Health Innovation East

Q&A for Invitation to Tender: Evaluation of B.Braun Elastomeric Devices with remote monitoring in Hertfordshire
Updated 17-11-23

Date Received	Question	Answer
13-11-23	Is the budget fixed for the tender? For example, is there any scope to increase the financial envelope or edit the scope of the outputs to reflect an alternative pricing structure.	The budget of the tender is flexible as outlined in the ITT document. We welcome bids that provide different scope and price options and take a modular approach to meeting the requirement.
14-11-23	It is proposed that the evaluation question on carbon footprint is addressed with modelling based on published literature and that Health Innovation East can suggest appropriate literature. Can we take from this that the literature search will have been completed on the evaluator's behalf? This question applies also to the evaluation question on financial savings.	We can provide appropriate literature although the evaluator may want to supplement this with a more comprehensive literature search.
14-11-23	The new pathway will be trialled with a small number of select patients, identified as suitable for the pilot by participating clinicians at ENHT. Are you able to provide an approx. number of patients and clinicians?	We have an MOU in place with the provider which states that we expect ENHT and HCT to take all reasonable steps to ensure eligible patients for the pathway are referred from Lister Hospital and QEII Hospital as appropriate. Where this is not the case, and there is an insufficient number of patients accessing the pathway (min. of 30 per month), the impact evaluation will be limited, and therefore evaluation activity will focus on implementation, acceptability, and feasibility. There will likely be under 5 referring clinicians.

14-11-23	Does Health Innovation East have any flexibility in the timeline for evaluation? The timeline from awarding the evaluation to completing IG is tight and would require completion of the evaluation specification no later than end of December. With the Christmas break in between, this would pose a real challenge. Would you accept tenders that propose a different timeline for all elements of the evaluation, including submission of the final output?	Yes, we can be flexible about timelines and encourage you to submit what you think is appropriate.
14-11-23	Thank you for the proposed methodology table. Has Health Innovation East done an evaluability assessment of the evaluation questions to check data availability and access?	Yes, we have highlighted all the data we think is required and spoken to Lister and HCT about providing the required information. All data included can be provided. Once the evaluation partner is on board, there will be further work to do around completing information governance requirements.
15-11-23	We would like consider site visits to conduct interviews and or focus groups with pharmacists and community staff to help us understand any technical or psychomotor constraints – will the provider teams would be willing to accommodate this?	Yes, this would likely be accommodated, and we can support with arrangements.
15-11-23	Could you advise about the exclusion of clinical outcome data? We are assuming that this would also exclude 30-day readmission and/or adverse event data as endpoints?	The impacts were selected based on what the implementing parties were most interested in seeing. The rationale is that there is unlikely to be much difference in clinical outcomes.
15-11-23	We would be in favour of publishing findings in an academic journal and assume this should be under an open access licence if the evaluation is publicly funded. Would OA fees be supported by Health Innovation East, or would you expect to see these included within the tender total value?	This would need to be costed separately and we could explore how we support this, beyond delivery of this specification.
16-11-23	Please can you identify whether there are existing ethical frameworks or guidelines provided, that we should adhere to in our application?	Where ethics approval is deemed necessary, we would recommend going through the NHS REC process.

16-11-23	Please can you supply details about the process for obtaining ethical approval, including any preferred or required ethics committees or boards.	As above, the NHS REC process.
16-11-23	Please can you confirm any support or resources that Health Innovation East can provide to assist us in the ethics application process.	Gaining ethics approval is the responsibility of the evaluation partner, if deemed necessary. Health Innovation East can support in finalising data requirements and approval processes at sites, and data to be collected via interviews/focus groups.
16-11-23	Do you have preferred format for the bid submission. Could you guide us to the appropriate template or outline the specific structure you had in mind?	We do not have a set template or preferred format. We ask that bidders use whatever format they see fit, ensuring all criteria outlined in the ITT are met. Please also see the ITT checklist for bidders and response sections.
16-11-23	What type of approach will B.Braun use to evaluate the budgetary impact of the elastomeric pump and remote monitoring?	A cost-effectiveness model will be created which compares the standard approach with the elastomeric hospital at home approach. The unit of effectiveness in this instance would be successful treatment of a patient via antibiotics. Capacity will also be considered, and the results of the model can be presented with and without the momentary value of capacity.
16-11-23	Will B. Braun evaluate the impact on capacity in a separate model, or will it be the same model as for the budgetary impact?	Because the two are intrinsically linked both will be evaluated in the same mode however it makes sense to provide to outputs. One which includes the monetary impact of reductions in bed stays and another which does not.
16-11-23	What time-horizon does the B.Braun evaluation cover for both the Budget Impact model and Capacity Impact model?	Costs and capacity on a patient level will have a maximum follow up of 3 months as this is the maximum length of the pilot. However, a 12-month period will be used to annualise the impact.
16-11-23	What software will B.Braun be using for their model? The ITT states "The role of the evaluation partner will be to…complete the model and validate the assumptions made by B.Braun". Considering this, it would be helpful	The model will be created in Excel. All costing sources and assumptions will be fully referenced. It is not expected that expert opinion will be required to fill

	to have clarity on the following, to assess the activity required by the evaluation partner "to complete the model": • Will the model have been parameterised? • Will the model have incorporated the variances around the data parameters? • Will a sensitivity analysis have been performed? If so, what type of sensitivity analysis? • Will the assumptions have been collated and clearly stated/referenced? Can you clarify whether B.Braun, or the evaluation partner, are responsible for the Statistical Analysis Plan for this evaluation and the cleaning and de-duplication of the data? • The statistical analysis of the data and if any sub-group analysis is expected? • How big is the data-set? • How will any missing data be managed? • In what format will the data be presented in? • Will the data from SystmOne and Lister come in separate files and formats, or will they be merged in one file?	sources of information. All fields will be fully parameterised. Univariate sensitivity analysis will be performed on the following inputs; cost of prefilled elastomeric device, cost of B.Braun elastomeric device, length of in patient stay with and without the elastomeric device and wait time for a prefilled elastomeric device. This can be expanded if other sources of variance are found during data collection. B.Braun will not be involved in the data collection and will only be creating the model in which the data is placed. The SAP and decisions regarding missing data need to be agreed between the evaluation partner, the Trust, Health Innovation East and B. Braun. Health Innovation East has created an Excel spreadsheet for the data to be collected, which can be shared with the evaluation partner once appointed. The spreadsheet covers data fields that will need to come from Lister and HCT, although in reality, this data may be sent from the sites separately with a common patient identifier for the evaluation partner to merge the datasets together into one database. B. Braun can support with the identification of literature to backup costings and carbon footprints and some of these will be used within the cost-effectiveness model itself.
16-11-23	Will there be an opportunity for regular engagement with B.Braun? If so, what is the anticipated frequency?	Yes, we have an MOU in place which states that a working group will be established, consisting of representatives from B.Braun, Lister Hospital, HCT, Health Innovation East and the evaluation partner.

		The working group will meet fortnightly (less if required and agreed by all parties).
16-11-23	What is the anticipated sample size of: Patients on the new pathway for survey? Community Clinicians who are visiting patients for anticipated survey/focus groups? Remote Monitoring Nurses for anticipated survey/focus groups? Patients on the OPAT pathway for survey?	We have an MOU in place with the provider which states that we expect ENHT and HCT to take all reasonable steps to ensure eligible patients for the pathway are referred from Lister Hospital and QEII Hospital as appropriate. Where this is not the case, and there is an insufficient number of patients accessing the pathway (min. of 30 per month), the impact evaluation will be limited, and therefore evaluation activity will focus on implementation, acceptability, and feasibility. There will likely be under 5 referring clinicians. Community clinicians will be nurses. HCT are proposing one nurse once a day is required to administer the IV. This is a variable workload dependent on location of patients and locations of staff. For example, if there were 7 patients within daily case load, a maximum of 7 nurses a day would be required if patients were spread across our localities. Less if we had more than 1 IV in a particular locality. This would then be up to 49 nurse visits per week of which it is likely it would be the same nurse for at least 4-5 days of that week.
17-11-23	How many patients are you looking to go through the 3 arms?	New pathway: Minimum of 30 per month 2-3 community clinician visits: We will not have data from this actual pathway, it will be modelled based on assumptions from the new pathway data. OPAT pathway: This depends on how many are deemed suitable for the new pathway.
17-11-23	After reading the document we understand that the analysis would be comparing 4 pathways, 1 of the	This is correct.

	comparators requires 2-3 visits per day but the intervention would require 1 visit. Is this correct?	
17-11-23	Will we use the pilot study data or just the main data collection?	Data will be collected by Lister, HCT and the evaluation provider (via surveys and qualitative methods) regarding the new pathway and the OPAT pathway. Primary data relating to the hospital pathway and the 2-3 visit per day pathway will not be collected.
17-11-23	Who will analyse the pilot study?	It will be the role of the evaluation partner to assess acceptability, feasibility, and impact of the new pilot pathway.
17-11-23	Are we evaluating all 3 arms or just the specialist arm?	We would like the evaluation partner to evaluate the new pathway in comparison to 3 alternative pathways. The 3 alternatives do not need to be evaluated in their own right, although some analysis will be needed to form a comparison. The ITT outlines where we expect primary data to be collected in relation to these pathways and where we anticipate that assumptions can be made based on pilot data and published literature.
17-11-23	Can there be some expert by experience (PPI) input for development of the patient questionnaire?	Yes, this would be accommodated, and we can support with arrangements.
17-11-23	Will all the data provided be anonymised by Lister and other centres as this will help and make processes and data sharing agreements go faster?	The data will need to be pseudonymised rather than anonymised, as patient-level data from Lister Hospital and HCT will need to be linked.
17-11-23	Will all 4 pathways be operational (and surveyable) during the data collection period? If not, could the normal pathway be surveyed as a comparator?	We do not need all the evaluation questions to be answered for all 4 pathways, only the ones relating to impact (i.e. you do not need to evaluate acceptability or feasibility of the alternative pathways). You also do not need to evaluate patient experience in relation to a hospital only stay and 2-3 community clinician visit pathway. We anticipate that it will be possible to assess the impact of the pathways via the pilot data; surveys (and qual data collection) relating to the new pathway; surveys relating the OPAT pathway; and

		published literature. The OPAT pathway will be operational and surveyable. We do not anticipate that any primary data will be collected in relation to the 2-3 community clinician visit pathway or the hospital only pathway.
17-11-23	Will it be possible to facilitate all focus groups, interviews, and the Theory of Change workshop via teams/zoom?	Yes, it is possible to deliver the sessions online or in person.
17-11-23	Does Health Innovation East and/or HCT have a good understanding of the financial costs and carbon footprints involved? We understand that literature will be provided, but will this be a significant quantity to search through or a more select/refined amount?	We can provide appropriate literature on financial costs and carbon footprints although the evaluator may want to supplement this with a more comprehensive literature search.