

Supplementary Material S1. Round 1 Delphi consensus questionnaires completed by participants.

Delphi consensus exercise to establish a core outcome set for research involving participants with abdominal aortic aneurysms

Background

We are currently working to decide which are the most important items to report for those undergoing planned repair of their abdominal aortic aneurysm (AAA). There are lots of ways of measuring how well a treatment has worked in clinical studies, known as “outcomes”. To best serve the needs of patients, doctors and other stakeholders in their care, and allow effective evaluation of the results of future clinical studies we need to decide which outcomes are most important.

This list of the most important outcomes (usually between 6 and 15 in number) is known as a “core outcome set”. We are aiming to produce a core outcome set by assessing how important each outcome is. The key stakeholders are patients with AAA and people involved in their care including the patient’s carers, vascular specialists (nurses and doctors), interventional radiology specialists, intensive care specialists, policy makers, hospital managers and industry manufacturers of surgical devices. The purpose of this Delphi exercise is to gain an insight into which outcomes these stakeholders value most.

We have searched the medical literature alongside holding focus groups with patients, carers and vascular nurses to produce the list of outcome measures in this survey. Patient groups in Germany, Sweden and the UK have rated functional outcomes (section 2 below) as being very important to them. It is possible that when completing this survey that you think all the outcomes are important, but we are trying to find which ones are essential. If you feel you don't have enough information to form an opinion on the importance of an outcome, please feel free to leave it blank. Please feel free to comment at the end of the survey, if you feel anything is unclear, or if you think any essential outcome is missing.

There are 8 sections consisting of 38 questions to complete in total. After collecting the results of these surveys, the outcome measures that people thought were least important will be removed. Outcome measures that appeared most important may be expanded to include more detail. The updated Delphi survey will then be sent around again for completion to again assess which outcomes are most important.

Informed Consent

Q1 1. I confirm that I have read and understand the participant information sheet version 1 dated 29/06/2022 for Development of a Core Outcome Set for studies investigating the elective treatment of those with Abdominal Aortic Aneurysms through European Delphi Consensus Survey and have had the opportunity to ask questions which have been answered fully.

- Yes (1)
 No (2)
-

Q2 2. I understand that my participation is voluntary, and I am free to withdraw at any time, without giving any reason and without my legal rights nor treatment / healthcare being affected.

- Yes (1)
 No (2)
-

Q3 3. I give/do not give consent for information collected about me to be used to support other research or in the development of a new test, medication, medical device or treatment (delete as applicable) by an academic institution or commercial company in the future, including those outside of the United Kingdom (which Imperial has ensured will keep this information secure).

- I give (1)
 I do not give (2)
-

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Q4 4. I understand that data collected from me are a gift donated to Imperial College and that I will not personally benefit financially if this research leads to an invention and/or the successful development of a new test, medication treatment, product or service.

Yes (1)

No (2)

Q5 5. I consent to take part in for Development of a Core Outcome Set for studies investigating the elective treatment of those with Abdominal Aortic Aneurysms through European Delphi Consensus Survey.

Yes (1)

No (2)

Q6 6. I give / do not give (mark as applicable) consent to being contacted about the possibility to take part in other research studies.

I give (1)

I do not give (2)

Q7 Please sign here to confirm consent to take part in for Development of a Core Outcome Set for studies investigating the elective treatment of those with Abdominal Aortic Aneurysms through European Delphi Consensus Survey.

End of Block: Informed Consent

Start of Block: DEMOGRAPHICS

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Q8 Please state which stakeholder group you represent:

- Academic researcher (1)
 - Caregiver or family member (2)
 - Industry (device manufacturers) (3)
 - Patient who has an AAA (4)
 - Service provider (service managers, hospital managers) (5)
 - Vascular anaesthetist (6)
 - Vascular interventional radiologist (7)
 - Vascular specialist nurse (8)
 - Vascular specialists physicians (intensive care physicians, and surgical liaison physicians) (9)
 - Vascular surgeon (10)
-

Q9 Which country do you reside in:

Q10 What is your email address?

End of Block: DEMOGRAPHICS

Start of Block: SECTION 1

Page Break

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For each statement, please indicate how important the outcome measure is after aneurysm repair.

Section 1 (3 questions)

This section asks about which the important outcomes are relating to the aneurysm itself, including size, growth, and development of new aneurysms.

a) That the aneurysm has stopped growing after treatment?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

b) The aneurysm rupturing after undergoing the repair operation?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

c) A new aneurysm developing in the aorta above or below the part treated in the repair operation?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

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Section 2 (9 questions)

This section asks about the importance of assessing outcomes relating to quality of life - which incorporates an individual's ability to complete everyday tasks such as socialising with friends, work, shopping, and cleaning, their level of pain or discomfort, and their mental wellbeing. Such outcomes are usually assessed by questionnaires.

a) Overall quality of life?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

b) Pain experienced?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

c) Having less anxiety now the aneurysm has been repaired?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

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d) Return to usual commitments, such as work, caring for others or volunteering duties?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

e) Recovery to the same mental (also known as cognitive) function? This would include the ability to do thinking tasks such as thinking through a list in one's mind or planning an event.

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

f) Return to previous level of physical ability? Examples include being able to climb stairs, walk to the shops, gardening, as well as sports.

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

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g) Return to previous level of social engagement and ability to partake in social events? This includes seeing friends and family as regularly as before the operation and feeling up to being part of social groups.

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

h) Returns to previous level of sexual function?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

i) Going back to a usual place of residence after undergoing aneurysm repair? For example, when discharged from hospital returning to the same home rather than to a different home or care setting.

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

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Section 3 (2 questions)

This section asks how important it is that patients are satisfied with their involvement in the decision-making process for their aneurysm and the treatment they received. These outcomes are commonly assessed by questionnaires.

- a) Patient satisfaction with their involvement in deciding if, how and when to treat their aneurysm?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

- b) Patient satisfaction with the overall treatment received?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

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Section 4 (2 questions)

This section asks about the importance of surviving the aneurysm repair operation.

a) Surviving the immediate operation period?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

b) Longer term survival (such as 5 - 10 years ahead)?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

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Section 5 (5 questions)

This section asks about the importance of outcomes relating to incomplete or failed treatment of an individual's aneurysm. This can sometimes occur and may require an additional procedure or need to attend further monitoring.

- a) Endoleak after endovascular repair, which is incomplete sealing of the aneurysm wall from blood flow and sometimes results in the need for further surgery? This encompasses all types of endoleak and is measured by visualising the endoleak using imaging techniques such as scan, ultrasound, or dye tests.

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

- b) Need for further short-stay procedures in addition to the first treatment? This would include undergoing minimally invasive procedures with an associated hospital stay of 1 – 2 days to diagnose or correct minor issues with the original operation during follow-up.

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

- c) Need for further major procedure after the first repair? This would include undergoing a redo operation if the first operation was not completely successful.

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

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d) Compliance with (or how well people attend) outpatient follow-up appointments for a physical check-up?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

e) Compliance with (or how well people attend) outpatient scans of the aorta to confirm that the operation was successful?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

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Section 6 (5 questions)

This section asks about outcomes relating to the amount of resources used in the treatment of aneurysms. This covers the cost of the devices used to re-line or repair the aorta, length of time in the intensive care unit, length of time in hospital and societal costs if someone is no longer able to work.

a) Total cost of the treatment and hospital stay?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

b) Length of time an individual spends in intensive or high-dependency care after treatment of their aneurysm?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

c) Total length of time an individual spends in hospital in total after treatment of their aneurysm?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

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d) Burden of follow-up appointments, aftercare, any further operations, or readmissions to hospital?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

e) The wider cost to society after treatment? This would include the cost from potentially not being able to work anymore, stays in rehabilitation centres, stays in nursing homes, and costs of long-term carers if required.

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

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Section 7 (7 questions)

This section asks about the importance of outcomes relating to general medical complications which can occur in a minority of those undergoing an operation and being in hospital.

a) Heart attack or other new heart problems (such as irregular heartbeat)?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

b) Stroke resulting in permanent impairment (also known as disability)?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

c) Damage to the kidney? This would include a permanent damage to the kidneys requiring dialysis (in which the role of the kidney is taken over by a machine).

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

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d) Damage to the lungs? This would include a chest infection which would be treated with antibiotics and possible failing of the lungs requiring temporary mechanical ventilation.

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

e) Infection of the surgical wound?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

f) Sepsis, which is a whole-body response to infection?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

g) Later development of cancer, that may or may not be related to repair of an aneurysm?

Not important				Somewhat important				Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

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Section 8 (5 questions)

This section asks about the importance of outcomes relating to complications associated with the treatment provided, also known as vascular adverse events. It covers a spectrum of possible outcomes from bleeding during the operation to blood clots developing in the vessels supplying the major organs.

- a) Major bleeding during or after the operation? This would include any bleeding that requires transfusion of blood or blood products

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

- b) Clots developing in the arteries supplying the legs with blood? Poor blood flow to the leg can result in need for an additional surgery, and at worst can result in amputation.

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

- c) Blood clots developing in the arteries supplying the bowel/guts? Loss of blood flow to the bowel can lead to a further operation involving removal of the bowel and may require creation of a stoma (bowel brought out to the side of the abdomen with passage of faeces into a bag).

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

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d) Long term or chronic pain or discomfort from the operation, including hernia at the operation scar?

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

e) Infection of the new aortic lining or graft? This would be an infection of the endovascular device in the case of endovascular aneurysm repair (EVAR) or infection of the sewn-in graft in the case of open surgical repair. This can require either long-term antibiotics or need for a further major aortic operation.

Not at all important		Not very important		Somewhat important		Important		Essential
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7	8	9

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Q60 Thank you for completing this survey, your time and input is greatly appreciated.

We will now compile the results and remove outcomes that are not held as important. We will get back in touch using the email address you have provided for the second round of the survey.

Best wishes,
The AAA COS Team

End of BI

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