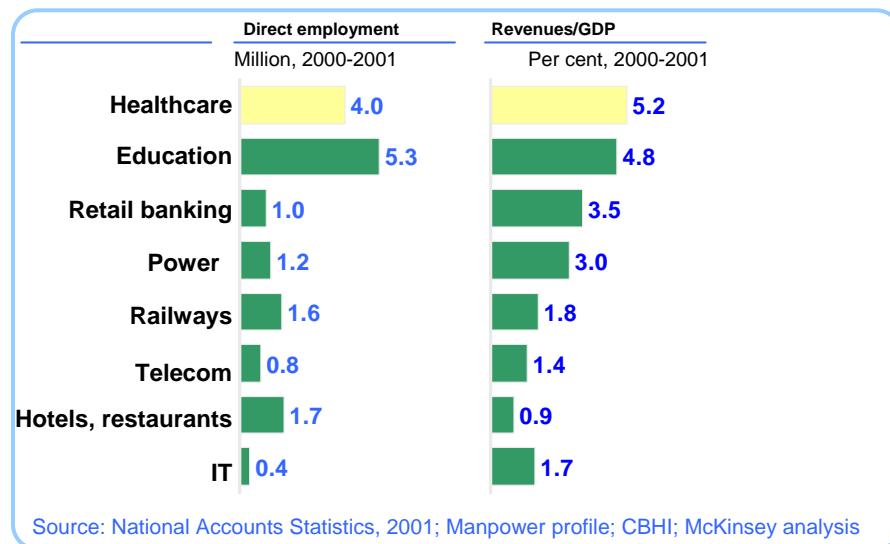


** Registered allopathic physicians only; *** Including registered Indian Systems of Medicine physicians
 Source: Asian Health Services; Indian Nursing Council; World Development report, 200; World Bank report, 2001; McKinsey analysis

Over the past 40 years, the prevalence of CAD in urban India has increased from 6 to 8 times. With 31.7 million diabetics, India is the diabetes capital of the world. Importantly, diabetes has been considered the CAD risk equivalent. Launching of preventive strategies, early detection and treatment hold the key to reducing of the cardiovascular disease burden. In order to achieve these targets it is fundamental to obtain data on the magnitude of the problem, identifying characteristics of disease and management

practices in India. An acute coronary event registry will be helpful in obtaining data with tools which are relatively inexpensive compared to randomized controlled trials, provides representative, population-based data with sufficient clinical detail and has a potential to generate new knowledge by identifying hypotheses for future randomized control trials. Building an ACS registry will require a coordinated approach through partnership with clinical academic centers, government agencies, private agencies and health care industry. Dr Kasliwal suggested that the aim of public-private partnerships should be to identify sustainable and reproducible strategies to help accelerate the impact of health service research on direct patient care and to improve the outcomes, quality, efficiency, and cost effectiveness of care. Private sector caters to a substantial proportion of patients and has state of art facilities, newer technologies and there is a greater use of information. The structural and organizational diversity of public and private health systems may help to improve the quality and reach of health care, provide evidence based knowledge to practioners, patients and policy makers. Data obtained through such partnerships will be helpful in governmnet's efforts to improve the quality of care. Dr Kasliwal highlighted the importance of healthcare in economy of the country by comparing the direct employment and revenue generated by this sector as compared to others (Figure 4)

Figure 3: Comparison of direct employment and revenue generated by various sectors



Dr Kasliwal gave the example of facilities and achievements of ESCORTS. The hospital uses an electronic system to track the patient's journey from initial registration through treatment and final discharge. The integrated electronic health record (EHR) is held in a single central database, incorporating a wide range of administrative and medical information, from laboratory and radiology analysis to pharmacy, stock control and billing data. Entire clinical details of the patient are accessible from any ward, any lab or any OPD room. The hospital has state-of-the-art software system for digital acquisition, storage and management of Echo-Doppler images. ESCORTS has also been part of multicentric registry, Survey of Assessment and Management of CoRonary Heart Disease PaTients (SMART). The objectives of this registry were to recognize in-hospital trends of management of coronary heart disease patients, assess therapy in terms of intensity, improve treatment practices based on contemporary evidence and set management protocols thereof. Chest pain was the reason for 89% of the hospital admissions, followed by dyspnea on exertion (10%) and congestive heart failure (CHF;1%). Sixty-nine percent of the patients were diagnosed to have unstable angina, 26% had AMI and 5% NSTEMI at presentation. Aspirin, nitrates, beta blockers, ACE inhibitors, statins and unfractionated heparin were used extensively. Low molecular weight heparin and GpIIb/IIIa inhibitor were used in 20% and 7% of the UA cases respectively. Angiography was done in 95% of the cases in this private sector set-up. The institute also has a community outreach program. The program aims to provide cardiac care to the deprived and underprivileged at their doorstep and simultaneously provides resident doctors an excellent opportunity to develop a concept of community health.

3.2 Scientific Session II: Operational Issues in Capturing Acute Coronary Syndrome

Chairperson: Dr LM Nath

3.2.1 ACS - Developing Reporting and Tracking Systems and Assessing Outcomes in Indian Scenario – Dr Prem Pais, Vice Dean & Head, Department of Cardiology, St. John’s Medical College, Bangalore

Dr Prem Pais reviewed the CREATE registry, the first large registry in ACS from any developing country. Recruitment of cases started in December 2000. Over 21,000 patients from 88 centers (44, 8, 13, 27 centers in South, East, West and North India) in 56 cities were recruited over 5 years. Both teaching (52.4%) and non teaching (48.6%) participated in this project.

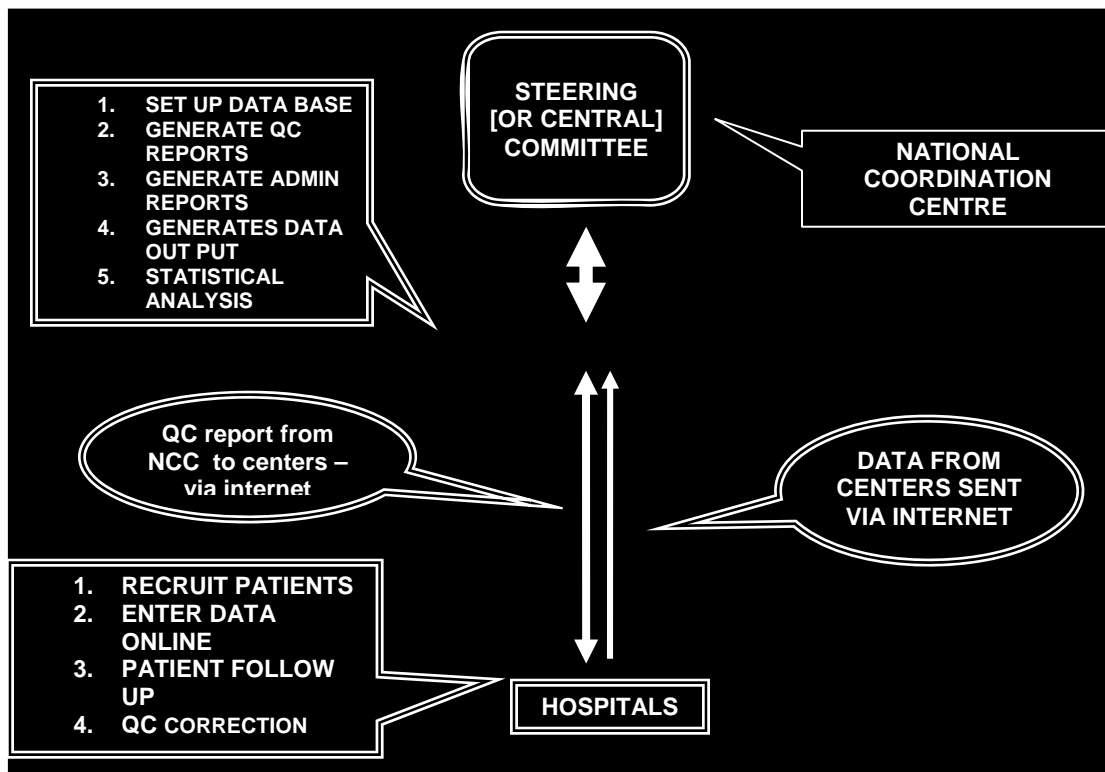
The National Coordinating Centre at St. John’s Medical College, Bangalore developed a simple 4 page case report form, three pages for in-hospital stay and one page for 30 day follow-up. Over 90% of the data is collected in numeric form or check boxes. The information in the proforma mainly consisted of patient identification number, treatment/procedure undertaken during hospitalization, events and outcome in the hospital, treatment taken after discharge, events and procedures after discharge upto 30 days from admission. The inclusion and exclusion criteria were set-up. All consecutive cases with typical signs and symptoms of ACS with ECG finding or signs suggestive of ACS, with or without ECG findings, but definite history of ACS were included. Exclusion criteria included definite inability to attend the 30-day follow up visit [lack of definite address, visitor from another city who is unlikely to come for the follow up visit], terminal illness other than index event that would limit the 30 day follow up visit and the patients who had been treated elsewhere for this episode without adequate records. The percentage of STEMI and NSTEMI cases registered with CREATE registry were 61% and 39% with mean age of 59.2 years and 62.6 years respectively. Around 24% of the both STEMI and NSTEMI cases had BMI>24.9. The median time from pain onset to presentation in NSTEMI (8.0 hrs) was greater than that in STEMI (5.0 hrs) cases. Mean door to treatment (thrombolysis) time was 50 minutes in STEMI cases. At presentation, STEMI and NSTEMI cases showed history of MI in 11.5 versus 26.6%, hypertension in 31.4 versus 47.5% and diabetes in 26.9 versus 35.8% respectively. Majority of the cases (53%) were from lower middle class, followed by upper middle class (26%), poor (14%)

and rich (7%). The death rates adjusted for age, sex, previous MI, diabetes mellitus, hypertension, presence of Cardiac Cath Lab was highest for poor (11.6%). Thirty day follow up of the cases also observed higher percentage of deaths and stroke in poor class. The lowest socioeconomic class had least access to angiography, PTCA and CABG though there were not any particular differences in drugs given across all socioeconomic groups. Follow up of the cases for 30 days showed higher death rates, recurrent MI, stroke, cardiac arrest, shock and bleeding in NSTEMI cases as compared to STEMI cases.

Dr Prem Pais suggested the need for expanding the study to more number of centres across the country. Simple methods for data collection including web based proforma need to be developed. A web based data collection and tracking system needs to be set up with connectivity for minimum 300 users and simultaneous access to around 50 users. Data may then be transferred to appropriate statistical software for analysis.

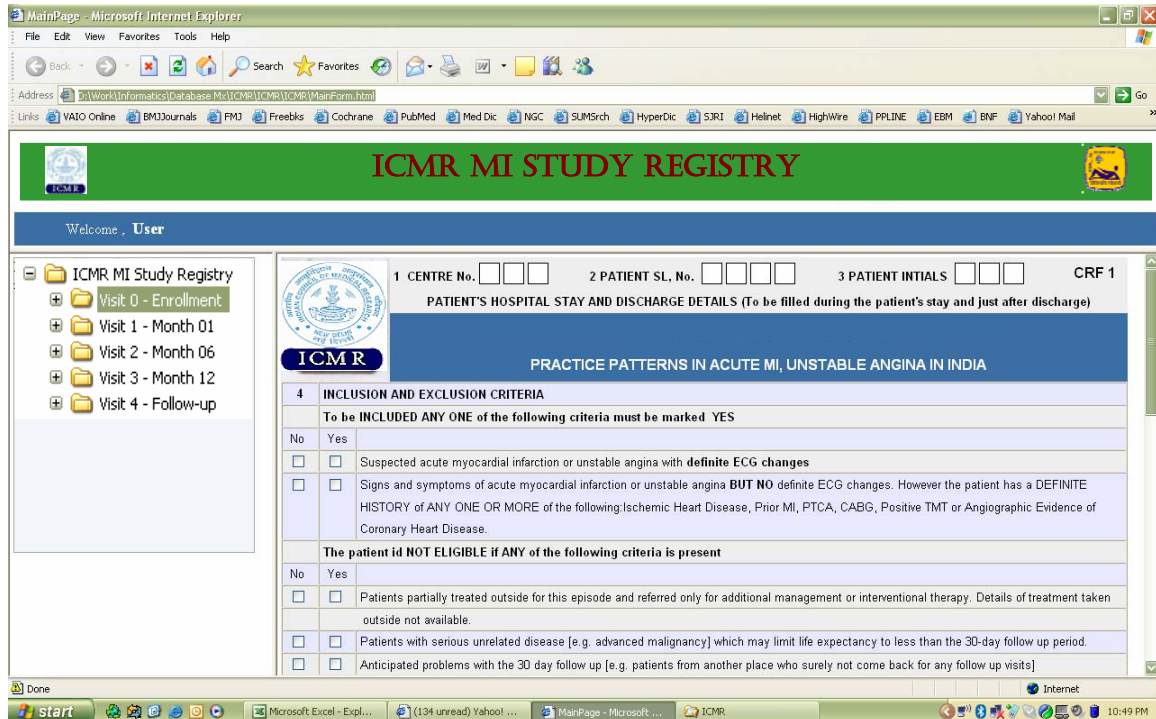
The organizational structure of such a web based network is shown in figure 5.

Figure 4: Proposed organizational structure of web based network for ACE registries



Dr Prem Pais also suggested the design of the web based proforma which could be floated on the website created for this specific purpose (Figure 5).

Figure 5: Design of the web based proforma



3.2.2 Operational Issues – Data Management – Dr Nand Kumar, Officer-in-charge NCRP, ICMR, Bangalore

Dr Nand Kumar presented the methodology for handling the registry. He illustrated the example of cancer database in the form of National Cancer Registry Program (NCRP) initiated by ICMR in 1981. NCRP has many objectives including (i) Generation of data on the magnitude and patterns of cancer based on morbidity and mortality information in different regions of the country according to age, sex, anatomical site of cancer and proportion of histological type or microscopic confirmation for each site, patterns of different types of cancer according to relative proportions or ratio in various population sub-groups such as religion, language spoken, educational status, clinical stage of disease at which patient comes to the hospital, when possible nature of treatment

received and outcome; (ii) undertaking epidemiological studies based on observations of the registry data; (iii) providing database for developing appropriate strategies to aid National Cancer Control Program; and (iv) developing human resource in cancer registration and epidemiology. Cancer registration by NCRP is through population and hospital based registries, both with distinct objectives. Hospital based cancer registries assist case control studies by rapid notification, participate in clinical research to evaluate therapy, promotes institutional based cancer control activities, help assess quality of hospital care and cancer services in covered area, helps plan hospital facilities and contributes to professional education. On the other hand, population based cancer registries are the foundations for sound, descriptive/ analytical studies, build a background for overall clinical research, provides indicators for cancer control activities, help assess effectiveness of preventive measures, helps to plan cancer services for geographic area and contributes to professional and public education

Dr Nand Kumar considered four key factors: (a) data collection, (b) data transmission to a central registry, (c) the procedure for collating information at a central registry and entering it into a common database, and (d) a tool to deal with that information through linkages to other databases, data analysis and reporting. Data collection is done by individual registries using a standardized common core proforma. The information in this mainly consists of patient identifying information, demographic facts, details, diagnostic criteria's, clinical stage of the disease and the type of treatment given. Attempts are also made to follow-up the cases. However, NCRP has encountered problems with follow-ups in majority of cases due to which it has not been possible to obtain data on stage of disease and treatment based survival. Modern electronic information technology has been used to capture information on cancer cases as and when they are microscopically diagnosed and reported. All collaborating centers transmit the required information on all malignant cases on-line through a web-site. Registries send the data to the Coordinating Unit as soft-copy in MS-Excel, ASCII or other formats. These data are then converted to a uniform format by the Coordinating Unit and quality control exercises are carried out. Several range checks (to ensure validity of numeric codes and their conformity with the keys to the codes), consistency checks (to obtain a logical relationship while relating the codes of two variables) and duplicate checks (based on registration number, name, age, sex and ICD-10) are also carried out by the Coordinating Unit. Once data is finalized in correspondence with the individual registries, annexure tables are generated and reports

prepared. Average cost per case by urban population based cancer registries (PBCR) is Rs 350/- whereas for rural PBCR is Rs 4100/-. The acute coronary event registries can be built on the cancer registries model.

3.2.3 Experiences with Web Based Surveillance Data Reporting – Dr M Bhattacharya, Professor and HOD, Deptt. Of Community Health Administration, National Instt. of Health and Family Welfare, New Delhi

Dr M Bhattacharya in her presentation suggested that first a consensus needs to be generated as to the components and their indicators which will be used for the monitoring system. To handle the information from different parts of the country, the promise of a web to manage information more intelligently and efficiently is very attractive. However, besides intelligent functioning the system must be robust and capable of recovering from minor defects and easy to maintain in daily use. When the user's need changes, it should be easy to be modified, reprogram and add new functionality. The system must also be able to scale up, if the requirement arises. Dr Bhattacharya illustrated the steps for implementation of a web based data collection and analysis system which included analysis of requirement, design of architecture, design of UI, design of DB, testing of system, repetitive gradual development, installment of system, training of users and operation of systems. Training of the personnel, data back up facilities are integral part of the web based registry. The system should have range, consistency and duplicate checks. Security issues at various levels, online data analysis and report generation were other issues which were discussed. The salient features of annual sentinel information system for HIV were illustrated.

4. Panel Discussion : Management Issues in patients with ACS

Moderator : Dr Upinder Kaul

Panelists: Dr HK Bali , Dr RR Kasliwal, Dr D Prabhakaran, Dr Sudhir Naik

Effective systems of care are required to deliver optimal care for patients with ACS. Currently, the guidelines issued by American College of Cardiology (ACC), the American Heart Association (AHA) for management of ST-segment-elevation MI and non ST-segment-elevation are used in India. The guidelines were discussed in detail.

The panel discussions focused on the need of having evidence based guidelines for Indian ACE patients. This will provide a general framework for appropriate practice to be followed subject to the practitioner's judgment in each individual case. These guidelines should primarily be for doctors in a hospital setup (emergency physicians, general physicians, rural doctors and cardiologists) who generally manage patients with ACS. Relevant information for general practitioners and others, including ambulance personnel, should also form a part of these guidelines. The guidelines may be designed to provide information to assist decision making based on the best information available in the country. It was felt that registries for collecting information about ACE patients in hospitals will provide the most recent information for local synthesis of these guidelines.

It was suggested that effective management of ACS requires collaborative systems of care which will ensure that patients have access to the services in a timeframe appropriate with their clinical condition. The potential benefits of the treatment available at tertiary care /specialized centres need to infiltrate to the levels downstream. The panelists suggested that the hospitals in rural/remote areas of the country and those with lesser facilities need to have a formal link with specialist centers for consultation as well transfer of acute cases. Development of such systems will ensure equity of access and equity of care. The system of care should address issues like consultation, treatment, acute inter-hospital transfers and education of patients, community, medical professionals and paramedical personnel.

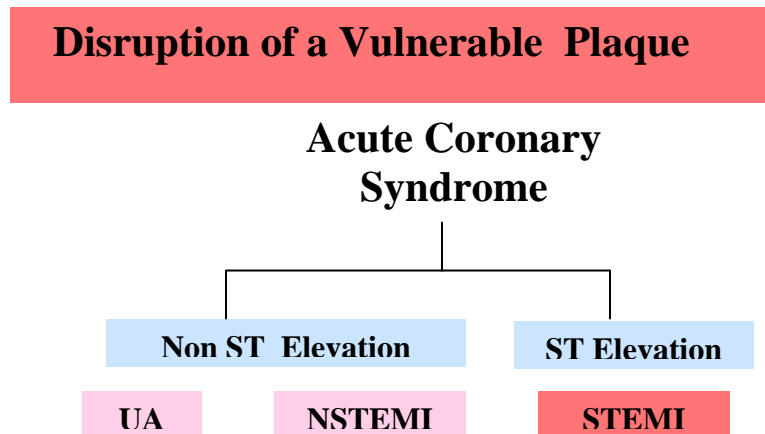
An initial working diagnosis is required to be established to guide clinical decision making and relies on clinical presentation and initial ECG findings, particularly the presence and absence of ST segment elevation. Current international criteria for the diagnosis of myocardial infarction have a strong emphasis on biomarkers, specifically troponin, given its high sensitivity and, in particular, specificity for myonecrosis. ACS data sets relating the presentation and management of ACS need to be compared between various health care providers. To gain the maximum benefit and cost efficacy from new drugs, treatment strategies should depend on the patients' level of risk.

Formal protocols for management of acute coronary events need to be developed and widely circulated so that early treatment can be facilitated.

5.1 Working Group I: Hospital Surveillance System for ACS - Data Needs and Formats

The Group focused on the questions regarding the definitions to be used for acute coronary syndrome by the network of registries across the country. At the outset of this discussion, it was agreed that Acute Coronary Syndromes (ACS) encompassing unstable angina and both ST- segment and non ST- segment ECG elevations are common causes of emergency hospital admission. Most of the patients with ST - segment elevation develop a Q-wave myocardial infarction (QwMI) whereas few develop non-Q-wave myocardial infarction (NQMI). Patients with non ST- segment elevation either develop unstable angina or non ST segment elevation myocardial infarction (NSTEMI). A relationship exists between disruption of vascular plaque and these events (as shown in Figure 6). At present, there is negligible information about ACS in the country. A National Acute Coronary Events (NACE) registry for capturing acute coronary events in hospitals in India was recommended. For the purpose of National Acute Coronary Events (NACE) registry, ACS will be defined as either unstable or intermediate coronary syndrome and/ or acute myocardial infarction.

Figure 6: Events leading to ACS



**UA : Unstable Angina; NSTEMI : non ST-segment elevation myocardial infarction;
STEMI : ST – segment elevation myocardial infarction**

Standard demographic variables like age, sex, weight, height, waist circumference, education, occupation and history of medical intervention for HT, DM etc need to be recorded. It was felt that these datasets will be useful in launching aggressive prevention programs in targeted groups.

It was agreed that identifying patients at higher risk of death, myocardial infarction, and recurrent ischaemia at presentation allows aggressive anti thrombotic treatment and early coronary angiography to be targeted to those who will benefit most. The same information can be used to assess the risk of an adverse outcome. It was however emphasized that risk assessment is a continuous process. The strategy for early risk stratification in patients presenting with chest discomfort should focus on patient's history including anginal symptoms, definite history of Ischemic Heart Disease/ Prior MI/ PTCA/ CABG/ Positive TMT or Angiographic Evidence of Coronary Heart Disease, ECG findings and biomarkers of cardiac injury. This information should be used to determine the high, intermediate, or low likelihood of acute ischemia.

The Group discussed the time at which ECG should be done and type of biomarkers which need to be analysed. It was agreed that ECG should be obtained rapidly in patients with ongoing chest discomfort or with history of coronary heart disease but whose discomfort has resolved by the time of evaluation. Biomarkers of cardiac injury should also be measured in all patients who present with chest discomfort consistent with ACS. Troponin is considered gold standard with demonstrable high sensitivity and specificity. However as all hospitals in the country providing care to ACS patients do not have troponin measurement facility, the other marker CK- MB may be used. However, it needs to be remembered that specificity of CK-MB for myocardial infarction is less than troponin as besides myocardium it is also present in skeletal muscle. In patients with negative cardiac marker within 6 hours of onset of pain, repeat sample should be obtained in the 6- to 12-hour time frame (at 9 hours of onset of symptoms).

The participants of this Workshop agreed that symptoms to door, door to needle and door to balloon time is crucial in the management of acute coronary syndrome. Recording of symptom to door time and reasons for delay is useful for patient education regarding early recognition and response to an acute coronary event. The transport time to hospital after recognition of symptoms by patient is variable as it depends on the

logistics related to transportation including modes of transport, type of city, etc. The type of procedure used for reperfusion depends on the facilities available at the hospital. Data on these parameters is not available in the country and needs to be captured by an appropriate instrument.

Regarding the therapeutic management of ACE patients in India, the participants mentioned that in the absence of country specific guidelines, use of those of American College of Cardiology (ACC) and the American Heart Association (AHA) is suggested. In order to understand the validity of these guidelines in Indian context and to develop evidence based guidelines for ACS management, the registry will sort to assess the management strategies being used in ACS patients and the treatment gaps.

The Working Groups also felt that in order to collect accurate data on the treatment results of hospital stays and to take measures to improve prevention methods, long-term observations of ACS patients is required. Therefore 30 days follow up data after hospital stay is required. Outcome/end point should be death, reinfarction, cardiac arrest, stroke, bleeding and heart failure. Core and optional data formats should be made available from the very beginning and protocol should specify the timeline for initiation of various approaches.

The Group discussed the logistics of the registry in detail. It was felt that the registry should have a dedicated staff, preferably non-medical data entry operator under the supervision of PI. Data collection procedures need to be validated and monitored using double entry and cross-checking by the PI. The case sheet should be used for extracting information manually and then filled on the electronic format for uploading. All records should be maintained as hard data as well as soft data for future references. The registry may be started in 100 hospitals which volunteer to participate in the study. A call for registration of a hospital as part of National Acute Events (NACE) Registry may be floated on the ICMR website as well through IJMR.

The Group suggested that the Institutional Ethics Committee should be informed about the Registry and requested for the waiving off the written consent to be signed by patients or their relatives. This is necessary as the Registry would be collecting data

systematically to look at some issues, which has already been recorded by the hospital and is available for other purposes.

The Group made following recommendations:

1. A need for systematic capturing and reporting of ACE in hospitals through National Acute Coronary Event (NACE) registry was emphasized.
2. A standard definition of acute coronary events may be used by all the centers.
3. Standard demographic variables like name, age, sex, weight, waist circumference, occupation, history of medical intervention for hypertension (HT), diabetes mellitus (DM) etc should be recorded. Risk factors like HT, DM, tobacco (smoking and non-smoking) and previous history of heart problems, sedentary lifestyles and information on socio-economic status should be recorded.
4. The symptoms to door, door to needle and door to balloon time in case of ACE patients needs to be recorded and correlated with outcome at discharge and 30 days (or longer follow up if possible) after hospitalization.
5. The registry may sort to assess the management strategies being used in ACE patients and the treatment gaps.
6. For long term observation of ACE patients, a 30 day follow up data may be collected by all registries. Optionally, six month data may also be tried to be collected.
7. A dedicated non-medical data entry operator under the PI was recommended. Contingency for running up the registry by the hospital may be provided.
8. A protocol for NACE registry and the questionnaire may be developed by ICMR. The electronic method of data collection and analysis needs to be validated. All records should be maintained as hard data or soft data for future references.
9. Institutional Ethics Committee may be informed about the Registry and requested for the waiving off written consent to be signed by patients or their relatives.
10. The study may be piloted in 5-6 hospitals and then expanded to 100 hospitals around the country volunteering to participate in the study. A call for participation in NACE registry may be floated at ICMR website.

5.2 Working Group II: IT Aspects-Connectivity, Data Transfer, Web Based Data Analysis and Reporting, etc

The consensus view of the Workshop participants was that ACS surveillance is an ongoing process involving systematic collection, analysis, interpretation and dissemination of health data. A well-designed and functional surveillance system is fundamental for providing the necessary information for appropriate and timely action and response. The methods of data upload; issues on data sharing and levels of security, quality checks, data management and training were discussed by the participants of the Workshop. The participants recommended that electronic systems may enhance the quality of the system by simplifying the reporting for the end users and the timeliness within the system, from event to action. The system should allow reporting from physicians (web form) and if possible from laboratories (direct from lab data system) over the internet. Users, with a unique ID at different healthcare level, could work with a common central server containing all case records. Privacy at different levels of data entry and data analysis may be assured. Tools for contact tracing need to be developed. However, as internet facilities are not available with all hospitals, therefore participating hospital may be categorized as intermediate or tertiary (or any other appropriate level) based on facilities available.

The following recommendations were made:

1. A core-committee comprising of IT and medical experts may be formed at ICMR
2. Registration of the medical institution/hospital at the beginning of the study using a registration form may be made mandatory.
3. The participating hospital may be categorized as intermediate or tertiary (or an appropriate level) based on facilities available.
4. The hospitals with internet facilities may use web based module whereas others may used paper based questionnaire.
5. The data entry module may be single form with details and variable windows.
6. Data elements for the data capture may be discussed and finalized by the core committee.
7. The format may be filled up by the nurse or the project staff under the guidance of the treating clinician at the participating hospital.

8. The form may be uploaded on the web based interface either by scanning, offline data entry program, or web based data entry.
9. The central coordinating unit at ICMR will be the repository for all the data.
10. The data access may be limited to individual institution's own data only.
11. Pooled analysis of the data will be done at ICMR.
12. Software may be developed for internal checks while the core group may choose some mechanism for external checks.
13. A team of trainers may be formed for training the data managers.
14. A demonstration project in four or five super-specialty hospitals may be initiated.

6. FINAL RECOMMENDATIONS

The workshop participants made the following recommendations:

1. A need for systematic capturing and reporting of ACE in hospitals through National Acute Coronary Event (NACE) registry was emphasized.
2. A core committee consisting of all key stakeholders including medical experts, biostatisticians and IT professionals may be formed at ICMR.
3. ICMR will act as a central coordinating unit and along with workshop participants should design the protocol for NACE registry. The protocol should contain a module for collecting acute coronary event core data during hospital stay and one month after discharge by all the participating hospitals. Another module should collect optional six month data after discharge. The data elements (as per recommendations of working group I) specified in this protocol should provide a framework for
 - (a) improving the public health and epidemiological understanding of acute coronary syndrome
 - (b) gather country based data for evidence based acute coronary syndrome management care to patients
 - (c) develop information systems for acute coronary events data collection and care

Each data element in acute coronary event database should contain specific definitions which should be followed by all participating hospitals.

4. The modules should be validated in 2-3 hospitals and modifications should be made accordingly. Subsequently 100 hospitals may be invited to create a nation wide network of ACE registries.
5. An electronic web based system (as per recommendations of working group II) for making fast and action oriented reporting should be developed by the Council with support from workshop participants with IT experience.

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An ICMR-WHO Workshop

“Developing a Web Based Module for Capturing Acute Cardiovascular Events in Hospitals”

16th and 17th October 2006

India International Centre, Conference Hall III (Annexe), 40 Max Mueller Marg, New Delhi -
110003 New Delhi

16th OCTOBER 2006 MONDAY	
9:30-10:00 am	Registration
Introduction and Welcome to the Workshop	
10:00 - 10:10 am	Dr Bela Shah Introductory Remarks
10:10 - 10:30 am	Dr NK Ganguly, DG ICMR Inaugural Address
10: 30– 11:00 am	Chief Guest’s Address Dr KK Talwar : Available Data and Needs for Undertaking Registry of Acute Coronary Syndrome in India
11:00 – 11:30 am	Tea
11:30 - 1:00 pm Chairperson : Dr R Tandon Rapporteur : Dr DK Shukla	Scientific Session I : Addressing a Sustainable Approach for Capturing Acute Coronary Syndrome Dr D Prabhakaran : Acute Coronary Syndrome Registries- Global Experiences Dr Bela Shah : National Surveillance Systems – Opportunities for Acute Coronary Events Surveillance Dr RR Kasliwal : Public Private Partnerships for Developing Web Based Acute Coronary Events Data
1:00 - 2:00 pm	Break
2:00 – 3:00 pm Chairperson : Dr LM Nath Rapporteur : Dr Harpreet Singh	Scientific Session II : Operational Issues in Capturing Acute Coronary Syndrome Dr Prem Pais : ACS - Developing Reporting and Tracking Systems and Assessing Outcomes in Indian Scenario Dr Nand Kumar : Operational Issues – Data Management Dr M Bhattacharya : Experiences with Web Based Surveillance Data Reporting
3:00 – 3:30 pm	Tea

<p>3:30 – 5:00 pm</p>	<p>Scientific Session III</p> <p>Working Group I : Hospital Surveillance System for ACS - Data Needs and Formats Moderator : Dr Prem Pais Rapporteur : Dr Ravinder Singh</p> <p>Working Group II : IT Aspects-Connectivity, Data Transfer, Web Based Data Analysis and Reporting, etc Moderator : Dr D Prabhakaran Rapporteur : Dr Geetha Menon</p>
<p align="center">17th OCTOBER 2006 TUESDAY</p>	
<p>9:30 -10:30 am Moderator : Dr Upinder Kaul Rapporteur : Dr Ashoo Grover Co- Rapporteur : Dr Ravinder Singh</p>	<p>Panel Discussion : Management Issues in patients with ACS</p> <p>Panelists: Dr HK Bali - Presentation Dr RR Kasliwal Dr D Prabhakaran Dr Sudhir Naik</p>
<p>10:30 -11:15 am Chairperson : Dr Bela Shah Rapporteurs : Dr Ravinder Singh</p>	<p>Presentation: Working Group I: Hospital Surveillance System for ACS - Data Needs and Formats</p> <p>Discussion</p>
<p>11:15 – 11:45 am</p>	<p>Tea</p>
<p>11:45 - 12:30 pm Chairperson : Dr Rajiv Gupta Rapporteur : Dr Geetha Menon</p>	<p>Presentation: Working Group II: IT Aspects-Connectivity, Data Transfer, Web Based Data Analysis and Reporting, etc</p> <p>Discussion</p>
<p>12:30 – 1:30 pm</p>	<p>Break</p>
<p>1:30 – 2:00 pm Chairperson : Dr LM Nath Rapporteur : Dr Meenakshi Sharma</p>	<p>Recommendations of the Workshop</p>

An ICMR-WHO Workshop on “Developing a Web Based Module for Capturing Acute Cardiovascular Events in Hospitals”

16th and 17th October 2006

WORKING GROUPS

Working Group members, whose backgrounds cover a broad spectrum of experience in ACS Research, will define the research questions for these registries, current gaps in knowledge, and the expected ACS trends in the nation. The group will first review ongoing programs and funded projects, if any, in the country. The Working Group will seek to identify high-priority areas in ACE research that deserve support. The objective will be to identify research directions that the Working Group believes require the most immediate action. Key questions to be incorporated in the format will be formulated. The methodology related issues including mode of data upload and analysis will be discussed.

Group I: Hospital Surveillance System for ACS - Data Needs and Formats

Points to be addressed include, but are not restricted to, are as follows:

1. Need for systematic reporting of ACS
2. Gaps in knowledge
3. Aim and Objectives
4. Possible approaches for collection of national data on ACS – Data Sources including available in-hospital data sets (electronic where ever possible)
5. Feasibility of establishing a community based registry in India??
6. Case Identification including Definitions of Acute Coronary Syndrome, Inclusion exclusion criteria
7. Management Patterns
8. Outcomes – Mortality, Recurrent MI, Other non fatal outcomes
9. Period of Follow Up
10. How much of information should be collected and who can collect this information, who will be responsible for filling the web based format
11. Data Collection Procedures
12. Validation of Data Collection Procedures
13. Formats, Consent forms, reporting formats
14. Step wise/ Tire Approach
15. Timeline for formats and guidelines

Group II: IT Aspects-Connectivity, Data Transfer, Web Based Data Analysis and Reporting, etc

Points to be addressed include, but are not restricted to, are as follows:

1. Methods of data flow
2. Data upload using a web based interface
3. Standards and structures of electronic medical records and patient database
4. Web based Data Analysis and Reporting
5. Development and Maintenance of information systems
6. Methods for verification of field level performance/ Data quality management
7. Categorization of hospitals and assessing the need for development of specific modules for each category of hospitals
8. Flexibility for add on information
9. Accessibility of information to various persons at various levels
10. Training of personnel
11. Need for piloting projects for connection of super specialty hospitals/ medical colleges with district hospitals/ or CHCs/ PHCs in order to provide access to remote areas
12. Ethical issues (related to both patient and hospitals)