

StaphTrav: a multicenter study on the importation of *Staphylococcus aureus* through intercontinental travel

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Background: Virulent and antibiotic resistant *Staphylococcus aureus* is a globally emerging pathogen. Exchangeable virulence factors have been proposed to drive this epidemic. Skin infections and colonization in travelers may contribute to the spread of such strains.

Aims of the study:

- To study importation of *S. aureus* into the European Union by international travel to destinations outside the European Union

Inclusion criteria (*NOTE: to be assessed after patient consent has been obtained*):

- Patient has legal (≥ 18 years of age) and mental status to give consent
- Patient is a permanent resident in a country of the European Union
- Submitting centre is located in the country of the patient's residence.
- Patient has pus producing skin infection on the day of the clinic visit
- **Onset of skin infections while abroad or within 30 days after return** to home country from a trip **outside the EU**. (*NOTE: the first clinic visit can be later than 30 days after return from trip as long as the **timepoint of onset** is within the given timeframe.*)

Participating center's input: Centers of travel medicine or any other institution that consults returning travelers are requested to send swabs for bacterial culture from

- 1.) putrid skin lesion(s) (single or multiple) **and**
- 2.) the nose (both anterior nares)

alongside with anonymized information on the patient and its travel history (survey form).

Methods:

- bacterial culture on selective media, methicillin resistance testing by selective media and PCR for presence of the mec-cassette, genotyping (spa, MLST)

Study centre output:

Submitting centres receive ...	Time frame
culture results (<i>S. aureus</i> positive <u>or</u> negative)	5-7 working days after arrival of swab
Results of methicillin resistance testing of <i>S. aureus</i>	10-12 working days after arrival of swab
summary report of submitted strains including own and other centres	once per year

Policy for joint publication of results:

Joint publication of results will be considered as soon as 100-150 imported *S. aureus* strains have been analyzed or after a study period of 2 years. Publication costs will be carried by the coordinating centre.

Ethical issues:

Ethical clearance: This protocol has been approved by the EC of the University of Tübingen Medical School on April 6th 2011 (Project no. 145/2011BO1). A copy of this approval letter is available on the StaphTrav homepage (in German). Existing approval in Tübingen, however, does not exempt the participating site from seeking local authorization from the competent EC. Templates of patient information and consent forms in English and German can be found on the StaphTrav homepage (www.staphtrav.eu). These should be adapted to the local setting and submitted to the competent EC alongside with this protocol.

Patient care: Responsible investigators at the submitting centres are responsible to treat eligible patients to the current medical standards and independent from his/her decision to participate in the StaphTrav study.

Consent: Potential participants will obtain a patient information sheet explaining the background, aims, procedures, risks and benefits involved in this study. Additionally, this sheet will inform patients that (i) participation is voluntary and has no influence on the quality of care and (ii) that they can withdraw consent to participate at any time in the future. A written consent form will be signed by both the local investigator and the patient and kept at the submitting centre.

Data Management, Access and Storage: The submitting centers pseudonym – without other identifying information – will be used to identify the material and the reported results. All laboratory investigations will thus be anonymous. Identifying patient information will only be available at the participating site. It is the participating center's responsibility to ensure storage of patient data according to national laws and regulations. Submitting centres are advised to keep unaltered identifying information (e.g. list of participants with pseudonyms) separately from patients' files and the laboratory results provided back to the centre in a locker that is accessible to the locally responsible investigator and the head of department only. Participants will be informed in a separate text on these issues and asked to agree to these by giving separate written consent. This form will be kept together with the general consent form at the submitting centre. Laboratory results at the Tübingen study centre will be stored in a data file without personal data and using the pseudonyms provided by the submitting centres. For internal use, a 4 digit numbered code starting from 8000 to 8999 will be added for internal reference. Access to this file will be protected with a 6 digit password. Only the study coordinator, one laboratory technician (Martina Henk) and one PhD student (Dennis Nurjadi) will have access to this database.

Shipping of specimens

It is the participating centre's responsibility to ship specimens in accordance to current national and international regulations. The following approach is advised:

Packaging:

- Use packing material conform with UN-Nr. 3373
- Swabs must close tight and be waterproof (1).
- Swabs must be put in **waterproof second cover** (2) that contains an **absorbent** (1a).
- **Second cover** must be put in **third** (= outer) cover (3a or 3b)
- Either second or third cover **must be rigid** (use either 2 or 3b).

Example:



(Picture source: Thurm V et al. (2007) Versand von medizinischem Untersuchungsmaterial. Deutsche Ärzteblatt, 104 (46), 3201-7)

Identification:

Outer cover must carry a black rhombus + UN3373 + "Biological Substance Category B":



Send swabs to:

StaphTrav

c/o AG Zanger
Institut für Tropenmedizin
Wilhelmstrasse 27
72074 Tübingen
Germany

(Picture source: Thurm V et al. (2007) Versand von medizinischem Untersuchungsmaterial. Deutsche Ärzteblatt, 104 (46), 3201-7)

Cost: The cost of shipping the specimens to Tübingen has to be carried by the participating study centre. Once a consortium has formed, however, StaphTrav will apply for external funding with the aim to cover these expenses in the near future. All costs for the laboratory analysis will be carried by the coordinating centre in Tübingen.

Contact:

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Further information:

www.staphtrav.eu