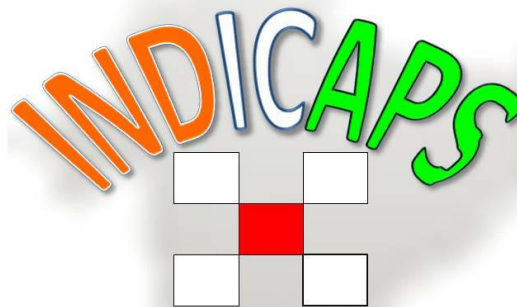


Indian Intensive Care Case Mix and Practice Patterns Study (INDICAPS)



July 14, 2010; October 13, 2010; January 12, 2011, April 13, 2011

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General information

1.1 Organization

Steering committee

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Deepak Govil (Delhi)

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Coordinating center

Department of Anaesthesia, Tata Memorial Hospital,
E. Borges Road, Parel, Mumbai 400012.

Protocol summary

Indian Intensive Care Case Mix and Practice Patterns Study (INDICAPS)

Design	Multicenter, All India one-day prevalence study
Target population	All patients present in the ICU on the second Wednesday of July 2010, October 2010, January 2011 and April 2011 i.e. July 14, 2010, October 13 2010, January 12, 2011 and April 13, 2011
Interventions	No intervention
Subgroup/ Sub-study analysis	<ul style="list-style-type: none">- Case-mix, severity of illness, prevalence of infection, hemodynamic monitoring and therapy, mechanical ventilation practices, nutrition and outcome- Seasonal and regional variations in the above- Epidemiology and variations in antibiotic use- Patterns of microorganisms and outcome- Prevalence and outcome of specific tropical febrile illnesses, including malaria, dengue fever, leptospirosis, scrub typhus- Prevalence and outcome of toxins and poisonings- Relation of ICU and hospital organizational issues to prevalence of infection and outcome- Organisation of intensive care services- End of life - Ethical decisions
Study duration	One year (point prevalence on 4 days)
Follow up period	ICU and hospital survival

2- Rationale and aim of the study

INDICAPS is the first large scale, multicentre survey launched by the ISCCM. The aim is to gather information about ICUs, organizational characteristics, patient casemix, the types and severity of illness, monitoring and therapeutic modalities used, types of infections, and other such data. There is scant data on the casemix and practices in Indian ICUs (1-9). Most of the available comes from single centre studies. There is a dire need to have data from Indian ICUs to reflect the vast spectrum of critical care illness, services and practices.

A point-prevalence study has been planned to enable participation from a large number of ICUs throughout the country. The recently published Extended Prevalence of Infections in Intensive Care II was a landmark point prevalence study that looked at infections in ICUs all over the world (10). This study is modeled on that study. However INDICAPS will be consist of data obtained on four different days over a year period, so as to capture any seasonal variations in disease patterns in patients presenting to the ICU.

This cross-sectional design makes it easy to follow, and spares busy clinicians the effort of maintaining data daily throughout the ICU stay of every patient. This will generate important data on Indian critical care.

3- Study outcomes

3.1 Primary outcome

The primary outcome measure is hospital mortality from all cause within the 30 days.

3.2 Secondary outcomes

The secondary outcome measures are:

1. Survival
2. ICU and hospital length of stay

4- Study description

4.1 Study design

A multicenter, all-India observational, one-day prevalence study, performed on four separate days.

5- Study population

5.1 Inclusion criteria

All patients present in the ICU on the second Wednesdays of July 2010, October 2010, January 2011 and April 2011

- **July 14, 2010**
- **October 13, 2010**
- **January 12, 2011**
- **April 13, 2011**

5.2 Exclusion criteria

There are no exclusion criteria, all patients should be included.

Detailed study course

6.1 Patients' enrollment

Patients' enrollment will be on each of four study days, July 14, 2010, October 13 2010, January 12, 2011 and April 13, 2011. All patients in the ICU on those days for the 24 hours starting **0800 am to 0800 am next day**.

6.2 Ethics committee approval

Even though this is a purely epidemiological study (with entirely anonymous data collection), it is advised to submit the protocol to the local ethics committee for approval. If your hospital does not have an ethics committee, please contact the co-ordinating centre.

6.3 Therapeutic intervention

The study is a purely observational study, no interventions are planned.

6.4 Daily documentation

Data collection includes:

- a. On admission: demographic characteristics, comorbidities, source of admission, primary and secondary admission diagnoses,
- b. Baseline data (on the study day), including parameters used to calculate SAPS II score and SOFA score and infections,
- c. Information on monitoring modalities, mechanical ventilation, nutrition, fluid therapy, other routine ICU practices
- c. Outcome at ICU and hospital discharge.

7- Organization

7.1 Documentation

Data will be recorded using pre-printed case report forms (CRF) by the attending intensivist or a trained research nurse. There are two CRFs:

Form 1 : ICU data form: This includes data on local organizational and patients' care facilities in each center. This has to be filled once only

Form 2: Individual patient data form: This contains individual patient information. A separate form is to be filled for each patient.

7.2 Collecting data

Data should preferably be entered electronically on the website http://isccm.org/ISCCM/ISCCM_IndICAPS.aspx

Those ICUs that are unable to do so can mail paper forms to the coordinating center (Department of Anaesthesia, Tata Memorial Hospital, E. Borges Road, Parel, Mumbai 400012).

7.3 Data management and archiving

7.3.1 Data property

The individual data provided by a participating ICU are primarily the property of the ICU who generated the data. All investigators have the right to access their data at any time.

7.3.2 Data control

Data control will involve the following levels

1. All participants will be provided with detailed information, including exhaustive definitions of medical terms. The coordinating center will provide a rapid response for any query throughout the study period (Please see contact information).
2. Data plausibility check will start at the entry level electronically, setting validity limits for each variable. Investigators will be queried in case of outliers or excessive numbers of missing values.

7.3.3 Subsequent use of data

The steering committee, on behalf of the investigators has the right to use all data that are pooled in the databank for scientific purposes. Investigators will be regularly informed about ongoing study activities. All participants have the right to access the data, pooled in the databank, for research purposes after the research project has been terminated, and with the approval of the steering committee. A copy of the databases generated by the project can only be provided to third-part entities after specific approval by the participating ICUs.

7.3.4 Archiving

A copy of the electronic databank will be kept in the coordinating centers and preserved for 15 years for subsequent use by the steering committee and investigators. It is recommended that a copy of CRFs be kept at each center for future reference.

7.3.5 Publication rules

Authorship will take the following elements into account: study design, study organization, data collection, patient enrolment, data analysis, and contribution to the manuscript

7.4 Sponsorship

This study is funded by the Indian Society of Critical Care Medicine.

8- Statistical analysis

Statistical analysis will be performed using SPSS for windows version 14.0 (Chicago, USA).

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