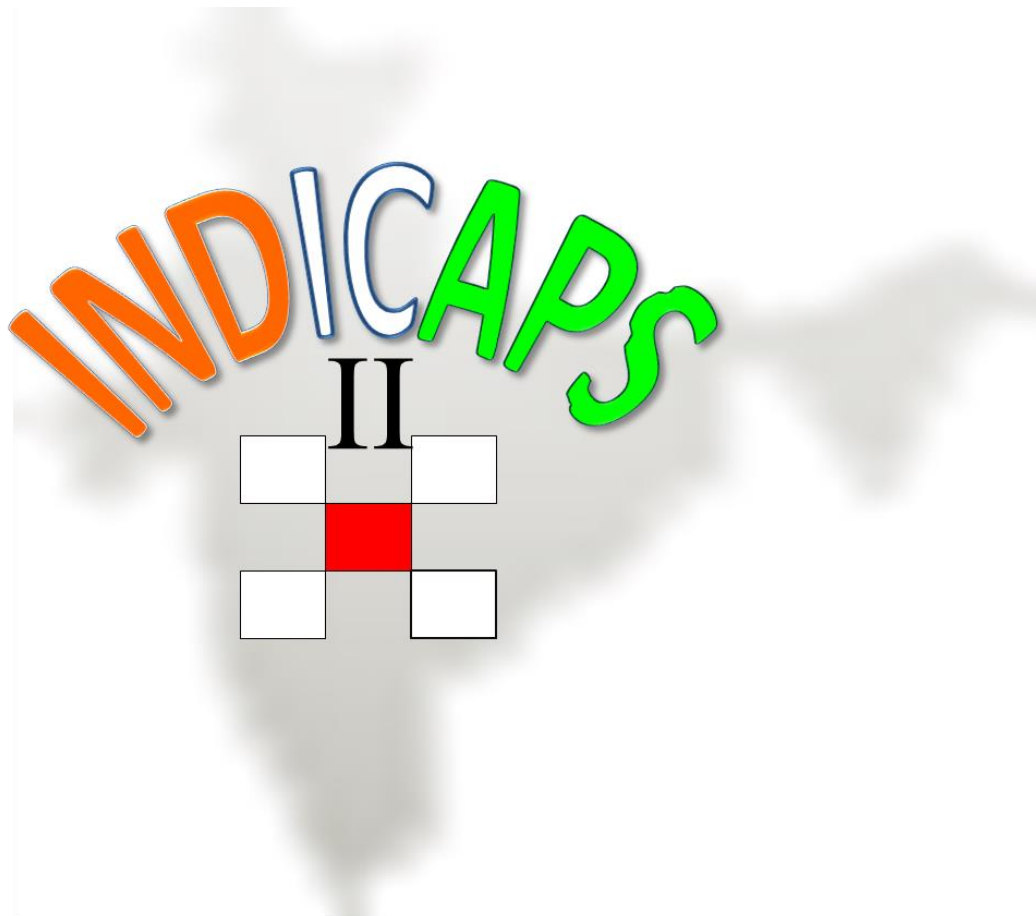


Indian Intensive Care Case Mix and Practice Patterns Study II (INDICAPS II)



August 23, 2018; October 25, 2018; December 13, 2018; April 11, 2019

INDICAPS II Summary protocol version 2 dated July 27, 2018

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

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Indian Intensive Care Case Mix and Practice Patterns Study (INDICAPS) 1-

General information

1.1 Organization

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Steering committee

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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 August 23, 2018; October 25, 2018; December 13, 2018; April 11, 2019
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- - 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)
Primary Outcome	ICU mortality at 30 days from the Study day
Secondary Outcomes	Hospital Mortality, ICU and hospital length of stay
Follow up period	Hospital discharge

2- Rationale and aim of the study

INDICAPS was the first large scale, multicentre survey launched by the ISCCM. The aim was 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. This was performed between July 2010 and April 2011 and published in 2016.[1] Over the last 8 years, there has been a significant difference in the delivery of intensive care services, critical care education, socioeconomic indicators, antibiotic resistance patterns and other aspects of practices in Indian ICUs. It is therefore necessary to revisit and resurvey the current trends in intensive care practices in India, and to reflect the vast spectrum of critical care illness, services and practices.

Similar to INDICAPS, which was a point-prevalence study of all patients present in the ICU on four different days over a one-year period, INDICAPS II will record data of all patients admitted to the ICU on 4 different days.

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 all-cause ICU mortality at 30 days from the study day.

3.2 Secondary outcomes

The secondary outcome measures are:

1. Hospital mortality
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

August 23, 2018; October 25, 2018; December 13, 2018; April 11, 2019

5.2 Exclusion criteria

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

Detailed study course

6.1 Patients' enrollment

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Patients' enrollment will be on each of four study days, **August 23, 2018; October 25, 2018; December 13, 2018; April 11, 2019**
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>

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 (Chicago, USA). Continuous variables will be compared with the use of the Student's *t*-test, analysis of variance, Mann–Whitney test or the Kruskal–Wallis test. Categorical variables will be compared using the Chi-square test. A two-tailed $P < 0.05$ will be considered as statistically significant.

Multivariate binary logistic regression analysis will be performed to determine the independent predictors of ICU mortality

9 - Reference:

Divatia JV, Amin PR, Ramakrishnan N, Kapadia FN, Todi S, Sahu S, et al. Intensive Care in India: The Indian Intensive Care Case Mix and Practice Patterns Study. Indian J Crit Care Med 2016;20:216-25