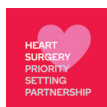


L PRIORITIES FOR ADULT CARDIAC SURGERY RESEARCH

Results from the James Lind Alliance Heart Surgery Priority Setting Partnership, in collaboration with the British Heart Foundation Chair of Cardiac Surgery at the University of Leicester and Heart Research UK.



Funded by



In partnership with



SCTS
Society for Cardiothoracic Surgery
in Great Britain and Ireland

FOREWORD

There are 7.4 million people in the UK (almost 10% of the entire British population) living with heart and circulatory disease, resulting in almost 170,000 deaths a year. The estimated cost of caring for people with heart disease is almost £4bn per annum. Over 35,000 adults undergo cardiac surgery in the UK every year. Another 1 million per annum undergo cardiac surgery worldwide. Although the short-term results of surgery are excellent, many patients fail to obtain long-term benefits for reasons that remain unclear. Advancement in the delivery of care through research for patients with heart disease — including those who require cardiac surgery — will improve outcomes and overall quality of life.

In 2015 the British Heart Foundation and the Society for Cardiothoracic Surgery in Great Britain and Ireland identified an unmet need for high quality clinical research in cardiac surgery. A key realisation was that the first step in the development of a programme of high quality clinical research was to develop a consensus as to the national research priorities.

The main conclusion was that the British Heart Foundation (as well as other funders of research into cardiovascular disease) would welcome an agreed set of national research priorities developed through a clear process of consultation and stakeholder engagement. The James Lind Alliance Adult Cardiac Surgery Priority Setting Partnership report represents the successful completion of this objective. Its success was based on generous funding from Heart Research UK. This supported staff who were dedicated solely to the project and had the time and resources to engage with all of the relevant stakeholders: patients, carers, and clinicians. The Priority Setting Partnership Steering Committee was truly multidisciplinary and devoted many hours of work to ensure the success of the project. There are too many people who made this project a success to name them individually. However, they should be proud of their achievement. This is the first time anywhere in the world that this kind of research prioritisation has been achieved in adult cardiac surgery.

This report we hope will enable all stakeholders to address the research priorities we have identified. I look forward to working with you as we start the process of translating our Top 10 priorities into a research programme that will lead to better care for patients.



**Professor Gavin Murphy,
BHF Chair of Cardiac Surgery**

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WHY UNDERTAKE A PRIORITY SETTING PARTNERSHIP FOR ADULT CARDIAC SURGERY?

Patients undergoing cardiac surgery in the United Kingdom benefit from the highest quality care. However, as a discipline, cardiac surgery is undergoing a period of change. Patients referred for cardiac surgery are increasingly elderly, often have multiple chronic conditions, and require more complex surgery than historical cohorts. In addition, new and potentially better diagnostic tests, less invasive treatments, and devices, are being introduced into clinical care at an accelerating rate. The best way to adapt to these changes, and to maintain the highest standards of care for patients, is through research. It is only through the generation of high quality evidence that we will be able to direct the best care, to the individual patient, at the right time.

High quality research requires engagement with all key stakeholders including healthcare providers, patients, and carers, as well as interdisciplinary research collaborations, and funding. Funders recognise the value of networks of researchers who address clinical research priorities, as these are more likely to generate research outputs that have direct impacts on care.

A James Lind Alliance Priority Setting Partnerships addresses these considerations. First, it brings together all of the relevant stakeholders at the beginning of the research process and ensures that their needs are central to the entire programme. Second, by identifying consensus around key topics, the partnership enables funders and researchers to focus their efforts on turning these into research questions and clinical trials the results of which will inform high quality care for patients. In addition, coordinated, collaborative approaches to address national research priorities can have important synergies, efficiencies, and added value, beyond the primary research. One example would be the development of a national research platform that can facilitate strategic partnerships with industry, or foster the development of the next generation of academic leaders.

In 2017, the Society for Cardiothoracic Surgery in Great Britain and Ireland, through the University of Leicester, commissioned the Adult Heart Surgery Priority Setting Partnership. Heart Research UK, the United Kingdom's second largest cardiovascular research charity provided generous funding that proved to key to the partnership's success.

PROJECT MILESTONES



NOVEMBER 2017

Heart Research UK funds the Heart Surgery Priority Setting Partnership (PSP).



JUNE 2018

Cochrane Heart Group joins the Priority Setting Partnership



DECEMBER 2018

Literature review, duplicate questions combined, already-addressed questions removed. **49** unanswered summary questions identified.



JUNE 2019

Second Survey closes. **492** participants. Questions narrowed down to **21** summary questions.



FEBRUARY 2017

British Heart Foundation identifies the need to develop a consensus around clinical research priorities.



MARCH 2018

Launch of First PSP Survey at Society for Cardiothoracic Surgeons (SCTS) in the UK and Ireland Annual Meeting, Glasgow. @heartsurgerypsp Twitter account launched.



NOVEMBER 2018

First Survey closes. **1080** questions submitted by **629** participants. Duration was 9 months, averaging **70** participants per month.



MARCH 2019

Second Survey launched at SCTS Annual Meeting, Westminster, London.



JULY 2019

Final Workshop, attended by patient, carer and clinician representatives at Leicester.

TOP 10
PRIORITISED QUESTIONS

THE TOP 10 PRIORITIES FOR ADULT CARDIAC SURGERY RESEARCH



QUALITY OF LIFE

How does a patient's quality of life (QOL) change (e.g. disability-free survival) following heart surgery and what factors are associated with this?



FRAILITY

How can we address frailty and improve the management of frail patients in heart surgery?



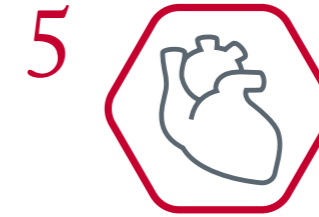
CHRONIC CONDITIONS

How can we improve the outcomes of heart surgery patients with chronic conditions (obesity, diabetes, hypertension, renal failure, autoimmune diseases etc.)?



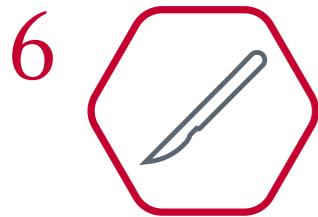
PREHABILITATION

Does prehabilitation (a programme of nutritional, exercise and psychological interventions before surgery) benefit heart surgery patients?



HEART VALVE INTERVENTION

When should heart valve intervention occur for patients without symptoms?



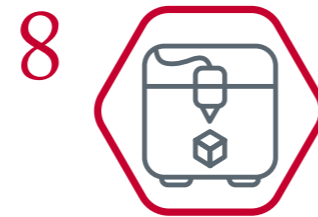
SURGICAL METHODS

How does minimally invasive heart surgery compare to traditional open surgery?



ORGAN DAMAGE

How do we minimise damage to organs from the heart-lung machine/ heart surgery (heart, kidney, lung, brain and gut)?



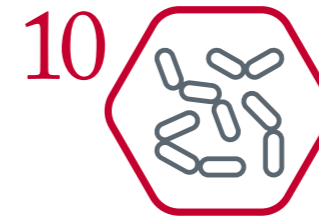
3D BIO-PRINTING

Can we use 3D bio-printing or stem cell technology to create living tissues (heart valves/heart) and repair failing hearts (myocardial regeneration)?



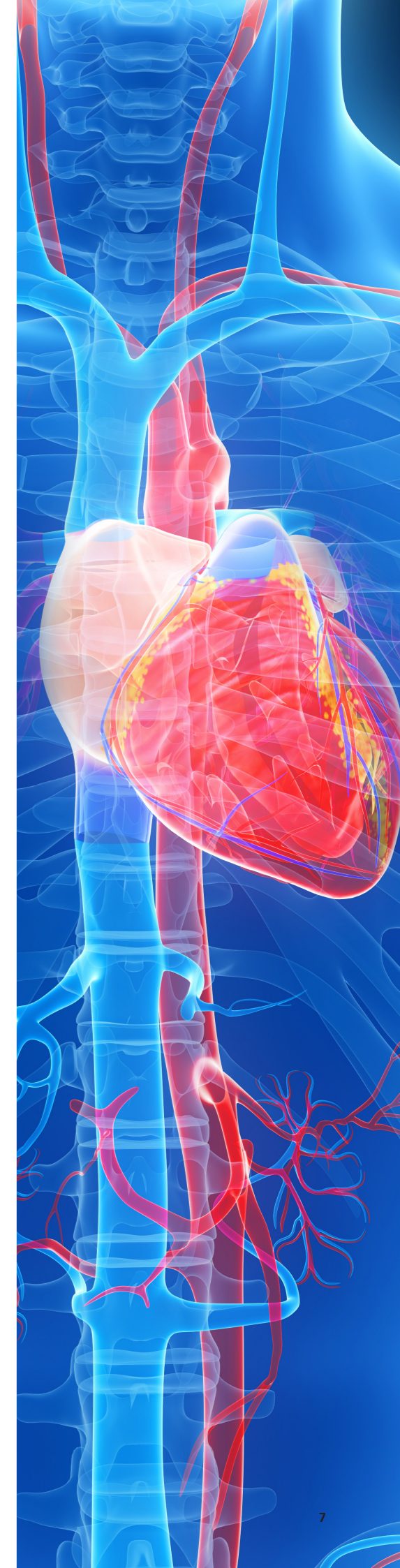
ATRIAL FIBRILLATION

What are the most effective ways of preventing and treating post-operative atrial fibrillation?



INFECTION

How do we reduce and manage infections after heart surgery including surgical site/sternal wound infection and pneumonia?



SETTING THE LIMITS OF THIS PRIORITY SETTING PARTNERSHIP

The scope of this PSP was restricted to clinical research in adult cardiac surgery. This excluded cardiopulmonary transplantation and surgery that considers the use of devices to treat heart failure. The treatment of these patients is separate from the generality of adult cardiac surgery in the UK, with distinct multidisciplinary teams, and specific research initiatives linked to NHS Blood and Transplant. Post-cardiotomy extracorporeal support (ECMO) was considered as eligible, as this is emerging as part of routine care.

The PSP did not consider research in children undergoing cardiac surgery. Children primarily present with congenital cardiac disease, they have different physiology to adults, and different clinical concerns, including child development. It was felt that a separate PSP is required to fully capture these research priorities. For this reason surgery for Grown Up Congenital Heart Disease was also excluded.

The PSP was focused on clinical research questions that would be addressed by clinical trials or clinical research programmes. It did not consider early phase translational research or technology transfer. Although these research areas are implied in Priorities 6 and 8, these Top 10 priorities should not undermine the crucial role of early phase research in the generation of new knowledge that precedes clinical evaluation.

At all phases of the PSP we identified clear preferences for each stakeholder group. Patients and carers placed great emphasis on the effects of cardiac surgery on quality of life and long-term outcomes, whereas clinicians voted predominately for research into the management of frailty, and patients with multiple medical conditions. These factors were reflected in the Top 10, however two highly contested topics were not included in this list: 'What are the best ways to prevent, diagnose, and treat, patients with acute aortic dissection?'; a priority for clinicians, and: 'How can we improve the communication between the medical team and patients/carers regarding the risks and benefits of heart surgery?'; a priority for patients and carers.

The exclusion of these priorities from the Top 10 reflects the balance of views by the group of stakeholders in the Final Workshop and the pre-specified view of the Steering Committee that the PSP should be restricted to the Top 10 priorities to provide focus for research teams and funders. It also attests to the transparency and the fidelity of the process that no one stakeholder group was dominant. This was attributable to the appointment of an independent Chair, Katherine Cowan, by the James Lind Alliance, and the exceptional work by the facilitators of the final workshop who were able to deliver consensus from an incredibly motivated group of stakeholders who often had strongly felt views!

We cannot exclude however, that on a different day, or with a different make-up of the working groups, that the final 10 priorities may be different and this should be borne in mind when interpreting this document.

The final session of the priority setting workshop commences, as representatives of the three demographics discuss their rationale behind voting for the Top 10 priorities.





HOW WERE THE PRIORITIES IDENTIFIED?

INITIAL SURVEY

The Heart Surgery PSP was launched at the annual meeting of the Society for Cardiothoracic Surgeons in the UK & Ireland (SCTS) in March 2018. The launch was celebrated with the release of the Initial Survey both online and in paper format. Attending the SCTS conference gave the Project Team access to hundreds of clinical delegates (cardiac surgeons, nurses and allied health professionals) to recruit as participants to the survey. Clinical members of the Steering Group also shared the surveys amongst their networks of contacts and at cardiac surgery outpatient clinics, further improving the recruitment rate.

Digital platforms such as Twitter and Facebook were utilised to disseminate the Initial Survey, as this was a pragmatic method of reaching participants with whom the Project Team were not in direct contact. This method proved particularly successful when recruiting from an international audience and multiple professional and patient groups. For example, Professor Paul Myles of the Alfred Hospital and Monash University, Australia, was able to distribute the Survey amongst colleagues in clinical networks across Australia and New Zealand. Distribution was also achieved in Europe and North America.

The Initial Survey was problematic due to the nature of its design. Traditionally, a survey asks questions for which participants provide answers — whether responses be tick-in-the-box, multiple choice or qualitative. However, the introductory stage of a priority setting partnership requests that participants propose the questions they wish to see addressed by research, thereby establishing the question pool for later prioritisation. In other words, the participants needed to ask questions, rather than provide answers. Many individuals in the patient/carer demographic did not feel they had research themes they wished to explore;

the standard of care they had received was deemed either excellent (thereby no gaps in knowledge demanded further exploration) or they felt under-qualified to volunteer a question. With other PSPs, for example the Diabetes PSP, patients often manage their chronic conditions daily with assistance from the clinicians and AHPs; cardiac surgery differs in that it is a highly specialist discipline with minimal patient input at the point of surgery, and surgeries offer an acute patient experience within the hospital setting. From this, patients often did not feel they had sufficient knowledge of the discipline and therefore declined participation in the Initial Survey.

As the aim of the Heart Surgery PSP was to bridge the gap between researcher and patient, the Project Team adopted multiple approaches to increase patient and carer participation and prevent their hesitation. One example was talking with the patients on the wards and at patient support groups, asking if they, or a family member, had raised concerns or questions regarding any aspect of their surgery during any time point of their care (before, during or after).

The Project Team stressed that submissions were required not only from medical experts – the exercise was equally as important to find out the priorities for patients and carers too. Every effort was taken not to elicit a response from these individuals (which would introduce researcher bias), but instead to allow patients and carers to think of their experience and any possible research questions in their own time before submitting their questions anonymously. Example submissions included ‘Will my organic replacement valve last? Or should I wait for signs of deterioration?’, ‘What are the recovery and success rates from various types of heart surgery?’ and ‘There seems to be a correlation between the time on a bypass machine and memory issues. I experienced some mental blocks post bypass surgery. Is there a better way of preventing this?’

Other questions, (including those submitted by the clinician demographic) concerned the following research themes:

- Anaesthesia
- Bypass surgery (CABG)
- Intraoperative management
- Longer-term outcomes
- Patient selection/risk stratification
- Post-operative management and complications
- Pre- and post-operative care
- Specific diseases and conditions
- Valve surgery
- Other themes (questions falling outside of the themes listed above)

The Initial Survey was open between March 2018 and November 2018, and resulted in the submission of 1,080 questions from 629 participants. This averaged at 70.3 participants per month, with peak recruitment for clinicians occurring at academic conferences and a steady influx of patient/carer responses across all months.

LITERATURE REVIEW AND DATA SYNTHESIS

The interim period between the Initial and Second Surveys allowed for analysis of the survey results and systematic reviews of existing evidence that potentially addressed these research questions. Expert members of the Project Team who performed this work were Dr Riccardo Abbasciano (Clinical Research Fellow), Ms Florence Lai (Senior Statistician), Dr Clare Gillies (Lecturer in Medical Statistics and Evidence Synthesis), and Selina Locke (Library Research Services Consultant). Their work removed any questions from the submission pool that had previously or were currently being addressed by research, thereby preventing replication, which would be wasteful of resources and effort. Duplicate submissions to the Initial Survey were combined into 'umbrella questions' which formed the final 49 questions available for votes in the Second Survey.

SECOND SURVEY

The Second Survey launched at the SCTS Annual Meeting in March 2019, exactly one year after the Initial Survey. The Second Survey provided questions to vote for the Top 10 in a tick-in-the-box fashion. This was quicker and easier to use, and the Heart Surgery PSP had curated a network of contacts for dissemination in addition to building upon the Initial Survey respondents (in comparison to starting from scratch the previous year).

Launching the Second Survey was also an opportunity for recruitment expansion. Twitter was again used to contact cardiac surgeons and other cardiac clinicians abroad. Domestically, the Second Survey was distributed to every known cardiac surgery patient support group across England, Scotland, Wales and Northern Ireland (totalling more than 120 support groups).

The Second Survey was open for 4 months, between March 2019 and June 2019 and receiving votes from 493 participants. Although the total number of participants for the Second Survey was lower than the total number for the Initial Survey (629), regular reviews of survey completion indicated that little additional information would be gleaned from further data and that it was acceptable to close this in June 2019.

Upon closure of the Second Survey, the Project Team's Senior Statistician and Library Research Services Consultant analysed the results, ranking the submissions to identify the top 21 questions from the 49 questions presented in the Second Survey. The Top 21 questions were identified by taking the top priorities of patients, carers and clinicians, therefore ensuring equal influence across the different stakeholder groups. These 21 questions were then available for the final priority setting exercise to establish the Top 10 research questions for cardiac surgery.

FINAL WORKSHOP

The final workshop took place at Leicestershire County Cricket Ground, at Grace Road, in Leicester. The group of delegates — including patients, carers and health professionals — were divided into three groups, with each group allocated a JLA Facilitator to assist in identifying the Top 10 priorities. Every effort was taken to ensure equal numbers of the three demographic representatives were present for a balanced system of prioritisation. It was also important to the Project Team that patient and clinicians attended from across the U.K. so that delegates were not centralised from the East Midlands and Leicestershire. This was to ensure the final result best reflected national research priorities, thus fulfilling the project's aim, and preventing any accusation of geographical or other bias.

At the workshop delegates were designated to one of the three working groups, where introductions were made to establish the collective experience of cardiac surgery. The groups then separately began the ranking of the final 21 questions. At the end of the morning session, each group's ranking was entered into an Excel spreadsheet to produce the first aggregate ranked list. Following this, three new groups were formed for the afternoon session to provide a fresh perspective and create novel opportunity for discussion of the ranked questions in the combined list. By the end of this session, each group had ranked the aggregate list of questions as per their group's agreed priorities.

The three groups were then united in the conclusive plenary phase of the workshop, allowing the JLA Advisor to ensure that no one group or individual dominated the prioritisation — all delegates were provided with equal opportunity to contribute and voice their reasoning for a particular argument for/against a priority to appear in the final ranking. For example, certain patient representatives felt that the question regarding clinician training to improve communication skills was strongly recommended to be in the Top 10. However, the counter-argument by other patients and clinicians was that medical education caters for this training, and communication skills are important across all medical disciplines — not just cardiac surgery.

For this reason, this priority did not make the final Top 10 list of questions, as it was agreed by the workshop majority that within the limit of ten priorities, others were more specific to the discipline and thus demanded higher prioritisation for research.

The aim of the final session was to establish the Top 10 questions for cardiac surgery research, which were agreed by general consensus of all delegates, or by majority votes where consensus was not present.

Copies of the paper surveys and marketing materials used across the project, shared at academic conferences and outpatient clinics throughout the U.K.

Scanning of the printed QR codes with a mobile devices directed participants to the online questionnaires for the Initial and Second Surveys, enabling ease of access and ensuring participation was as user-friendly as possible.



NEXT STEPS

Many hundreds of participants formulated and voted for their cardiac surgery research priorities, donating their time and ideas to the project. The role of this Priority Setting Partnership was to identify what was most important to those affected by cardiac surgery, and provide a set of priorities for the research agenda which could potentially be translated into future clinical trials. It is important to recognise that the establishment of the Top 10 priorities at the Final Workshop did not draw conclusion to this goal; the prioritisation is just the beginning. It is thus incredibly important that results are transparent and shared to increase exposure to potential funders and researchers. It is this method that will ensure the issues that matter most to frontline clinicians, patients and carers will be included in the research agenda.

Members of the Steering Group were initially selected for their expertise, ability to represent their chosen demographic and provide influence within professional and patient networks. It is hoped that Steering Group members will therefore adopt a proactive role in result dissemination. The date of publication will have been carefully selected to permit maximum impact upon the research community; the announcement should not be delayed for too long, but allow for sufficient statistical analysis for correct presentation of results.

Example methods of dissemination to networks include:

- Social media (Twitter, Facebook)
- Newsletters
- Websites
- Relationships with sector publications/journals
- Relationships with funding charities
- Presentations at conferences and workshops
- Print and broadcast media

The Project Team also encourages cardiac surgery professionals or patient advocates

to share this report. The purpose of exposure is to recruit potential funders and participants to research which addresses these priorities, ensuring that results will assist in shaping of future protocols and improve clinical services.

If you would like to request any materials (e.g. infographics of timeline, the final Top 10 priorities) for dissemination, or a PDF version of this report, please contact the Project Team at:

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As the Top 10 priorities have been written in general terms (thereby increasing inclusivity of their audience), the Steering Group may have to refine research themes into potential research questions to be explored by funders.

Research funders can be found via the following:

- The National Institute for Health Research (www.nihr.ac.uk)
- The Association for Medical Research Charities (www.amrc.org.uk)
- The Medical Research Council (www.mrc.ac.uk)
- Wellcome (www.wellcome.ac.uk)

In addition, cardiovascular disease-specific research funders include:

- The British Heart Foundation (www.bhf.org.uk)
- Heart Research UK (www.heartresearch.org.uk)

If you have any queries or comments about this work, please contact:

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Further information about the project can be found at:

www.le.ac.uk/heart-surgery-psp

APPENDIX: THE LONG LIST OF QUESTIONS FOR ADULT CARDIAC SURGERY RESEARCH

These are the unanswered questions that came from cardiac surgery professionals, people using services and their carers. The questions that were asked many times have been grouped and summarised in a single question. A full list of all questions submitted and the questions belonging to each group can be found on the JLA website (www.jla.nihr.ac.uk).

- Does ERAS (Enhanced Recovery After Surgery) improve outcomes in heart surgery?
- Is restricted or liberal fluid management better for heart surgery?
- How does different anaesthetic management (choice of anaesthetic drugs, use of steroid at induction. Mode of delivery – intravenous vs volatile) affect outcomes of heart surgery?
- What are the best blood vessels to use for bypass surgery?
- Is it possible to develop effective artificial vein grafts for coronary surgery?
- How are patients selected for PCI (coronary stenting) or coronary bypass surgery?
- What is the best strategy for patient blood management in heart surgery?
- What is the best way of measuring for the pumping function of the heart (cardiac output) during and after surgery?
- How does minimally invasive heart surgery compare to traditional open surgery?
- How does a patient's quality of life (QOL) change (e.g. disability-free survival) due to heart surgery and what factors are associated with this?
- What are the long-term outcomes, including life expectancy, after heart surgery?
- What are the benefits of heart surgery in older patients?
- How can we address frailty and improve the management of frail patients on heart surgery?
- How can we improve the outcomes of heart surgery patients with chronic conditions (obesity, diabetes, hypertension, renal failure, autoimmune diseases etc.)?
- What patient factors (ethnicity, underlying conditions, biomarkers, genetics etc.) affect/predict heart surgery outcomes?
- What are the best cardiovascular medications for management in heart surgery (e.g. ACE-inhibitors, antiplatelet, anticoagulant)?
- What is the impact of prolonged artificial ventilation after heart surgery?
- What is the best time for removing temporary pacing wires following heart surgery? What are the complications associated with pacing wires?
- What are the most effective ways of preventing and treating post-operative atrial fibrillation?
- What is the best way to prevent and manage pain after heart surgery? What is the best way to manage pain in drug-dependent patients?
- How do we minimise damage to organs from heart-lung machine/heart surgery (heart, kidney, lung, brain and gut)?
- How do we reduce and manage infections after heart surgery including surgical site/sternal wound infection and pneumonia?
- How best to clinically manage heart failure patients before heart surgery?
- What is the best strategy for managing acute heart failure patients before heart surgery?
- Does Left Atrial Appendage Occlusion (LAAO) device reduce the risk of stroke after heart surgery?
- What are the best ways to prevent diagnose and treat patients with acute aortic dissection (including long-term management)?
- Are percutaneous stents better than traditional open surgery for diseases of the thoracic aorta?
- What is the best choice of heart valve replacement in young adults?
- How do transcatheter techniques for heart valve surgery compare to traditional open surgery (TAVI vs AVR)?
- What is the best way to manage infective endocarditis (infection in the heart valve)?
- When should heart valve intervention occur for patients without symptoms?
- What can patients do (in terms of their lifestyle choices – exercise, diet, smoking, well-being etc.) before and after heart surgery to improve outcomes?
- Does prehabilitation (a programme of nutritional, exercise and psychological interventions before surgery) benefit heart surgery patients?
- Does improving Vitamin D levels before surgery improve the outcomes of heart surgery?
- How can we improve the communication between the medical team and patients/carers regarding the risks and benefits of heart surgery?
- Can we use 3D bio-printing or stem cell technology to create living tissues (heart valves/heart) and repair failing hearts (myocardial regeneration)?
- Can we use Big Data (artificial intelligence, computer simulation etc.) to help predict and plan treatment in heart surgery patients?
- Does having access to specialist cardiac nurses or consultants by electronic methods improve outcomes for heart surgery patients?
- Do outcomes of heart surgery and follow-up time vary by postcode/location and how to reduce the variation?
- Is there an association of time on a waiting list with outcomes of heart surgery? Does cancellation of heart surgery affect outcomes?
- What level of heart surgeon's caseload maximises safety and successful surgical outcomes?
- Does publication of surgeon-specific outcome data influence patient selection for heart surgery?
- What is the impact of intra-hospital transfer of critically ill heart patients on the outcomes of surgery?



ACKNOWLEDGEMENTS AND DISCLAIMER

The members of the Steering Group wish to acknowledge the grant funding from Heart Research UK, without whom this project would not have been successful.

Thank you to everyone who supported this project, the Steering Group members, the James Lind Alliance advisers and support staff who advised and facilitated the partnership and the people, groups and organisations who took part at all the different stages.

This report is based on a James Lind Alliance (JLA) priority setting process, which was commissioned and funded by Heart Research UK for adults involved in cardiac surgery. The views expressed in the publication are those of the author(s) and not necessarily those of the Heart Research UK, JLA, NIHR, its arm's length bodies or other government departments.

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- Peter Read, Leicester Cardiac Surgery PPI Group
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- Kiranjit Kaur, Registered Nurse, Glenfield Hospital, Leicester
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PATIENT AND CARER DELEGATES FOR THE FINAL WORKSHOP WERE:

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- Liz Jackson, patient carer representative, Leicestershire
- Anthony Locke, patient representative
- Ann Mason, cardiac stent patient, Leicestershire
- Doug MacGrath, CABG patient, Leicestershire
- Rosemary Watson, CABG patient, patient representative
- Elaine Williams, NIHR employee and carer representative
- Gil Wheeler, heart transplant patient, patient representative
- Janette and Terry Wright, patient and carer representatives
- Sarah Murray, patient representative and carer



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