European Sepsis Care Survey

Study Protocol

European Sepsis Care Survey

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1. Background, Introduction

Sepsis is one of the most common diseases and represents a huge challenge for health care systems all over the world. In 2017 almost 50 million sepsis cases and 11 million sepsis related deaths were registered. The costs associated with sepsis are immense and mean significant economic burdens for hospitals as well as health care systems. Nevertheless, structures of sepsis care and the implementation of measures for sepsis therapy are not clear in Europe.

2. Objective

The objective of this survey is to investigate the current state of sepsis care around Europe. The study is aiming at hospital structure, emergency departments, wards, intensive care units and clinical diagnostic and microbiological service. A second step might be to develop more detailed recommendations regarding sepsis care and to call governments for implementation.

METHODS

3. Design

This study will be conducted as an European-wide cross-sectional survey using an online questionnaire.

4. Questionnaire

The questionnaire was created and harmonized by the steering committee (see 11. Steering committee), and is composed of items asking single choice, multiple choice and open questions.

The survey will be address the following parts:

- (1) General structures of the hospital.
- (2) Sepsis care at the emergency department
- (3) Sepsis care at the wards
- (4) Sepsis care at the intensive care unit
- (5) Quality management / hospital improvement programs for sepsis

No patient's data are collected.

The questionnaire will be self-completed by the responsible person of each participating hospital. The expected time for completion of the survey is approx. 30-40 min.

Test-Link to Survey: https://sepsissurvey.sslsurvey.de/ESC_Survey-total_2021
Only for testing purposes!

In order to inhibit uncontrolled repeated survey participation hospitals will get an individual survey entry (individual survey link) only after registration (see 9. Hospital registration). The questionnaire can be processed together with colleagues of each hospital (e.g. if one person is not able to answer all questions) by sharing the survey link.

4. Handling of confidential information

The survey queries potential confidential hospital information. If necessary, local hospital coordinators should obtain approval to participate in the survey from their hospital board prior to participation. The decision whether this is necessary is the responsibility of the participating person of each hospital. All data will be handled confidentially. Conclusions about individual hospitals will not be drawn and not published.

5. Technical realization, and data protection rules

The questionnaire will be conducted by using the survey software LamaPoll. LamaPoll meets the requirements of the European General Data Protection Regulation (EU GDPR) and is DIN ISO 27001 certified. The host is located in Germany.

6. Testing

A technical and content testing of the online questionnaire is performed in the run-up. Comments and corrections were integrated into the final version of the survey.

7. Local ethical approval, institutional review board

The University Medicine Greifswald, Germany will provide an institutional review board approval. If necessary, participating hospitals have to obtain additional local ethical committee approval.

8. National coordinators

A national coordinator will be designated for each participating country. The national coordinators are responsible for disseminating the survey in their countries and for the recruitment of a representative hospital selection. They are contact persons and experts for the respective country. For country-related aspects, their advice is consulted.

The European Sepsis Alliance will be the primary platform to recruit national coordinators. Members of other European societies are also invited to become a national coordinator. For each country there is one coordinator. If there are several applications, the first responder will be designated as the national coordinator. All national coordinators agreeing to participate will be provided with a copy of the study protocol. National coordinators get the questionnaire previously for testing purposes to reveal country specific issues/problems. If necessary, translation work of the questionnaire will be conducted by the national coordinator.

7. Sampling strategy, representativeness and prevention of bias

National coordinators are asked to identify and recruit the hospitals. An invitation letter for the recruitment will be provided on request. Nevertheless, the invitation by the national coordinator should be as personal as possible to achieve a high response rate. The recruitment should be done within 4 weeks. For reasons such as COVID-19 or vacation, extensions are possible.

In order to include as much hospitals as possible the following recruitment will be conducted:

1. Full census approach

   In order to reach as many hospitals as possible, large national societies and networks should be contacted by the national coordinators. These societies should call their members to register online for the survey (see 9. Hospital registration). Societies having only contact with a specialized or very limited group of hospitals should not be used exclusively.

2. Random sample approach

   If the full census approach is not feasible, national coordinators can also choose a random sample approach. This random sample should be a proportion of all hospitals and met the following criteria:

   a) The hospitals are chosen randomly.
   b) The chosen hospitals should reflect the distribution of hospital sizes in this country (see 8. Distribution of hospital sizes).
   c) The hospitals should be collected from all parts of the country and should include municipal/regional/peripheral hospitals and university hospitals.
   d) In order to avoid bias, hospitals particularly interested in sepsis or hospitals with close personal contact to the national coordinators should not be preferential selected.
   e) Hospitals not willing to participate should be replaced by hospitals of the same size.
   f) Hospitals not willing to participate should be counted.

The steering committee will check the hospital selections based on the stated criteria (a-f). If there is any doubt about the representativeness, the steering will request the national coordinator for additional hospitals.

8. Distribution of hospital sizes

National coordinators are asked to provide information on the distribution of hospital sizes in their country. Based on this information the representativeness will be calculated for each country.

Please provide information about the distribution of hospital sizes in your country at:
https://sepsissurvey.sslsurvey.de/ESC_Survey-hospital-size-distribution

9. Hospital registration

Hospitals willing to participate have to register first. Registered hospitals will receive the survey subsequently by email with individual access data. This procedure will inhibit uncontrolled repeated survey participation.

Hospitals can be registered at:
https://sepsissurvey.sslsurvey.de/Hospital-Registration-European-Sepsis-Survey

This link can be used if the survey will be disseminated via networks or societies.
National coordinator can use this link for hospital registration.
Hospitals can also register themselves.

10. Survey conduction

The participating hospitals will be asked to complete the survey within 30 days. If the survey will not be completed in this time period, we send a reminder email asking to complete the survey within the next 14 days. Extensions of time, e.g. due to COVID-19, are possible. If no response is received during this time the national coordinator should strive to replace the participating hospital. Once the survey has

been completed, a check for quality of data will be performed, and queries issued to hospitals via email. After ambiguous answers have been resolved, the database will be closed and the statistical analyses will be performed.

11. Steering committee

The steering committee consists of members of the European Sepsis Alliance and representatives of European societies.

The composition of the survey content is designed by the steering committee. The steering committee advises especially in terms regarding specific issues and questions. Furthermore, the steering committee supervises the hospital selection.

Steering committee member:

(alphabetical order)

- Adam Linder, Sweden (Chair ESA working group research)
- Christian S. Scheer, Germany (Principal investigator)
- Daniela Filipescu (Vice-Chair of European Sepsis Alliance)
- Evangelos Giamarellos-Bourboulis, Greece (Chair of European Sepsis Alliance)
- Evgeny Idelevich, Germany (Representative ESCMID/Study Group for Bloodstream Infections, Endocarditis and Sepsis (ESGBIES)
- Konrad Reinhart, Germany (Founding president Global Sepsis Alliance)
- Matthias Gründling, Germany (Quality management project Sepsisdialog)
- Ricard Ferrer (Representative European Society of Intensive Care Medicine (ESICM)
- Said Laribi (Representative European Society for Emergency Medicine (EUSEM)
- Representative from ESAIC

12. Endorsement

In order to achieve a high participation, WHO and European societies (EUSEM, ESAIC, ESICM, ESCMID, ESS) will be asked to endorse and support this survey.

11. Reporting

The reporting of this survey will consider the recommendations *Checklist for Reporting Results of Internet E-Surveys* (CHERRIES) and the *Consensus-Based Checklist for Reporting of Survey Studies* (CROSS).

12. Statistical analyses

According to the distribution of hospital sizes and participation the level of representativeness will be indicated for each country and each hospital size. Descriptive statistics will be obtained for all items of the questionnaire. Mean and standard deviation will be used for normally distributed variables, mean and interquartile range for skewed distributions, proportions for categorical variables. Also, 95% confidence intervals (95%CI) will be calculated. Groups will be compared by means of parametric or nonparametric tests for quantitative variables and Pearson's Chi_2 test (Fisher exact test where appropriate) for categorical variables. In all cases, two-tailed tests will be applied. P-value <0.05 will be considered significant. Bonferroni correction will be used whenever relevant.

Statisticians:

Marcus Vollmer, Greifswald, Germany

Sylvie Chevret, Paris, France

12. Estimated timeline

Recruitment of organizations, countries and country coordinators: June 2021

Survey launch: July 2021 (appointment of national coordinators, analysis of hospital size distribution of each country, hospital selection, survey implementation, queries and data cleaning)

Results analysis: November 2021

Publication of results and recommendations: February 2022

Meeting to present results to European Institutions: April 2022

This timing is just one estimation that may change. Due to the corona pandemic extensions are possible.

13. Publication, authorship and contributing collaborators

A manuscript will be submitted to a high ranked peer-reviewed journal. The European Sepsis Alliance steering committee and the national coordinators from each country will be listed as authors.

One contributing person (local coordinator) from each hospital will be named as a member of the *European Sepsis Care Survey Study Group*. The *European Sepsis Care Survey Study Group* will be also listed in the author byline. All study group members will be acknowledged as collaborators and PUBMED listed.

14. Funding

The survey is funded by the European Sepsis Alliance and an Educational grant from Becton Dickinson S.A.U. (BD).

15. Participating countries (only confirmed countries by 25.8.2021)

Belgium	Germany	Romania	Netherlands
Czech Republic	Greece	Russia	Italy
Denmark	Moldova	Spain	Portugal
Finland	Norway	Sweden	Turkey
France	Poland	United Kingdom	Israel