

## Editorial

### A web based module for capturing acute coronary events in Indian hospitals

Web-based secure communication systems have revolutionized data collection systems in medical research. Such systems provide opportunities for a study with exceptionally large sample sizes and have the potential to provide timely information about current trends in disease incidence, treatment, and outcomes. Globally, National Audit of Myocardial Infarction Project (MINAP)<sup>1</sup>, Prospective Registry Evaluating Outcomes after Myocardial Infarction: Events and Recovery Quality Improvement (PREMIER-QI)<sup>2</sup>, Acute Myocardial Infarction in Switzerland (AMIS)<sup>3</sup>, Internet Tracking Registry of Acute Coronary Syndrome (i\*trACS)<sup>4</sup>, *etc.*, are a few of the cardiovascular disease (CVD) registries using internet for real time data collection. Despite India's internationally renowned competence in information technology, there are no web-based disease registries for CVDs suggesting a need for undertaking pilot projects in this area, which if found successful, can be replicated throughout the country.

Planning and evaluation of preventive strategies for acute coronary syndrome (ACS) requires disease surveillance with a broad concept of collecting data on risk factors, disease patterns, disability and health practices. Several population based cross-sectional studies in India have shown a rising trend in the prevalence of coronary artery disease (CAD) in urban India<sup>5-12</sup> (from 1% in 1960 to 10.5% in 1998) as well as in rural India (a two fold increase)<sup>10, 13-14</sup>. It has been estimated that India had the highest number of deaths (over 1.5 million) in the world due to CAD in 2002<sup>15</sup> which is expected to double from 1985 to 2015<sup>16,17</sup>. The INTERHEART study in 52 countries observed high prevalence of CAD risk factors like diabetes, hypertension, smoking, dyslipidaemia and obesity in Indian population<sup>18</sup>. The prevention and treatment of CAD will require a highly responsive healthcare system.

In India, though specialized healthcare centers do provide state of the art technologies for cardiovascular care, but the healthcare delivery varies from State to State as well as within the State. Not only the number of primary and community healthcare centers is inadequate, there is a shortage of physicians (particularly with specializations in cardiology) and other healthcare staff. In cardiac care, more than 75 per cent of the care is provided by private sectors, which are concentrated in urban areas<sup>19</sup>. This highly inadequate preventive and therapeutic cardiac care, especially in rural/remote areas, poses a challenge for development of a sustainable cardiac disease surveillance system.

The framework of ACS surveillance in community will require measurement of incidence and mortality along with types of ACS (unstable angina and both ST-segment elevation and non ST-segment elevation myocardial infarction), and modes of treatment. For this, a step-wise approach to ACS surveillance is suggested. ACS patients can be categorized into three groups: hospital admissions, "out of hospital" deaths, and "non fatal" events. Each group will require standard case definitions and markedly different measurement tools providing unique datasets, which altogether will make available the baseline estimates. The hospital admissions will provide not only data on frequency of hospital admissions but also on patient characteristics, types of events, treatment, vital status at discharge and outcome after different time intervals of the acute event. Though there will be limitations due to bias caused by selection of highly selective cases, it still may provide rough estimates of the basic cost of cardiac care in acute cases. The recording of "out of hospital" deaths will provide mortality rates whereas "non fatal" events datasets will be useful in measuring incidence rates of the disease. Of these groups, the easiest to record is the hospital admissions with acute coronary event (ACE)

and the most difficult will be the “non fatal” events. Protocol development for each step will require scientific deliberations and consensus among various stakeholders. This may be tackled best in a step-wise approach.

To address the issue of obtaining datasets for hospital admissions, an interactive workshop on “Developing a web-based module for capturing Acute Cardiovascular Events (ACE) in hospital” was held in October 2006 in Delhi and was organized by the Indian Council of Medical Research (ICMR), New Delhi, in collaboration with WHO. The focus of the Workshop was to identify opportunities for capturing ACEs in Indian hospitals, discuss methodologies and benefits of global ACE registries, reporting and tracking systems and assessing ACE outcomes, public-private partnerships and web-based system for data collection, transfer and analysis.

Using a standard definition for ACS by the network of registries across the country will help in comparison of data across different regions. ACS encompassing unstable angina and both ST-segment elevation and non ST-segment elevation myocardial infarction (MI) are common causes of emergency hospital admission. Most of the patients with ST-segment elevation develop a Q-wave myocardial infarction (QwMI) whereas a few develop non-Q-wave myocardial infarction (NQMI). Patients with non ST-segment elevation ECG either develop unstable angina or non ST-segment elevation myocardial infarction (NSTEMI). For the purpose of National Acute Coronary Events (NACE) registry for capturing ACE in Indian hospitals, ACS will be defined as either unstable or intermediate coronary syndrome and/or acute myocardial infarction.

Identification of patients at a higher risk of death, MI and recurrent ischaemia at presentation allows aggressive anti-thrombotic treatment and early coronary angiography to be targeted in those who will benefit most. The strategy for early risk stratification in patients presenting with chest discomfort or whose discomfort has been resolved by the time of evaluation needs to focus on patient's history including anginal symptoms, definite history of ischaemic heart disease/ prior MI/ percutaneous transluminal coronary angioplasty (PTCA)/ coronary artery bypass graft (CABG)/ positive treadmill test (TMT) or angiographic evidence of coronary heart disease, risk factors for ACS including diabetes, hypertension, dyslipidaemia and smoking, ECG findings and biomarkers of cardiac injury. This

information could be used to determine the high, intermediate, or low likelihood of acute ischaemia as outlined in the Fig. Among the biomarkers, troponin is considered to be the gold standard with demonstrable high sensitivity and specificity, but may require 6 h to become positive. In the absence of troponin measurement facility, an alternate marker CK-MB may be used, though this is less specific for MI than troponin as besides myocardium, it is present in skeletal muscle also. In patients with negative cardiac markers in less than six hours of the onset of pain, a repeat sample should be obtained at six hour time frame from onset of symptoms.

Symptoms to door, door to needle and door to balloon time is crucial in the management of ACS. As per the American College of Cardiology (ACC)/ the American Heart Association's (AHA) 2004 Guidelines<sup>20</sup> for ST segment elevation, the goal is to keep total ischaemic time within 120 min. The transport time to the hospital after recognition of symptoms by the patient is variable as it depends on the logistics related to transportation. The ACC and AHA recommend the door to needle time to be within 30 min in patients in whom fibrinolysis is indicated whereas the door to balloon (percutaneous coronary intervention) time to be within 90 min. Data on these parameters are not available in India and need to be captured by appropriate instruments.

Guidelines for management of ACE patients in India are also not available. Adherence to ACC/AHA guidelines has been shown to improve cardiac patients' survival and quality of life<sup>21</sup>. Use of anti-platelet therapy, statins, angiotensin-converting enzyme (ACE) inhibitors, and  $\beta$ -blockers apparently has additive effects in reducing 6 month mortality in cardiac patients. To understand the validity of these guidelines in Indian context and to develop evidence-based guidelines for ACS management, an assessment of management strategies being used in ACS patients and the treatment gaps is required. Accurate data on the treatment outcomes of hospital stays requiring long-term observations (30 days and 6 months follow up data after hospital stay) of ACS patients can help plan better prevention strategies.

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

Presentation	Observations	History	ECG	Serum cardiac markers
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Step I: Working diagnosis	High likelihood of ACS	Chest pain  Previously documented CAD including MI / PTCA/CABG or angina  Risk factors for ACS	New or presumably new ST-segment elevation or T wave inversion with symptoms	Elevated troponin, elevated CK-MB
Step II: ECG				
Step III: Cardiac biomarkers (Either of troponin, CK-MB, CPK)	Intermediate likelihood of ACS	Chest pain	Abnormal ST segments or T waves not documented to be new	Normal
Step IV: Final Diagnosis (either of previous 2 steps +ve)	LOW likelihood of ACS	??? Ischaemic symptoms	Normal ECG	Normal

**Fig.** Identification of high, intermediate and low likelihood of ACS. ACS, acute coronary syndrome; ECG; electrocardiogram; CK-MB, creatine kinase MB; CPK, creatine phosphokinase; CAD, coronary artery disease; MI, myocardial infarction; PTCA, percutaneous transluminal coronary angioplasty; CABG, coronary artery bypass graft.

timely action and response. An electronic system enhances the quality of the system by simplifying the reporting for the end users and the timeliness within the system, from event to action. There is a need to develop a system which allows 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 levels, could work with a common central server containing all case records. Privacy and confidentiality at different levels of data entry and data analysis needs to be assured. Tools for contact tracing need to be developed. However, as internet facilities are not available in all hospitals, therefore participating hospitals with internet facilities may use web based module whereas others may use paper based questionnaire. Participation in this registry will be on voluntary basis. The hospitals participating during the initial survey will then recruit 5 to 10 hospitals in their regions, thereby slowly enhancing the representativeness of the data and building unique systems for enhancing capacity at various healthcare levels.

The workshop recommended the need for a NACE registry targeting the following areas:

(i) *Improve understanding of characteristics of ACS patients in India:* For this standard demographic variables like age, sex, weight, height and education as well as established risk factors and history of medical intervention for these should be recorded.

(ii) *Improving risk stratification for understanding outcomes in ACS patients:* The tools include patient's history including anginal symptoms, definite history of ischaemic heart disease/ prior MI/PTCA/CABG/ positive TMT or angiographic evidence of coronary heart disease, evaluation of symptoms in patients with chest discomfort related to CAD, ECG findings and biomarkers of cardiac injury. Impact of diagnostic strategies on management and outcomes needs to be studied.

(iii) *Improving management of ACS patients:* This includes (a) keeping total ischaemic time within 120 min by reducing symptoms to door, door to needle (initiation of fibrinolytic therapy) and door to balloon time (percutaneous coronary intervention), (b) analysing the adherence to ACC/AHA therapeutic guidelines and validation of these guidelines in Indian context, and (c) impact of therapeutics on outcomes in ACS patients.

(iv) *Improving data management*: A web-based system for making the reporting fast and action oriented needs to be developed.

(v) *Capacity building*: A network of ACS registries needs to be created using a systematic approach thereby enhancing the capacity at various healthcare levels.

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