Tender Specifications

for

HAI-Net mortality review validity and reproducibility study

Framework service contract

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November 2015

Table of Contents

Introduction to ECDC

The European Centre for Disease prevention and Control (ECDC) is an agency of the European Union, established by the European Parliament and Council Regulation 851/2004 of 21 April 2004. Its purpose is to identify, assess and communicate current and emerging threats to human health from communicable disease. Within this broad mission statement, the main technical tasks of the Centre fall into the following four categories:

- The publication of independent scientific opinions, bringing together technical expertise in specific fields through its various EU-wide networks and via ad hoc scientific panels;
- The provision of technical assistance to EU member states, communication of the Centre's activities and results and dissemination of information tailored to different audiences;
- The development of epidemiological surveillance at the European level and the maintenance of networks of reference laboratories; and
- Early Warning and Response based on 'round the clock' availability of specialists in communicable diseases.

Further information about the Centre can be found on the ECDC website www.ecdc.europa.eu.

The tender process

The purpose of competitive tendering for awarding contracts is two-fold:

- to ensure the transparency of operations;
- to obtain the desired quality of services, supplies and works at the best possible price.

The applicable regulations, namely directives **92/50/EEC, 93/36/EEC and 93/37/EEC**, oblige the ECDC to guarantee the widest possible participation, on equal terms in tender procedures and contracts.

1 Overview of this tender

1.1 Description of the contract

The services required by ECDC are described in the terms of reference in **section 2** of the present tender specifications.

In drawing up a tender, tenderers should bear in mind the provisions of the draft contract in **Annex I**. In particular, the draft contract indicates the method and the conditions for payments to the contractor.

Tenderers are expected to examine carefully and respect all instructions and standard formats contained in these specifications and the invitation to tender. An offer which does not contain all the required information and documentation may be rejected.

1.2 Timetable

Activity	Date	Comments
Launching of tender	23/11/2015	Dispatch of contract notice to the OJ
Site visit or clarification meeting (if any)	-	Not applicable to this tender
Deadline for request of clarifications	28/01/2016	-
Deadline for submission of offers	**05/02/2016**	At 16:30 local time if hand delivered
Interviews (if any)	-	Not applicable to this tender
Opening session	12/02/2016	-
Date for evaluation of offers	Opening date plus 1 week	Estimated
Notification of award to the selected Tenderer	Evaluation date plus 3 weeks	Estimated
Contract signature	Notification date plus 2 weeks	Estimated

1.3 Participation in the tender procedure

This procurement procedure is open to the natural or legal person wishing to bid for the assignment and established in the European Union, European Economic Area and Stabilisation and Association Agreements countries.

Tenderers must not be in any situation of exclusion under the exclusion criteria indicated in section 3.1 of these tender specifications and must have the legal capacity to allow them to participate in this tender procedure (see section 3.2.1).

Please note that any attempt by a tenderer to obtain confidential information, enter into unlawful agreements with competitors or influence the evaluation committee or ECDC during the process of examining, clarifying, evaluating and comparing tenders will lead to the rejection of his tender and may result in administrative penalties.

1.4 Participation of consortia

A consortium may submit a tender on condition that it complies with the rules of competition.

A consortium may be a permanent, legally-established grouping or a grouping which has been constituted informally for a specific tender procedure. Such grouping (or consortium) must specify the company or person heading the project (the leader) and must also submit a copy of the document authorising this company or person to submit a tender. All members of a consortium (i.e., the leader and all other members) are jointly and severally liable to ECDC.

In addition, each member of the consortium must provide the required evidence for the exclusion and selection criteria (see section 3 of these tender specifications). Concerning the selection criteria 'technical and professional capacity', the evidence provided by each member of the consortium will be checked to ensure that the consortium **as a whole** fulfils the criteria.

The participation of an ineligible person will result in the automatic exclusion of that person. In particular, if that ineligible person belongs to a consortium, the whole consortium will be excluded.

1.5 Subcontracting

If subcontracting is envisaged, the tenderer must clearly indicate in the tender which parts of the work will be subcontracted. The total value of the subcontracted part of the services cannot represent the total value of the contract value.

Subcontractors must satisfy the eligibility criteria applicable to the award of the contract.

If the identity of the subcontractor is not known at the time of submitting the tender, the tenderer who is awarded the contract will have to seek ECDC's prior written authorisation before entering into a subcontract.

Where no subcontractor is given, the work will be assumed to be carried out directly by the tenderer.

1.6 Presentation of the tender

Tenders must comply with the following conditions:

1.6.1 Double envelope system

Offers must be submitted in two sealed envelopes. The inner envelope contains 3 separate inner envelopes clearly marked Envelopes A, B and C (see Invitation to tender).:

The content of each of these envelopes shall be as follows:

1. Envelope A – Administrative documents
   One original and one copy of:
   - The signed, dated and duly completed **Tender Submission Checklist** using the template in **Annex IX**;
   - The duly filled in, signed and dated **Exclusion Criteria and Non-Conflict of Interest Declaration**(s) as requested in section 3.1 and using the standard template in **Annex II**;
   - The duly filled in, signed and dated **Legal Entity Form**(s) as requested in section 3.2.1 and using the standard template in **Annex III** as well as the requested accompanying documents;

- The duly filled in, signed and dated **Financial Identification Form**[1] using the template in **Annex IV**;
- Financial and economic capacity documents as requested in section 3.2.2;
- The technical and professional capacity documents as requested in section 3.2.3;
- A statement containing the name and position of the tenderer's **authorised signatory**; and
- In case of consortia, a **consortium agreement** duly signed and dated by each of the consortium members specifying the company or person heading the project and authorised to submit a tender on behalf of the consortium (please see section 1.4 of these tender specifications)**.**

2. Envelope B – Technical proposal
   - One original (unbound, signed and clearly marked as "Original") and four copies (bound and each marked as "Copy") of the Technical Proposal, providing all information requested in section 4.1.

3. Envelope C – Financial proposal
   - One signed original and four copies of the Financial Proposal, based on the format in found in **Annex VII**.

Tenderers are welcome to submit in an environmentally friendly way, e.g., by choosing a simple and clear structure (list of contents and consecutive page numbering), double-sided printing, limiting attachments to what is required in the technical specifications (no additional material) and avoiding plastic folders or binders. This will not affect the evaluation of the tender.

1.6.2 Language

Offers must be submitted in one of the official languages of the European Union. ECDC prefers, however, to receive documentation in English. Nonetheless, the choice of language will be not play any role in the consideration of the tender.

1.7 Confirmation of offer submission

In order to keep track of offers due to arrive, tenderers who do not hand deliver their offers are requested to complete and return the form found **Annex VIII**.

1.8 Contacts between ECDC and the tenderers

Contacts between ECDC and tenderers are prohibited throughout the procedure, except in the following circumstances:

1.8.1 Written clarification before the deadline for submission of offers

Requests for clarification regarding this procurement procedure or the nature of the contract should be done **in writing only** through the eTendering website at https://etendering.ted.europa.eu in the "questions and answers" tab, by clicking "create a question".

[1] In the case of a consortium, only **one** Financial Identification Form for the whole consortium shall be submitted, nominating the bank account into which payments are to be made under the contract in the event that the respective tender is successful.

Each request for clarification sent to ECDC should indicate the publication reference and the title of the tender.

The deadline for clarification requests is indicated in the timetable under section 1.2. Requests for clarification received after the deadline will not be processed.

At the request of the tenderer, ECDC may provide any additional information or clarification resulting from the request for a clarification on the eTendering website (see above).

ECDC may, on its own initiative, inform interested parties of any error, inaccuracy, omission or other clerical error in the text of the contract notice or in the tender specifications by publishing a corrigendum.

Tenderers should regularly check the eTendering website for updates.

1.8.2 After the closing date for submission of tenders

If, after the tenders have been opened, some clarification is required in connection with a tender, or if obvious clerical errors in the submitted tender must be corrected, the ECDC may contact the tenderer, although such contact may not lead to any alteration of the terms of the submitted tender.

1.8.3 Visits to ECDC premises

No site visits at ECDC's premises are deemed necessary for this procedure.

1.8.4 Interviews

The Evaluation Committee will not conduct interviews for this procedure.

1.9 Division into Lots

This tender is not divided into lots. The tenderer must be in a position to provide all the services requested.

1.10 Variants

Not applicable

1.11 Confidentiality and public access to documents

All documents presented by the tenderer become the property of the ECDC and are deemed confidential.

In the general implementation of its activities and for the processing of tendering procedures in particular, ECDC observes the following EU regulations:

- Council Regulation (EC) No. 1049/2001 of 30 May 2001 regarding public access to European Parliament, Council and Commission documents; and
- Council Regulation (EC) No. 45/2001 of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

The tender process will involve the recording and processing of personal data (such as a tenderer's name, address and CV). Such data will be processed pursuant to Regulation (EC) No. 45/2001.

Unless indicated otherwise, a tenderer's replies to questions and any personal data requested by ECDC are required to evaluate the tender in accordance with the tender specifications and will be processed solely for that purpose by ECDC. A tenderer is entitled to obtain access to their personal data on request and to rectify any such data that is inaccurate or incomplete.

If you have any queries concerning the processing of your personal data, you may address them to the ECDC Data Protection Officer dpo@ecdc.europa.eu. You also have the right of recourse at any time to the European Data Protection Supervisor for matters relating to the processing of your personal data

1.12 Contractual details

A draft contract is attached to these technical specifications as **Annex I**.

ECDC wishes to conclude a framework contract to provide a validity and reproducibility study of mortality review for the Healthcare-Associated Infection surveillance Network (HAI-Net). A framework contract will establish the terms governing specific contracts to be awarded during a period of up to twenty-four months; in particular, with regard to price.

Signature of the framework contract imposes no obligation on the Centre to order services. Only the implementation of the framework contract through specific contracts/order forms is binding for ECDC.

Each specific contract/order form will contain details of deliverables and timelines for particular services to be provided.

1.13 Electronic exchange of documents

Please refer to the draft contract attached to these technical specifications as Annex I. The related documentation can be found at: *http://ec.europa.eu/dgs/informatics/supplier_portal/index_en.htm*. Other applications currently under development may be implemented on a voluntary basis during the contract execution.

1.14 Additional information

By virtue of article 134(1)(f) and article 134(3) of the Rules of Application of the Financial Regulation, ECDC reserves the option to launch further negotiated procedure, with the contractor chosen as a result of the present call for tender, for new services consisting in the repetition of similar services during the three years following the signature of the original contract.

2 Terms of reference

The terms of reference will become an integral part of the contract that may be awarded as a result of this tender procedure.

2.1 Introduction: Background to the invitation to tender

2.1.1 ECDC surveillance activities

In the founding regulation of ECDC (851/2004 EC) it is stated that ECDC within its mandate shall coordinate the surveillance activities of communicable diseases at the Community level. To achieve this, ECDC shall collect, collate, evaluate and disseminate relevant scientific and technical data, and maintain the database(s) for such epidemiological surveillance (Regulation 851/2004, Article 5).

2.1.2 Healthcare-Associated Infection surveillance Network (HAI-Net)

HAI-Net is a European network for the surveillance of healthcare-associated infections (HAIs). The network is coordinated by ECDC.
The activities of HAI-Net are largely based on the activities of the former 'Improving Patient Safety in Europe' (IPSE) project. The coordination of IPSE was transferred to ECDC in July 2008. In addition, HAI-Net provides support to Member States to respond to the COUNCIL RECOMMENDATION of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections (http://ec.europa.eu/health/patient_safety/docs/council_2009_en.pdf).
The main priorities of HAI-Net are the coordination of the ECDC point prevalence survey of HAIs and antimicrobial use in European acute care hospitals, the European surveillance of surgical site infections (SSIs), the European surveillance of HAI in intensive care units (ICUs) and the repeated point prevalence surveys of HAIs and antimicrobial use in European long-term care facilities.

HAI-Net surveillance of SSIs aims to describe and monitor the epidemiology of SSIs at European level and to draw up European reference tables for inter-hospital comparisons of risk-adjusted SSI rates. Seven surgical categories are under surveillance: coronary artery bypass graft, cholecystectomy, colon surgery, caesarean section, hip prosthesis, knee prosthesis and laminectomy.

HAI-Net surveillance of infections acquired in ICUs specifically targets ICU patients because they are at high risk of morbidity and mortality associated with HAIs. It collects data from the national HAI surveillance networks on the incidence of ICU-acquired pneumonia, ICU-acquired bloodstream infections, ICU-acquired urinary tract infections and ICU-acquired catheter-related infections. It also collects data on common antimicrobial resistance markers in microorganisms responsible for ICU-acquired infections and, optionally, on antimicrobial use in ICUs.
On 5 May 2015, ECDC published a protocol for EU surveillance of CDI, based on the results of a pilot survey to test the feasibility of CDI surveillance in Europe, incorporating recommendations from the final meeting of the ECDIS-Net project [1]. ECDC may consider publishing a revision of this EU protocol before the end of 2015.

From January 2016 onwards, ECDC intends to receive CDI surveillance data from EU/EEA Member States that have been collected using this protocol. The protocol does not include collection of raw *C. difficile* typing data. As in the pilot survey, it does include collection of the PCR ribotype identified at Member State level.

2.1.3 Mortality data

In 2013, the European Commission requested ECDC to collect additional data on mortality from HAIs, in accordance with the Council recommendation of 9 June 2009 on patient safety, including the prevention and control of HAIs (2009/C 151/01). ECDC proposed that an optional variable is added to estimate the relationship between HAI and death in the ICU in patients with at least one HAI. The proposal was discussed with members of HAI-Net at the Third Joint Meeting of the ARHAI Networks on 11-13 February 2015.

HAIs are a major public health problem in Europe with more than 80,000 patients with an HAI on any given day in European acute care hospitals, which results in an estimated 3.2 million deaths attributable to HAIs

each year. However, the availability of data on attributable mortality is limited, hampering accurate estimates of the burden of HAIs. A significant obstacle to the estimation of attributable mortality is the presence of multiple contributing factors making it often challenging to estimate to what extent an HAI contributes to morbidity or mortality.

Attributable mortality of HAIs is usually estimated by the difference in the relative risk of death between patients with and without HAIs from comparative studies, e.g. matched cohort or case-control studies or by modeling approaches, using multi-state models, marginal structural models, Cox regression models, etc. As a first step, using a matched cohort approach with propensity score in the HAI-Net ICU data, an estimated number of 9,373 deaths per year were attributed to HAIs the ECDC report on surveillance of HAIs in ICUs 2008-2012 [ECDC surveillance report on healthcare associated infections in intensive care units in Europe, in press]. However, statistical approaches have several limitations, and the results are heavily dependent on the statistical method used. In addition, these statistical methods can only be applied to patient-based data.

Another approach to estimate the mortality attributable to HAIs is to perform mortality review studies. Mortality review is a descriptive evaluation of the cause of death of every patient who died with a HAI. Each death is reviewed by one or two clinicians and classified as totally, partially, or not attributable, based on clinical judgement. The validity of mortality reviews has never been established (e.g. through autopsy studies). Moreover, standardisation of the criteria and review process across hospitals and countries is also necessary. Methodologies to judge the relationship between HAI and death vary considerably. An example of a detailed, but highly specific, method was developed by the French Ministry of Health in the context of the mandatory reporting system of HAI-related deaths in France ("Signalement des décès liés aux infections nosocomiales"). This method includes a root cause analysis to determine, in addition to the relationship between HAI and death, to which extent the HAI could have been avoided.

To address the request from the Commission for ECDC to collect additional data on mortality from HAIs, ECDC is planning to add mortality review as part of the HAI-Net protocols. The main objectives for ECDC are:

- to estimate the burden in terms of mortality of certain types of HAI in the EU/EEA;
- to harmonise and validate a methodology for assessing attributable mortality in HAIs;
- to explore inter-country variations in the proportion of deaths in patients with HAI which are attributed to the HAI.

To estimate the true burden of HAIs in terms of mortality, the method needs to maximise both specificity and sensitivity, thus avoiding overestimation but also underestimation of the number of HAI-related deaths in the EU/EEA.

Once validated, the applied method for mortality review will be similar in all HAI-Net surveillance protocols, and data will be collected at the HAI case level, i.e. both in light and standard surveillance protocols.

2.1.4 Proposed method

A new variable describing the relationship of death to HAI is proposed by ECDC for the HAI-Net protocols for surveillance of HAIs in the ICU, SSIs and CDIs.

The variable is proposed to include five levels:

- No death (patient was alive on discharge or on date of last follow-up);
- Death, HAI definitely contributed to death;
- Death, HAI possibly contributed to death;
- Death, no relationship to HAI;
- Death, relationship to HAI unknown or not verified.

The development of a mortality review tool (e.g. algorithm) needs to be considered. The tool should take into account the following components that were agreed at the Third Joint Meeting of the ARHAI Networks on 11-13 February 2015:

- Probability of death without the HAIs, as estimated at admission (e.g. according to severity score on ICU admission – SAPS II);
- Active state of the HAI or a complication of the HAI at the time of death;
- Absence of another cause of death during the current hospitalisation/ICU admission;
- Presence of a plausible patho-physiological mechanism to account for the contribution of HAI to the death of the patient (e.g. infection type, involved microorganisms, antimicrobial resistance);
- Life expectancy of the patient according to McCabe score (without influence of HAI): 0:Non-fatal – 1: Ultimately fatal (>=1 year - <5years survival) – 2: Rapidly fatal (<1 year survival).

In addition, cases of withholding and withdrawal of life supporting therapy in the ICU, the appropriateness of antimicrobial treatment and the contribution of antimicrobial-resistance should be taken into account. In cases where the HAI contributed to the death of the patient, the contribution of antimicrobial resistance (AMR) must also be assessed e.g. according to similar levels

- AMR of the responsible microorganism definitely contributed to death;
- AMR of the responsible microorganism possibly contributed to death;
- no relationship to AMR of the responsible microorganism;
- relationship to AMR of the responsible microorganism unknown or not verified.

Estimating the validity of mortality review for HAIs is challenging due to the lack of autopsy studies, the lack of other 'gold' standard for attribution of causality and the presence of additional factors that often contribute to death of patients with HAIs. Nevertheless, face validity and content validity can be assessed by an expert group, and construct validity can be tested against the assessment by the expert group of real and mock case studies.

In addition to validity, the reproducibility of the mortality review instrument among evaluators, settings and countries participating in HAI-Net will be assessed. The reproducibility (or inter-rater variability) can be determined by appropriate statistical tests, e.g. Cohen's kappa.

2.2 Description of the services & scope of the contract

2.2.1 Contract objectives and scope

The objective of the project is to provide a mortality review methodology for HAIs in European hospitals that participate in HAI-Net and estimate the validity and reproducibility of this mortality review methodology.

2.2.2 Description of the tasks

The contractor(s) should finalise the criteria for classification of deaths according to association with HAI and design and perform a study of the validity and reproducibility of mortality review for HAIs, and in particular infections in ICUs, SSIs and CDIs. The study will be performed in hospitals that participate in HAI-Net. To this end the contractor should:

(1) **Coordinate an expert meeting** with objective to support the development of the study protocol. To this end the contractor will liaise with ECDC experts. The meeting will be attended by 10 experts in HAIs. Travel and accommodation of participants will be organised by ECDC with a third party. The contractor will be responsible to propose an agenda for approval by ECDC and prepare the materials and the minutes of the meeting;

(2) **Develop the study protocol.** The study protocol will include the mortality review tool and the methodology for assessment of validity and reproducibility (type of study, estimation of the hospital

and patient sample size, recruitment procedure, selection and training of evaluators, data collection and analysis of validity and reproducibility).

(3) **Identify and recruit the participating centres and evaluators**;

(4) **Develop training material including real and mock patient case studies** to support the validation and reproducibility study and training of the evaluators

(5) **Coordinate a kick-off meeting**, attended by approximately 30 participants from the participating countries and centres. Travel and accommodation of participants will be organised by ECDC with a third party. The contractor will be responsible to propose an agenda for approval by ECDC and prepare the materials and the minutes of the meeting;

(6) **Coordinate execution of the study**, including collection of the data;

(7) **Analyse the data** according to the study protocol;

(8) **Coordinate a meeting to present the final results and draft the report.** The meeting will be attended by the participants of the kick-off meeting and the expert group meeting. Travel and accommodation of participants will be organised by ECDC with a third party. The contractor will be responsible to propose an agenda for approval by ECDC and prepare the materials and the minutes of the meeting ;

(9) **Write a report** with the results and conclusions of the study, including recommendations to the HAI-Net for the implementation of the mortality review;

(10) **Provide ECDC with a manuscript,** ready for submission to an open-access peer-reviewed journal, with the final results of the study. The manuscript must be co-authored by ECDC and approved by the ECDC Chief Scientist.

2.2.3 Deliverables, reporting and project schedule

The deliverables are listed below. The deadlines mentioned for these deliverables are estimated and may change. The final dates for delivery of the deliverables will be indicated in the specific contracts. Interim stages of these deliverables will be defined in specific contracts when applicable.

(1) The contractor will provide a detailed updated project work plan, including verifiable milestones, at project inception with timelines and general methodological approach. Deadline for this deliverable: at the latest two weeks after the signature of the contract.

(2) The contractor will provide the minutes of the expert meeting, including recommendations on the study protocol for the assessment of validity and reproducibility of the mortality review. Deadline for this deliverable: 30 June 2016.

(3) The contractor will provide a study protocol that will include the methodology and in particular the type of study, the mortality review tool, estimation of the hospital and patient sample size, the recruitment procedure, the evaluator selection and training, the data collection and analysis process. The protocol will be submitted to ECDC for review and the contractor will respond to the comments received by making modifications if indicated. Deadline for this deliverable: at the latest by 15 September 2016.

(4) The contractor will provide training material for the evaluators, including real and mock patient case studies. Deadline for this deliverable: 15 October 2016.

(5) The contractor will produce draft minutes of the kick-off meeting. Deadline for this deliverable: 15 November 2016.

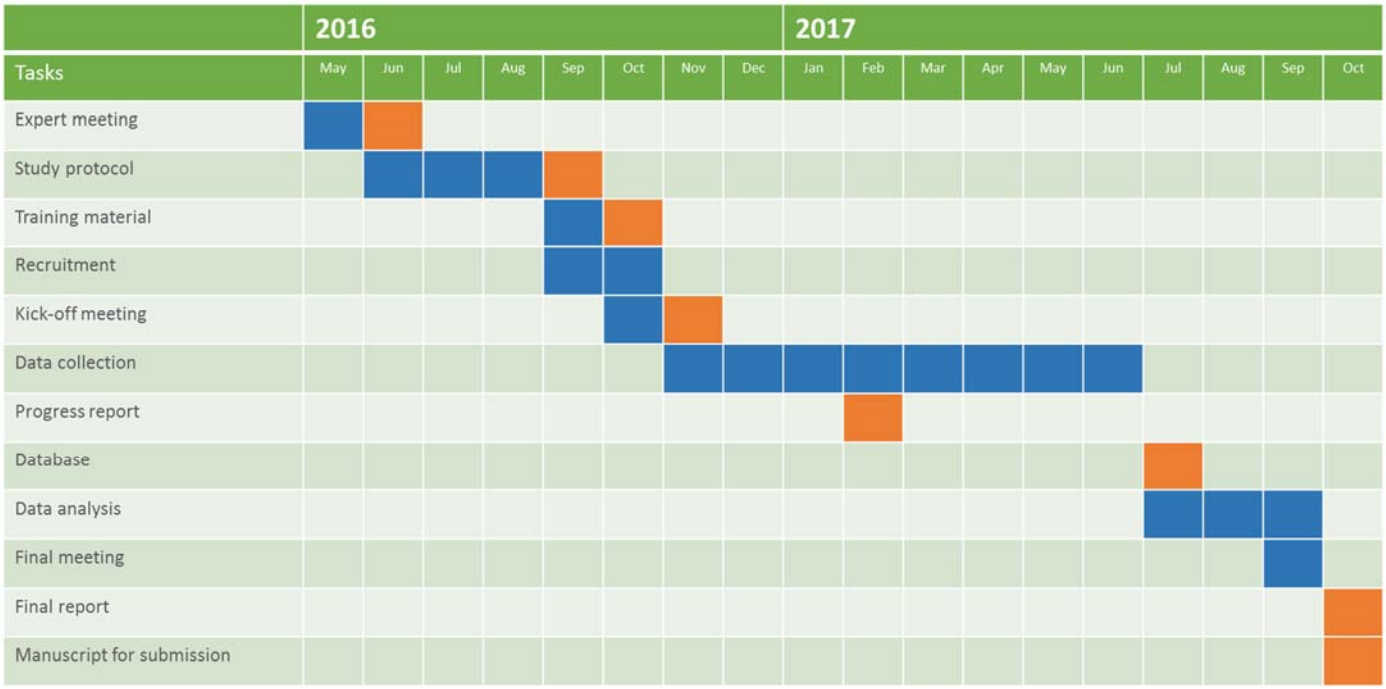
(6) The contractor will submit an interim progress report to ECDC including the final minutes of the kick-off meeting and describing the progress of the study. Deadline for this deliverable: 15 February 2017.

(7) The contractor will provide the study database to ECDC. Deadline for this deliverable: 31 July 2017.

(8) The contractor will provide a final report with analysis of the data, interpretation, conclusion and recommendations for the implementation of mortality review in HAI-Net. The report will take into account the outcome of the final meeting. Deadline for this deliverable: 15 October 2017.

(9) The contractor will provide a manuscript ready for submission to a peer-reviewed journal providing open access to published articles, describing the results and interpretation of the study, co-authored and approved by ECDC. Deadline for this deliverable: 15 October 2017.

Tentative project schedule



Activity

Deliverable

2.2.4 Duration of the contract

The framework contract will be automatically renewed once for one year. The length of the FWC will not exceed two years.

The estimated length of specific contracts is between six months and one year. ECDC is not obliged to issue any specific contracts. ECDC may issue any number of individual contracts.

2.2.5 Place of performance of the contract

None of the tasks are expected to be performed on the ECDC premises. The meetings will take place in Stockholm, unless otherwise specified by ECDC. The contractor will only cover their own expenses to attend the meetings.

2.2.6 Reference documents

- Kaoutar B, Joly C, L'Hériteau F, Barbut F, Robert J, Denis M, Espinasse F, Merrer J, Doit C, Costa Y, Daumal F, Blanchard HS, Eveillard M, Botherel AH, Brücker G, Astagneau P; French Hospital Mortality study group. Nosocomial infections and hospital mortality: a multicentre epidemiology study. J Hosp Infect. 2004 Dec;58(4):268-75.
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2.3 Prices

2.3.1 Currency of tender

Prices must be quoted in Euro.

Conversions should use the rates published in the C series of the Official Journal of the European Union on the day when the invitation to tender was issued. This information is also

available on the Website of the European Central Bank at the following URL: http://www.ecb.int/stats/eurofxref

The Financial Proposal Form in **Annex VII** must be used to submit a tender.

2.3.2 All-inclusive prices

The estimated budget for the entire duration of the framework contract is € 110,000.

Prices submitted in response to this tender must be inclusive of all costs involved in the performance of the contract (e.g. to include delivery, supply and installation, maintenance, travel, subsistence, etc.). No expenses incurred in the performance of the services will be reimbursed separately by ECDC.

2.3.3 Price revision

Prices submitted in response to this tender shall be fixed and not subject to revision for Specific Contracts concluded during the first year of performance of the Framework Contract.

From the beginning of the second year of performance of the Framework Contract, prices may be revised upwards or downwards each year, where such revision is requested by one of the contracting parties by notice served no later than three months before the anniversary of the date on which the Framework Contract became effective.

Specific Contracts shall be concluded on the basis of the prices in force on the date on which they are signed. Such prices shall not be subject to revision.

See the article about “Prices” of the contract for calculation.

2.3.4 Costs involved in preparing and submitting a tender

ECDC will not reimburse any costs incurred in the preparation and submission of a tender. Any such costs must be paid by the tenderer.

2.3.5 Protocol on the Privileges and Immunities of the European Union

The Centre is, as a rule, exempt from all taxes and duties, and in certain circumstances is entitled to a refund for indirect tax incurred, such as value added tax (VAT), pursuant to the provisions of articles 3 and 4 of the Protocol on Privileges and Immunities of the European Union. Tenderers must therefore quote prices which are exclusive of any taxes and duties.

2.3.6 Payments

Payments under the contract shall be executed only if the contractor has fulfilled all their contractual obligations by the date on which the invoice is submitted, including specified deliverables.

2.3.7 Financial guarantees

ECDC may require a pre-financing guarantee or a performance guarantee from the Contractor chosen as a result of this tendering procedure. When such guarantee is requested, the specific conditions related to the provision of a guarantee are included in the draft contract (**Annex I**). The costs for the guarantee shall be borne by the Contractor.

3 Exclusion and selection criteria

3.1 Exclusion criteria

All tenderers shall provide a declaration on their honour (see Annex II), duly signed and dated by an authorised representative of the tenderer, stating that they are not in one of the situations of exclusion listed in the Annex II.

The successful tenderer shall provide the documents mentioned as supporting evidence in Annex II before signature of the contract and within a deadline given by the contracting authority. This requirement applies to all members of the consortium in case of joint tender.

The contracting authority may waive the obligation for a tenderer to submit documentary evidence if such evidence has already been submitted for another procurement procedure and provided the documents were issued not more than one year earlier and are still valid. In such cases, the candidate or tenderer must declare on his honour that the documentary evidence has already been provided in a previous procurement procedure, provide reference to that procedure, and confirm that there has been no change in the situation.

3.2 Selection criteria

Tenderers must submit evidence of their legal, economic, financial, technical and professional capacity to perform the contract.

3.2.1 Legal capacity

Requirement
A tenderer is asked to prove that they are authorised to perform the contract under the national law as evidenced by inclusion in a trade or professional register, or a sworn declaration or certificate, membership of a specific organisation, express authorisation or entry in the VAT register.

Evidence required
The tenderer shall provide a duly filled in and signed Legal Entity Form (see **Annex III**) accompanied by the documents requested therein.
(Where the tenderer has already signed another contract with ECDC, they may provide instead of the legal entity file and its supporting documents a copy of the legal entity file provided on that occasion, unless a change in his legal status occurred in the meantime).

3.2.2 Economic and financial capacity

Requirement
The tenderer must be in a stable financial position and have the economic and financial capacity to perform the contract.

Evidence required
Proof of economic and financial capacity shall be furnished by the following documents:

- balance sheets or extracts from balance sheets for at least the last two years for which accounts have been closed (where publication of the balance sheet is required under the company law of the country in which the economic operator is established);
- a statement of overall turnover and turnover concerning services/supplies covered by the contract during the last three financial years.

If, for some exceptional reason which ECDC considers justified, the tenderer is unable to provide the references requested by the contracting authority, he may prove his economic and financial capacity by any other means which ECDC considers appropriate.

The Centre reserves the right to request any additional documentary evidence it deems necessary or useful in order to verify a tenderer's economic and financial standing.

3.2.3 Technical and professional capacity

Requirement(s)
The tenderer's technical and professional capacity will be evaluated using the following criteria:

A) Suitability of the organisation and staffing structure available for the activities covered by the contract;

B) Relevant qualifications in the fields of medicine, infectious diseases and epidemiology and expertise of key personnel allocated to the project;

C) Technical experience, knowledge and capability in epidemiology of healthcare-associated infections and in research study design and execution;

E) The ability to prepare and present clear and concise reports and scientific articles in English and for an international audience, incorporating feedback from international collaborators.

F) Involvement in relevant research activities, particularly for the health sector.

Evidence required
The following documents or information shall be presented as evidence of compliance with the technical and professional capacity criteria:

A) Details of the structure of the organisation (including the number of staff members) and relevant subcontractors;

B) Professional accreditations or references held by the tenderer and relevant subcontractors; CVs of the key experts that will carry out the project (preferably using the template in **Annex VI**), covering work experience, education and training, organisational and technical skills, attesting the drafting and presentation skills;

C) A list and description of recent activities (in the last 3 years) in the field of epidemiology of healthcare-associated infections; including at least 1 example of a project on subjects related to this tender conducted in an international environment.

4 Award of the contract

Offers are opened and evaluated by a committee, possessing the technical and administrative capacities necessary to give an informed opinion on the offers. The committee members are nominated on a personal basis by ECDC under guarantee of impartiality and confidentiality. Each of them has equal voting rights.

Only the tenders meeting the requirements of the exclusion and selection criteria will be evaluated in terms of quality and price.

4.1 Technical proposal

The assessment of technical quality will be based on the ability of the tenderer to meet the purpose of the contract as described in the terms of reference. To this end, the technical proposal shall contain the following information to allow evaluation of the tender according to the technical criteria mentioned in section 4.2:

- A description of the approach proposed and the proposed methods to be applied; means to be used to meet the objectives of the terms of reference and assessment of the main issues, limitations, risks of the analyses to be carried out as well as the proposed mitigation measures;
- Work organisation and planning (including major milestones and dates for meetings with ECDC to report on progress, as requested in section 2.2.3 of these tender specifications);
- Description of the involvement of the proposed key experts (roles and responsibilities) to execute the planned activities, in particular to cover the key analyses and investigations of the study.

The information in the technical proposal must be consistent with the terms of reference and must be signed by the tenderer.

4.2 Technical evaluation

The quality of technical offers will be evaluated in accordance with the award criteria and the associated weighting as detailed in the evaluation grid below.

No	Criteria	Max points	Awarded score
1	**Allocation of resources and project management**: - Quality of the proposed activities and planning of tasks (sequence, duration) in order to achieve the objectives; - Appropriateness of allocation and management of resources, expertise and responsibilities, including coordination and mobilization of the team and possible subcontractors; - Realistic time deadlines for prompt implementation and verifiable milestones for completion of tasks.	**30**	
2	**Methodology** - Quality and appropriateness of the proposed methods to perform the required analyses; - Scientific validity of the proposal;	**30**	
3	**Technical implementation** - Consistency of the proposed implementation with the tender specifications - Appropriateness of the proposed technical implementation to achieve the specified objectives - Validity and quality of the approach to recruit a representative sample of participating centres - Quality of the evaluation of the difficulties, limitations and risks as well the proposed mitigations by the tenderer.	**40**	
	TOTAL	**100**	

Only tenders scoring **70 points** or more (of a maximum of 100) points against the technical award criteria will have their financial proposal evaluated.

Offers scoring less than **60%** for any award criterion will be deemed to be of insufficient quality and eliminated from further consideration.

4.3 Financial proposal

The financial proposal should be presented in the format found in **Annex VII**.

4.4 Choice of the selected tender

The contract will be awarded to the tenderer offering the best value for money, taking into account the awarding criteria listed above. No award criteria and sub-criteria other than those detailed above will be used to evaluate the offer.

The weighting of quality and price will be applied as follows:

Score for tender X	=	cheapest price / price of tender X	*	Total quality score (out of 100) for all criteria of tender X

"Price of tender X" is the total price in Annex VII in the scenario worksheet (calculation of reference price), i.e. the sum of all Work Packages for all years.

4.5 No obligation to award

Completing the procedure of the call for tenders in no way imposes on the ECDC an obligation to award the contract. ECDC shall not be liable for any compensation with respect to tenderers whose offers have not been accepted, nor shall ECDC be liable when deciding not to award the contract.

4.6 Notification of outcome

Each tenderer will be informed in writing about the outcome of the call for tender.

If tenderers are notified that a tender has not been successful, tenderers may request additional information by fax or mail. At the discretion of ECDC, this information can be given in a follow-up letter providing further details in writing, such as the name of the tenderer to whom the contract is awarded and a summary of the characteristics and relative advantages of the successful tender. However, ECDC would like to stress that it is not free to disclose any information affecting the commercial interests of other tenderers.

List of Annexes

Annex I — Draft contract

Annex II — Exclusion criteria and non-conflict of interest declaration

Annex III — Legal entity form

Annex IV — Financial identification form

Annex V — Authorised signatory form

Annex VI — Curriculum Vitae template

Annex VII — Financial proposal form

Annex VIII — Confirmation of offer submission

Annex IX — Tender submission checklist