



Questions and answers from interested parties from the breakout sessions of our open market consultation meetings

The Nightingale open market consultation meetings generated lively discussion. Here you can read each question and answer that was raised during the breakout sessions. The questions and answers have been grouped into three topics: Why? How? and PCP.

Why?

1. *Give a clearer definition of the main problem*

Patients die because signs of deterioration are missed. Patient deterioration is often overlooked or not detected at all. One of the reasons is the intensity in monitoring and supervision which decreases from intensive care, via the ward, towards home.

For more detail see the [Nightingale Common Challenge document](#)

2. *What are the technical requirements/specifications?*

The main specifications are described in the [Nightingale Common Challenge document](#); these will be developed even further before being published in the tender package on 1 November 2017. Technical specifications will be defined in more detail by interaction between contenders and consortium partners during the different phases.

3. *What is the target patient population?*

Patients hospitalised after high risk surgery, day surgery or after a short stay in the ER department; patients at home immediately after hospitalisation after surgery; and acute patients.

4. *Which patient population will be tested in phase 3?*

This will be determined during the tender process. We are likely to concentrate on the high-risk inpatient population (elective and non-elective). We will preferably, but not exclusively, include post-operative patients. Testing with patients at home will be defined at a later stage.

5. *Are nursing homes also considered as well as the patients' homes?*

Use in nursing homes is not currently in Nightingale's scope due to the added complexity of an additional Electronic Patient File, however there is no reason why the generic solution Nightingale is looking for couldn't work in nursing homes.

6. *Who will be contacted when problems arise in the home? What are the legal implications?*

When problems arise in the home the standard procedures that are used today will be used. There are no other legal implications, as per current normal practice.

7. *Why are the present solutions lacking?*

Too many false positive (alarm fatigue) and false negative (loss of trust in the system) results; not enough adapted to the specific context of the patient. The Nightingale objective is prediction and early detection of vital instability to prevent death and disability by wearable smart monitoring leading to safer care.

8. *Who will interpret the data in the hospital and who will interpret the data at home?*

In hospital this will mainly be nursing staff on the ward, however this may also be physicians depending on the severity of the problem. At home this will be the patient and family/co-habitants but depending on the problem potentially other care providers such as nurses, GPs, other non-medical care providers that come to the home.

9. *What is the role of the patient?*

Input to the system (symptoms, signs, feelings) and respond to specific questions/suggestions from the system.

10. *What do the different stakeholders in the different hospitals envisage the benefits are?*

Improvement in patient outcome as a result of earlier and better detection of deterioration, enabling better targeted and more appropriately timed interventions, thereby improving value (outcome/cost). The long term benefits could be a reduction in the costs of additional care; a reduction in the length of stay in hospital; less re-admissions to intensive care; less re-admissions from home to hospital; decline in mortality.

11. *What do you mean when you talk about a self-learning/AI system?*

A system that continuously analyses the parameters, processes, interventions and outcomes of every patient in the system in real time by analysing the correct and incorrect results of the algorithm in use; and by adapting/improving this algorithm when required. This type of system requires access to these different parameters and to the ultimate outcome of the patient (in the Electronic Patient File).

12. *What can be provided as input for the solution from existing data? Does this include labs, medication?*

Structured data can be used immediately (lab, diagnostic codes, medication, parameters from a wearable devices or from other devices entered by care providers or the patient); unstructured parameters either need to be 'reformatted' i.e. analysed by NLP or changed to a structured format. This will vary from hospital to hospital and in the patient setting.

13. *Is pre-op monitoring before hospitalisation in Nightingale's scope?*

This is not in our scope however we are happy to hear from companies keen to develop this.

How?

14. *Can/will procuring hospitals make historical data available to contenders in order to better understand the problem, define possible solutions and structure the business case? For example clinical data, EWS data, EWS failures, misses/near-misses.*

Yes, the procuring hospitals will provide anonymised examples, information and data to the contenders to better understand the problem and test possible solutions. However this will have to be very targeted, and therefore limited, and in mutual agreement.

15. Can the consortium partners provide standard interfaces for data input into the solution?

The consortium partners have different Health Information Systems solutions so that interfaces have to be tested separately, but standard (HL7 and other) solutions are preferred and should be applicable to different consortium partners.

16. Will the Nightingale solution replace existing solutions that are lacking?

Only limited solutions (< level 3) have been used extensively in some of the consortium hospitals so Nightingale seeks to introduce novel solutions.

17. Who is responsible for the patient when they are at home?

In the immediate post-hospital phase, which Nightingale concentrates on, the hospital will take responsibility but will have to share information, decisions and solutions with the home team (primary care physician, home nurse, social worker)

18. Who will take responsibility for change management in testing hospitals and in the patients' home?

The consortium partners

19. Are IT departments on board to do testing and give input?

Yes

20. How will patient empowerment and involvement be guaranteed? Should the solution actively engage patients and other care-providers?

Patients and other care-providers will be required to be interactive in two ways. Firstly, by providing feedback on a prototype in the form of a focus group when the prototype is ready as their views are very important. Secondly, patients would be required to be interactive in the form of inputting data to the developed device.

21. How will Nightingale ensure stakeholder involvement during different phases?

Direct contact between contenders and consortium partners

22. How can it be guaranteed that the solution will be correctly used by participants in various hospitals during testing?

Testing will involve adequate training sessions organised by the consortium together with tenderers following the intended use/manuals as provided by the tenderers.

23. Is the Nightingale solution stand-alone or integrated with EPD? Can/should data be transferred to company and analysed there or within a hospital information system?

Information has to be shared with EPD and analysed preferably within EPD to avoid transfer of sensitive data outside of the hospital protected environment

24. How does the consortium envisage the solution dealing with variable patient characteristics? Such as different data types and numbers

The proposed algorithm has to define patient parameters to be used, which are available in the patient record

25. Should there be different solutions depending on home versus hospital? What about there being different types of patients and types of EPD?

The proposed solution should be as generic as possible and usable in both environments; the context (hospital ward versus home) could be one of the parameters which the algorithm takes into account

26. Who is liable in case of under-alarming?

During the evaluation phase the responsibility remains with the treating physician. During the commercial phase proper functionality will be the responsibility of the manufacturer

27. Are national call centres available in any/all of the participating countries?

No

28. Who owns the generated data? Where should they go when the home patient changes care centre?

The data is owned by the hospital that initiates the monitoring.

29. Do companies have to comply with open standards?

As much as possible

30. What about privacy and confidentiality? Is there a hospital firewall?

Compliance with European and national data protection legislation is mandatory and the flow of data needs to be encrypted and secure. The data captured from the wearble device at home needs to be transferred to the electronic patient record, this algorithm will run with suggestions/actions to be performed which need to be transferred back to the patient and their environment. As a result, data needs to be kept in the EPR and not in a 'data vault' outside the hospital's protected environment which is where the system primarily starts and operates.

31. In which phase do companies need to comply with requirements?

This will be specified for each phase of Nightingale

32. What kind of feedback to Nightingale is required?

The solution and algorithm needs to be known to the consortium; feedback needs to be diversified and not just 'red flags'.

33. Are partial solutions accepted?

Solutions have to fulfil the functional description and need to meet at least level 3. The system criteria will be specified in the tender documents.

34. *Can we have a care pathway from each hospital?*

The specific test environment will be defined in the later phases. The solution needs to be as generic as possible, with the parameters used created specifically in the context of a care pathway

35. *Are you looking more for a platform than a targeted solution?*

Yes in the sense that the solution can use parameters to adapt to specific environments, context, etc.

36. *What are the EU rules with respect to data, validation etc?*

Medical device and software as a medical device (SAMd) rules were introduced in April 2017. While these rules have yet to be made more explicit, they have to be followed.

37. *Do you have a simulated test environment for validation and CE approval?*

No

38. *Is there opportunity for companies to have one-to-one discussions with the consortium in this phase of the project?*

Not in this phase of the project

PCP

39. *How will the collaboration between procurers and contenders be organised?*

The main process of the tender, including the collaboration between procurers and contenders, will be described in the tender documents. Extra contact between procurers and contenders during phases 2 and 3 of the tender are anticipated and will be planned.

40. *How will collaboration/co-tendering between different contenders be facilitated? Speed-dating? Face-to-face (one-on-one) rather than online? Can you provide more info from questionnaires to find correct partner?*

Collaboration opportunities are facilitated by the Nightingale website, take a look at our [collaboration opportunities webpage](#) to find other companies who are interested in collaboration. In addition, if you are interested in forming a consortium don't forget to let the Nightingale team know about expertise you have and expertise you are looking for on enquiries@nightingale-h2020.eu to ensure you are listed on the collaboration opportunities table. This table is updated weekly.

41. *How will enough contact between procurers and tenderers be guaranteed during different phases? How will the availability of experts be guaranteed? Will the experts help to develop the appropriate system/algorithm?*

The Nightingale consortium will plan contact between procurers and tenderers during the different phases, these will be detailed in the tender documents. After publication of the tender, feel free to suggest more times for further contact (potentially with specific experts). The Nightingale consortium will look at every suggestion and decide if this is feasible/necessary. Experts from the Nightingale consortium will not help to develop the appropriate system / algorithm, but can provide valuable feedback to the tenderers.

42. What about insurers/payers?

The consortium realises the important role of insurers/payers in this project and will involve them at an early stage.

43. For the business case: technology is not the issue but who is going to pay for the solution?

Hospitals and (indirect) health insurers/government have the intention to pay for the solution if the business case is healthy. Also, after completion of the PCP, the consortium commits to conduct a [Public Procurement of Innovative Solutions \(PPI\)](#) if the PCP is successful.

44. For the business case: is there a relation between risk of patient and cost?

Yes, if the solution lowers the risks normally it results in lower costs for the health care system and makes it worth investing in the solution.

45. How does the business case take into account the different health care systems in the various involved countries? What about reimbursement?

The business case as presented during the open market consultations shows the potential effectiveness of the Nightingale solution. Reimbursement differs per country, with one of Nightingale's goals to get reimbursement for the solution in every country.

46. How will the consortium commercially implement the solution after conclusion of the PCP?

As mentioned above, after completion of the PCP, the consortium commits to conduct a PPI if the PCP is successful. Success of the PCP will depend on whether the solution passed all the evaluation criteria, if it is fully accepted by caregivers and patients; and if it clearly shows best value for money etc.

47. Is CE label required for testing?

The solution does not need to be CE certified for testing, but for the next phase (commercialisation) CE registration will be required.

48. What kind of tendering consortium do you prefer: big, small, combined?

We don't prefer any kind of tendering consortium, we only encourage tenderers to find partners in order to maximise the impact of the offered solution.

49. Will every solution be tested in all 5 hospitals?

Yes, in phase 3 every offered solution will be tested in all 5 hospitals.

50. Who will provide resources for testing?

The Nightingale consortium will provide resources for testing.

51. Can you publish interested company names for collaboration?

Yes take a look at our [collaboration opportunities webpage](#) which is updated weekly.

52. Will there be a clinical trial looking for efficacy in this PCP? What is the effect of not having that for further commercialisation? Is validation required within time frame of PCP?

There will not be a clinical trial during the PCP, since it is not possible in this short period of time. After the PCP, in consultation with the Nightingale consortium, a clinical trial could be possible in order to stimulate further commercialisation. Validation is not required within the time frame of the PCP.

53. Would you choose different parts of solutions from different proposals?

The best total solutions will be selected for the next phase and asked to further develop their own solution, not to integrate their solution with another tenderer with a different solution.

54. Can vendor solutions be combined during the tender?

Before the deadline of submitting a proposal in the tender process, vendors can combine their solutions to be able to offer what they see as the best total solution. After submission of a proposal it's not possible for different tenderers to combine solutions.

55. Can we offer 2 solutions?

The Nightingale consortium expects that tenderers self-assess what their best solution for Nightingale is and offer this best solution as proposal for the tender.

56. Regarding interaction between procurers and tenderers, what is public and what is confidential during the different phases, including the pre-tender period?

To guarantee equality and transparency, every communication between procurers and tenderers will be public for other participants in the tender, unless the tenderer clearly states that specific information is confidential and cannot be shared.

57. Can you put EU PCP documents on the Nightingale website?

Nightingale has a webpage dedicated to explaining [Pre-commercial Procurement](#). For examples of other PCPs visit [Thalea PCP](#): or [Silver PCP](#).

58. Who owns the IP of commercial submission?

The tenderer (submitter) will own the IP of their submission.

59. How can a tenderer protect background IP?

Background IP should be clearly described and if possible be protected by patent(s). The contract with the tenderer will specify that each party's background remains the property of such party and will include specific provisions if and under which conditions a licence on such background would be required for the performance of the contract. If necessary, background can also be marked as confidential information.

60. What do you mean by the "commercialisation of foreground IP in 5 years"?

This is defined as sales generated with the 'Nightingale solution' within 5 years after finalising PCP.

61. Can Nightingale propose standard documents for submission?

Yes, we will provide standard documents for the submission of a proposal.

62. Can we shift IP discussion into phase 1 to expedite process?

We will not shift the IP discussion, this will not delay the current timeline.

63. Should there be a lead in each tendering consortium?

Yes, in every tendering consortium there should be one lead supplier who will be integrally responsible for contract compliance in each phase (development, deliveries, payment etc)

64. What is the intended sale price?

There is no intended sale price determined yet and this is not up to the Nightingale consortium but up to the tendering consortium. During the tender, the Nightingale consortium will assess the total cost of ownership of the solution, whether it is reasonable and if it gives good value for money etc.

65. Is it possible to create a consortium with a partner who did not participate in an OMC? Can a company not attending OMC subscribe to tender?

Yes to both.

66. Will details of the award process be shared with those who do not progress to the next stage?

Information on which tenderers progress to the next phase will be made public on our website, however detailed information about their assessments will not.

67. How will price matter for awarding?

We will ask for best value for money. Tenderers' price of performing the R&D in each phase of the tender will count towards awarding, however the main focus is the best quality. In the tender documents this will be described clearly.

68. Is subsidy equal for all contenders? In different phases?

The maximum subsidy per tenderer per phase is equal and will be detailed in the tender documents. The paid subsidy by the Nightingale consortium to the tenderer will be based on the price the tenderer has offered (for performing R&D for Nightingale in that phase) and may differ per tenderer and per phase.

69. Is there an obligation for consortium partners to buy a solution?

No, however after completion of the PCP the consortium commits to conduct a PPI.

70. Can non-EU companies collaborate in the tender?

Only if the company (or consortium) conducts at least 51% of their Nightingale R&D activities in the EU.

71. Will evaluation criteria be made public? Will they change over time?

Yes, the evaluation criteria will be made public and detailed in the Nightingale tender documents. The main evaluation criteria will not change over time, only details/sub-criteria can change in a later phase.

72. What are the advantages for participating companies?

Five top university hospitals formulated a clear need for a missing solution. Normally, this “needs” assessment has to be done by the company, without clear knowledge of whether their product is really needed. This reduces the risk of developing a useless product. Furthermore, the five hospitals, with a lot of knowledge and expertise will test, and evaluate your idea and later on your product/system for free. They will give you valuable feedback and can act as early adaptors for your product/system.

73. What is the deadline to submit once the tender is published?

Approximately 2 months.

74. How will solutions at different levels and different costs be compared? What level is Nightingale aiming for?

In the Nightingale tender various different aspects will be assessed, including the level of sophistication and the total cost of ownership of the solution. A higher level of sophistication could lead to more points on the award criteria, however a higher price could lead to less points. It's up to the tenderer to find an optimal and feasible balance. Award criteria for comparison will be public after publication of the tender. For the level Nightingale is aiming for read the [Nightingale Common Challenge document](#).

75. Can we have the Aachen PCP as a case study?

Yes, visit www.thalea-pcp.eu to read more

76. What about shared IP?

Usually, when procuring or buying an R&D process or product the contracting authority will pay and, consequentially, be the owner of the IPR.

In a PCP the tenderer (developer) receives payment and keeps the IP (shared with the contracting authority). Generated IP of Nightingale shall be owned by the contractors and the Nightingale consortium partners shall have royalty-free access rights to the generated IP for internal use (for research purposes etc)

77. What is most important criterion for last phase?

A working solution acceptable to patient and care providers. For more information we refer to the next version of our Common Challenge document on the Nightingale website. Final details about the award criteria will be made public after publication of the tender documents.

78. Who owns the IP if a company develops something (different from the Nightingale solution) based on an idea from a consortium partner?

In principle, the contract only regulates the development of the Nightingale solutions. Any other results should not be generated under this framework. In the unlikely case this occurs,

the ownership will depend on the contribution of the different parties involved and will have to be discussed in good faith between the parties.