# Improving the quality and patient relevance of perioperative research

Thesis submitted for the degree of PhD

University College London 2023

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M.B.B.S, M.A. (Cantab), FRCA

# Declaration

I, Ritchie Oliver Caleb Boney, confirm that the work presented in my thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

# Abstract


### *Background:*

Health research has recently evolved from being exclusively expert-led towards an inclusive collaboration between patients and healthcare professionals (HCPs). However, Anaesthesia and Perioperative Medicine (APOM) have lagged other disciplines in embracing this collaborative approach. We conducted two research initiatives to demonstrate the feasibility and benefits of stakeholder participation. The first – the Anaesthesia and Perioperative Care Priority Setting Partnership (APoC-PSP) – brought stakeholders together to agree priorities for future research. The second – the Core Outcome Measures for Perioperative and Anaesthetic Care (COMPAC) initiative – employed stakeholder collaboration to develop a Core Outcome Set (COS) for future trials.

### *Methods:*

**APoC-PSP:** Stakeholders volunteered research ideas and suggestions via an online survey. Those suggestions were condensed into a shortlist and prioritised through a second online survey. Finally, the highest priority topics were discussed at a stakeholder workshop, where the 'Top Ten' research priorities were agreed.

**COMPAC:** A systematic review was conducted to understand recent trends in APOM trial outcome reporting. We then undertook a survey seeking stakeholder views regarding important outcomes after major surgery. Stakeholder representatives then participated in a modified Delphi process to agree a perioperative Core Outcome Set.

### *Results:*

**APoC-PSP**: 1,476 research ideas and suggestions were received from 623 contributors. These were refined into 92 'summary' research questions and ranked by 1,718 second survey respondents. At the final workshop, 23 stakeholder representatives discussed the 25 highest-ranked questions and agreed the 'Top Ten' research priorities.

**COMPAC:** The systematic review found widespread variation in outcome reporting. In the stakeholder survey, over 90% of ~4,000 respondents rated clinical outcome measures critically important, but patient-centred outcomes were rated lower, particularly among HCPs. Sixty-seven stakeholders contributed to the Delphi process, which yielded eight core outcomes and four ‘additional important patient-centred’ outcomes from a 64-outcome longlist.

### *Conclusions:*

Collaborative consensus methodology was used to agree future priorities and outcome measures for APOM research. Both initiatives found areas of close agreement between different stakeholders, while also uncovering some significant differences between HCPs’ and service users’ perspectives. These results highlighted the importance of comprehensive stakeholder participation to avoid missing certain stakeholder viewpoints and maximise relevance of APOM research to all users.

# Impact Statement

The APoC-PSP and COMPAC initiatives are, to our knowledge, the first UK-wide research studies in the fields of Anaesthesia and Perioperative Medicine (APOM) to address future directions in APOM research using consensus methodology with equitable participation of patients, carers and healthcare professionals (HCPs). Their most important impact, therefore, is to demonstrate the value of patient and public involvement (PPI) in APOM research, challenge the perception of APOM research as the preserve of experts, and to inform the future conduct of PPI activity for APOM research.

The APoC-PSP illustrated both the feasibility and value of seeking service user and HCP involvement to agree APOM research priorities. It yielded the first set of UK-wide research priorities that can genuinely claim to reflect the views of all ‘users’ of APOM research, and hence represents arguably the best current guidance for directing future perioperative research efforts, at least in the UK. The top ten research priorities have been widely adopted and endorsed, and have informed numerous ongoing national and international multi-centre research studies, and have prompted similar endeavours in other countries to develop APOM research priorities.

The COMPAC initiative similarly illustrated the value of consulting service users and HCPs when selecting APOM trial outcomes. The problem of variable or inconsistent outcome reporting in APOM research, and the obstacles it poses for appraising new findings against existing evidence, or conducting systematic reviews, is well recognised. While the core outcome set developed via the COMPAC initiative is not the final solution to this problem, it represents an important step towards reducing variation and improving the consistency and standardisation of outcome measurement in perioperative research. It also raises the profile of patient-centred outcomes in APOM research, highlighting their fundamental value alongside clinical outcome measures.

More generally, the APoC-PSP and COMPAC initiatives have both made important contributions to current understanding of effective PPI in APOM research methodology, and the benefits of stakeholder collaboration in APOM research. Both initiatives highlighted methodological strengths and weaknesses of collaborative participatory research. They also demonstrated differences between stakeholder groups’ viewpoints, highlighting the importance of achieving diversity of stakeholder representation in order to

avoid inadvertently omitting the views of certain stakeholder groups. They also showed that effective engagement of stakeholders in research that spans a wide-ranging healthcare area such as APOM may require different approaches from areas with a clearly-defined patient population and/or cohort of relevant HCPs.

While both initiatives have already impacted the APOM research landscape in terms of new trial design, their medium- to long-term legacy remains to be seen. In the meantime, both initiatives have made important contributions to proving the feasibility and benefits of a participatory approach when deciding future APOM research directions, highlighted similarities and differences between the viewpoints of different stakeholder groups in APOM research, and provided valuable methodological learning to inform future stakeholder research collaborations, as well as the conduct of PPI in APOM research more widely.

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All authors were members of the APoC-PSP Steering Group and contributed to all stages of the APoC-PSP. All authors reviewed and helped edit the final published manuscript

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Core Outcome Measures for Perioperative and Anaesthetic Care (COMPAC): a modified Delphi process to develop a core outcome set for trials in perioperative care and anaesthesia

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https://www.ncbi.nlm.nih.gov/pubmed/34740438 10.1016/j.bja.2021.09.027

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Elsevier

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All authors were members of the COMPAC initiative Steering Group, developed the methodology, participated in the Delphi process and co-wrote the final manuscript

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# Glossary of terms and abbreviations

| | |
|---|---|
| AAGBI (now AoA) | Association of Anaesthetists of Great Britain and Ireland (now Association of Anaesthetists) |
| APoC | Anaesthesia and Perioperative Care |
| APoC-PSP | Anaesthesia and Perioperative Care [Research] Priority Setting Partnership |
| APOM | Anaesthesia and Perioperative Medicine |
| CAPSMG | Cochrane Agenda and Priority Setting Methods Group |
| Clinician | Healthcare professional (anyone whose job or work involves caring for, and/or research related to, patients receiving healthcare) |
| COMET Initiative | Core Outcome Measures for Effectiveness Trials Initiative |
| COMPAC | Core Outcome Measures for Perioperative and Anaesthetic Care |
| COS | Core Outcome Set |
| DoH | [UK] Department of Health |
| EDI | Equality, diversity and inclusivity |
| HCP | Healthcare professional (anyone whose job or work involves caring for, and/or research related to, patients receiving healthcare) |
| HCP-SU | 'Healthcare professional – service user', i.e. any healthcare professional who also had experience of anaesthesia and/or perioperative care as a patient or carer |
| HIC | High income countries |
| HRA | [NHS] Health Research Authority |
| HRQoL | Health-related quality of life |
| HSRC | [NIAA] Health Services Research Centre |
| HTA | Healthcare Technology Assessment |
| ICF | Intensive Care Foundation |
| ICM | Intensive Care Medicine |
| ICM-PSP | Intensive Care Medicine Priority Setting Partnership |
| ICS | Intensive Care Society |
| ICU | Intensive Care Unit |

| | |
|---|---|
| JLA | James Lind Alliance |
| LMIC | Low and middle income countries |
| MRC | Medical Research Council |
| NETSCC | NIHR Evaluation, Trials and Study Coordinating Centre |
| NICE | National Institute for Health and Care Excellence (UK) |
| NIAA | National Institute of Academic Anaesthesia |
| NIAA-RPE | The Research Priority Exercise (RPE) conducted by the NIAA in 2008-9 |
| NIHR | National Institute of Health and Care Research (UK) |
| P-COMMaS | Patient-Centred Outcome Measures for Major Surgery |
| Perioperative care | All aspects of patient care before and after surgery, from initial contemplation of surgical treatment options through to full recovery from surgery |
| Perioperative Medicine | The healthcare specialty covering all aspects of perioperative care |
| PPI | Patient and public involvement |
| PPIE | Patient and public involvement and engagement |
| PLG | Patient Liaison Group (of the Royal College of Anaesthetists) |
| POM | Perioperative Medicine |
| PRO | Patient-reported outcome |
| PROMs | Patient-reported outcome measures |
| PSP | [Research] Priority Setting Partnership |
| RCoA | Royal College of Anaesthetists |
| RCS (Eng) | Royal College of Surgeons (England) |
| RCT | Randomised controlled trial |
| REC | Research Ethics Committee |
| RPE | Research Priority Exercise |
| Service user | Patient or carer (anyone ‘using’ – i.e. receiving care from – a healthcare service, whether for themselves or a relative/friend) |
| SG | Steering Group |
| WHO | World Health Organisation |

# *Chapter 1: Introduction. Research waste, and the value of stakeholder participation in health research*

## 1.1 Overview

This thesis describes two research projects in Anaesthesia and Perioperative Medicine (APOM): the Anaesthesia and Perioperative Care Research Priority Setting Partnership (APoC-PSP), and the Core Outcome Measures for Perioperative and Anaesthetic Care (COMPAC) Initiative. Both employed collaborative stakeholder participation to enable patient-clinician co-production of, respectively, research priorities for future research in APOM, and core outcomes for future perioperative research trials. The shared overarching aim of both projects was to improve future research by making it more relevant to, and more inclusive of, its end users.

Both projects reflected a wider recent trend towards patient-centred research, which has been driven by two main concerns. Firstly, the democratic 'moral' imperative – namely, that health research should be more inclusive and representative of its end users; secondly, the value imperative – i.e. the increasing recognition of the extent of wastage in health research, with growing emphasis on maximising the societal value derived from research funding.

This thesis will focus mainly on the second of these concerns. Research is expensive, takes time and effort, and may yield erroneous conclusions if its purpose, design or conduct are flawed. Just as governments should be accountable for maximising public utility through prudent management of limited public funds, so too research funders seek to maximise the utility and impact of their research by allocating funds to well-designed studies with a high chance of improving patient health and/or wellbeing.

This chapter describes the origins of medical research funding, before reviewing the increasing competition for scarce research funding, the increasing involvement of patients and the public in medical research, and then introducing the concept of research 'waste' – i.e. the conduct of unproductive and/or low quality research that does not yield valuable new information. I then discuss recent efforts to reduce research waste through a) increasing stakeholder participation and b) the creation of quality standards for designing, conducting and reporting health research.

This thesis explores two specific opportunities for reducing waste in perioperative research. These are a) better selection of research topics with greater relevance to end users; and b) better selection and reporting of outcomes in research trials. This chapter provides a general overview of how these issues affect health research in general. In subsequent chapters, I shall illustrate how they may help to reduce waste in APOM research specifically.

## 1.2 A brief history of health research

Attempts to understand and treat disease can be traced back at least as far as the third millennium B.C. in ancient Egypt and Mesopotamia.(1) The earliest documented description of human activity approximating to a medical 'trial' appears in the Bible, in the book of Daniel (1:12-15), when King Nebuchadnezzar ordered youths of royal blood to eat only wine and red meat for three years, while another group of (non-royal) youths consumed only beans and water, and observed the results. (The bean-and-water group allegedly fared better, despite their lowly lineage).

The eighteenth-century naval surgeon James Lind – of whom more later – is frequently cited as the 'father of clinical research' for his experiments on scurvy. He administered six different potential remedies to six pairs of scorbutic sailors, and observed the results – most notable of which were 'the most sudden and visible good effects …from the use of oranges and lemons.'(2) However, well into the nineteenth century, medical research consisted mainly of isolated, individual experiments based on prior observations, generally conducted and self-funded by gentlemen scientists of independent means. Other famous examples include Edward Jenner's discovery of smallpox vaccination in 1796,(3) Jon Snow's observations of disease spread during a cholera epidemic in Soho in 1854,(4) and Ignaz Semmelweis's investigations into hand hygiene to reduce puerperal fever in Vienna during the 1840's.(5)

Medical research as a coordinated activity involving formal collaboration between individuals and institutions did not become common until the mid-nineteenth century, as part of a wider trend towards the professionalization of science and medicine. New

professional scientific bodies, such as the British Association for the Advancement of Science (founded in 1831), growth in political support for scientific research (for example, the award by parliament in 1849 of a grant to the Royal Society ‘for the promotion of science’), and the spread of university science faculties all facilitated the coordination and formalization of efforts to extend the boundaries of scientific knowledge.(6) Such institutions ushered in the now-familiar notion of research as a collective activity led by recognised experts and enabled by financial and logistical resources.

## 1.3 Medical research funding

The latter half of the nineteenth century brought a widespread push for the ‘endowment of science’, promoting scientific research by trained experts in dedicated institutions, rather than the self-funded dabblings of private amateurs.(7, 8) Several livery companies in the City of London started providing endowments either for scientific research in existing university departments, or to found new scientific faculties and laboratories.(9) The growth of hospital and university laboratories during the nineteenth century was another manifestation of medical research’s transformation into an expert-led endeavour demanding specialist training, techniques and equipment.(10)

Government funding of medical research soon followed. In the UK, this began with the inauguration of the publicly-funded Medical Research Committee and Advisory Council in 1913 under the chairmanship of Lord Moulton. In 1920, this Medical Research Committee was granted its own royal charter and executive powers, following the creation in 1919 of a new nationwide Ministry of Health responsible for administering National Health Insurance. The Medical Research Committee thus became the Medical Research Council (MRC), an ‘arm’s-length’ corporate body, independent of government but publicly funded, tasked with ‘responsibility for the adequacy of the national effort in medical research’.(11) And though funded by the Ministry of Health, the notion that scientific decisions should be made independently from government – as first proposed in 1918 by Lord Richard Haldane, and thereafter known as the ‘Haldane Principle’ (12) – ensured that the MRC’s research strategy was largely free from political interference.

The perceived importance of this national effort grew considerably as the Second World War loomed. MRC funding and promotion of medical research increased significantly during the war years; examples include the mass production of penicillin(13) and the MRC streptomycin randomised controlled trial (RCT) which pioneered the use of randomisation in research.(14)

After the war, the creation of the National Health Service (NHS) facilitated ongoing collaboration between the clinicians and institutions charged with delivering healthcare to patients, and the research funding organisations that set the direction of academic research. Meanwhile the fundamental role of universities in the promotion and conduct of research was cemented by the 'dual support mechanism' (whereby universities received an annual fixed grant from UK funding councils, supplemented by project grants from research councils for specific research endeavours).(15) Over the latter half of the twentieth century, this symbiotic relationship between research and healthcare organisations allowed academic medicine to flourish.

### *1.3.1 The present day*

The continued proliferation of health research funding and activity in the UK has confirmed its status as a global leader in health research. A recent report ranked the UK number one in the world for biomedical research,(16) and the success of UK health research is clearly reflected in the impact of its medical journals(17) and the additional economic investment attributable to public funding of UK health research.(18, 19) Research funding has grown steadily over the twenty-first century; the Association of Medical Research Charities estimates that UK public funding of medical research totalled £3.2 billion in 2018,(20) up from £2.03 billion in 2014 and £1.19 billion in 2004-5.(21)

However, despite growth in overall research funding, competition remains intense. The MRC received 1,095 research grant applications in 2011-2, of which 26% were successful, compared with 1,539 in 2017-8 of which 24% were successful.(22) Deciding how best to distribute research funding is a continual challenge. The overall aim of medical research – namely, to improve human health – is generally agreed, but deciding which research will yield the greatest health benefits is contentious. Those who allocate research funds must consider a range of issues when considering research proposals. How significant is the

problem under investigation? How likely is the proposed research to find a solution? Is the research methodologically sound? How much will it cost, and how long will it take? The COVID-19 pandemic, and the urgent search for effective treatments and prevention strategies it engendered, brought such questions into even sharper relief.

### *1.3.2 Current research fund allocation processes*

To help decide how to allocate limited research funds, many research funding bodies have formal frameworks for reviewing grant applications. This may include internal review by a panel of research experts, or external peer review, and – increasingly – non-medical input from one or more 'lay' representatives. However, each research organisation has its own particular research priorities, areas of expertise, budgetary constraints, culture and organisational structure.

A scoping review commissioned in 2008 by the James Lind Alliance (JLA) – a non-profit UK-based organisation which facilitates the involvement of patients and clinicians in the development of health research priorities – explored how the UK's main funding organisations set their research agendas, and the extent of patient and public involvement (PPI) in decision making. They identified 52 medical research funding bodies, including 49 voluntary sector organisations or medical charities; two Department of Health (DoH) funded bodies, and one research council, with research budgets ranging from tens of thousands to hundreds of millions of pounds. Thirty-one (60%) operated a 'responsive' model (with researchers submitting applications, followed by a process of peer review to decide which applications to fund). All the funding organisations reported using some form of peer review to make research funding decisions. However, while twenty-one (40%) reported having identified agendas for research, only seven (13%) said they would only consider research proposals that addressed those agendas. Meanwhile levels of PPI in research funding decisions were highly variable. Most organisations involved patients and the public to develop their research priorities, but only eleven (21%) used PPI in assessing funding applications.(23)

The report's findings reflect the 'traditional' model of research funding, whereby funding decisions are made principally within the research community itself by experts with extensive knowledge of the subject. This model is underpinned by the assumption that

such experts are most familiar with current knowledge gaps, most able to understand the research methods and processes in their field, and therefore best placed to make decisions about the relative merits of competing research proposals.

However, this notion has been challenged in recent decades. Several commentators have argued that experts are likely to have their own agendas and biases, and that the likely overall benefit to society of the research in question may be better appraised by non-experts from outside the field. Furthermore, the relative merits of competing research proposals and their possible impact on improving patient health are arguably better judged by those most affected by the problem being researched.

### *1.3.3 Patient and public involvement (PPI) in medical research*

The expert-led process of research fund allocation described above has therefore been superseded in recent decades – in parallel with a wider move away from paternalistic medicine and towards patient empowerment – by an increasing trend towards actively involving patients and the public in the design and conduct of medical research. PPI has several perceived benefits (as discussed later in this chapter), such as producing more relevant, better designed research studies, and faster uptake of new evidence.(24, 25) Stringent PPI has therefore become an expected norm of medical research, required for most research funding applications and encouraged by journal editors.(26)

However, while the benefits of PPI are widely acknowledged, it is also recognised that PPI requires considerable time, money and resources, often relying heavily on the goodwill of patient and public volunteers. Furthermore, not all PPI is equally valuable. ‘Tokenistic’ PPI (where PPI input has minimal influence on research), using flawed approach(es) to elicit patient and public views, or insufficient consideration of equality, diversity and inclusivity (EDI), are all potential pitfalls whereby well-intentioned PPI activity may fail to improve the underlying research.

## 1.4 The scandal of research waste and inefficiency

Faced with ever-increasing competition for research funding, and the growing expectation of researchers and research funders to demonstrate impact, the concept of research waste has received increasing attention. A review by Chalmers and Glasziou in 2009 estimated that the vast majority of research funding is in fact 'wasted', which they defined as 'does not yield valuable new information'.(27) They estimated that around 85% of research funding (which in 2010 amounted to approximately $100 billion worldwide) is wasted, and highlighted various underlying reasons for 'wasteful' or 'inefficient' research, summarised in figure 1.

Perhaps the first discussion of research waste to receive significant attention was a BMJ editorial by Doug Altman in 1994, entitled 'The scandal of poor medical research'.(28) In this editorial, which the BMJ's readers would later choose as its most influential paper of the past twenty years,(29) Altman criticised 'researchers who use the wrong techniques (either wilfully or in ignorance), use the right techniques wrongly, misinterpret their results, report their results selectively, cite the literature selectively, and draw unjustified conclusions,' and complained that 'huge sums of money are spent annually on research that is seriously flawed through the use of inappropriate designs, unrepresentative samples, small samples, incorrect methods of analysis, and faulty interpretation.' He concluded that 'we need less research, better research, and research done for the right reasons.'

Twenty years later, research waste was still considered a sufficiently important problem for the Lancet to run a series of articles in June 2014 under the theme, 'Research: increasing value, reducing waste' which similarly discussed causes of unproductive or wasteful research, and potential efforts to address them. The commissioning editors made 17 recommendations to increase value, which spanned five specific areas for improvement (research priorities; research design, conduct, and analysis; research regulation and management; accessibility of research; reporting), variously aimed at research funders, regulators, journals, academic institutions, and researchers themselves.(30)

A commentary by Moher et al in 2016 struck a cautiously optimistic tone that the Lancet series had begun to initiate the recommended changes: '[it]…seems to have provoked several important discussions and is on the agendas of several key players.'(31) Nonetheless, the issue remains stubbornly persistent, as bemoaned in a recent review by

Pirosca et al entitled ‘Tolerating bad health research: the continuing scandal’.(32) Pirosca explored the quality of 1,659 randomised trials included in recent Cochrane reviews, and found that the risk of bias was high for 1013 (62%), unclear in 494 trials (30%), and low in only 133 (8%). She concluded that ‘most randomised trials are bad and… the research community has tolerated this for decades. This has to stop: we need to put rigour and methodology where it belongs – at the centre of our science.’

In this section, I shall briefly explore factors contributing to research waste and how they relate to the work described in this thesis.

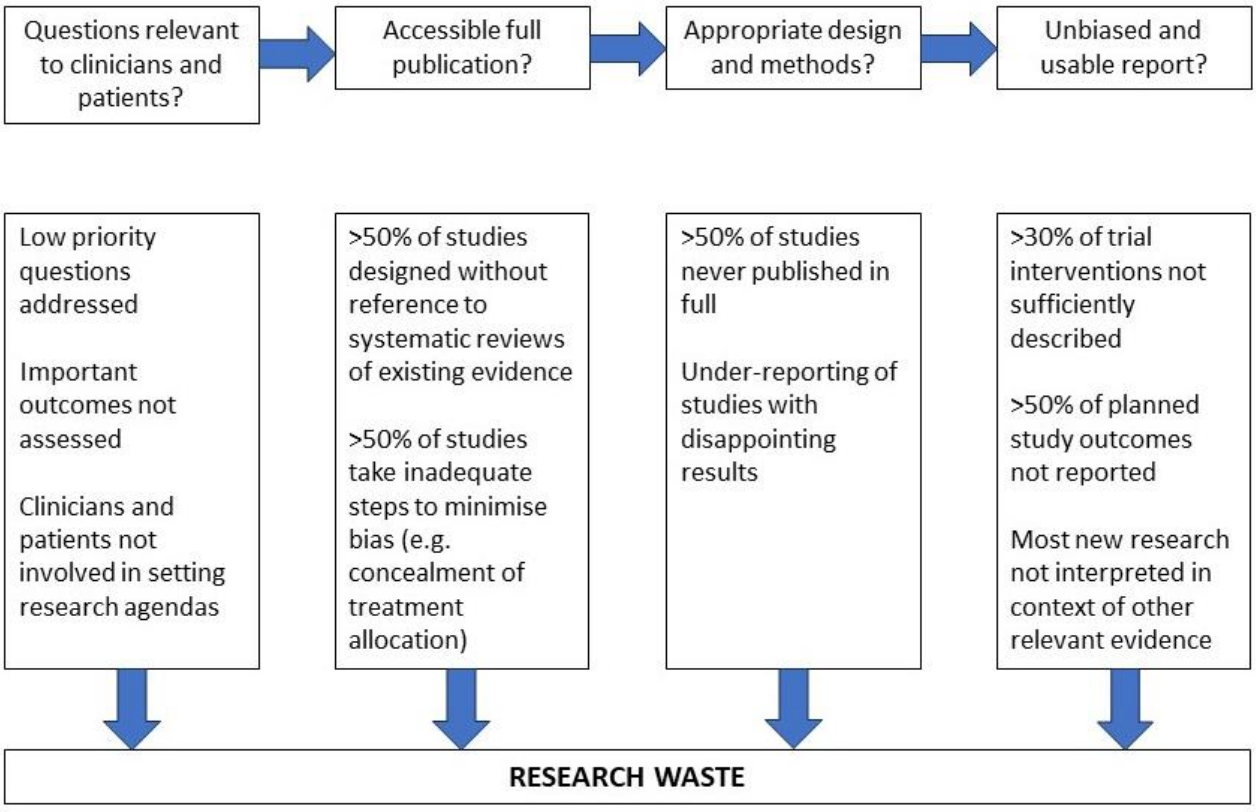


**Figure 1**. Stages of waste in the production and reporting of research evidence relevant to HCPs and service users (adapted from Chalmers and Glasziou, 2009)

### *1.4.1 Failure to publish*

First, a large proportion of completed research never gets published. Several authors have demonstrated that such under-reporting disproportionately affecting ‘negative’ trials, i.e. studies which show no benefit of the intervention under investigation, and that even when their results are published, ‘negative’ trials are less likely to be published promptly, (33, 34) or to progress from abstracts to full published reports.(35, 36)

Furthermore, the overall rate of nonpublication is likely underestimated: even with the advent of mandatory trial registration over the last two decades, not all unpublished research can easily be found, since many studies do not meet the criteria for mandatory prospective registration. Estimating trial publication rates requires exhaustive searching for all studies undertaken: the commonest approaches involve consulting research ethics committees (RECs, for studies submitted for ethical approval), conference abstracts (for studies presented), and searching trial registries, but even exhaustive searching using recognised methods may not uncover all relevant studies.

Most evidence, however, points to a ballpark figure of fifty percent of research remaining unpublished.(37) For example, a review by Schmucker et al. of 17 cohorts of studies approved by RECs found that, on average, 46% were published,(38) while a recent large study of clinical trial publication rates found that 57% of 4,347 trials registered in ClinicalTrials.gov had been published (while another 10% had reported results but without journal publication).(39) Overall, Chalmers and Glasziou estimate the rate of non-publication at around fifty percent.

Various reasons for not publishing research findings have been highlighted. Researchers themselves may be reluctant to publish negative results, fearing that it may harm their citation rate and/or their chances of future funding; journals too – especially high-impact ones – may prefer to publish newsworthy positive ‘breakthrough’ results than negative studies that may not be as widely read or cited.(40) However, non-publication means that researchers cannot replicate or learn from ‘disappointing’ results found by others, and may perpetuate the expenditure of further research resources on unproductive lines of investigation that are unlikely to advance scientific knowledge.

### *1.4.2 Conducting new research where published research already exists*

Secondly, failure to appraise the existing evidence base sufficiently when designing new research leads to unnecessary research being conducted. Chalmers and Glasziou posited that ‘New research should not be done unless, at the time it is initiated, the questions it proposes to address cannot be answered satisfactorily with existing evidence. Many researchers do not do this.’ Several other authors have also highlighted this issue: for example, Clarke et al conducted several assessments at various timepoints of randomised trials published in five major medical journals, and found that ‘only a small proportion of trial reports provided sufficient information to assess the contribution of the new results to the totality of the available evidence.’(41) Robinson et al. also found that in reports of 1,523 RCTs published between 1963 and 2004, fewer than 25% of relevant preceding trials were cited – the ‘potential implications [of which] include ethically unjustifiable trials, wasted resources, incorrect conclusions, and unnecessary risks for trial participants.’(42)

While the failure to appraise existing evidence before undertaking new research is perhaps a fault of research funders as well as researchers, it is clearly incumbent on the whole research community to avoid unnecessary replication of previously published research, and not to waste scarce research funds investigating questions that have already been answered.

### *1.4.3 Poor research methodology*

Weaknesses in the design, conduct and analysis of research have been highlighted as another contributor to research waste.(43) Examples of flaws identified by various authors that may introduce elements of bias include using incorrect statistical methods,(44) underpowered studies,(45) flaws in randomisation,(46) failure of allocation concealment,(47) and failure to handle missing data appropriately.(48)

Moreover, the effects of methodological errors on end results may be subtle. Whereas discredited studies may be dismissed as wholly invalid, seemingly minor imperfections in study design or conduct may not invalidate the study, but may introduce uncertainty regarding true effect sizes, ‘soft’ outcome signals (such as effects that almost reach statistical significance, but not quite), and poor reproducibility of findings.(49)

### *1.4.4 Incomplete, inaccurate and/or unusable research reporting*

A fourth source of waste highlighted by Glasziou and others was inadequate, incomplete or biased reporting of research, such that research users cannot properly interpret the results.(50, 51) Such oversights may relate to inadequately described randomisation,(52, 53) or ambiguous language that leaves the reader uncertain about the details of the trial's conduct.(54) Even where research methods were judged to be valid and scientifically robust, several commentators have criticised the frequency of poor reporting and/or drawing unjustified conclusions, which have grave ramifications for interpreting and applying research results.(55) Reporting standards such as the CONSORT guidelines for RCTs, STROBE for observational studies, PRISMA for systematic reviews (56-59) help reduce such failings, but are not endorsed by all journals, and in any case are frequently not enforced by journals and/or adhered to by authors.(60)

### *1.4.5 Other causes of research waste*

Finally, both the Lancet 'Increasing value: reducing waste' series and the Chalmers and Glasziou review from 2009 highlighted two additional factors contributing to research waste, which are the main focus of this thesis. The first concerns research priorities, research agendas, and the problem of researchers and research funders choosing the 'wrong' questions for research. The second was the selection of flawed trial outcomes at the design stage, and/or failure to report pre-specified outcomes at the publication stage.

This thesis explores each of these issues with specific reference to their implications for APOM research.

## 1.5 Reducing research waste through stakeholder engagement and collaboration

Foremost among Chalmers's and Glasziou's recommendations to address the issues contributing to research waste was to 'increase involvement of patients and clinicians in shaping research agendas and specific questions', and thereby make research more

relevant to clinicians and patients. Several national research organisations have likewise proposed greater involvement of patients, carers and clinicians in choosing research priorities,(26, 61-63) and the UK National Institute for Health and Care Excellence (NICE) similarly endorses stakeholder collaboration and participation in developing its guidance.(25) Such recommendations clearly resonate with the emphasis across the health research landscape on increasing stakeholder participation in all aspects of research design and conduct.

### *1.5.1 Clinician engagement in research*

While stakeholder engagement has largely focused on increasing patient and public involvement (PPI), there has also been work exploring the benefits of increasing frontline clinicians' engagement with research. The widely lamented 'knowledge translation' or 'evidence-to-practice' gap, whereby new research evidence takes an average of 17 years to become integrated into clinical practice,(64) is perhaps the main driver for engaging clinicians more actively in research, the hope being that new knowledge will be translated more quickly when clinicians are active participants in research.(65, 66) However, the notion that involving practising healthcare professionals may make research more relevant to everyday clinical practice has also been cited as a likely benefit.(67)

### *1.5.2 Benefits and costs of patient and public involvement (PPI) in research*

Meanwhile several commentators have explored the benefits of engaging patients and the public more actively in research.(68, 69) Foremost is the notion of justice: that is, the inherent right of patients and the public – whether as voluntary participants in research, as the intended beneficiaries of healthcare interventions, and as the principal funders of most UK health research (either through general taxation or donations to medical charities) – to participate in the design and conduct of research.

Secondly, robust PPI at the design stage can make health research more relevant to its end users. Patient or public contributors with lived experience may reveal new angles or hitherto unrecognised issues beyond the researchers' focus, that may nonetheless be of interest to patients the research aims to serve. Thirdly, patient involvement in designing

research may yield higher quality research, by identifying design flaws before a trial begins.(68) Fourthly, there are pragmatic justifications: for example, evidence that effective PPI increases recruitment and retention to clinical trials, by ensuring that interventions are acceptable and not overly burdensome to patients, and/or by early identification of potential obstacles to recruitment or retention.(70)

Finally, successful PPI has been shown to increase patient engagement in research, enhance public trust in science, and build bridges between 'experts' in the research community and patients.(71, 72) This is the principal reason why the UK's NIHR promotes PPI in research so enthusiastically,(26) and why evidence of robust PPI has become a requirement for trials seeking NIHR funding and/or portfolio adoption.(73) Increasing public engagement also has benefits for research funders and institutions, who are increasingly required to demonstrate research impact not only in terms of quantifiable metrics such as publications, trials completed, and numbers of patients recruited, but also its public impact.

However, PPI activity is time- and resource-intensive. For researchers, PPI entails identifying and approaching potential contributors, organising and delivering PPI events, and analysing the data obtained. Meanwhile the demands on patient and public contributors are no less onerous: the need to travel to PPI events, take time off work, caring or other usual life roles, and incur financial costs may all present significant burdens and obstacles, many of which are not compensated.

Quantifying the benefits and costs of PPI in practice is therefore notoriously challenging.(74) There are no agreed metrics or easy benchmarks for 'good' PPI, although there are several published recommendations for how to conduct PPI (and how not to conduct it).(72, 73) Assessing the impact of PPI is an area of great interest, however: firstly because PPI activity is resource-intensive, and reliant on the goodwill of its contributors; secondly because methodologically rigorous PPI is hard to define (for example, it may relate more to 'how' the PPI activity is conducted than what form it takes); thirdly because of the pragmatic dividends from well-conducted PPI activity in terms of successful recruitment and retention to research trials.

This final point is perhaps the main justification underpinning this thesis. The role of 'productive' PPI in reducing research waste – for example, by identifying pragmatic obstacles to recruitment and retention at an early stage, or promoting a focus on research questions and outcomes that are genuinely important to patients – can hardly be

overstated. However ‘wasteful’ PPI – i.e. that which has no significant impact on research design or conduct, and where the input of PPI contributors is ultimately ignored or deemed invalid – merely exacerbates the problem of research waste.

## 1.6 Stakeholder engagement and collaboration in Anaesthesia and Perioperative Medicine: the APoC-PSP and COMPAC initiatives

While PPI has long been embraced in several areas of health research such as pain medicine,(75) surgery and anaesthesia have been generally slower to adopt PPI in research.(76) This is perhaps at least partly due to surgery and anaesthesia traditionally involving an unconscious patient, whose experience of events is therefore limited. However, the relatively young specialty of perioperative medicine – encompassing all stages of a patient’s healthcare journey from initial contemplation of surgery to full recovery and beyond – has arguably broadened the reach of these fields, bringing the experiences of surgical patients during their perioperative journey into sharper focus.

Against this backdrop, the two pieces of work reported in this thesis sought to demonstrate the feasibility and benefits of a collaborative stakeholder-engagement-driven approach for research in APOM, and to explore the impact of involving patients and clinicians on the eventual results. I describe two APOM research initiatives which included significant PPI activity at every stage, both of which sought to reduce research waste through collaborative, consensus-based methodology involving partnership between patients, carers, clinicians and researchers.

The Anaesthesia and Perioperative Care Research Priority Setting Partnership (APoC-PSP) was a research prioritisation exercise aiming to identify the most important questions for future perioperative research, and thereby to maximise the relevance of future research to patients and clinicians. Using an initial consultation to invite research suggestions, followed by a prioritisation and consensus process to agree the most important ones, a ‘Top Ten priorities’ for APOM research was produced.

Meanwhile the Core Outcome Measures for Perioperative and Anaesthetic Care (COMPAC) initiative used a similar process of evidence scoping, stakeholder consultation,

followed by a modified Delphi consensus process, to develop a ‘Core Outcome Set’ for APOM trials. Its purpose was to achieve agreement across multiple stakeholder groups regarding the most important outcome measures in research involving surgical patients, and thereby improve consistency and reduce unwarranted selectivity and variation in reporting trial outcomes.

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# PART 1

# Research Priorities in Anaesthesia and Perioperative Medicine

# *Chapter 2: Research agenda setting – how do we choose the 'right' questions to research? Previous research priority setting initiatives in Anaesthesia and Perioperative Medicine*

## 2.1 Introduction

This chapter explores processes for determining health research agendas. While formal processes for selecting and prioritising research topics have become widespread in recent years across medical research funders, there is no agreed methodological approach. I begin by exploring recent criticisms of 'inappropriate' research fund allocation, before reviewing current methods for setting research agendas, and then describing previous research priority setting initiatives in anaesthesia and related specialties.

## 2.2 Controversies in research agenda setting

As total research spending and competition for funding have steadily grown, so has the emphasis on maximising value from research funds, including prioritising what to research. The adoption of formal processes for research priority setting in UK health research dates back to the launch of the NHS's Research and Development Programme in 1991;(77) however, the optimum methodology for research priority setting is still debated.(78) Here I examine some recent criticisms of previous research funding decisions, before discussing newer approaches to setting research agendas.

### *2.2.1 Research funding does not align with disease burden*

Most funders agree that research funding should be allocated roughly in proportion to a disease's societal impact. This viewpoint has a clear ethical justification: the greater the suffering caused by a disease, the greater the potential benefits of research into better treatment or prevention strategies. In some areas, there is also a strong economic

argument. Chronic diseases that cause significant disability may render individuals unable to work or perform other life roles, and increase healthcare costs. The adverse consequences of underfunding research into diseases which cause significant mortality and morbidity, and which carry a major cost burden to society, are well documented,(79) and have led to widespread appeals for more research into prevention of chronic and increasingly common conditions such as obesity.(80)

However, several studies have demonstrated that public funding of research does not correlate with disease burden.(81-84) In 2006, the UK government therefore recommended that the population impact of diseases should be rigorously assessed, to help determine society's health priorities and in turn, inform research priorities.(85) Since then, the discrepancy between disease burden and research funding has gradually declined, with the four biggest disease burdens (cancer, coronary heart disease, dementia and stroke, which in 2012 accounted for 55% of all deaths and 5.5 million disability adjusted life years),(86) are gradually becoming more balanced in terms of research funding allocations. In 2008, 66% of government research funding went to cancer, 21% to coronary heart disease, 9% to dementia and 4% to stroke; by 2012, cancer received only 45%, whereas the proportions allocated to dementia and stroke research had risen to 21% and 12% respectively.(87) A further review of NIHR research funding in 2018 found continuing improvement in the correlation between disease burden and UK research funding.(88)

### *2.2.2 Different stakeholders have different research priorities*

Suboptimal allocation of research funds can also occur when researchers' priorities differ from those of patients and clinicians. Several studies have highlighted a mismatch between researchers' priorities and those of patients and/or clinicians. For example, Tallon et al. described a proclivity among osteoarthritis researchers for drug trials, contrasting with clinicians' and patients' preferences for evaluations of physiotherapy and surgical interventions.(89) A similar mismatch was found by Macmillan Cancer Research in 2004 when exploring what research patients with cancer felt was most urgently required. Cancer patients' highest priority was research into strategies to help people living with cancer, and to reduce the impact of cancer on everyday life; however, only 4% of cancer research funding at the time was addressing such issues, while 43% was being directed to research

into cancer cell biology.(90) Other studies of cancer patients' priorities have echoed this mismatch between meaningful concerns for cancer patients and those addressed by current cancer research.(91, 92)

This mismatch between the research that patients and/or clinicians want to see, and the research that actually gets done, has also been observed in many other areas of healthcare, from kidney disease to perinatal care and asthma.(93-95) A 2002 review of UK randomised controlled trials (RCTs) showed that even non-commercial funders disproportionately favoured drug trials over trials of non-drug interventions, in spite of the well-documented importance to patients and clinicians of investigating treatments other than drugs.(96) A report for the JLA in 2006 likewise found frequent mismatches between researchers' priorities and those of patients and clinicians.(97)

The issue is neatly encapsulated in a letter to the Lancet in November 2011 from the founder of the Italian Cochrane Centre, Alessandro Liberati, just before his death from multiple myeloma:

'I have had the opportunity to consider from more than one perspective the mismatch between what clinical researchers do and what patients need. I am a researcher; I have responsibility for allocating funding for research; and I have had multiple myeloma for the past decade… Left to themselves, researchers cannot be expected to address the current mismatch. Researchers are trapped by their own internal competing interests – professional and academic – which lead them to compete for pharmaceutical industry funding for early-phase trials instead of becoming champions of strategic, head-to-head, phase 3 studies.' His letter concludes with an impassioned call for a formal research governance strategy to help shape the research agenda: 'An essential component of any new governance strategy would be to bring together all the stakeholders…'(98)

## 2.3 Research priority setting methodology

The recent worldwide coronavirus pandemic – which prompted a rapid explosion in clinical research into COVID-19 – has clearly demonstrated how societal disease burden influences the research agenda,(99) while also emphasising the importance of health

research in generating findings that are ‘useful’ both to patients and the clinicians treating them. But what is the best way to agree research priorities for a particular disease or specialty?

### *2.3.1 Research priority setting in low and middle income countries (LMIC)*

Research prioritisation has traditionally been an area of interest principally in LMIC.(100, 101) This interest has been stimulated by several factors, including the often glaring gaps between healthcare provision and population health needs, large disparities in access to healthcare, the frequent absence of research and/or healthcare policy, and – most obviously – by the dearth of health research funding and infrastructure compared with high income countries (HIC).(102-104) Approaches such as the CHNRI (Child Health and Nutrition Research Initiative) method have been successfully used for research priority setting in the LMIC context,(105) while Multiple Criteria Decision Analysis (MCDA) has been used to support biomedical translational research priority setting.(106) Many commentators conclude that – because research priority setting is highly context-dependent – there is no single ‘gold standard’ methodology.

### *2.3.2 The High Income Country (HIC) research priority setting context*

Varying approaches to research priority setting are also seen in HIC. A recent narrative review by Bryant et al. of research priority exercises (RPEs) in HIC similarly described a range of methods for different diseases and in different contexts. Eleven examples were included in the review, most of which involved gathering views and opinions about important research topics from relevant stakeholders (for example, via surveys, questionnaires, or workshops), followed by some form of consensus methodology (e.g. a Delphi process or nominal group technique) to agree which research topics were most important.(107)

Another recent systematic review of global health research priority setting since 2001 analysed methodologies used in 165 published RPEs, of which 82 (50%) were conducted in high income countries. The most common methodologies were the CHNRI method (26%), followed by the Delphi method (24%), James Lind Alliance method (8%), the

Combined Approach Matrix (CAM) method (2%) and the Essential National Health Research method (<1%).(108)

Several authors have concluded that approaches to research priority setting are dictated not purely by scientific considerations, but by local or cultural factors, as well as time and resource constraints.(109) However, notwithstanding the influence of local context on RPE methodology, the variety of methods seen across different RPEs has prompted the publication of guidelines and principles for methodologically sound research priority setting. The most widely cited of these comes from a review of literature and WHO-led RPEs published by Viergever et al in 2010,(110) which recommended 'Nine common themes of good practice' for research priority setting (see Table 1). These themes are echoed in more recent RPE reporting guidelines produced by Tong et al, and in the conclusion of Bryant's narrative review.(109)

In summary, while there is no widely accepted gold standard for priority setting because of the overriding importance of local context and resources, general agreement exists that research priority setting should be informed by credible evidence, involve a broad spectrum of stakeholders, and follow a transparent process, ideally overseen by independent advisors.

| **Preparatory work** | |
|---|---|
| ***1. Context*** | Decide which contextual factors underpin the process. What resources are available for the exercise? What is the focus of the exercise (i.e. what is the exercise about and who is it for)? What are the underlying values or principles? What is the health, research and political environment in which the process will take place? |
| ***2. Use of a comprehensive approach*** | Decide if use of a comprehensive approach is appropriate, or if development of own methods is the preferred choice. These approaches provide structured, detailed, step-by-step guidance for health research priority setting processes from beginning to end. |
| ***3. Inclusive-ness*** | Decide who should be involved in setting the health research priorities and why. Is there appropriate representation of expertises and balanced gender and regional participation? Have important health sectors and other constituencies been included? |

| | |
|---|---|
| ***4. Information gathering*** | Choose what information should be gathered to inform the exercise, such as literature reviews, collection of technical data (e.g. burden of disease or cost-effectiveness data), assessment of broader stakeholder views, reviews or impact analyses of previous priority setting exercises or exercises from other geographical levels. |
| ***5. Planning for implementation*** | Establish plans for translation of the priorities to actual research (via policies and funding) as a priority at the beginning of the process. Who will implement the research priorities? And how? |
| **Deciding on priorities** | |
| ***6. Criteria*** | Select relevant criteria to focus discussion around setting priorities. |
| ***7. Methods for deciding on priorities*** | Choose a method for deciding on priorities. Decide whether to use a consensus based approach or a metrics based approach (pooling individual rankings), or a combination. |
| **After priorities have been set** | |
| ***8. Evaluation*** | Define when and how evaluation of the established priorities and the priority setting process will take place. Health research priority setting should not be a one-time exercise! |
| ***9. Trans-parency*** | Write a clear report that discusses the approach used: Who set the priorities? How exactly were the priorities set? |

**Table 1.** A checklist for health research priority setting: nine common themes of good practice (Viegever et al)

### *2.3.3 Research priority setting in the UK*

In the UK, the Cochrane Collaboration has led the way in research priority methodology, having 'recognised the need for a more accountable and systematic approach to selecting research questions for systematic reviews'.(111) It established the Cochrane Agenda and Priority Setting Methods Group (CAPSMG, http://capsmg.cochrane.org) to address the gap in evidence on priority setting methodology and has issued some general recommendations for research priority setting.(112) The CAPSMG also works closely with the JLA, whose philosophy is described in the following section.

### *2.3.4 The James Lind Alliance (JLA)*

An early adopter of collaboration between patients, carers and clinicians in setting research agendas was the aforementioned James Lind Alliance (JLA), a non-profit organisation which 'brings patients, carers and clinicians together in Priority Setting Partnerships (PSPs) to identify and prioritise …unanswered questions'. The JLA was established in 2004 with financial support from the UK's MRC and Department of Health (DoH), and sought to address the imbalance described previously between 'what research gets done' and 'what research is needed' (i.e. the research priorities of patients and clinicians). Its mission was to 'open up discussion between patients and clinicians to agree priorities for future research on the effects of treatments'. (113)

In 2013, the JLA became part of the UK National Institute for Health Research (NIHR), the research arm of the NHS which aims to 'improve the health and wealth of the nation through research'. The JLA therefore plays an important role in elucidating NHS research priorities, and its strapline, 'Tackling treatment uncertainties together' reflects its collaborative mission of identifying and promoting the research priorities of all users of medical research.

Since its inception, the JLA's PSPs have set an unofficial benchmark – for the UK, at least – in robust research priority setting, due to their perceived inclusivity, objectivity (each PSP is overseen and managed by an independent JLA adviser) and transparency. PSPs have been conducted in a wide variety of healthcare disciplines, with over a hundred completed to date and around fifty more currently in progress, both in the UK and internationally.(114)

### *2.3.5 Previous research priority setting exercises in Anaesthesia, Perioperative Medicine and Critical Care*

The rest of this chapter reviews the methodological approaches and outputs of previous UK-based research priority exercises (RPEs) within Anaesthesia and the closely-related specialty of Critical Care (hereafter referred to as Intensive Care Medicine, or ICM). One has been undertaken in Anaesthesia and two in ICM, including a recent PSP, led by the JLA and described below in detail for its similarity to the APoC-PSP.

## 2.4 NIAA research priority exercise (2008-9)

The only previous anaesthesia-focused RPE was conducted by the newly established UK National Institute of Academic Anaesthesia (NIAA). The NIAA was created in 2008 to provide ‘a coordinated infrastructure for academic anaesthesia across the UK’ and thereby improve collaboration within the UK academic anaesthetic community. One of its first tasks was to develop its research agenda.(115) The methodology employed and results are described below.

### *2.4.1 Methods:*

The NIAA’s RPE comprised several successive stages. The first stage sought ideas for future research via a questionnaire sent to all ~11,200 fellows of the Royal College of Anaesthetists (RCoA) and members of the Association of Anaesthetists of Great Britain and Ireland (AAGBI). The questionnaire was also sent to the fourteen members of the RCoA Patient Liaison Group (PLG). Suggested research questions were then grouped by theme and a longlist of research questions developed.

A second questionnaire was then sent out to the same mailing list, asking respondents to score each longlist research question out of ten. Suggestions from stage one which had not made the longlist, but might nonetheless be promising candidates for specific NIHR funding streams, were also reviewed at a meeting with the NIHR Evaluation, Trials and Study Coordinating Centre (NETSCC). Finally, an expert panel consisting of 16 clinical anaesthetists (selected by the NIAA Research Council for their research expertise) and 3 lay representatives from the PLG convened to agree the final research priorities.

### *2.4.2 Results:*

In stage one, 268 individuals submitted 447 research suggestions, which were condensed into a longlist of fifteen research questions for the second ‘scoring’ questionnaire. These questions were scored by 2,226 respondents to the second questionnaire. The research

priorities subsequently agreed by the expert panel (based on the scores received and expert discussions with NETSCC) are shown in Table 2.

| Research question |
|---|
| What interventions can prevent perioperative cardiac complications? |
| Does a brief period of preoperative exercise training improve outcomes after major surgery? |
| What perioperative management strategies improve outcome in head injury? |
| What interventions prevent the development of chronic pain after surgery? |
| Does an enhanced perioperative care package improve outcomes? |
| Under what circumstances should aspirin be discontinued in the postoperative period? |
| Would actively targeting preoperative blood pressure in the intraoperative period reduce the incidence of postoperative complications? |
| Does conventional (as opposed to tight) glycaemic control improve perioperative outcome? |
| What is the place of 'anti-neuropathic' pain medications in the treatment of postoperative pain? |
| What are the best arrangements for the preoperative assessment of elective surgical patients? |
| Would higher nurse to patient ratios during the first 48 h after operation reduce the complication rate after major abdominal surgery? |
| What is the impact of same day surgery on primary care? |
| How should patients for day surgery and 23 h surgery be selected? |
| Does the use of locoregional anaesthesia prevent cancer recurrence? |

**Table 2.** The 2008-9 NIAA RPE's final list of research priorities

### *2.4.3 Commentary:*

In the discussion, the authors describe the RPE's two main aims as follows:

- 'To identify research questions in anaesthesia and perioperative medicine that are important to both clinicians and patients'

- ‘To present these in a coherent format to major funding bodies in order to elicit calls for commissioned research.’

However, while the second of these aims is discussed at length, the consideration of whether the research priorities were indeed ‘important to both clinicians and patients’ is brief. The authors commented that ‘the lay members of our panel made a substantial contribution to the exercise’ but glossed over the imbalance between the respective contributions of clinicians and lay representatives. While the JLA’s guidelines had not yet been published when the NIAA began its priority setting exercise, the authors acknowledged that the JLA process ‘is rigorous and provides a strong framework for public involvement, but can be protracted’. They concluded: ‘we did not work with the JLA on the current exercise because of our desire to consider questions apart from therapeutic uncertainties, and to complete our initial priority setting exercise relatively quickly.’

## 2.5 Intensive Care Society research prioritisation exercise (ICS-RPE, 2000)

Meanwhile an RPE for the related specialty of Intensive Care Medicine (ICM) was conducted in the year 2000. It was led by the Intensive Care Society (ICS) and is summarised briefly here.(116, 117)

### *2.5.1 Methods:*

Lead clinicians in 325 Intensive Care Units (ICUs) across the UK were invited to submit research suggestions, which were refined by a nominal group of twelve ICM experts to produce a shortlist of candidate research questions, before a final round of ranking by those ICM clinicians who had responded to the original invitation.

### *2.5.2 Results:*

811 research suggestions received in the first round were condensed into a shortlist of 100 questions. Nine received strong support from both clinicians and the nominal expert group, and were therefore badged as future research priorities for critical care (Table 3):

| | Research question |
|---|---|
| 1. | Does early intervention alter ICU outcome? |
| 2. | Do patients admitted to HDU have better outcomes than those admitted to general wards? |
| 3. | Does the nurse:patient ratio affect patient outcomes? |
| 4. | Does inter-hospital transfer, due to shortage of available beds, affect patient outcomes? |
| 5. | Does early enteral feeding improve outcome? |
| 6. | Does optimisation of perioperative care of surgical patients improve outcome? |
| 7. | Do district general hospital ICUs perform as well as major/university centres? |
| 8. | Does regionalisation of paediatric intensive care improve outcome? |
| 9. | Do pulmonary artery catheters affect patient outcomes? |

**Table 3.** ICS-RPE research priorities for UK Intensive Care Medicine, October 2000

### *2.5.3 Commentary:*

While the exercise achieved its stated aim of defining a succinct set of nationally-agreed priorities for future research, no patients or carers were invited to contribute to this ICS-led exercise. A decade later, the ICS acknowledged that the research landscape had shifted: ‘To date, the research agenda has largely been determined by medical researchers and scientists, but there is a growing expectation that patients, multidisciplinary clinical staff (as opposed to clinical researchers) and the public should be involved in identifying clinical research priorities’. An Intensive Care Priority Setting Partnership (ICM-PSP) was therefore proposed, aiming ‘for the first time, to give a novel perspective by giving more equitable weight to the views of patients, their families, and the wider community of intensive care health professionals.’(118)

## 2.6 Intensive Care Medicine Priority Setting Partnership (ICM-PSP, 2014)

The ICM-PSP, led by the Intensive Care Foundation (ICF) in collaboration with the JLA, sought ‘to identify and prioritise unanswered questions about adult intensive care that are important to people who have been critically ill, their families, and the health professionals who care for them’.

### *2.6.1 Methods:*

The ICM-PSP followed the JLA ‘s recommended methodology,(119) starting with an idea-generating first stage, followed by a refining and prioritising second stage using a modified Delphi survey, before a final face-to-face consensus workshop to agree a ‘top ten’ list of research priorities.

The process sought to engage multiple stakeholders via notices in ICU staff rooms and relatives’ waiting rooms, inviting patients and family members at ICU follow-up clinics, and promotion through social media and ICU Steps (a support group for ICU patients and their relatives). Invitations to the final workshop were also targeted to maximise diversity of clinicians and service users, and to ensure balanced representation of both groups.

### *2.6.2 Results:*

One hundred and forty-six ICUs across the UK publicised the ICM-PSP to patients, relatives and staff. 484 participants (individuals or groups) with experience of intensive care contributed ideas in the first survey, of whom 418 were clinicians (86%), 41 patients (8.5%), and 18 relatives (3.7%). In total they provided 1,210 free text suggestions, which were condensed into 151 research ‘themes’, and further refined by the ICM-PSP Steering group into 37 research topics for the second stage Delphi survey.

513 respondents participated in the Delphi survey, comprising 433 individual clinicians (84%), 17 groups of clinicians (3.3%), and 63 patients and family members (12%). Of the 37 candidate research topics, 13 were ‘shared’ top priorities across both clinicians and service users; six others featured in the ‘top ten’ ranked topics for either clinicians or service users. These 19 topics were shortlisted for the final priority setting workshop, at

which twelve were selected as research priorities (Table 4), with the top three priorities ranked in order of priority. (The remaining nine were unranked).

| | |
|---|---|
| **Top 3 priorities for intensive care research:** | |
| 1. | How can patients who may benefit from intensive care be identified early and admitted to the ICU at the right time? |
| 2. | How can patients and their families be best supported as they start living at home again (eg, health and social care services, ICU support groups, long-term follow-up)? |
| 3. | What is the best way to identify patients with, or at risk of delirium or agitation – how should the immediate and long-term effects of delirium or agitation be monitored and managed? |
| **Other high priorities for intensive care research (unranked):** | |
| 4. | What is the best way to prevent, diagnose and treat hospital-acquired infection (eg, ventilator-associated pneumonia, bloodstream infections related to the use of invasive lines)? |
| 5. | When should physical rehabilitation start and what rehabilitation methods during and after critical illness achieve the best outcomes for patients? |
| 6. | How can we enhance patient comfort during intensive care (ie, minimise pain, discomfort, agitation and anxiety) and does this improve patient outcome? |
| 7. | How can the physical consequences of critical illness (such as muscle wasting, weakness, nerve damage) be prevented and what is the best way to support recovery from these after intensive care? |
| 8. | What psychological support should be provided for patients in intensive care? |
| 9. | How can we predict who will benefit from intensive care before admission and during treatment in the ICU? |
| 10. | What is the best way of ensuring new knowledge and the latest defined standards are introduced into clinical practice in a timely and effective way? |
| 11. | How can we use the experiences of patients and families to improve intensive care? |
| 12. | What is the best way of preventing damage to the lungs of patients receiving respiratory support (ventilation)? |

**Table 4.** Research priorities for UK Intensive Care Medicine, ICM-PSP (2014)

### *2.6.3 Commentary:*

The ICM-PSP authors noted the ‘relatively low survey response rate from patients and families’ and discussed why ‘ICU patients and their relatives are a relatively hard-to-reach population’. They considered that some patients and relatives ‘may have found the scope of the project (spanning their complete intensive care journey and hospital stay) too overwhelming, or felt it was not relevant to their particular experience of critical illness’; ‘many patients remember little of the acute phase of their critical illness’; and recognised that having a relative in ICU is a highly anxious time for family members, who may have been reluctant to revisit those anxieties by participating in the ICM-PSP. While acknowledging that ‘the major limitation of this project was the modest response from patients and family members’, they also highlighted measures taken to achieve a balance of clinicians and service users at the final workshop.

In any event, the considerable efforts made to include the voices of patients and relatives stands in marked contrast to the earlier ICS-RPE. In a subsequent analysis, the authors also explored similarities and differences between clinicians’ and service users’ research priorities. They noted areas of overlap, mainly related to patient comfort on ICU, communication with ICU staff, post-ICU rehabilitation, and timely identification of deteriorating patients. However they also noted clear differences, for example ‘most disease-specific and treatment-related research themes (e.g. ‘liver/gastrointestinal’, ‘renal’, ‘monitoring’) were suggested only by clinicians’.(120)

## 2.7 Conclusions

The need for establishing explicit research agendas in a climate of ever-increasing competition for research funds is widely agreed; however, the optimum methodology for research priority setting is not. Nevertheless, most commentators now agree that research priorities should broadly reflect disease burden and include all stakeholders’ viewpoints. Hence there is growing acceptance of collaborative stakeholder approaches to research

priority setting, such as that enshrined in the JLA's 'bringing patients, carers and clinicians together' PSP methodology.

Within the fields of Anaesthesia and ICM, research priority setting to date has been largely dominated by clinicians. However, reflecting the growth in patient and public involvement (PPI) across the spectrum of health research since the turn of the century, there is a clear trend towards steadily increasing patient and carer contribution in RPEs in Anaesthesia and ICM, although the ICM-PSP is arguably the only RPE in Anaesthesia and Perioperative Medicine (APOM) thus far to seek meaningful input from service users. Moreover, even where service user participation was explicitly sought and encouraged, several barriers to service user engagement were encountered.

In the case of the ICM-PSP, the contributions of patients and carers also highlighted certain areas of research interest – mostly those which directly affect patients' and carers' experiences – where viewpoints of service users and clinicians were closely aligned, and other areas (often related to technical aspects of ICU clinical care) which were dominated by clinicians. I explore this idea further with reference to the results of the APoC-PSP in chapter 5.

In the next chapter, I compare the respective research priorities of the ICS-RPE and the ICM-PSP to examine how service user involvement may influence the outputs of an RPE.

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# *Chapter 3: A qualitative comparison of research priorities generated in the ICS-RPE with those from the ICM-PSP*

## 3.1 Introduction

One of my main aims in this thesis was to explore how using a collaborative approach with participation of service users and clinicians affects the output of consensus exercises in Anaesthesia and Perioperative Medicine (APOM). While the theoretical benefits of greater patient and public involvement (PPI) in research are generally agreed, the real world impact on research outputs is difficult to quantify. To explore this further, I now describe a qualitative comparison of the research priorities generated by the two distinct ICM RPEs.

## 3.2 Methods

This qualitative comparison used content analysis to compare the principal subject matter themes for each dataset, and to describe their respective linguistic styles. Similarities and differences were then identified. The two datasets consisted of a) the research priorities produced in the ICS-RPE and b) the priorities from the ICM-PSP. Each dataset was carefully read, re-read and considered in different orders, and then subjected to content analysis based on word frequency, use of scientific language, syntax and linguistic tone. Overarching themes appearing across research questions were extracted.

A framework analysis was also conducted, in which the research priorities in each dataset were considered against the three components of healthcare quality as defined in the 2008 NHS Next Stage review, 'High Quality Care for All' chaired by Lord Ara Darzi.(121) Darzi defined high quality healthcare as being 'clinically effective, personal, and safe', since when quality in healthcare has been measured using the three domains of clinical effectiveness, patient experience and patient safety. Each question from the ICS-RPE and the ICM-PSP was therefore reviewed in turn for its relevance to each of these domains, such that each dataset could be summarised by the extent to which it addressed each aspect of healthcare quality.

## 3.3 Results

### *3.3.1 ICS-RPE research priorities*

#### Content analysis

The ICS-RPE's research questions are short, precise and all framed as binary yes/no questions, tending to contain an implicit null hypothesis for a research trial. For example, 'Does early enteral feeding improve outcome?' translates into the null hypothesis: 'Early enteral feeding does not improve ICU patient outcomes.' They contain several technical terms and medical jargon such as 'early intervention', 'enteral feeding', 'regionalisation' and 'pulmonary artery catheter'. Specific technical or clinical research questions also appear – for example, the effects of early enteral feeding and use of pulmonary artery catheters.

Common words and phrases include 'outcome' and 'improve/affect/alter'. Predominant themes include the structure and organisation of Intensive Care (e.g. staffing ratios, regionalisation of paediatric services, district general versus university teaching hospital ICU) and the possible benefits of preventive measures before patients deteriorate (such as High Dependency Unit (HDU) admission, and optimisation of perioperative care).

#### Framework analysis

**Clinical effectiveness:** All nine (100%) research questions suggest research aiming to improve the clinical effectiveness of ICU care. Eight (89%) describe interventions to improve the 'outcome' for ICU patients, and the only question not to contain the word 'outcome' is: 'Do district general hospital ICUs perform as well as major/university centres?', where the phrase 'perform as well' demonstrates that this question similarly concerns the clinical effectiveness of ICU care.

**Patient Safety**: Three of the nine questions (33%) were judged to relate to improving patient safety or preventing avoidable harm – whether through planned admission to HDU rather than general wards ('Do patients admitted to HDU have better outcomes than those…?), or through increasing staffing levels ('Does nurse:patient ratio affect patient

outcomes?'), or by reducing non-clinical inter-hospital transfers ('Does inter-hospital transfer, due to shortage of available beds, affect patient outcomes?')

**Patient/carer experience:** No questions (0%) were judged to relate to improving patient experience. Neither the word 'experience' nor the phrase 'patient experience' appear in any of the questions, and none of the questions were considered to suggest interventions or research whose principal aim could reasonably be interpreted as improving patient experience.

### *3.3.2 ICM-PSP research priorities*

**Content analysis**

The ICM-PSP's research questions are generally longer, and framed in lay-friendly language, avoiding medical jargon and technical terms. All are phrased as open-ended questions with several possible answers, in an almost conversational tone: for example, 'How can patients who may benefit from intensive care be identified early…' Six questions (50%) begin with 'How…?'; five (42%) begin with 'What…?', and one question (8%) with 'When…?', inviting a general exploration of a topic rather than a null hypothesis. The word 'outcome' only appears in two questions (17%).

The linguistic and syntactical differences are best illustrated by comparing the style and wording of two questions from each exercise that both address essentially the same uncertainty:

- 'Does early intervention alter ICU outcome?' (ICS-RPE)
- 'How can patients who may benefit from intensive care be identified early and admitted to the ICU at the right time?' (ICM-PSP)

Common words and phrases appearing in the ICM-PSP questions include 'support' and 'the best way'; recurring themes include how patients can be best supported beyond their ICU stay (during recovery on the ward, or after discharge from hospital) and interventions to maximise post-ICU physical and psychological recovery. Preventive or proactive measures to minimise recognised complications of ICU admission featured prominently (for example, muscle wasting, hospital-acquired infection and ventilator-associated lung

damage). The medium to long-term sequelae of ICU admission are also a theme of several questions.

**Framework analysis**

**Clinical effectiveness:** Six questions (50%) were considered to relate to improving clinical effectiveness, as they all suggest interventions that might improve ICU resource utilisation, dissemination of best practice and/or clinical outcomes for patients. These were questions 1 (early identification of patients who may benefit from ICU care), 4 (preventing/treating hospital-acquired infection), 5 (physical rehabilitation), 6 (enhancing patient comfort), 9 (predicting which patients will benefit from ICU), and 10 (improving knowledge dissemination).

**Patient Safety:** Four questions (33%) were deemed to concern efforts to minimise avoidable harm and/or maximise patient safety while on ICU, namely questions 3 (preventing/treating delirium/agitation and its consequences), 4 (preventing/treating hospital-acquired infection), 7 (minimising the physical consequences of critical illness, and supporting recovery afterwards), and 12 (preventing ventilator-associated lung damage).

**Patient/carer experience:** Five questions (42%) were considered principally to address patients' and/or their families' experiences during and after an ICU stay, and during recovery or rehabilitation – i.e. getting back to normal life – after ICU discharge. These questions clearly concerned the personal perspectives of patients on ICU and their families, implicitly acknowledging the importance of 'support' and 'rehabilitation' for recovery during and after an ICU admission. These questions notably touched only peripherally on the clinical effectiveness of ICU care, if at all. These five questions were numbers 2 (supporting patients and families after discharge), 5 (physical rehabilitation), 6 (enhancing patient comfort), 8 (improving psychological support for ICU patients) and 11 (using patients' and families' experiences to improve intensive care).

## 3.4 Discussion

This comparison illustrated marked differences, both in linguistic format and thematic content, between the ICM research priorities generated in the ICM-PSP through collaboration between clinicians and service users, and those generated in the ICS-RPE by clinicians alone. The questions from the ICM-PSP were presented in more lay-friendly terms without medical jargon, while their content included both clinical effectiveness research and patient-oriented research aiming to improve patient/carer experience, in contrast to the ICS exercise, whose research priorities focused on improving clinical effectiveness and patient safety.

One obvious explanation for these findings is that equitable participation of service users alongside clinicians in the ICM-PSP brought patient experience to the fore as an important area for research, whereas the patient/carer voice went unheard in the ICS RPE owing to the absence of patient or carer representatives. However, there are certain caveats to this conclusion. Firstly, the two exercises were conducted fifteen years apart, during which time the UK research landscape had changed significantly. Indeed, the authors cite the change in research culture as a justification for the ICM-PSP: ‘There is a growing expectation that patients, multidisciplinary clinical staff… and the public should be involved in identifying research priorities’.

Secondly, although the two exercises used similar consensus methodology, they were not identical: for example, the JLA process emphasises research *uncertainties*, rather than explicit research questions, which likely accounts for at least some of the differences between the two outputs. Finally, the contribution of service users to the ICM-PSP should not be exaggerated: although the clinician-service user balance at the final workshop was roughly even, the majority of contributors (>80%) during both survey stages were clinicians.

## 3.5 Conclusions

The above analysis demonstrates that collaborative methodology seeking contributions from distinct stakeholder groups affects both the material content and linguistic

presentation of the ensuing ICM research priorities. Priorities generated through inclusive collaboration with service users are more likely to include patients' and relatives' perspectives of how research could improve their experiences of care. Similar results have been noted in other areas of research priority setting.(122)

The next chapter describes the methods and results of the Anaesthesia and Perioperative Care PSP (APoC-PSP).

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# *Chapter 4: The NIAA Anaesthesia and Perioperative Care Research Priority Setting Partnership (APoC-PSP)*

## 4.1 Introduction

This chapter reports the first of the collaborative research initiatives described in this thesis. The Anaesthesia and Perioperative Care Research Priority Setting partnership (APoC-PSP) was commissioned by the NIAA Research Council in late 2012, with the aim of redefining the NIAA's research agenda by incorporating patient and public viewpoints. Because of its pedigree in facilitating research priority collaborations between patients, the public and clinicians, the James Lind Alliance (JLA, described above) was approached to lead the design and conduct of the APoC-PSP.

The APoC-PSP's aims were agreed as follows:

1) To bring together patients, carers and clinicians to identify and prioritise unanswered questions for research in anaesthesia and perioperative care

2) To agree, by consensus, the 'top ten' most important unanswered questions from those identified

3) To publicise the results among the anaesthetic and perioperative community, and disseminate the results to funding bodies in order to maximise their impact on the future research agenda

## 4.2 Methods

The APoC-PSP was conducted in accordance with JLA guidelines and overseen by an independent JLA adviser.(119) Funding was provided by the NIAA funding partners, and administrative support by the NIAA Health Services Research Centre (HSRC). A Steering Group (SG) comprising clinician representatives of the NIAA funding partners, patient and carer representatives from affiliated partner organisations, and the JLA adviser, oversaw

the conduct of the PSP via monthly teleconferences to discuss progress, resolve any methodological issues and agree next steps.

The APoC-PSP began in late 2013, and concluded in mid-2015, with results published later that year.(123) The timeline and stages of the project are summarised in Table 5.

| Timeline | Activity | Description |
|---|---|---|
| Late 2013 – early 2014 | Stakeholder organisation engagement and affiliation | Scoping relevant charities and professional organisations; potential partner organisations identified and invited to affiliate; stakeholder engagement meeting. |
| June – July 2014 | 'Idea-gathering' online survey | Inviting research suggestions via online survey of stakeholders, plus additional research proposals from affiliated partner organisations |
| August – December 2014 | Research question shortlist development | Classifying and refining initial research suggestions, removing duplicates/invalid submissions<br>SG meeting to develop a shortlist |
| December 2014 – January 2015 | Literature reviews | Reviewing existing research literature to appraise evidence base for each question. All questions subsequently classified as a) fully answered already; b) partially answered; or c) still mostly unanswered |
| February – March 2015 | Interim prioritisation online survey | Second online survey – respondents were asked to nominate their ten most important research questions |
| May 2015 | Final consensus workshop | JLA-led face-to-face consensus workshop of invited stakeholder representatives.<br>Agreement of final 'Top Ten research priorities' |
| December 2015 | Publication | Full results published in BMJ Open |

**Table 5.** Summary and timeline of the Anaesthesia and Perioperative Care Priority Setting Partnership

### *4.2.1 Eligible stakeholders*

'Any person or organisation with an interest in anaesthesia and/or perioperative care' was deemed eligible to participate in the APoC-PSP. Participants were assigned to two groups which were NOT mutually exclusive (i.e. any stakeholder could be a member of one or both groups):

- ***Healthcare professionals (HCP):*** any researcher or clinician whose work involves patients receiving anaesthetic or perioperative care, i.e. anaesthetists, surgeons, theatre staff, operating department practitioners, surgical ward and ITU nurses, GPs, community nurses, etc.
- ***Service users:*** patients with experience of undergoing surgery, or those who may do so in the future, and carers/relatives with experience of caring for a patient after surgery.

### *4.2.2 Inviting partner organisations, defining scope and terms of reference*

Relevant stakeholder organisations were invited to join as official partners in the APoC-PSP. We approached all subspecialist UK anaesthetic societies, other organisations representing APOM HCPs, and over a hundred patient organisations (via nominations from specialist anaesthetic societies, suggestions from NIHR INVOLVE,(26) and web searches for surgical patient organisations and charities). Potential partner organisations were invited to a scoping meeting in October 2013; those that agreed to participate were subsequently affiliated (see table 6 below), and volunteers sought from among them to form the Steering Group (SG). SG membership was finalised in November 2013, with terms of reference and the methods protocol agreed in early 2014.

| Professional organisations (25) | Patient member organisations (20) |
|---|---|
| RCoA (Royal College of Anaesthetists) | Age UK |
| AAGBI (Association of Anaesthetists of Great Britain and Ireland) | AIMS (Association for Improvement in Maternity Services) |
| *BJA (British Journal of Anaesthesia* – journal of the RCoA) | The Colostomy Association |

| | |
|---|---|
| *Anaesthesia* (journal of the AAGBI) | Ehlers-Danlos Support UK |
| ACTA (Association of Cardiothoracic Anaesthetists) | Headway |
| AfPP (Association for Perioperative Practice) | IA (Ileostomy & Internal Pouch Support Group) |
| APAGBI (Association of Paediatric Anaesthetists of Great Britain and Ireland) | ICPV (Independent Cancer Patients' Voice) |
| APAA (Association of Physicians' Assistants (Anaesthesia)) | Kangaroo Club |
| ARS (Anaesthetic Research Society) | Lay Committee of the RCoA |
| BARNA (British Anaesthetic and Recovery Nurses Association) | NCRI CLG (National Cancer Research Institute Consumer Liaison Group) |
| BSOA (British Society of Orthopaedic Anaesthetists) | National Childbirth Trust (NCT) |
| CARG (Cochrane Anaesthesia Review Group) | North Trent Cancer Research Network Consumer Research Panel |
| DAS (Difficult Airway Society) | Oesophageal Patients Association (OPA) |
| FPM (Faculty of Pain Medicine) | Patient Liason Group of RCS (Eng) (Royal College of Surgeons (England)) |
| NASGBI (Neuroanaesthesia Society of Great Britain and Ireland) | Patients Association |
| NIAA Health Services Research Centre | Polycystic Kidney Disease Charity |
| OAA (Obstetric Anaesthetists' Association) | Prostate Cancer Support Federation |
| RA-UK (Regional Anaesthesia UK) | Royal National Orthopaedic Hospital Patient Group |
| RCS (Eng) (Royal College of Surgeons (England)) | The Swallows (Head & Neck cancer support) |
| SEA UK (The Society for Education in Anesthesia) | The Urostomy Association (UA) |
| SOBA (Society of Obesity and Bariatric Anaesthesia) | |

| | |
|---|---|
| SPARC (South Coast Periop Audit & Research Collaboration) | |
| SWARM (South West Anaesthesia Research Matrix) | |
| VASGBI (Vascular Anaesthesia Society of Great Britain and Ireland) | |
| WAAREN (Welsh Anaesthesia Audit, Research & Engagement Network) | |

**Table 6.** Partner organisations affiliated with the APoC-PSP. (Shaded box = organisations with at least one SG member)

## Definition of scope

Although the APoC-PSP was initially conceived as a PSP for Anaesthesia, the NIAA Research Council amended its name before it began to 'The Anaesthesia and Perioperative Care PSP'. This followed agreement within the Council that perioperative care is inseparable from anaesthesia, and that including 'Perioperative Care' in the name would help distinguish it from the 2008 Anaesthesia RPE. However, the SG decided to exclude any questions related only to ICM, since the ICS was already conducting its own PSP as previously described.(118) The scope was therefore defined as encompassing 'all aspects of anaesthesia and perioperative care, other than the surgery itself', which were defined in the surveys as follows:

*'**Anaesthesia** concerns the use of drugs (including anaesthetic gas) given to a patient before, during or after an operation. This may be a general anaesthetic (to make the patient unconscious), or regional anaesthesia (to remove sensation and pain in one area, such as a limb), or general pain control.*

***Perioperative care** comprises every aspect of patient care before, during and after surgery.'*

The SG acknowledged the ambiguities of these definitions and potential overlaps with other disease areas, but agreed this reflected the imprecise boundaries implicit in perioperative medicine.

### *4.2.3 Gathering research suggestions and ideas*

Suggestions for APOM research were invited via an online 'ideas-gathering' survey. This ran for two months from June – July 2014 and asked respondents to submit up to three ideas for research (with space for futher explanation). Respondents were also asked for basic demographic information, and consent to their suggestions being recorded on NICE's Database of Uncertainties of Effects of Treatments (DUETs).(124)

The survey was advertised and publicised using the SG's collective enthusiasm and resources. None of the members had formal marketing or advertising experience or training, nor did we engage professional advice or assistance with promotion (other than (3) below). However, the group agreed in advance – in accordance with JLA methodology – that professional promotion was beyond the PSP's budget and timeframe, and the goal was to achieve a diverse spread of responses from HCPs and service users rather than comprehensive national coverage. Responses were monitored while the survey was live, and further promotion was deliberately targeted towards any underrepresented stakeholder groups, aiming to achieve a roughly even balance of HCP and service user responses.

Publicity and promotional activities undertaken included:

1) All partner organisations advertised the survey to their members via newsletters, emails, social media and their websites.
2) All anaesthetists on the RCoA membership database were emailed at least once regarding the survey.
3) Two professionally-designed posters were commissioned for display in hospital and GP outpatient clinics.
4) Word of mouth: SG members disseminated the survey to friends, families, colleagues and acquaintances with recent experience of having surgery.

5) The anaesthetic trainee-led research and audit groups, and the NIAA HSRC's 'QuARC' (Quality, Audit and Research Coordinator) network, were contacted to promote and disseminate the survey within their hospitals and personal networks.

In addition to the individual responses received via the survey, each partner organisation was invited to submit three research suggestions on behalf of their organisation.

### *4.2.4 Classifying and refining research suggestions*

A subgroup of five SG volunteers (two anaesthetists, two lay representatives, and the SG coordinator) was selected to classify the suggestions into themes. A classification system was agreed by the subgroup at a face-to-face meeting chaired by the JLA adviser; any disagreements regarding classification were resolved via discussion or through the wider SG. For any questions initially deemed inadmissable (e.g. incomplete/unclear suggestion, duplicate response, or 'out of scope'), a low threshold was adopted for retention: if doubts were voiced among the subgroup, the question was retained. The final classifed 'longlist' of original research suggestions was reviewed and agreed by the SG in October 2014.

At a second subgroup meeting in December, the longlist was refined into a shortlist of 'summary' questions. This process involved similar suggestions being merged into broad summary questions: for example, the suggestions 'Could taking pre-operative vitamin D supplements reduce postoperative complications?' and 'Does a carbohydrate preload benefit diabetic patients having surgery?' were incorporated into a single question: 'How can preoperative nutritional modifications improve outcomes after surgery?' To improve ease of review in the prioritisation survey, the salient research topic contained within each question was highlighted in bold (see Table 7 below).

This shortlist was then reviewed and ratified by the SG as being a comprehensive summary of all the individual suggestions submitted in the first survey.

### *4.2.5 Literature scoping reviews:*

Literature reviews were performed to find existing research relevant to each summary question, in order to avoid including any questions that had already been adequately answered by previous research. All questions were thereafter categorised as a) already

answered by existing research; b) partially answered, but more research still needed; or c) largely unanswered, therefore further research required. We applied the JLA's recommended criteria for defining a research question as 'unanswered', namely either a) no recent (within the past 3 years) high quality published systematic reviews; or b) up-to-date systematic review(s) concluded that uncertainty still persists.(125)

Literature searches were conducted by the SG coordinator (OB) as follows. The Cochrane Library and OVID Medline were first searched for relevant systematic reviews. Where none was found, other relevant review articles summarising the primary evidence base were sought. Literature searches were also conducted in OVID Medline and Web of Science for recent national audit publications and large randomised controlled trials. Where they were judged to contribute significantly to the evidence base, these were also included.

New topics for research not proposed in the original survey were also sought, including reviewing the conclusions of all anaesthesia and perioperative medicine Cochrane reviews for additional research questions, and consulting research experts within the specialist anaesthetic societies.

### *4.2.6 Interim prioritisation*

A second online survey was then conducted to prioritise the proposed research topics in order of importance to stakeholders. This prioritisation survey asked respondents to nominate their ten most important research questions from the shortlist of summary questions. It remained open for two months (February – April 2015) and was again accessible via the NIAA website and advertised through similar channels, informed by prior experience of which strategies had proved most effective. More use was made of Twitter to target particular patient and professional audiences, and the majority of promotion was targeted towards service users rather than HCPs, with the aim of achieving similar response numbers from both.

However, in order to mitigate any inadvertent imbalance in stakeholder group response numbers, the SG agreed *a priori* to apply extra weighting to the underrepresented group's responses, as per JLA guidelines.(126) Specifically, the SG decided that if either group totalled more than two-thirds of responses, the underrepresented group's responses would

be weighted double to achieve approximately even representation. JLA guidelines also recommend that only *shared* priorities (i.e. those nominated by all stakeholder groups) should progress to final prioritisation. The SG therefore decided in advance to remove any questions nominated overwhelmingly (defined as >90% of responses) by only one group, as these would by definition not be shared priorities.

After survey closure, nominations for each question were counted, and the distribution of responses from clinicians and service users calculated. The questions were then ranked from most popular (i.e. with the most nominations as a 'top ten' question) to least popular. After excluding any that had been nominated overwhelmingly (>90% of responses) by one group only, the most popular 25 questions were taken forward for the final workshop.

### *4.2.7 Final prioritisation: agreeing the 'top ten' priorities*

All partner organisations were invited to send a delegate to the final prioritisation workshop, which was held on 12th May 2015 and used a modified Delphi process facilitated by three independent JLA advisers to achieve consensus on a final 'Top ten' research priorities. Delegates attended voluntarily, with remuneration of travel expenses, and were sent preparatory information beforehand about the workshop's format, including the list of 25 research questions for consideration.

During the workshop, delegates were divided into three smaller groups (with similar proportions of HCP and service user representatives) to discuss the relative importance of the 25 questions within their groups for an hour. A JLA facilitator guided each small group discussion, ensuring that all voices and opinions were heard, and suggesting further avenues for discussion to resolve any conflict or deadlock. At the end of this session, each group compiled a draft ranking of the questions.

The three groups then came together in a plenary session to compare their respective draft rankings, discuss points of agreement or disagreement, and consolidate any emerging consensus. JLA facilitators again helped guide this discussion towards overall consensus by echoing opinions voiced, highlighting different perspectives, suggesting adjustments, and then compiling an overall draft ranking based on majority consensus.

After lunch, the three small groups were then shuffled (maintaining the HCP/service user balance); each new group spent a further hour discussing and ranking the questions again. In the final plenary session, the groups reconvened for further collective discussion of the emerging aggregate ranking, aiming to reach a consensus about the most important questions. At the end of this session, the final ranking and ‘top ten’ priorities were presented to the group, and ratified by all delegates.

## 4.3 Results

### *4.3.1 Initial survey*

A total of 1,420 research suggestions were submitted by 623 respondents. Eleven partner organisations (three patient organisations, eight anaesthetic specialist societies) submitted a further 56 suggestions, giving a total of 1,476 research suggestions.

Almost all individual respondents (98%) were aged between 25 and 75 years old (see Figure 2). Two hundred and eighty-eight (46%) identified as male, 323 (52%) as female, and 12 respondents (1.9%) did not disclose their gender identity.

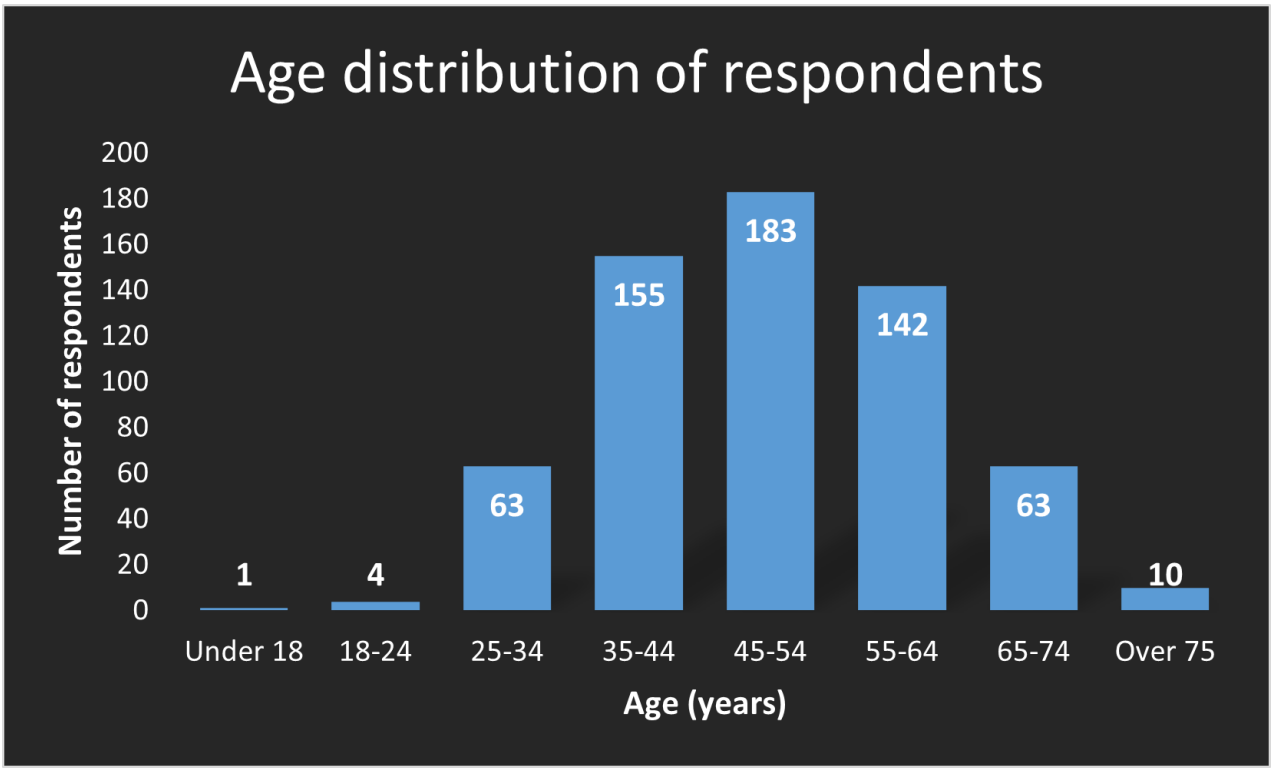


**Figure 2.** Age distribution of respondents to the initial APoC-PSP survey

The ethnic diversity of respondents was fairly similar to that of the UK population overall based on the 2011 England and Wales census data (see Figure 3).(127) Five hundred and twenty-seven respondents (85%) identified as 'White', 55 (8.8%) as 'Asian, Asian British or Asian Welsh', and 10 (1.6%) as 'Mixed or multiple ethnic groups', compared with 86%, 7.5% and 2.2% of the 2011 population of England and Wales respectively. However we observed a relative under-representation of respondents from 'Black, Black British, Black Welsh, Caribbean or African' (only six respondents, 0.96%, compared with 3.3% of the 2011 population) and 'Other ethnic groups' (only 1 respondent, 0.16%, versus 1.0% of the population).

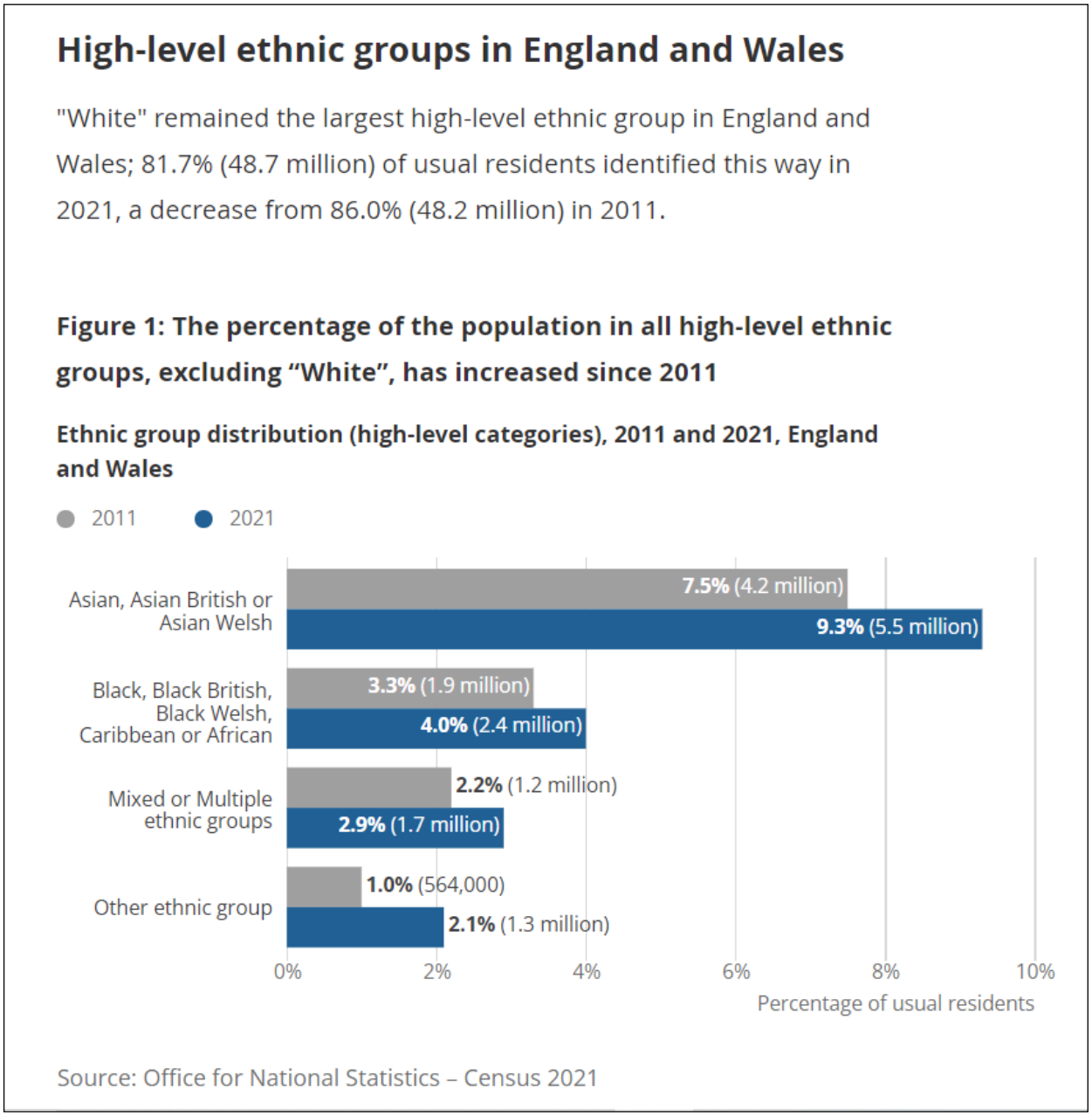


**Figure 3.** England and Wales resident population ethnicity data, 2011 and 2021 census

With regard to stakeholder groupings, 391 (63%) described themselves as HCPs, and 365 (59%) as service users (307 (49%) as patients with experience of surgery and/or anaesthesia, and 58 (9.3%) as carers). One hundred and thirty-three (34%) of the 391 HCPs also identified as a patient or carer, hence the total of HCPs and service users is greater than the number of respondents overall.

### *4.3.2 Classification of questions and development of longlist*

One hundred and fifty-one responses (10%) were deemed inadmissible by the SG and therefore excluded. Reasons for exclusion were ‘unclear suggestion’ (19); ‘duplicate response’ (29 suggestions); ‘outside scope’ (41); ‘no discernible research question’ (31); and, ‘generic healthcare question’ (31).

The remaining (valid) 1,325 research suggestions were compiled into a longlist and classified into themes by the SG subgroup, as shown in Figure 4.

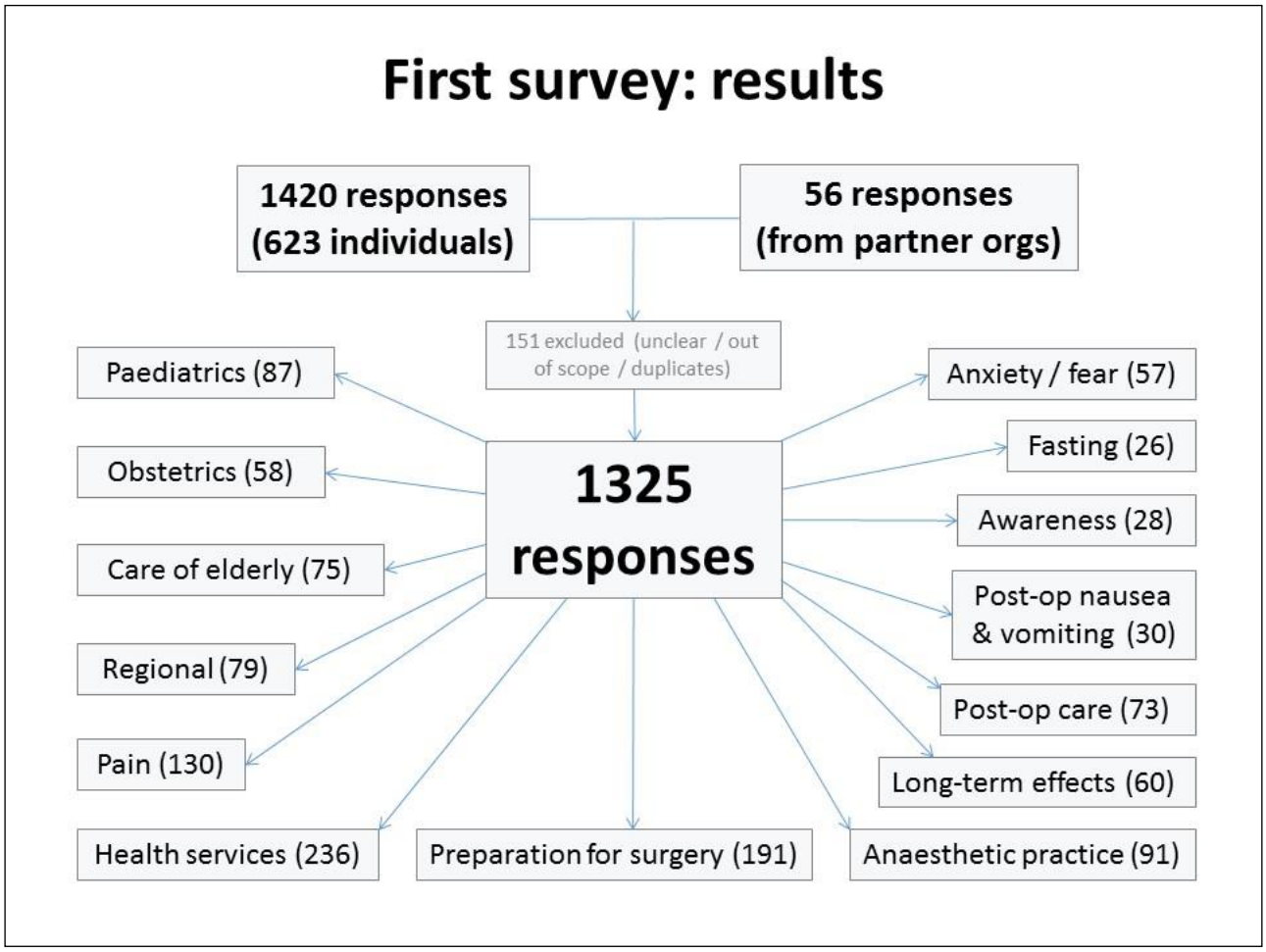


**Figure 4.** Classification of research suggestions submitted in the APoC-PSP’s initial ‘ideas-gathering’ survey

### *4.3.3 Development of the shortlist research questions*

The classified longlist of 1,325 original suggestions was subsequently refined into a shortlist of 92 summary questions divided into 16 broad themes, as listed below (Table 7), with the salient topic in each question highlighted in bold:

| Theme | Summary question |
|---|---|
| **MATERNITY** | How can **pain relief during childbirth** be improved? |
| **MATERNITY** | How do epidurals affect **progress and outcomes** of labour (childbirth), and how can **adverse effects** be minimised? |
| **MATERNITY** | How can detection and management of **maternal bleeding** during childbirth be improved? |
| **MATERNITY** | How do anaesthetic interventions during pregnancy or around the time of birth **affect the baby**? |
| **MATERNITY** | How can anaesthesia for **Caesarean sections** be improved? |
| **MATERNITY** | What anaesthetic strategies can reduce complications and deaths in **higher risk pregnancies**? |
| **CHILDREN** | How can we reduce **pain after surgery** in children and newborns? |
| **CHILDREN** | How can we **reduce anxiety** in children undergoing surgery? |
| **CHILDREN** | What are the effects of anaesthesia on the **developing brain**? |
| **CHILDREN** | How can **pre-operative assessment** for children be improved? |
| **CHILDREN** | How can we improve outcomes through **better monitoring** of children around the time of surgery? |
| **CHILDREN** | What **intravenous fluids** should we give children having surgery? |
| **CHILDREN** | What are the **long-term effects** of anaesthesia in babies? |
| **CHILDREN** | What can we do to improve outcomes for **higher risk children** having surgery? |
| **CHILDREN** | What is the best way to **organise anaesthetic and surgical services** for children? |
| **ELDERLY CARE** | How can the anaesthetic team improve outcomes for **hip fracture patients**? |
| **ELDERLY CARE** | How can we reduce the effects of anaesthesia on **brain function**, particularly in the elderly? |
| **ELDERLY CARE** | What are the consequences of **low blood pressure** around the time of surgery, particularly in the elderly? |
| **ELDERLY CARE** | How can we reduce the **risks** of anaesthesia in elderly patients? |
| **ELDERLY CARE** | How can we **improve recovery** from surgery for elderly patients? |

| | |
|---|---|
| **PERIOPERATIVE CARE DELIVERY** | How can protocols, guidelines, checklists and care pathways **improve the safety and effectiveness** of anaesthesia? |
| **PERIOPERATIVE CARE DELIVERY** | How can operating **theatre efficiency** be improved? |
| **PERIOPERATIVE CARE DELIVERY** | How can patient care around the time of **emergency surgery** be improved? |
| **PERIOPERATIVE CARE DELIVERY** | What is the best way to **organise specialist surgical services**? |
| **PERIOPERATIVE CARE DELIVERY** | How can **patient data** be used to improve perioperative care? |
| **PERIOPERATIVE CARE DELIVERY** | What **outcomes** should we use to **measure the 'success'** of anaesthesia and perioperative care? |
| **PERIOPERATIVE CARE DELIVERY** | How do we decide which **clinicians** should deliver the different elements of perioperative care? |
| **TRAINING** | How can we most effectively deliver training to improve **quality and safety** in anaesthesia and perioperative care? |
| **TRAINING** | Should anaesthetists receive more training on caring for patients with **specific medical problems** (eg Ehlers Danlos syndrome?) |
| **TRAINING** | Would greater use of **Physician's Assistants (Anaesthesia)** be beneficial? |
| **TRAINING** | What training or resources could improve perioperative care in **developing countries**? |
| **PAIN** | How can anaesthesia and pain relief be improved for patients with **Ehlers Danlos Syndrome**? |
| **PAIN** | How can pain control be improved in patients with **longstanding medical conditions**? |
| **PAIN** | How can we better **predict the severity** of pain immediately after surgery? |
| **PAIN** | How can we improve our use of **drugs** to provide better pain relief before and after surgery? |
| **PAIN** | How can we use **non-drug therapies** to provide better pain relief before and after surgery? |
| **PAIN** | How can we better **assess perioperative pain** in adults and children? |
| **PAIN** | What are the risk factors for developing **chronic pain** after surgery? |
| **PAIN** | What can we do to stop patients developing **chronic pain** after surgery? |
| **PAIN** | What can we do to reduce the **side effects** of pain relief medications? |
| **REGIONAL ANAESTHESIA** | What are the risks and benefits of **epidural and spinal injections** for major abdominal surgery? |
| **REGIONAL ANAESTHESIA** | How can the effectiveness of **epidural and spinal injections** be improved? |
| **REGIONAL ANAESTHESIA** | How do we improve **involvement of patients** in decision-making about regional anaesthesia? |

| | |
|---|---|
| **REGIONAL ANAESTHESIA** | How can the **effectiveness** of regional (local) anaesthetic techniques (other than epidural and spinal injections) be improved? |
| **REGIONAL ANAESTHESIA** | For **which patients** does regional (local) anaesthesia give **better outcomes** than general anaesthesia? |
| **REGIONAL ANAESTHESIA** | How can the **risks and side effects** of regional (local) anaesthesia be minimised? |
| **COMPLEMENTARY MEDICINE** | How can **acupuncture** be used to improve recovery from surgery? |
| **COMPLEMENTARY MEDICINE** | How can **hypnosis** help control anxiety and improve recovery around the time of surgery? |
| **COMPLEMENTARY MEDICINE** | How can complementary medicine **help with recovery** from surgery? |
| **COMPLEMENTARY MEDICINE** | How can **psychological techniques** improve post-operative patient outcomes and satisfaction? |
| **COMMUNICATION** | How can we improve communication **between the teams** looking after patients having surgery? |
| **COMMUNICATION** | How could we improve communication between **healthcare staff and patients** before and after surgery? |
| **COMMUNICATION** | How can we promote **compassion and empathy** among staff caring for patients having surgery? |
| **COMMUNICATION** | What are the benefits of increased **patient and carer involvement** in perioperative care? |
| **ACCIDENTAL AWARENESS** | What is the best method for monitoring the **depth of anaesthesia**? |
| **ACCIDENTAL AWARENESS** | How can accidental awareness under general anaesthesia be **detected and avoided**? |
| **ACCIDENTAL AWARENESS** | What is the best way to **reduce the harm** caused by accidental awareness under general anaesthesia if it occurs? |
| **LONG-TERM EFFECTS** | How can anaesthetic technique and perioperative care help reduce the risk of **cancer recurrence**? |
| **LONG-TERM EFFECTS** | What can be done to **speed up recovery** from anaesthesia? |
| **LONG-TERM EFFECTS** | What **long-term harm** may result from anaesthesia, in particular following **repeated anaesthetics**? |
| **ANXIETY / STRESS** | How can we **reduce** anxiety and stress **before** an operation? |
| **ANXIETY / STRESS** | How can we **reduce** anxiety and stress **at the start** of an anaesthetic? |
| **ANXIETY / STRESS** | How can we **reduce** a patient's anxiety and stress immediately **after** an operation? |
| **ANXIETY / STRESS** | What can we do to help patients with **needle phobia**? |
| **ANXIETY / STRESS** | Should patients routinely be offered **sedation for minor procedures**? |
| **PATIENT EXPERIENCE** | How can the patient's experience **before** surgery be improved? |
| **PATIENT EXPERIENCE** | What should be **discussed with patients** before surgery, and what is the best **setting** for this discussion? |

| | |
|---|---|
| **PATIENT EXPERIENCE** | How can we better implement fasting guidelines to avoid **excessive pre-operative fasting** and improve the patient experience? |
| **PATIENT EXPERIENCE** | How can better information improve patients' **expectations of pain** after surgery? |
| **PREPARING FOR SURGERY** | What **fasting guidelines** should patients follow before surgery? |
| **PREPARING FOR SURGERY** | How can we improve medical assessment to determine the **risk of harm** after surgery? |
| **PREPARING FOR SURGERY** | How can **pre-operative assessment** for adults be improved? |
| **PREPARING FOR SURGERY** | How can **patient education programmes** improve outcomes after surgery? |
| **PREPARING FOR SURGERY** | How can **weight loss programmes** improve outcomes after surgery? |
| **PREPARING FOR SURGERY** | How can preoperative **nutritional modifications** improve outcomes after surgery? |
| **PREPARING FOR SURGERY** | How can preoperative **exercise or fitness training**, including physiotherapy, improve outcomes after surgery? |
| **PREPARING FOR SURGERY** | Does treating **pre-operative anaemia** improve outcomes after surgery? |
| **PREPARING FOR SURGERY** | How should a patient's **existing drug regime** be modified before and after surgery? |
| **ANAESTHETIC PRACTICE** | How can we minimise the **risk of physical injury** in patients undergoing anaesthetic? |
| **ANAESTHETIC PRACTICE** | How can the anaesthetist help reduce the risk of **complications after surgery**? |
| **ANAESTHETIC PRACTICE** | What is the best choice of **intravenous fluids** to improve outcomes after surgery? |
| **ANAESTHETIC PRACTICE** | How can we better detect and treat **major bleeding**? |
| **ANAESTHETIC PRACTICE** | Does **cardiac output monitoring** improve outcomes after surgery? How can we improve cardiac output monitoring? |
| **ANAESTHETIC PRACTICE** | How can we make **airway management** safer? |
| **RECOVERING FROM SURGERY** | What causes **nausea and vomiting** after surgery? |
| **RECOVERING FROM SURGERY** | How can we **prevent nausea and vomiting** after surgery? What is the **best treatment** if it occurs? |
| **RECOVERING FROM SURGERY** | What is the **impact of nausea and vomiting** after surgery on a patient's overall recovery? |
| **RECOVERING FROM SURGERY** | How can we **reduce complications** (adverse events) after surgery? |
| **RECOVERING FROM SURGERY** | Does post-operative **intensive care** improve outcomes in **higher risk patients** having major surgery? |
| **RECOVERING FROM SURGERY** | How should we **plan discharge** from hospital after surgery, and what would help patients recover at home after discharge? |

| | |
|---|---|
| **RECOVERING FROM SURGERY** | How can we **improve patient recovery** from surgery? |
| **RECOVERING FROM SURGERY** | How can we minimise the **side effects** patients experience after surgery and anaesthesia? |
| **RECOVERING FROM SURGERY** | Do **enhanced recovery programmes** (fast track surgery to speed up patient recovery) improve short and long-term outcomes? |

**Table 7.** Shortlist of summary research questions for the APoC-PSP interim prioritisation survey

### *4.3.4 Literature reviews*

Following the literature reviews of published research, 61 (66%) of the 92 shortlist questions were judged ‘unanswered’, 31 (34%) as ‘partly answered’, and none as fully answered. There were no additional questions arising from either the literature reviews or from expert advice that were not already included within the shortlist questions. All 92 questions were therefore included in the interim prioritisation survey, and no new ones were added.

### *4.3.5 Interim Prioritisation*

The interim prioritisation survey was completed by 1,718 respondents, of whom the vast majority (98%) were again aged 25 to 75 (see Figure 5). Six hundred and twenty-eight (37%) described themselves as service users, while 1,393 respondents (81%) identified as HCPs – 325 of whom (23%) also identified as service users.

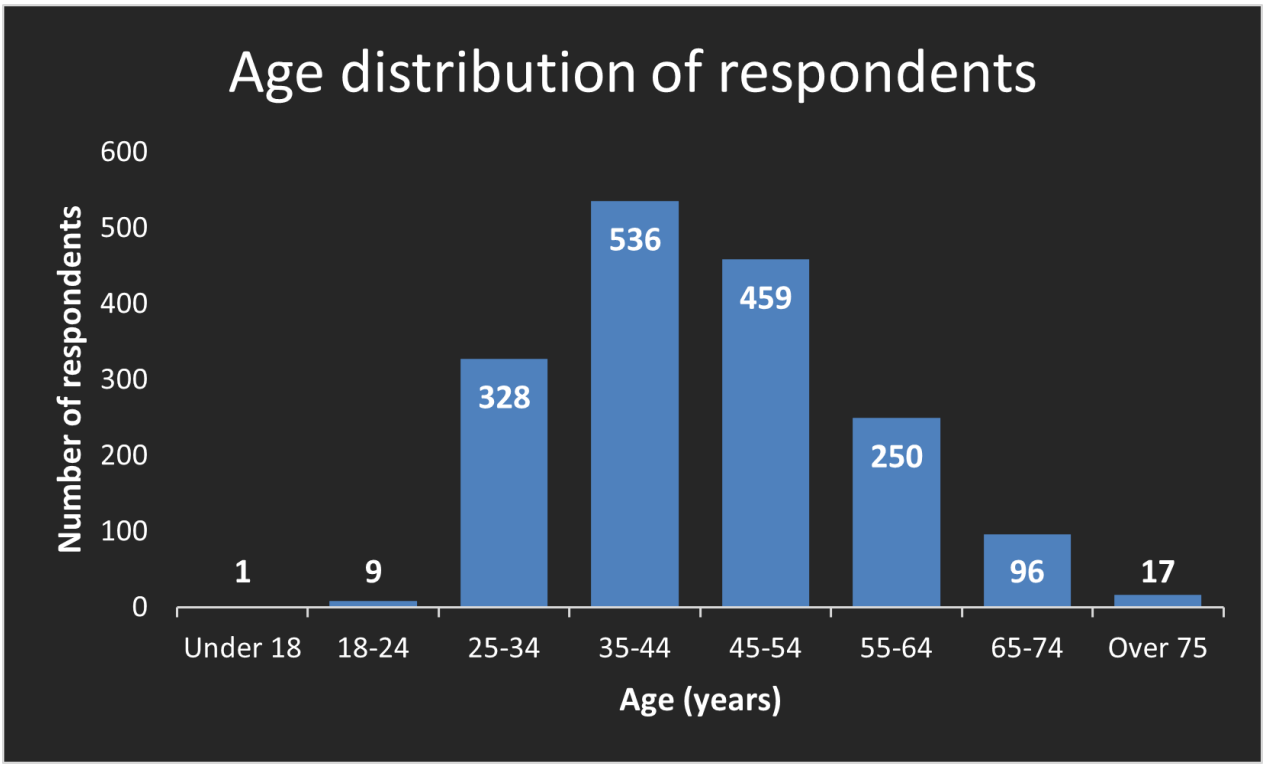


**Figure 5.** Age distribution of respondents to the APoC-PSP second (prioritisation) survey

Because the number of HCP responses was more than double that of service users, service users' responses were double counted to achieve a more evenly balanced final representation of HCP and service user views, as per JLA guidance described earlier. Nominations for each question were then totalled, and the most popular 25 questions (those with the most nominations overall) selected for the final workshop. These 25 highest-ranked research questions, and their respective rankings from HCPs and service users, are shown in Table 8.

All 25 questions had been nominated by both HCP and service user respondents, with no questions meeting the threshold for removal described previously (i.e. receiving >90% of its nominations from only one stakeholder group). The largest skew observed for any single question was 70% of nominations from HCPs, 30% service users (one question); all others were closer to 50:50.

| Research question | Overall rank | HCP rank | Service user rank | Theme |
|---|---|---|---|---|
| How can we reduce the effects of anaesthesia on **brain function**, particularly in the elderly? | 1 | 3 | 1 | **ELDERLY CARE** |
| For **which patients** does regional (local) anaesthesia give **better outcomes** than general anaesthesia? | 2 | 1 | 5 | **REGIONAL ANAESTHESIA** |
| How can preoperative **exercise or fitness training**, including physiotherapy, improve outcomes after surgery? | 3 | 5 | 3 | **PREPARING FOR SURGERY** |
| Do **enhanced recovery programmes** (fast track surgery to speed up patient recovery) improve short and long-term outcomes? | 4 | 2 | 14 | **RECOVERING FROM SURGERY** |
| What **outcomes** should we use to **measure the 'success'** of anaesthesia and perioperative care? | 5 | 4 | 12 | **PERIOPERATIVE CARE DELIVERY** |
| Does post-operative **intensive care** improve outcomes in **higher risk patients** having major surgery? | 6 | 7 | 7 | **RECOVERING FROM SURGERY** |
| What are the effects of anaesthesia on the **developing brain**? | 7 | 9 | 4 | **CHILDREN** |
| What are the consequences of **low blood pressure** around the time of surgery, particularly in the elderly? | 8 | 8 | 11 | **ELDERLY CARE** |
| What **long-term harm** may result from anaesthesia, in particular following **repeated anaesthetics**? | 9 | 12 | 2 | **LONG-TERM EFFECTS** |
| Does **cardiac output monitoring** improve outcomes after surgery? How can we improve cardiac output monitoring? | 10 | 6 | 33 | **ANAESTHETIC PRACTICE** |
| What can we do to stop patients developing **chronic pain** after surgery? | 11 | 13 | 8 | **PAIN** |
| How can the anaesthetist help reduce the risk of **complications after surgery**? | 12 | 11 | 17 | **ANAESTHETIC PRACTICE** |
| How can we **reduce complications** (adverse events) after surgery? | 13 | 17 | 13 | **RECOVERING FROM SURGERY** |
| How can we **improve recovery** from surgery for **elderly patients**? | 14 | 19 | 9 | **ELDERLY CARE** |
| How can operating **theatre efficiency** be improved? | 15 | 10 | 27 | **PERIOPERATIVE CARE DELIVERY** |

| | | | | |
|---|---|---|---|---|
| What should be **discussed with patients** before surgery, and what is the best **setting** for this discussion? | 16 | 28 | 6 | **PATIENT EXPERIENCE** |
| How can we improve **communication between the teams** looking after patients having surgery? | 17 | 27 | 10 | **COMMUNICATION** |
| How can we most effectively deliver training to improve **quality and safety** in anaesthesia and perioperative care? | 18 | 18 | 19 | **TRAINING** |
| How can anaesthetic technique and perioperative care help reduce the risk of **cancer recurrence**? | 19 | 16 | 28 | **LONG-TERM EFFECTS** |
| What is the best choice of **intravenous fluids** to improve outcomes after surgery? | 20 | 15 | 32 | **ANAESTHETIC PRACTICE** |
| How can patient care around the time of **emergency surgery** be improved? | 21 | 14 | 37 | **PERIOPERATIVE CARE DELIVERY** |
| How can we reduce the **risks** of anaesthesia in elderly patients? | 22 | 21 | 23 | **ELDERLY CARE** |
| How can **pre-operative assessment** for adults be improved? | 23 | 20 | 35 | **PREPARING FOR SURGERY** |
| How do epidurals affect **progress and outcomes** of labour (childbirth), and how can **adverse effects** be minimised? | 24 | 24 | 30 | **MATERNITY** |
| How can we **improve patient recovery** from surgery? | 25 | 34 | 18 | **RECOVERING FROM SURGERY** |

**Table 8.** The 25 highest-ranked questions from the APoC-PSP interim prioritisation survey

### *4.3.6 Final Prioritisation Workshop*

Twenty-three delegates attended the final workshop (13 HCPs, 10 service users), which was facilitated by three independent JLA advisers. The final 'Top Ten research priorities' agreed and ratified by all delegates is shown in Table 9.

During the final plenary discussion, all representatives unanimously agreed that the priorities should not be ranked in any order of importance, as there was no clear consensus highlighting any as obvious favourites across all participants.

| |
|---|
| What can we do to stop patients developing **chronic pain** after surgery? |
| How can patient care around the time of **emergency surgery** be improved? |
| What **long-term harm** may result from anaesthesia, particularly following **repeated anaesthetics**? |
| What **outcomes** should we use to **measure the 'success'** of anaesthesia and perioperative care? |
| How can we **improve recovery** from surgery for **elderly patients**? |
| For **which patients** does regional (local) anaesthesia give **better outcomes** than general anaesthesia? |
| What are the effects of anaesthesia on the **developing brain**? |
| Do **enhanced recovery programmes** (fast-track surgery to speed up patient recovery) improve short and long-term outcomes? |
| How can pre-operative **exercise or fitness training**, including physiotherapy, improve outcomes after surgery? |
| How can we improve **communication between the teams** looking after patients throughout their surgical journey? |

**Table 9.** The APoC-PSP's final top ten research priorities for Anaesthesia and Perioperative Care

## 4.4 Discussion

The APoC-PSP achieved its two principal aims of bringing together patients, carers and clinicians to identify and prioritise unanswered questions for research in anaesthesia and perioperative care, and agreeing a set of 'top ten' research priorities. However, several aspects of the JLA methodology deserve scrutiny. In this section, I discuss strengths and limitations of the APoC-PSP, and ambiguities about its legacy.

### *4.4.1 Strengths*

The APoC-PSP's main strengths were its stakeholder inclusivity, and the transparency of its methods. Almost two thousand stakeholders – around a third of whom were service users – contributed to this consensus process; no previous research priority setting exercise in Anaesthesia or related specialties (including the ICM-PSP described earlier) has achieved this order of service user engagement. Furthermore, the range and balance of stakeholder representation demonstrated that the APoC-PSP was significantly more inclusive than the NIAA's earlier exercise in 2008-9.

A second strength of the APoC-PSP was its funding and endorsement across a wide spectrum of specialist anaesthetic societies and other professional bodies. The stakeholder collaboration promoted by the JLA-recommended process was echoed by the collaboration between different Anaesthesia- and/or Perioperative Medicine-focused organisations in supporting this JLA-led initiative and agreeing in advance to promote and endorse its results.

### *4.4.2 Limitations*

#### 4.4.2.1 JLA methodology

While the JLA guidance aims to maximise objectivity and transparency at all stages of the process, various aspects nonetheless may allow inadvertent bias to creep in. For example, during the initial set-up phase – which includes activity such as defining the scope, engaging relevant stakeholders and choosing SG members – we aimed for diverse representation, but may have inadvertently introduced potential biases by virtue of which partner organisations affiliated, and which vested research interests were represented or absent on the SG.

Later stages of the JLA process also entail arguably subjective judgments. Classification of initial suggestions, removal of out-of-scope suggestions, and construction of a shortlist of 'summary' research questions all required some degree of manipulation of the initial 'raw' research suggestions. On a similar note, how information is presented (such as the wording of a research question, or its prominence relative to other competing questions) may affect how survey respondents and workshop participants perceive it, and – by extension – how much consideration they give it.

We attempted to minimise such biases and subjectivity by making all such decisions collectively within the SG (or the subgroup who classified research questions and compiled the shortlist). Similarly, we tried to give all questions equal prominence both in the second survey (where the order of questions was automatically reversed for consecutive respondents) and for the final workshop (by jumbling up how questions were presented for each small group); however, such biases can never be fully eliminated from a consensus process such as this.

Thirdly, condensing similar primary suggestions into broader summary questions necessarily entailed a loss of detail and granularity. Such decisions were again made collectively by the SG; while some SG members expressed misgivings about removing specific details from individual research suggestions, most felt the broad-ranging nature of the resulting summary questions was a strength of PSP methodology, since the PSP's ultimate purpose was to identify important topics for future research rather than generate rigid research hypotheses.

This process of reducing large amounts of raw free text data to more manageable chunks of summarised data leads to perhaps the biggest potential flaw in the PSP process: namely, the tendency for detail to be lost in increasingly vague generalisations. In a wide-ranging PSP like the APoC-PSP, the JLA process risks producing unfocused research priorities that are insufficiently granular to generate research hypotheses, merely restating research aspirations that are arguably relevant for almost any planned trial. For example, most perioperative research studies might at least partly address the research priority *'How can we improve recovery from surgery for elderly patients?'*, unless their remit fell exclusively within paediatric or obstetric surgery.

#### 4.4.2.2 Stakeholder representation

In a simlar vein, while JLA methodology aims to maximise inclusivity and breadth of stakeholder representation, the 'reach' of any PSP depends on the success of efforts to publicise it. Similarly, the responses received (and hence the results) depend on which stakeholder group(s) view and respond to these efforts. Given the extremely broad range of theoretically eligible stakeholders in the APoC-PSP (since almost anyone may become a surgical patient), and the more than 5 million patients who have an intervention under

anaesthesia in the UK every year,(128) even 2,000 respondents is arguably a very modest sample of the relevant stakeholder population.

Furthermore, much has been written about the challenges of engaging ‘hard to reach’ groups who may face economic, cultural, educational and/or pragmatic barriers to participation.(129-131) Frequently underrepresented groups whose voices may not be adequately heard in participatory research such as the APoC-PSP include ethnic minorities, non-English speakers, those with lower levels of educational attainment, internet poverty, neurodiversity, socioeconomic deprivation, and social isolation.(132-134) Physical and/or mental health disability, and work commitments may similarly prevent participation, particularly for the face-to-face elements such as the final workshop.

The importance of achieving their input to PSPs is underscored by the increasing recognition that socioeconomic deprivation is a risk factor for poor outcomes from healthcare interventions,(135) and that black and minority ethnic communities suffer worse health across multiple domains (such as diabetes, kidney failure and mental health).(136-138) Including viewpoints from hard-to-reach groups is therefore essential to ensuring comprehensive stakeholder representation.

Like many other PSP’s, we found that elderly and ethnic minority service users (who are disproportionately likely to need surgery, and whose views we were therefore particularly keen to include) were underrepresented in our responses. With hindsight, different strategies may have been required to achieve greater participation from these groups. The underrepresentation of these groups also calls into question the APoC-PSP’s claim to represent a definitive consensus regarding important research topics across all stakeholders.

#### 4.4.2.3 Dissemination

A final limitation of the APoC-PSP was the limited time and resources allocated to dissemination and publicisation. Although the APoC-PSP received all necessary funding and professional support of the Anaesthetic specialist societies up to its completion, no explicit strategy for promoting the results was developed, and nor did the SG fully consider the importance of dissemination efforts until after the final workshop.

In the years since its completion, the APoC-PSP's research priorities have perhaps received less attention among funders and researchers than might have been hoped before its inception. However, appraising the consequences of this oversight is difficult, and despite the lack of a formal dissemination plan, the research priorities remain visible among the main funders of perioperative research, and are frequently cited in research funding applications and reports of published research. I shall explore the APoC-PSP's impact and legacy further in my final chapter.

### *4.4.3 Did the JLA approach to research priority setting affect the results?*

While the APoC-PSP's goal was to generate an agreed set of research priorities, it did not explicitly appraise their content or character. In the next chapter, I therefore examine the research priorities themselves, comparing them with those from the NIAA's first research priority setting exercise in 2009, and exploring similarities and differences between service users and clinicians. Following on from the comparison of the two different ICM research priority exercises' outputs (see Chapter 2), I will test the following two hypotheses:

- Collaboration between service users and HCPs in setting APOM research priorities produces different priorities than expert-led processes.
- Service users and HCPs prioritise similar topics in APOM research

# *Chapter 5: The APoC-PSP's research priorities explored*

## 5.1 Introduction

This chapter is divided into two parts. The first compares and contrasts the research priorities generated from the two APoC research priority exercises (RPEs) – i.e. the NIAA-RPE described in Chapter 2, and the APoC-PSP described in Chapter 4. Qualitative content analysis is used to explore similarities and differences between the outputs of each exercise and offer possible explanations for them.

The second part examines differences observed in the APoC-PSP between the views of clinicians and service users (patients and carers) regarding important research priorities. Data from the interim prioritisation survey (in which respondents chose their ten most important research questions from a shortlist of 92) was explored to compare the relative popularity of each of the 92 shortlist research questions in the PSP's prioritisation survey between HCPs and service users.

## 5.2 Comparison of research priorities between the APoC-PSP (2014-5) and the NIAA-RPE (2008-9)

### *5.2.1 Background*

Although the benefits of involving patients and carers in setting research priorities are increasingly recognised, the influence of service user involvement on the final output is unclear. The examples from Chapter 2 of research agenda setting for asthma and cancer, and the outputs from the ICM-PSP, suggest that service user participation significantly affects the research priorities generated, by highlighting topics that service users care about which might be overlooked if research priorities were selected purely by researchers. We therefore compared the NIAA-RPE's results with those of the APoC-PSP, to examine the effect of service user involvement on research priority setting in APOM.

### *5.2.2 Methods*

Content analysis was used to describe the main research topics and themes contained within the NIAA-RPE's fourteen headline research priorities and the APoC-PSP's top ten research priorities. Similarities and differences between the main themes were presented in a side-by-side comparison, with research priorities from each RPE arranged into three groups according to the degree of similarity or overlap (high, moderate or low).

A framework analysis was also performed for the research priorities arising from the two RPEs, in which each research priority was alongside the three 'Darzi' domains of healthcare quality (clinical effectiveness, safety, and patient experience).(121) Research questions were coded according to which of these three quality domain(s) they addressed (tables 11 and 12), and the frequency of each domain across the headline priorities from each RPE compared. The aim of this framework analysis was to test the first hypothesis elaborated at the end of the previous chapter:

- Collaboration between service users and HCPs in setting APOM research priorities produces different priorities than expert-led processes.

### *5.2.3 Results*

**Content analysis (Table 10)**

Four of the NIAA-RPE's research priorities addressed very similar topics to four of the APoC-PSP's top ten research priorities. These similar research topics are highlighted in bold in Table 10. A moderate degree of similarity was considered to exist between one question from each RPE (both alluding to improving patient care for emergency surgery), and also between a broad-ranging research priority from the APoC-PSP (regarding recovery after surgery in elderly patients) and five of the NIAA-RPE priorities, which all referenced improving perioperative outcome or reducing perioperative harms. Four questions from both RPEs were designated 'low degree of overlap' as there was no obvious similarity in the topics they addressed.

| NIAA-RPE (2008-9) | APoC-PSP (2014-5) |
|---|---|
| ***High degree of similarity*** | |
| Does a brief period of **preoperative exercise training improve outcomes** after major surgery? | How can **pre-operative exercise or fitness training**, including physiotherapy, **improve outcomes** after surgery? |
| What interventions prevent the development of **chronic pain** after surgery? | What can we do to stop patients developing **chronic pain** after surgery? |
| Does an **enhanced perioperative care package** improve outcomes? | Do **enhanced recovery programmes** (fast-track surgery to speed up patient recovery) improve short and long-term outcomes? |
| Does the use of **locoregional anaesthesia** prevent cancer recurrence? | For which patients does **regional (local) anaesthesia** give better outcomes than general anaesthesia? |
| ***Moderate similarity*** | |
| What perioperative management strategies improve outcome in head injury? | How can patient care around the time of emergency surgery be improved? |
| Would actively targeting preoperative blood pressure in the intraoperative period reduce the incidence of postoperative complications? | How can we improve recovery from surgery for elderly patients? |
| Would higher nurse to patient ratios during the first 48h after operation reduce the complication rate after major abdominal surgery? | |
| Does conventional (as opposed to tight) glycaemic control improve perioperative outcome? | |
| What interventions can prevent perioperative cardiac complications? | |
| What is the place of 'anti-neuropathic' pain medications in the treatment of postoperative pain? | |
| ***Low similarity*** | |
| What are the best arrangements for the preoperative assessment of elective surgical patients? | How can we improve communication between the teams looking after patients throughout their surgical journey? |
| What is the impact of same day surgery on primary care? | What outcomes should we use to measure the 'success' of anaesthesia and perioperative care? |
| How should patients for day surgery and 23 h surgery be selected? | What long-term harm may result from anaesthesia, particularly following repeated anaesthetics? |
| Under what circumstances should aspirin be discontinued in the postoperative period? | What are the effects of anaesthesia on the developing brain? |

**Table 10.** Comparison between research priorities from the NIAA-RPE and the APoC-PSP

**Framework analysis (Tables 11 and 12)**

All fourteen research priorities (100%) from the NIAA-RPE were judged as relating to research to improve clinical effectiveness of perioperative care (Table 11). Five (36%) also proposed interventions or investigations to improve patient safety; while three priorities (21%) concerned interventions to improve perioperative patient experience.

The APoC-PSP's research priorities echoed this emphasis on clinical effectiveness, with eight research questions (80%) addressing interventions to improve the effectiveness of care, three (30%) addressing patient safety concerns, and two (20%) pertaining to patient experience of care in the postoperative period (Table 12).

| Research question | Healthcare quality domain(s) addressed |
|---|---|
| What interventions can prevent perioperative cardiac complications? | Clinical effectiveness |
| Does a brief period of preoperative exercise training improve outcomes after major surgery? | Clinical effectiveness |
| What perioperative management strategies improve outcome in head injury? | Clinical effectiveness |
| What interventions prevent the development of chronic pain after surgery? | Clinical effectiveness; patient experience |
| Does an enhanced perioperative care package improve outcomes? | Clinical effectiveness |
| Under what circumstances should aspirin be discontinued in the postoperative period? | Clinical effectiveness; patient safety |
| Would actively targeting preoperative blood pressure in the intraoperative period reduce the incidence of postoperative complications? | Clinical effectiveness; patient safety |
| Does conventional (as opposed to tight) glycaemic control improve perioperative outcome? | Clinical effectiveness |
| What is the place of 'anti-neuropathic' pain medications in the treatment of postoperative pain? | Clinical effectiveness; patient experience |

| | |
|---|---|
| What are the best arrangements for the preoperative assessment of elective surgical patients? | Clinical effectiveness; patient experience |
| Would higher nurse to patient ratios during the first 48 h after operation reduce the complication rate after major abdominal surgery? | Clinical effectiveness; patient safety |
| What is the impact of same day surgery on primary care? | Clinical effectiveness; patient safety |
| How should patients for day surgery and 23 h surgery be selected? | Clinical effectiveness; patient safety |
| Does the use of locoregional anaesthesia prevent cancer recurrence? | Clinical effectiveness |

**Table 11.** Domain(s) of healthcare quality addressed in the NIAA-RPE research priorities

| **Research question** | **Healthcare quality domain(s) addressed** |
|---|---|
| What can we do to stop patients developing **chronic pain** after surgery? | Clinical effectiveness; patient experience |
| How can patient care around the time of **emergency surgery** be improved? | Clinical effectiveness |
| What **long-term harm** may result from anaesthesia, particularly following **repeated anaesthetics**? | Patient safety |
| What **outcomes** should we use to **measure the 'success'** of anaesthesia and perioperative care? | Clinical effectiveness |
| How can we **improve recovery** from surgery for **elderly patients**? | Clinical effectiveness; patient experience |
| For **which patients** does regional (local) anaesthesia give **better outcomes** than general anaesthesia? | Clinical effectiveness |
| What are the effects of anaesthesia on the **developing brain**? | Patient safety |

| | |
|---|---|
| Do **enhanced recovery programmes** (fast-track surgery to speed up patient recovery) improve short and long-term outcomes? | Clinical effectiveness |
| How can pre-operative **exercise or fitness training**, including physiotherapy, improve outcomes after surgery? | Clinical effectiveness |
| How can we improve **communication between the teams** looking after patients throughout their surgical journey? | Clinical effectiveness; patient safety |

**Table 12.** Domain(s) of healthcare quality addressed in the APoC-PSP research priorities

### *5.2.4 Discussion*

This analysis demonstrates considerable similarity in the overall results of these two distinct RPEs. Although the NIAA-RPE included only a small contribution from non-clinicians, they were conducted barely five years apart, and both processes employed similar consensus methods based on prioritisation of candidate topics according to their popularity among a large number of respondents. The HCP respondents in each exercise also consisted overwhelmingly of anaesthetists: although we were unable to track precisely where our respondents came from, it is likely that many of the same individuals contributed to both exercises. It is therefore perhaps not surprising that at least some of the original 'most popular' research topics were still popular (despite new research results appearing in the interim) a mere half decade later.

Similarly, the research questions produced in both RPEs clearly prioritised research addressing clinical effectiveness most highly, followed by research to address patient safety issues, and finally research seeking to improve patient experience of perioperative care. However, it is worth noting that the theme of communication appears in the APoC-PSP but not the NIAA-RPE, echoing the ICM-PSP in which the theme 'comfort/ communication/ psychological' appeared in 42% of service users' research suggestions but only 17% of those from HCPs.(120) Improving communication in healthcare thus emerges as a 'hot' research topic for service users in both PSPs, but less so for clinicians.

This comparison between the headline research priorities from each RPE may not in itself provide much insight into why the outputs turned out as they did. However, the broad similarity between the outputs of the two APOM RPEs contrasts with the ICM RPEs, in

which the research priorities from the HCP-led ICS-RPE were without exception aimed at improving clinical effectiveness, with no attention to patient experience, whereas the ICM-PSP produced research priorities with significant attention to patient experience.

Why, then, does service user involvement in ICM research priority setting appear to produce priorities addressing both clinical effectiveness and patient experience, whereas service user participation in research priority setting for Anaesthesia and perioperative care appears to have only modest impact on the ensuing research priorities? The data here provides scope only for speculation – there is insufficient detail to support any theories to explain the similarities observed – but the difference may be attributable firstly to the greater time lapse between the two ICM RPEs (fifteen years, compared with the 5-6 years between the NIAA-RPE and the APoC-PSP), and secondly the participant populations who contributed to the exercises.

Regarding HCPs, ICM clinicians may be more 'science-hungry' than anaesthetists and perioperative HCPs, working as they do in a discipline whose boundaries are dependent on new scientific breakthroughs, and where promising new interventions may improve survival in an extremely sick patient population. It is perhaps unsurprising, then, that an RPE involving only ICM HCPs produces research priorities focused almost exclusively on clinical effectiveness. Anaesthesia and Perioperative Care, in contrast, is less frequently a matter of life and death: in fact the relative rarity of catastrophic patient outcomes and the importance placed on avoiding patient harm may explain why the HCP-led NIAA-RPE produced at least some research priorities that also addressed patient safety and patient experience.

Meanwhile patients and carers who have been through an Intensive Care admission have frequently experienced a long and possibly harrowing period of extreme stress with significant long-term emotional and psychological sequelae.(139, 140) This frequently traumatic experience may explain why ICM service users prioritise research aiming to improve their experience. In contrast, undergoing surgery – while often also a significant life event for patients and their families – usually affects patients and their relatives over a shorter timeframe, and may (though not always) therefore have a less traumatic impact on their lives than an unplanned ICU admission. Surgery is also in many cases a proposed cure or solution for a defined medical problem, whereas an ICU admission may involve several concurrent problems. Users of perioperative services may therefore value

research that improves the chance of successful surgery (i.e. clinical effectiveness) more highly than research to improve their perioperative experiences.

### *5.2.5 Conclusion*

In summary, the above comparisons suggest that the APoC-PSP, which explicitly fostered collaboration between patients, carers and clinicians to agree research priorities, did not yield a fundamentally different set of research priorities from the earlier NIAA-RPE. This contrasts with the ICM-PSP, which (as discussed in Chapter 3) generated research priorities with significantly more emphasis on improving patient experience than the ICS-led RPE, whose research priorities almost exclusively focused on improving clinical effectiveness.

## 5.3 Comparison between service users' and clinicians' research priorities from the APoC-PSP

### *5.3.1 Background*

The mismatch observed in other areas of health research between service users' and HCPs' research priorities was discussed in Chapter 2. Echoing this finding, the APoC-PSP SG noted anecdotally at various stages of the APoC-PSP that certain research topics appeared more popular with service users than with HCPs, and vice versa. Secondary post-hoc analyses were therefore conducted to determine whether service user contributors to the APoC-PSP had different research priorities from HCP contributors. Our null hypothesis for these analyses was as follows:

- Service users and HCPs prioritise similar topics in APOM research

### *5.3.2 Methods*

This analysis explored the results of the APoC-PSP's second prioritisation survey, which asked respondents to choose their ten most important research questions from a shortlist of 92 summary research questions (which were based on the original suggestions received in the first survey).

For the purposes of this analysis, respondents were categorised into three mutually exclusive groups:

- Service users (patients and/or carers)
- Healthcare professionals (HCPs) with no experience of anaesthesia or perioperative care as a patient or carer
- 'Healthcare professional – service users' (HCP-SUs) i.e. healthcare professionals who also had experience of anaesthesia and/or perioperative care as a patient or carer

The 92 shortlist questions for the prioritisation survey were categorised by the APoC-PSP SG according to which domain(s) of healthcare quality (clinical effectiveness, patient safety, or patient experience) they addressed. Questions that were deemed to address more than one domain, or where there was disagreement regarding which domain(s) they addressed, were excluded from this analysis, since its principal purpose was to explore whether certain domains of research were more popular with specific stakeholder groups.

For the remaining *single domain* research questions, we then conducted two separate analyses:

1) To determine **between-group differences in the relative popularity of questions in each domain**. For this analysis, we compared the mean number of votes for questions within each domain, and then calculated the likelihood of members of each group voting for a question within each domain. We also compared the relative popularity of questions in each domain with different groups by exploring which questions were more popular with a) HCPs than service users; b) HCP-SUs than service users; c) HCPs than HCP-SUs.

2) To identify domains where questions with **highly skewed responses** were most frequently observed. We defined highly skewed response as any question where

the proportion of votes from one group was *more than double* that of at least one other group. (For example, if 50% of HCPs but only 22% of HCP-SUs and 20% of service users voted for a particular question, the question would be categorised as highly skewed). Comparing questions with highly skewed responses allowed us to identify domains with the biggest between-group differences.

Unpaired student's t-tests were used to compare mean number of votes per question between groups; chi-squared tests were used to compare differences in proportions between groups.

### *5.3.3 Results*

The prioritisation survey received responses from 1,718 participants, of whom 1,068 were HCPs (62%), 303 were service users (18%), and 325 were HCP-SUs (19%). Twenty-two respondents (1.3%) did not provide information about which stakeholder group they belonged to. (Table 13)

| Respondent category | Number (%) |
|---|---|
| HCPs | 1,068 (62%) |
| Service users | 303 (18%) |
| HCP-SUs | 325 (19%) |
| No response (missing data) | 22 (1.3%) |
| **All respondents** | **1,718 (100%)** |

**Table 13.** Categorisation of respondents to the second (prioritisation) APoC-PSP survey

The 92 research questions were classified by the APoC-PSP SG as follows: 66 (72%) relating to clinical effectiveness; 46 (50%) addressed patient experience; 28 (30%) addressed patient safety (see Appendix 2). Fifty questions (54%) addressed a single domain only, whereas 42 (46%) addressed two or more, and were therefore excluded from

this analysis. Of the 50 ‘single domain’ questions, 25 (50%) related to clinical effectiveness, 19 (38%) to patient experience, and six (12%) to patient safety.

#### 5.3.3.1 Between-group differences in popularity of questions in each domain

Mean (SD) total votes for questions in each healthcare quality domain are shown by group in Table 14. Across all 1,718 respondents, the most popular research questions were those addressing patient safety, which received a mean of 256 votes each, followed by questions addressing clinical effectiveness, (mean 211 votes each), and finally questions addressing patient experience (mean 85 votes per question). HCPs and HCP-SUs voted significantly more frequently for clinical effectiveness and patient safety questions, but significantly less frequently for patient experience research questions, compared to service users (all $p<0.0001$, chi-squared test).

| Quality domain | All respondents (n=1,718) | HCPs (n=1,068) | Service users (n=303) | HCP-SUs (n=325) |
|---|---|---|---|---|
| Clinical effectiveness | 211 (115) | 145 (88) | 25 (16) | 40 (22) |
| Patient experience | 85 (39) | 40 (22) | 29 (18) | 15 (7) |
| Patient safety | 256 (114) | 167 (68) | 33 (20) | 55 (30) |

**Table 14.** Mean (SD) votes received for questions in each domain in the APoC-PSP prioritisation survey

Table 15 displays the relative preference of HCPs, service users and HCP-SUs for questions within each domain, based on the calculated likelihood of a randomly selected member of each group voting for a question within that domain. The same data is shown in Figure 6, illustrating that service users are less likely than HCPs or HCP-SUs to vote for clinical effectiveness and patient safety questions, but more than twice as likely to vote for patient experience questions.

| Quality domain | All respondents (n=1,718) | HCPs (n=1,068) | Service users (n=303) | HCP-SUs (n=325) |
|---|---|---|---|---|
| Clinical effectiveness | 12.28% | 13.58% | 8.25% | 12.31% |
| Patient experience | 4.95% | 3.75% | 9.57% | 4.62% |
| Patient safety | 14.90% | 15.64% | 10.89% | 16.92% |

**Table 15.** Percentage likelihood of a respondent voting for any single question in each domain, illustrating the relative preferences of each group for questions in each domain in the second (prioritisation) APoC-PSP survey

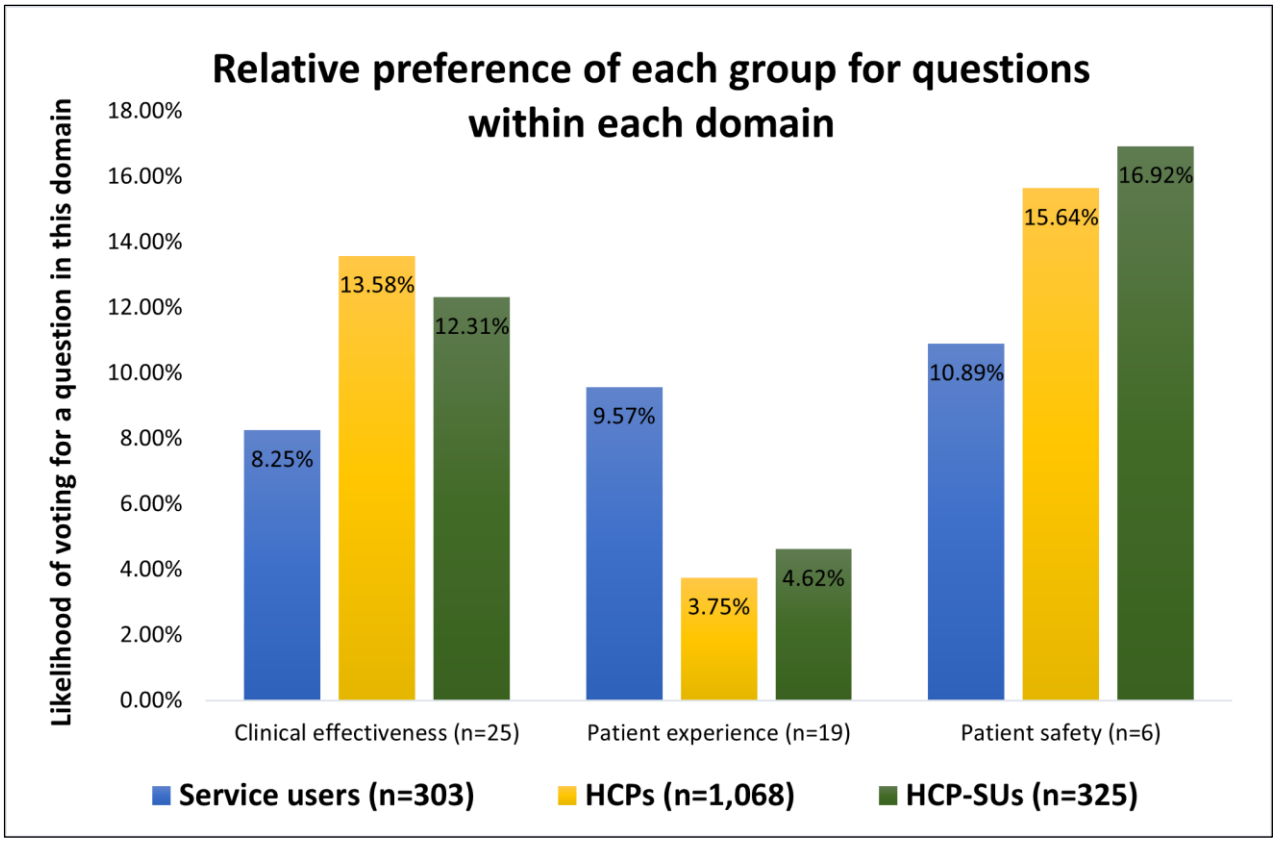


**Figure 6.** Relative preference of each group for questions within each domain, APoC-PSP second (prioritisation) survey

Regarding the relative popularity of questions in each domain, the vast majority (21 questions, or 84%) of the 25 clinical effectiveness questions were more popular with HCPs than service users (p=0.00067, Chi-squared). Nineteen (76%) also received proportionally more votes from HCP-SUs than from service users (p=0.0093). However no significant difference was found between HCP-SUs and HCPs (p=0.16).

In contrast, all but one (95%) of the 19 patient experience questions received proportionally more votes from service users than HCPs (p<0.0001). Fifteen (79%) were also rated more highly by service users than by HCP-SUs (p=0.012).

However, no significant between-group differences were found regarding the popularity of the six questions addressing patient safety. This comparison is summarised in Table 16.

| Quality domain | Proportion of votes from each group | | |
|---|---|---|---|
| | **HCPs > Service users** | **HCP-SUs > Service users** | **HCPs > HCP-SUs** |
| Clinical effectiveness questions, n=25 | 21 (84%) | 19 (76%) | 16 (64%) |
| Patient experience questions, n=19 | 1 (5%) | 4 (21%) | 4 (21%) |
| Patient safety questions, n=6 | 5 (83%) | 5 (83%) | 3 (50%) |

**Table 16.** Between-group comparison of relative popularity of questions within each domain, based on proportion of votes received from each group in the second (prioritisation) APoC-PSP survey

#### 5.3.3.2 Questions with highly-skewed responses

Twenty-one questions (42%) of the 50 single-domain questions considered in this analysis received a skewed response. Eleven (52%) related to clinical effectiveness, and ten (48%) to patient experience. None pertained to patient safety. Eight of the clinical effectiveness questions (73%) were over twice as popular with both HCPs and HCP-SUs as with service

users; two (18%) were over twice as popular with HCPs as with service users, and one (concerning anaesthetic training) was more popular with service users than HCPs or HCP-SUs.

Meanwhile all ten patient experience questions (100%) were more than twice as popular with service users as with HCPs and HCP-SUs. The 21 highly-skewed questions are shown in Table 17, with the group(s) for which that question was more than twice as popular highlighted in grey.

| Research questions | Stakeholder group | | |
|---|---|---|---|
| | Service users (n=303) | HCPs (n=1,068) | HCP-SUs (n=325) |
| **Clinical effectiveness questions** | | | |
| 1. Should anaesthetists receive more training on caring for patients with specific medical problems? | 66 (22) | 20 (2) | 13 (4) |
| 2. Would greater use of Physician's Assistants (Anaesthesia) be beneficial? | 11 (4) | 82 (8) | 22 (7) |
| 3. Do enhanced recovery programmes (fast track surgery to speed up patient recovery) improve short and long-term outcomes? | 35 (12) | 299 (28) | 70 (22) |
| 4. What outcomes should we use to measure the 'success' of anaesthesia and perioperative care? | 28 (9) | 278 (26) | 81 (25) |
| 5. What is the best way to organise anaesthetic and surgical services for children? | 8 (3) | 77 (7) | 40 (12) |
| 6. How can operating theatre efficiency be improved? | 9 (3) | 203 (19) | 67 (21) |
| 7. For which patients does regional (local) anaesthesia give better outcomes than general anaesthesia? | 35 (12) | 319 (30) | 82 (25) |
| 8. How can weight loss programmes improve outcomes after surgery? | 12 (4) | 105 (10) | 26 (8) |

| | | | |
|---|---|---|---|
| 9. Does treating pre-operative anaemia improve outcomes after surgery? | 19 (6) | 139 (13) | 47 (15) |
| 10. Does cardiac output monitoring improve outcomes after surgery? How can we improve cardiac output monitoring? | 15 (5) | 284 (27) | 57 (18) |
| 11. What is the best way to organise specialist surgical services? | 6 (2) | 62 (6) | 19 (6) |
| **Patient experience questions** | | | |
| 12. How can complementary medicine help with recovery from surgery? | 25 (8) | 13 (1) | 9 (3) |
| 13. How can psychological techniques improve post-operative patient outcomes and satisfaction? | 30 (10) | 41 (4) | 16 (5) |
| 14. How could we improve communication between healthcare staff and patients before and after surgery? | 76 (25) | 63 (6) | 17 (5) |
| 15. How can we promote compassion and empathy among staff caring for patients having surgery? | 58 (19) | 48 (5) | 20 (6) |
| 16. How can we reduce anxiety and stress before an operation? | 64 (21) | 46 (4) | 20 (6) |
| 17. How can we reduce anxiety and stress at the start of an anaesthetic? | 16 (5) | 28 (3) | 8 (3) |
| 18. How can we reduce a patient's anxiety and stress immediately after an operation? | 22 (7) | 8 (1) | 3 (1) |
| 19. Should patients routinely be offered sedation for minor procedures? | 26 (9) | 12 (1) | 9 (3) |
| 20. How can the patient's experience before surgery be improved? | 29 (10) | 22 (2) | 9 (3) |
| 21. How can better information improve patients' expectations of pain after surgery? | 36 (12) | 54 (5) | 18 (6) |

**Table 17.** Skewed responses observed in the APoC-PSP prioritisation survey: number (%) of respondents from each group who voted for each question

### *5.3.4 Discussion*

Some clear common ground was observed between the research priorities nominated by HCPs, service users and HCP-SUs, with all three groups prioritising patient safety research most highly. However, HCPs and HCP-SUs preferred research relating to clinical effectiveness over research to improve patient experience, whereas service users valued improving patient experience more highly than clinical effectiveness. The 19 patient experience research questions were (with one exception) all more popular with service users than with HCPs, and over half of these were more than twice as popular (i.e. fulfilling our criteria for a 'skewed' response). Meanwhile the six patient safety questions, although more popular overall with HCPs and HCP-SUs than with service users, appear to have received more evenly balanced support, with no significant differences in popularity observed between groups.

Voting behaviour within the HCP-SU group was much more closely aligned with that of HCPs than service users – that is, HCPs who also have experience as service users are more 'HCP-like' in their responses. Differences between the HCP-SU and service user groups were generally slightly smaller, however, than between HCPs and service users.

### *5.3.5 Interpretation*

While it is impossible to draw firm conclusions regarding the reasons for these findings, various possible explanations arise. Firstly, that (perhaps unsurprisingly) service users and HCPs tend to prioritise research topics according to their own perspectives. For patients and carers, their experience of care may matter as much as its effectiveness: they want treatment to be successful, but they also want the experience to be positive, or at least minimally traumatic or unpleasant. For HCPs, providing the most effective care possible to their patients may be more important than how the patient experiences the care they provide.

Similarly, this finding likely reflects the nature of healthcare training (which traditionally emphasised the scientific aspects of diagnosis, measurement, treatment, and acquiring clinical skills) and of the medical profession's primary focus on curing disease and ill

health. While communications skills and holistic approaches to patient care feature more prominently in contemporary medical and nursing training than they did historically, it is likely that many HCP and HCP-SU respondents to the APoC-PSP surveys were trained in a healthcare culture that prized clinical effectiveness more than patient experience.

The finding that HCPs with experience as service users tend to respond primarily as HCPs rather than as service users may likewise reflect their personal perspectives. Many of this group are likely to have been predominantly HCPs with occasional service user experience; and while some may have been HCPs living with chronic health conditions themselves and/or who fulfil a carer role alongside their HCP role, many will have experienced healthcare mainly as HCPs rather than as service users. Moreover, even those HCPs with extensive experience as patients or carers may prefer to view themselves (and hence priorities for research) in the empowering role of professional expert than the arguably more vulnerable role of patient or carer.

The apparent consensus between groups regarding the popularity of patient safety research may reflect a basic recognition that healthcare systems should always strive to minimise avoidable harm. For most HCPs, this sentiment runs deep: non-maleficence is one of the fundamental principles of medical ethics. Personal experience of patient safety events in the workplace – which may cause moral injury to the staff involved – may impact HCPs personally in a way that more abstract concepts (such as reducing postoperative complications) may not. For service users, the fear and mistrust engendered by recent high profile patient safety failures in the NHS have brought patient safety into the public consciousness. These fears may be all the more prescient in APOM, where patients are required to place great trust in the surgeons performing their operations, and the anaesthetists anaesthetising them, to keep them safe.

## 5.4 Conclusion

Returning to my original hypotheses of the start of the chapter, the comparison between outputs of the NIAA-RPE and the APoC-PSP does not support the hypothesis that collaboration between service users and HCPs produces substantively different APOM

research priorities than expert-led processes. However, various factors cast some doubt on this conclusion. Firstly, the significant differences observed between the outputs of the ICS-led RPE and the ICM-PSP respectively; secondly, the likely considerable overlap between contributors to the original NIAA-RPE and the later APoC-PSP (meaning that many of the same views may have been put forward in both exercises); and thirdly the modest time period between the data-gathering phases of each RPE.

With regard to the second hypothesis – that service users and HCPs prioritise similar topics in APOM research – the above analysis shows that, while patient safety research is viewed as an important priority by all stakeholder groups, significant differences exist between service users and HCPs regarding research addressing clinical effectiveness and patient experience. HCPs are more likely to prioritise research focusing on improving clinical effectiveness, whereas service users are more likely to prioritise research addressing patient experience. This conclusion has important ramifications for research agenda setting: failure to include either of these groups risks overlooking, or at least underestimating the importance of, research priorities that matter more to that stakeholder group.

In the next chapter, I explore free text comments submitted in the first APoC-PSP survey to gain further insights into stakeholder views about improving perioperative patient experience.

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# *Chapter 6: Qualitative analysis of free text comments from the APoC-PSP first survey: insights into perioperative patient experience*

## 6.1 Introduction

This chapter explores additional insights into perioperative patient experience that emerged from free text comments submitted in the APoC-PSP's initial 'ideas-gathering' survey. The survey asked respondents to suggest up to three possible research questions, with an opportunity to elaborate in a free text box. During the process of reviewing and classifying research suggestions, several SG members felt that respondents' free text comments, while not specifically suggesting a research topic, offered valuable insights into aspects of perioperative care they considered important, including detailed personal reflections on their own individual experiences.

While these comments were not explicitly incorporated in the shortlist of summary research questions, the SG felt that these personal narratives contained worthwhile learning opportunities for enhancing service users' experiences of perioperative care, and that a separate 'analysis of themes' arising from these comments was warranted.

### *6.1.1 The relevance of patient experience in healthcare research*

Countless examples in the literature exist of exploring patient perspectives to understand, and thereby improve, service users' experiences of healthcare. The justification for this research is that – in addition to emerging evidence that patient experience correlates with clinical outcomes and patient safety (141) – the patient's experience of healthcare is an important measure of healthcare quality in its own right, as stated in the 2008 Darzi review.(121)

While improving patient experience is itself increasingly viewed as a desirable endpoint, many commentators have highlighted other benefits associated with positive patient experience. Patients reporting positive experiences of healthcare also experience better health outcomes,(142-144) use less healthcare resource,(145) and are more likely to adhere to medical advice, preventive health measures and medication.(146) High ratings

for patient experience are also beneficial for healthcare providers, being consistently linked to better staff retention and patient loyalty.(147) Finally, positive patient experience is associated with fewer patient complaints and litigation.(148, 149)

The increased emphasis on patient experience (rather than just on clinical outcomes) also extends to patients having major surgery.(150) In fact, the growing appreciation of major surgery as a pathway of care – indeed, a 'perioperative journey' rather than a single event – has increased the focus on patient experience as an integral part of that journey.(151-153)

Although the APoC-PSP's main purpose was not explicitly to explore perioperative patients' experiences, the SG agreed that the insights into patient experience potentially contained within the free text comments should be explored further. A qualitative analysis was therefore undertaken, with the aim of identifying additional important aspects of service users' perioperative care experiences and suggestions for improvement that were not captured in respondents' research suggestions.

## 6.2 Methods

Respondents to the ideas-gathering survey were categorised into the same three stakeholder groups as for the comparison described above, i.e. HCPs, service users, and HCP-SUs (i.e. HCPs also with experience as patients and/or carers). Three separate datasets were thus produced. However, because the aim of this qualitative analysis was to gain insights into the perioperative experiences of patients and their carers informed by their personal perspectives, the HCP dataset was not analysed. Thus only the two datasets consisting of free text comments from service users and HCP-SUs were examined.

A thematic content analysis was conducted for each dataset using a data-driven, inductive approach (i.e. with themes 'emerging' from the data, rather than applying pre-specified labels or themes), as described below. Having undertaken local training in qualitative research methods, the main author followed a step-wise process of analysis to extract underlying themes and ideas voiced in the free text comments.(154) The step-wise

analysis process used nVivo software (version 12.0) and was similar to that described in other qualitative analyses of free text responses to healthcare surveys:(155-157)

- Thorough familiarisation with each dataset through careful reading and re-reading of all free text comments.

- In order to gain a broad overview of the range of sentiments expressed, basic sentiment analysis was applied to all comments by assigning a single, mutually exclusive ‘sentiment’ code. These were ‘positive’, ‘negative’, ‘containing both positive and negative elements’, or ‘neutral’. Only elements relating to patient experience were considered; therefore those comments which discussed an aspect(s) of patient care or anaesthesia with no bearing on patient experience were designated ‘unrelated to patient experience’, and were excluded from further analysis.

- Preliminary ‘second order’ codes (i.e. short phrases to encapsulate the specific details or concepts raised in each comment) were then assigned to each comment to develop a ‘work-in-progress’ codebook. Comments were tagged with these codes when a particular concept was voiced either explicitly or implicitly: for example, the code ‘Hospital environment’ was applied to both 'The ward wasn’t cleaned properly’ and ‘One patient even had a TV on all night’. The number of second order codes assigned to each comment was not limited: thus some comments which raised multiple issues were tagged with multiple codes.

- All provisionally coded comments in the dataset were then re-checked against this preliminary codebook, with the preliminary codes being refined and/or adjusted – and some comments recoded as necessary – as the analysis progressed. Where certain distinct themes appeared within a particular code, new codes and/or subcodes were created. This process continued until all comments within the dataset had been coded.

- The comments tagged under each code were examined for coherence, i.e. to check that they all mentioned, or at least referred to, the theme in question. Incorrectly classified comments or chunks of text were recoded as necessary.

- Similar second order codes were grouped into ‘overarching themes’ or categories.

- A second qualitative research expert then checked a proportion (around 10%) of the coded comments; the two researchers discussed the final arrangement of codes and themes until agreement was reached.
- Codes and themes – and their relative frequencies – were summarised, and relevant examples extracted to illustrate each one.

## 6.3 Findings

The ideas-gathering survey was completed by 623 respondents, of whom 232 (37%) were service users and 133 were HCP-SUs (21%). One hundred and six (46%) service user respondents (46%) and 61 (also 46%) HCP-SUs submitted free text comments. The sentiment categorisation of the comments from each group as 'positive', 'negative', 'both positive and negative', 'neutral' or 'unrelated to patient experience' is shown in Table 18.

| Sentiment expressed | Number of comments (%) assigned to each sentiment | | |
|---|---|---|---|
| | **Service users (n=106)** | **HCP-SUs (n=61)** | **Total (n=167)** |
| **Positive** | 2 (1.9%) | 2 (3.2%) | 4 (2.5%) |
| **Negative** | 59 (56%) | 16 (26%) | 74 (46%) |
| **Both positive and negative** | 19 (18%) | 4 (6.6%) | 23 (14%) |
| **Neutral** | 22 (21%) | 22 (36%) | 40 (25%) |
| **Unrelated to patient experience** | 5 (4.7%) | 19 (31%) | 22 (14%) |

**Table 18.** Sentiment codes assigned to free text comments submitted in the APoC-PSP first survey

Five service user comments (4.7% of all service user comments) and 19 HCP-SU comments (31%) did not relate to patient experience and were therefore excluded from further analysis.

The majority of service users' comments were negative in sentiment, whereas HCP-SUs' comments were more often neutral. Service users' comments often contained personal reflections explaining why they thought the research they'd proposed was important, whereas HCP-SUs' comments occasionally contained personal reflections from their perspective as service users, but more often cited observations from their experience as HCPs to explain their suggestions for improving patient experience. HCP-SU comments were generally less emotive in tone, and appeared to draw less frequently on personal experience of trauma or distress than on their observations of patients having surgery and perioperative care.

The main topics and themes relating to patient experience elicited from the free text comments, and their respective frequencies, are summarised in Table 19. These themes are then further explored using specific examples.

| Overarching theme | Specific theme | Service user comments (n, %) | HCP-SU comments (n, %) |
|---|---|---|---|
| **Interactions with healthcare staff and/or environment** | Communication and/or information issues | 79 (75%) | 13 (21%) |
| | (Lack of) compassion and/or empathy from healthcare staff | 17 (16%) | 2 (3.2%) |
| | (Not) being listened to, feeling 'dismissed' or unheard | 17 (16%) | 1 (1.6%) |
| | Variability/inconsistency of care | 21 (20%) | 5 (8.2%) |
| | (Lack of) joined up care between HCPs and/or organisations | 20 (19%) | 0 (0%) |
| | Patient choice, autonomy, empowerment, and involvement in care decisions | 23 (22%) | 4 (6.6%) |

| | | | |
|---|---|---|---|
| | Issues with the hospital and/or other healthcare environment | 13 (12%) | 1 (1.6%) |
| | Excessive pre-operative fasting and/or waiting times | 2 (1.9%) | 4 (6.6%) |
| **Postoperative recovery** | Postoperative comfort/discomfort (including pain and nausea) | 25 (24%) | 15 (25%) |
| | Postoperative confusion, agitation and/or disorientation | 14 (13%) | 2 (3.3%) |
| | Medium to long term postoperative recovery issues | 40 (38%) | 8 (13%) |
| **Worries, concerns and anxieties** | Anxiety, psychological distress, or specific worries about anaesthesia/surgery | 43 (41%) | 4 (6.6%) |
| | Concerns about patient safety and/or risks of patient harm | 13 (12%) | 14 (23%) |

**Table 19.** Topics and themes relating to patient experience in free text comments submitted by respondents to the APoC-PSP first survey

### *6.3.1 Interactions with healthcare staff and/or environment*

#### Communication and/or information issues

Three-quarters of service users' (though less than a quarter of HCP-SUs') comments highlighted issues relating to perioperative communication and information. These ranged from staff not communicating at all with patients, or communication that was deficient (for example, perceived as overly rushed, jargon-laden, unsympathetic or belittling). Inadequate explanation, lack of information, feeling 'fobbed off', not being able to speak to the 'right' person, not being updated or appraised of progress in their care, and not having adequate opportunity to ask questions or voice concerns were all commonly reported.

Inconsistent messages from different staff, or perceived failure of communication and/or information sharing between different healthcare staff, were also highlighted. Furthermore, service users often described the negative consequences of poor communication – such

as increased anxiety, or 'losing faith' in the quality of care provided – and the positive effects of good communication, such as reassurance and peace of mind. Examples from service users included:

- *'I wasn't aware what anaesthesia would be used, nor post-operative pain relief. I was assured that I would be pain-free, but not the detail.'*
- *'Although the nursing, anaesthetic and consultant staff were generally fine, the first person I met was hostile and said that's your bed no 3 and then just pointed. Apart from being rude it made me anxious about my treatment…'*
- *'In my wife's case [cancelled operation], they failed to notify me of what was happening to her and, after the department was closed, it was very difficult to find out.'*
- *'Many patients would be more reassured if they could speak to the surgeon and anaesthetist who actually performed [the operation].'*
- *'Many people are confused by the terminology used and due to apprehension, fear or embarrassment, often fail to ask for clarification. Plain English is rarely used in medical settings and this can lead to additional anxiety for patients.'*
- *'Body language! It is not always what is said to the patient that gives the wrong impression.'*
- *'Many patients contact the College [of Anaesthetists] for advice because they have been unable to get helpful information from their GPs… they do not seem to think it is their remit to explain anaesthesia, possible side effects and what to expect before and after the operation to their patients.'*
- *'In hospital, and particularly outside hospital, there are many departments who are just not connected'*
- *'The anaesthetists told me every step they were doing and made me very relaxed.'*

Examples from HCP-SUs included:

- *'Often procedures are poorly explained; is the surgery going to help improve the problem; what risk is the patient prepared to accept for the possible outcome from surgery?'*

**(Lack of) compassion and/or empathy from healthcare staff**

Some service users reported appreciation of the kindness they experienced from healthcare staff, but several also provided vivid and distressing reports of indifference when they sought help, for example:

- *'I had minor surgery under local anaesthetic when I was 14, and the doctor thought I was 'making a fuss' when I shrieked with pain as he put the scalpel in…'*
- *'Where was the care? I was very confused, still in pain… I can't remember any TLC, drinks etc. why not? It's a big operation, I was told, and the HCA was far from helpful'*
- *'I have watched the compassion and caring deteriorate relentlessly over the years… it is a horrible feeling to have to FIGHT for everything, in an environment that is otherwise so uncaring and dismissive.'*
- *'I had a doctor come up to me with the expression 'oh god, I've got to see that one'…'*

One HCP-SU, however, provided a positive example of compassionate care:

- *'I had a superb anaesthetist for a major operation of 8 hours – she said something very simple at the time of being induced which made me totally relaxed - "My job is to keep you safe and I will''*

**(Not) being listened to, feeling 'dismissed' or unheard**

Instances of having their concerns dismissed, ignored or belittled were described with understandable bitterness and by some service users. Many of these implied a sense that medical staff 'thought they knew better', and in many cases, a consequent lack of trust in the people and/or system caring for them:

- *'When I had a cancer operation at [hospital name], the Anaesthetist totally ignored me when I twice told her I had had polio, and as a consequence I suffered from effects for the next two months'*
- *'I am also disappointed that there was NO follow up immediately after his discharge to see if he was coping with pain. It was almost impossible to get anyone to take ANY notice'*
- *'I always have a bad recovery from anethesia… I always end up on oxygen and with a very slow pulse rate... I feel that no one listens'*
- *'At last someone had actually listened to me and helped me'*

Meanwhile one HCP-SU echoed these feelings:

- *'We advised the surgeon and anaesthetist that my mum had been a difficult anaesthetic patient an had a DVT before and she tended not to follow regular patterns of other patients. We were ignored'*

**Variability/inconsistency of care**

Many patients and carers described the variable standard of care they'd received, both within a single admission and between different episodes at different hospitals. All of these comments described discrepancies in the degree of caring and compassion demonstrated by the staff looking after them, with words like 'wonderful' and 'marvellous' used to describe the positive experiences, contrasting with words like 'rude', 'terrible', 'hostile' and 'far from helpful' for the negative experiences:

- *'I had a wonderful surgeon and team pre and post op, but had not received this wonderful care at previous operations (albeit different hospitals) – but I believe we should be aiming for a universal standard of care throughout the country.'*
- *'As his partner, I am upset by the varying quality of care he received whilst in hospital.'*
- *'[I received] nutritional and physiotherapy advice which I found wonderful concerning bowel surgery, but sometimes conflicting or otherwise inadequate after a joint bowel and gynaecological operation'*

HCP-SUs also highlighted variability in care, for example:

- *'Patients with abdominal surgeries often struggle with pain, but only selected patients get seen by physiotherapists'*
- *'Whilst some hospitals offer pre operative assessment with an anaesthetist or an anaesthetic nurse, not all patients are offered pre op assessments'*

**Lack of joined-up care between HCPs and/or organisations**

Several service users complained about the lack of coordination between different healthcare providers. Sometimes these referred to absence of follow-up, or information sharing; others felt that support provided in hospital should have continued beyond

hospital discharge. These comments gave an overall impression of lack of confidence in the healthcare system as a whole and fear of 'falling through the cracks' when transitioning between healthcare providers, for example:

- *'Local Health visitors, Clinical Care Nurses, Oncologists, dieticians, GP's, GP based nurses, relaxation therapists, mobility specialists etc. So many disconnected resources and each does not know what the other is doing…'*
- *'Seldom are bad experiences from previous operations considered in future operations.'*
- *'Lots of patients go home not knowing what exercises they can / can't do, or without good support to help them do exercise to aid recovery even if they do know'*
- *'The care I received from all staff at the hospital during my two knee replacement operations in 2011 was excellent – but I felt some aspects could have carried on once I was home: e.g. I would have benefitted from more structured physiotherapy.'*

**Patient choice, autonomy, empowerment and involvement in decision making**

Several patients described not being sufficiently involved in decisions about their care, not being given all the available options, and failure to discuss the risks and benefits of the proposed treatment. These shortcomings were reported both regarding decisions about surgery itself, and anaesthetic choices:

- *'I'm not convinced that micro surgery was the best option for me but wasn't offered open surgery.'*
- *'Why are there not more options to a full general anaesthetic?'*
- *'Look at "the bigger picture" – i.e. not just assume that either the patient should have the operation, regardless of the impact upon them as a whole, or that an operation isn't worthwhile because the person isn't going to be cured (but may have a better quality of life).'*
- *'I have needle phobia, so I kept asking to be anaesthetised without injections. Sometimes they were okay with this… but sometimes they just refused and it gave me a lot of distress'*
- *'Patients are not involved enough or asked what they would like.'*

HCP-SUs also echoed these concerns, for example:

- *'Some patients prefer to be treated locally rather than in distant tertiary centres, but aren't given the option'*

### Issues with the hospital and/or other healthcare environment (n=14)

Several service users described problems with the hospital physical environment, and the negative impact it had on their healthcare experience. These ranged from general impressions that the hospital environment was unwelcoming, to specific issues like not being allowed visitors, the ward being too cold, noisy or unclean, or finding the hospital environment confusing and disorienting:

- *'When visiting my husband after operations - unless he has been fortunate enough to have a room on his own – the general noise and disruption on the ward makes it hard to relax and sleep'*
- *'The written instructions said friends etc were not allowed in… but I discovered that everyone else had partners there'*
- *'Patients' cases were put in lockers, but the unit closes before some patients return from theatre, so they are left overnight without their suitcase, or all weekend if it is a Friday afternoon.'*
- *'[Patients were] pushed around like cattle in the day case unit, then expected to WALK to the operating theatre, and then expected to get up an hour after surgery and be well enough to push off home…'*

### Excessive pre-operative fasting and/or waiting on day of surgery

Two service users and four HCP-SUs highlighted detrimental effects of excessive fasting, both in terms of patient experience (through increasing discomfort and anxiety) and clinically, for example by risking dehydration. Examples of such comments included:

- *'16 hours without anything to drink resulted in late diagnosis of dehydration and still being in the recovery area after out-patients had closed'*
- *'I was starved from midnight the day before and hung around the ward for hours as I did not go to theatre until late morning.Some others were less fortunate as it was well into the afternoon before they had their ops.I feel this is a long time to go without nutrition and*

*hydration and for some it is unnecessary. Anxiety levels are also raised during this waiting period'*

HCP-SU comments included:

- *'Long all day lists with minimal perioperative staff lead to frustation from patients'*
- *'NBM is still too long for elective work, causing patient discomfort'*
- *'Most elective patients are fasted for longer than necessary, probably to their detriment. How can the barriers to this be addressed?'*

### *6.3.2 Postoperative recovery issues*

**Postoperative comfort/discomfort including pain, nausea**

Several service users described distressing pain experiences postoperatively. Pain severity, failure to respond promptly and/or with effective analgesia, and the distress they suffered were common features in almost all these accounts, for example:

- *'Morphine not working after hysterectomy so I was in immense pain; no anaesthetist to talk to - "gone home"'*
- *'My epidural came out in recovery and wasn't dispensing the right amount of pain relief. After fixing it several times it was removed and a morphine pump driver used instead. It took a while for the team to establish what was happening…'*
- *'In the night I was left in severe pain while waiting for oramorph which I had requested…'*

HCP-SUs also highlighted concerns about the management of postoperative pain, for example:

- *'A lot of patients are expecting analgesia, when we should be communicating that some pain is not a sign of something going wrong'*
- *'My daughter had knee surgery for a dislocated patella, was told she would have no pain on waking… but woke SCREAMING in agony for hours'*

**Postoperative confusion, agitation or disorientation**

Some comments recalled frightening experiences of postoperative confusion, and the distress it caused to both patients and carers. Various comments suggested that confusion could be reduced by improving patients' access to familiar faces and environments, for example:

- *'[My husband] thought the nurses were conspiring against him, plotting to kill him, and he "saw" them kill the man opposite. He didn't dare sleep at night… It was one of the more anxiety producing aspects of the whole thing'*
- *'Other [patients] on the ward were raving, hallucinating and becoming aggressive which was quite frightening'*
- *'I spent 7 days in ITU totally disorientated – I think a sun lamp would have helped keep my body clock in sync'*

Two HCP-SUs also described the distress caused by confusion and agitation:

- *'I suspect much of the disorientation and 'confusion' seen in elderly patients is because we don't take the trouble to understand how much we and their environment isolates them from their coping mechanisms'*
- *'While in hospital, my father lost track of time. He might have realised it was still winter and not July had he been able to see the snow on the ground. He might've also had a better appreciation of the passing of time, had the clock on the wall not been permanently stopped at 3.20.'*

**Medium to long term postoperative recovery issues**

Several patients and carers described challenges in their longer-term postoperative recovery, often alluding to some aspect of recovery which was unexpectedly difficult. Physical, psychological and emotional sequelae were all highlighted, as were both short-term and longer-term recovery issues – though even those that mentioned short-term recovery problems implied a significant long-term impact on the patient's wellbeing. Included in this theme were comments expressing concern about possible long-term harms from anaesthesia:

- *'Even after a successful outcome of the surgery itself, there can be significant issues related to recovery… related to long term effects of the drugs employed … and the invasion of the body in major surgery'*

- *'I find that once discharged you feel very alone and unsure about things to be worried about.'*
- *'[Surgery] left me with core muscles that were cut through, meaning walking, standing and climbing stairs was a major issue especially after being discharged from hospital 2 weeks to the day of my surgery. I'm still waiting for physio 6 months later'*
- *'After surgery I was shocked at how weak I was, I could barely sit up and could not stand. This was scary to me. It would have been helpful to have known before that this would be the case, and how long it would take to resolve... I really fear this awful feeling again and know I face more surgery in the future'*
- *'Each time after surgery I have noticed my memory seems to be less reliable, I am concerned that this could be the result of the anaesthesia given.'*

HCP-SUs' comments also highlighted concerns about long-term postoperative recovery, for example:

- *'Most people have a joint replacement because of pain or immobility. Surely what is most important is the long term outcome/pain?'*

### *6.3.3 Worries, concerns, fears and anxieties*

#### Anxiety, perioperative psychological distress, or specific worries about anaesthesia/surgery

Many service users voiced a wide range of anxieties and fears arising at various stages of their perioperative experience. These included feeling vulnerable, loss of autonomy, being disempowered, not knowing what was happening, being confused about what was normal and what was a cause for concern, and a generalised sense of heightened anxiety throughout their perioperative journey:

- *'My surgical epidural came out in recovery… it took a while for the team to establish what was happening and caused me and my family considerable concern.'*
- *'Having had many different operations in my life, I still get more anxious each time a new operation is needed. Talking to staff has not always helped…'*
- *'We [the RCoA] have received numerous queries from patients who are seriously concerned about anaesthesia…'*

- *'It would have been better if someone said what sensations commonly happen and not to worry.'*
- *'It was a long time to go without nutrition and hydration, and for some it is unnecessary. Anxiety levels are also raised during this waiting period.'*

HCP-SUs also commented on the adverse psychological effects of increased anxiety, for example:

- *The whole experience [not knowing what's normal] is very damaging to patients at a time they are at their most vulnerable and need the most support'*

**Concerns regarding patient safety and/or risks of patient harm**

Both service users and HCP-SUs voiced concerns about aspects of care they felt was unsafe or risky, including patients being discharged from hospital too quickly after an operation (or into their usual home environment where support available during recovery might be inadequate), and concerns that reliable information about allergies or reactions to drugs during previous anaesthetics was frequently not available.

- *'It's impossible to monitor patients effectively for pain management at home [after early discharge]'.*
- *'I have had three anaesthetics in the past year and know they have had trouble every time, but the next anaesthetist cannot find the information in my notes?'*
- *'If [elderly patients] were picked up from hospital by the care agency that normally looks after them in their own home, it would be a friendly face and they would feel more relaxed about going home and they would feel safe…'*
- *'Often, patients are discharged home prematurely, without adequate support in place.'*
- *Documenting allergies: sometimes myths get propagated like codeine makes me constipated and so I am allergic. Often patients don't know what they're truly allergic to'*

## 6.4 Discussion

Although this survey was not designed to gather insights into patient experience, several respondents' comments nonetheless provided valuable learning for improving perioperative patient experience. Furthermore, while free text comments did not explicitly contribute to the longlist of research priorities developed from the APoC-PSP first survey, the themes highlighted in this analysis suggest several topics for future research.

Some themes highlighted in this analysis already appear in the APoC-PSP's top ten research priorities: for example, some of the concerns around communication, consistency of care and continuity are at least partially addressed by the research question, 'How can we improve **communication between the teams** looking after patients throughout their surgical journey?' Similarly, research on interventions to improve postoperative pain management, or reduce postoperative delirium, would clearly address the priority of improving recovery from surgery for elderly patients, and the priority of improving patient care around the time of emergency surgery.

Finally, the themes emerging from this analysis provide a rich resource for local or national quality improvement. Some examples might include improving preoperative patient information, improving preoperative shared decision making by introducing multi-disciplinary clinics for high-risk surgical patients; initiatives to reduce preoperative waiting times for elective surgical patients on the day of surgery; or improving postoperative communication and reducing anxiety through patient-centred communication ward rounds.

## 6.5 Conclusion

The free text comments received in the APoC-PSP first survey provided useful insights into service users' perioperative experiences. They suggest several opportunities for improving surgical service user experience. Foremost among these were information provision and communication, greater compassion and empathy among HCPs caring for surgical patients, improving long-term recovery, and reducing perioperative anxiety.

# PART 2

# Outcome measurement and reporting in Anaesthesia and Perioperative Medicine research

# *Chapter 7. Outcome selection in medical research: what should we measure? Challenges and controversies around outcome reporting in perioperative research*

## 7.1 Introduction

This chapter provides an overview of outcome measurement and reporting in medical research, before focusing on how outcomes are commonly measured and reported in Anaesthesia and Perioperative Medicine (APOM) research. I shall illustrate the fundamental importance of robust, reliable outcome measurement in perioperative medicine, both for evaluating clinical practice and for perioperative research trials. I then discuss some of the shortcomings and flaws in current health research outcome measurement and reporting – and specifically perioperative research – and recent initiatives to address them.

Finally, I describe the rationale underlying the COMPAC initiative, and the linked Standardised Endpoints in Perioperative Medicine (StEP) initiative, and their aim of improving outcome measurement in future APOM research trials.

## 7.2 Background

Here I shall briefly review the evolution of outcome measurement and reporting in medical research, illustrating how outcomes have become inherently more complex and nuanced with increasing scientific understanding of disease.

### *7.2.1 Outcome measurement in the nineteenth century*

Early medical trials in the nineteenth century were mostly concerned with finding cures for infectious diseases with high mortality rates. Diseases such as syphilis, tuberculosis and pneumonia were often a death sentence, and ‘research’ simply meant any scientific efforts to find cures or treatments for them. Outcomes were rarely formalised: studies of new

experimental therapies generally involved administering them to patients with a particular disease (usually in a non-blinded fashion) and observing their disease trajectory. The principal outcome measured was – in most cases – mortality (or survival). Meanwhile simultaneous observation of how patients' signs and symptoms changed or improved, and how quickly (time to recovery), or the occurrence of new signs and symptoms (i.e. possible side effects) might also have been recorded.

Some of the most famous examples of rudimentary nineteenth century research trials are, perhaps unsurprisingly, those that achieved a dramatic survival benefit. John Snow's discovery that contaminated water from the Soho street pump was the source of a cholera outbreak in 1854,(4) and Semmelweisz's introduction of antiseptic hand hygiene on Vienna's labour wards in the 1860's,(5) both became widely known because of the dramatic reduction in mortality that ensued. In a world where death was the most visible consequence of poor health, mortality was the main outcome of interest.

### *7.2.2 Outcome measurement in chronic disease research*

Although medical research continues to address mortality, healthcare resources across the world are increasingly targeted towards chronic diseases that may not prove fatal but which cause significant human suffering. Conditions as diverse as osteoarthritis, asthma, inflammatory bowel disease, and cataracts may cause long-term ill health, and carry a major cost burden to both healthcare providers and society at large, precisely because they are rarely fatal but adversely affect health and quality of life in myriad other ways, generally over a long timeframe.

Investigating new interventions to lessen the impact of these and other chronic diseases has, therefore, become a major focus of modern medical research. The outcomes selected for such research are, however, less clear cut than mortality or survival. Taking the examples above, evaluating new interventions might now require the measurement of more complex multidimensional outcomes such as:

- Pain severity and/or frequency, mobility, functional capacity (osteoarthritis)
- Breathlessness, cough, frequency and severity of asthma attacks, peak expiratory flow rate, reversibility (asthma)

- Abdominal pain, bloating, cramping, frequency of bowel opening, fever, weight loss, requirement for surgical intervention, side effects of immunosuppressants (inflammatory bowel disease)

- Visual acuity, visual fields, photosensitivity, colour perception, facial recognition (cataracts)

The range of possible outcome measures in medical research has, therefore, become almost limitless, and often highly specific to the intervention being investigated. Furthermore, chronic disease research often requires multidimensional, complex outcome measures to assess the effect of a new therapy on (for example) symptoms of inflammatory bowel disease, or chronic back pain. Selecting appropriate outcome measures for trials addressing the many ways in which chronic diseases can affect patients has therefore become another highly specialised, expert-led aspect of trial design.

## 7.3 Perioperative outcome measurement

### *7.3.1 Why is perioperative outcome measurement necessary?*

Reliable measurement of outcomes after surgery is integral to delivering and advancing high-quality surgical care. Firstly, all healthcare professionals (HCPs) need to know their outcomes: in order to demonstrate their practice is safe and competent, they require evidence of clinical activity performed and resulting outcomes. Secondly, patients need outcome data, because informed consent and collaborative shared perioperative decision-making presupposes the availability of up-to-date, reliable information regarding the likely benefits and possible risks of the various treatment options under consideration.

Thirdly, healthcare providers depend on reliable, comparable data to evaluate their processes and outcomes, and thereby benchmark their practice against other providers. Providers also need outcome data to plan health service delivery: for example, knowledge of how many patients have a particular operation each year, demographics of the surgical population, mean length of ICU stay, time to hospital discharge, and the frequency of postoperative complications are all vital to the financial and logistical planning of surgical

services. Without reliable data about previous surgical outcomes, managing future bed capacity, patient flow and healthcare costs is all but impossible.

Outcome measurement in perioperative research trials is equally fundamental. Clinical trials can only discriminate between beneficial, ineffective, and harmful interventions by measuring outcomes that are relevant to patients, clinically important, and valid. Consistent reporting of outcomes between different trials is also essential for comparing and contrasting results between different studies, and for producing reliable evidence syntheses by combining data from separate trials in systematic reviews and/or meta-analyses.

### *7.3.2 Current perioperative outcome measurement and reporting trends*

Traditionally, commonly reported postoperative outcomes have fallen into two broad categories, namely clinical outcomes and healthcare resource use outcomes. The former include measures such as postoperative mortality, postoperative morbidity or 'complications' (i.e. deviations or setbacks from the 'normal' recovery trajectory), and measures of surgical 'success' such as total excision of a cancer, or cure of the disease/problem which the operation was intended to treat.

Outcomes describing healthcare resource use include measures such as hospital length of stay, unplanned hospital readmission rates, and costs of perioperative care. Resource use measures are widely used for three reasons. Firstly, because resource use correlates closely with cost, which healthcare providers generally want to minimise (especially in resource-intensive areas such as surgery and perioperative care); secondly, because they are relatively easy extracted from patient notes and electronic health records by administrative staff with no medical training; and thirdly because resource use correlates closely with clinical recovery. The duration of a patient's stay in hospital, and the amount of healthcare resource consumed, generally reflects their ongoing need for hospital treatment: measures such as hospital length of stay therefore serve as a proxy for a patient's clinical trajectory.

However, a third category of outcome measure – patient-centred outcomes – is growing in prominence alongside these traditional measures. Patients, clinicians and researchers have all recognised that traditionally reported clinical outcomes during the index hospital

admission for surgery do not adequately describe the multifaceted nature of recovery from surgery, or medium-to-long term health-related outcomes in surgical patients.(150, 158) With many procedures – for example hip or knee arthroplasty – intended principally to improve quality of life (rather than merely extending survival), most patients care about how their operations affect them well beyond the hospital admission. Furthermore, postoperative mortality and morbidity are (fortunately) rare outcomes for most surgical procedures. While these may be key metrics for certain operations with persistently high rates of postoperative mortality and morbidity, such as emergency laparotomy or hip fracture,(159, 160) they are clearly insufficient to capture the outcome of hernia repairs or laparoscopic cholecystectomy.

Resource use measures are likewise widely regarded as insufficiently detailed to capture the full spectrum of recovery after surgery. In an era of enhanced recovery programs and a major shift towards day surgery and shorter hospital stays for most surgical procedures, length of hospital stay and other resource use measures do not discriminate between ‘good’ and merely ‘adequate’ postoperative recovery. A patient who suffers significant postoperative pain, nausea, anxiety and sleep disturbance may still go home the day after a robotic prostatectomy, similar to a patient who suffers none of these problems after the same operation. Furthermore, even if one makes a ‘perfect’ recovery to their full level of preoperative function by three months postoperatively, whereas the other suffers persistent pelvic pain, intermittent urinary incontinence, and erectile dysfunction, both patients may consume similar amounts of healthcare resource over subsequent months and years.

The need for more complex and nuanced outcome measures that capture not just ‘what went wrong’ in the immediate aftermath of an operation, and which also extend beyond the surgical inpatient stay, has therefore been widely acknowledged. Recovery from surgery is increasingly viewed as complex, multifaceted, and largely subjective (i.e. dependent on the perceptions of surgical patients, since only they have lived experience of their own recovery and are therefore uniquely able to assess it) However, there is little consensus about which additional outcomes to measure, and how.(161)

## 7.4 Outcome measurement in perioperative research

Various approaches have been used in recent decades to measure the effects of interventions in perioperative research trials. In this section, I provide a brief overview of the advantages and disadvantages of different outcome measurement strategies. (N.B. I have previously examined this topic more fully in a review article for the Canadian Journal of Anaesthesia in 2016).(162)

### *7.4.1 Clinician-described or patient-reported*

Outcome measures may be classified into those recorded by clinicians, and those reported by patients. Patient-reported outcome measures (PROMs – such as rating of postoperative pain) are considered 'subjective' because they reflect patients' perceptions, whereas clinician-described outcomes are considered 'objective' measures based on clinical evidence.

However, this distinction is not clear-cut. There is clearly a degree of subjectivity in assessing and diagnosing certain clinician-described outcomes (e.g. postoperative atelectasis, or left ventricular failure). Discrepancies between patient-reported and clinician-reported assessments of ostensibly the same outcome have also been noted, for example when measuring postoperative pain or functional status.(163-165) Finally, PROMs usually encapsulate outcomes that patients experience directly (such as pain severity), whereas clinician-described outcomes may not (such as postoperative acute kidney injury).

On a more pragmatic note, clinician-reported outcomes are generally less onerous to measure and collect, and may be reported more consistently than PROMs (where one patient's severe pain would be rated only as mild pain by another patient). Collecting PROMs may also place an additional burden on patients already struggling with the physical and emotional challenges of recovery from surgery.

### *7.4.2 Adverse events or recovery*

Outcome measures may also be categorised as recording (abnormal) adverse events, or (normal) postoperative recovery. Both approaches have strengths and weaknesses.

Adverse events can generally be observed clinically and/or confirmed from diagnostic tests, whereas recovery is harder to quantify, and is generally assessed using PROMs, or indirect measures of functional capacity. PROMs may be assessed using either specific questionnaires quantifying postoperative recovery after specific operations, such as the Oxford hip and knee score (166-169) or more general questionnaires developed for evaluating health-related quality of life (HRQoL).(170) Functional capacity is generally assessed by a standardized measure of physical function (e.g., six-minute walk test).(171)

Certain specific 'milestones' of postoperative recovery – such as early mobilisation, or return to oral intake – are increasingly being reported in perioperative trials.(172-175) These milestones or recovery 'goals' are usually reported in the context of adherence to enhanced recovery programmes; however, if such outcome measures are shown to reliably reflect swift and/or uncomplicated in-hospital postoperative recovery, their use in perioperative research trials is likely to become more commonplace.(175) Indeed, metrics to quantify 'positive' or uncomplicated recovery may in time prove more useful than those describing complicated recovery trajectories, both for research trials and audit of everyday practice.

### *7.4.3 Perioperative Patient-reported Outcome Measures (PROMs)*

Notwithstanding the promise of specific recovery endpoints described earlier, PROMs are widely used to evaluate and quantify recovery after surgery in perioperative research trials. PROMs are by definition patient-centred, and may capture important sequelae following surgery that measures of adverse events do not. Being multidimensional, PROMS also provide a comprehensive, holistic measure of patient recovery after surgery. Finally, because they can be repeated at intervals, they provide information regarding the timecourse of a patient's recovery over the medium to long term.

However, PROMs have several drawbacks. These include both pragmatic issues and issues of scientific validity. On a pragmatic level, they are typically onerous to collect, requiring significant resources and expertise. They require a visit to every patient, explanation of how to complete the PROM, and considerable time to collect all the required information; furthermore they may yield incomplete data (if patients are unable to complete all parts of a PROM, or do not complete it at every planned timepoint). Staff

usually require training in their use, patients may misunderstand the questions being asked, and they may also prove overly burdensome for patients to complete, particularly in the immediate postoperative period.

PROMS also require rigorous psychometric evaluation, testing and validation: for example, new PROM tools require validation against existing tools, and evaluation of their validity, reliability and feasibility in a clinical setting. The use of PROM measurement tools that have not been appropriately tested is common in perioperative research(176) and provides another justification for standardization of outcome measurement. Finally, PROMs are subjective tools, and the effects of unmeasured, potentially confounding variables during their completion (such as time of day, a patient's mood, or degree of engagement) makes comparison between patients and/or institutions uncertain.

### *7.4.4 Postoperative complications*

Postoperative complications (or morbidity) might, therefore, appear to be a simpler and more objective outcome measure than PROMs or indirect markers of recovery. As an outcome measure in research trials, they have several obvious advantages: they are (usually) important to both patients and clinicians; they have cost and resource use implications for healthcare providers; and they are relatively easy to measure. Furthermore, postoperative morbidity is increasingly recognized as a predictor of long-term outcome.(177, 178) Recent characterization of the high-risk surgical population has also sharpened the focus on reducing perioperative morbidity.(179) Although high-risk patients comprise only 10-15% of all surgical patients, they account for over 80% of postoperative complications and resource costs.

Nonetheless, postoperative complications do not describe surgical outcome beyond the immediate perioperative period. Recent evidence suggests that long-term recovery takes months to years – at any rate, significantly longer than the timeframes examined in most perioperative research.(180-182) Hence, there is a growing interest in longer term recovery endpoints to quantify the overall success of surgery.(183-185)

Recording postoperative morbidity is also problematic. Firstly, agreeing what constitutes a deviation from the postoperative norm is debatable. For example, delayed return of gut function after intra-abdominal surgery, or temporary postoperative oxygen requirement are

arguably within the ‘normal’ postoperative trajectory: there is no clear timepoint after which a persistent oxygen requirement or inability to tolerate enteral intake becomes pathological. Secondly, grading the severity of postoperative complications is complex. Distinguishing between trivial, temporary and life-threatening complications, and the duration of their impact, is clearly desirable: a postoperative stroke may be devastating for a patient and their family, whereas an asymptomatic postoperative acute kidney injury may resolve in a few days with no apparent long-term consequences. However the commonly-used systems for quantifying severity, (such as the Clavien-Dindo classification) all suffer from a degree of inherent subjectivity.(186-189) Severity is variously based on the degree of physiological derangement, its duration, or the invasiveness of treatment required; however, the long-term sequelae – i.e. the impact on a patient’s quality of life and/or survival – are arguably more important criteria for measuring complication severity.

**Postoperative morbidity scores**

Various scoring systems have been developed to quantify and compare overall postoperative morbidity for different procedures. These include the Postoperative Morbidity Survey (POMS),(190, 191) Cardiac Postoperative Morbidity Score (C-POMS),(192) and the Comprehensive Complication Index.(187, 193) While a robust system for quantifying overall postoperative morbidity would appear advantageous, such systems also pose challenges. They may be cumbersome to administer and require specific training in their use, which limits their utility. They require thorough validation and share the weakness of other composite outcomes of masking important differences in the rates of their individual components. The POMS and C-POMS, in particular, were validated to detect morbidity that prevents hospital discharge; as healthcare systems and processes evolve, such measures may require refinement.

### *7.4.5 Resource use measures*

Measures of healthcare resource consumption (e.g. critical care and hospital length of stay, and unplanned readmission rates after surgery) are commonly reported outcomes in perioperative research. The principal advantages of these measures are ready

accessibility from hospital data, close correlation with clinical outcomes, and patient relevance (since patients do not generally want to stay in hospital longer than necessary).

However, resource use is only a proxy for clinical outcome. Despite abundant evidence linking postoperative complications with increased length of stay and higher costs,(194-196) resource use is also affected by several other factors (e.g. availability of community-based support, clinician behaviour, and hospital discharge policy) that may limit its reliability as a marker of perioperative clinical outcomes. 'Readiness for hospital discharge' has been proposed as an endpoint that may more precisely reflect a level of postoperative clinical recovery where inpatient care is no longer required, and which may be less susceptible to confounding by local discharge procedures or other factors that prevent or delay hospital discharge even when a patient is medically dischargeable. However the precise timepoint at which a patient is deemed dischargeable may be much harder to discern from hospital records than the actual time of leaving hospital, and is also subject to clinician variation.

### *7.4.6 Patient-reported experience measures (PREMs)*

Finally, overall patient experience or satisfaction with care may be an outcome of interest. The importance of patient satisfaction after surgery and/or anaesthesia has been increasingly recognized both in its own right and as a metric for healthcare quality.(197-199) Furthermore, there is evidence linking positive patient experience and clinical outcomes: patients who have a good postoperative clinical outcome are more likely to report positive experiences of care.(150, 200)

Concerns have arisen, however, over the use of non-validated tools to measure patient experience despite the availability of well-validated instruments.(201, 202) Furthermore in most healthcare cultures, clinicians are directly accountable for clinical outcomes – and thus may be found culpable in cases of medical malpractice leading to clinical harm – but less so for patient experience. Perhaps because of the primacy of clinical outcomes, patient experience is rarely chosen as a primary outcome for APOM research trials.

### *7.4.7 Conclusion*

In summary, outcome measurement in APOM research has evolved beyond the traditional metrics of postoperative mortality and morbidity and resource use, with more complex, nuanced outcomes increasingly reported. This reflects the steadily increasing complexity of surgical procedures, the expanding population deemed eligible for surgery who might not have been considered suitable candidates in previous decades, and the growing appreciation of the multifaceted nature of surgical recovery. There is therefore an overall trend towards greater focus on patient-centred outcomes, and on medium to long-term outcomes rather than just those occurring in the immediate perioperative period.

In the next section, I further explore challenges and current debates regarding outcome measurement in healthcare research, before focusing on how they apply to anaesthetic and perioperative research.

## 7.5 Criticisms regarding outcome measurement and reporting in clinical trials

As outcome measures reported across all areas of health research have become increasingly complex and multidimensional, various concerns have been raised regarding potential shortcomings of commonly reported outcomes. A comprehensive summary was provided in a recent review by Heneghan and Goldacre, which criticised ‘the use of surrogate, composite and subjective endpoints; a failure to take account of patients’ perspectives when designing research outcomes; publication and other outcome reporting biases, including the under-reporting of adverse events; the reporting of relative measures at the expense of more informative absolute outcomes; misleading reporting; multiplicity of outcomes; and a lack of core outcome sets.’(203)

The problems they identified are summarised in Table 20. In this section, I shall briefly examine these concerns, before exploring how they apply to APOM research.

| Stage of research | Outcome problems | Examples |
|---|---|---|
| **Design** | Poor choice of trial outcomes | Surrogate outcomes<br>Composite outcomes<br>Subjective outcomes<br>Complex scales<br>Lack of relevance to patients and/or clinical decision makers |
| **Methods** | Flawed or incomplete collection of outcomes | Missing data<br>Poorly specified/defined<br>Inconsistent measurement or collection |
| **Publication** | Selective reporting | Publication bias<br>Reporting bias<br>Underreporting of adverse events<br>Switched outcomes |
| **Interpretation** | Inappropriate interpretation | Relative measures<br>'Spin'<br>Multiplicity<br>Core outcome sets |

**Table 20.** Why clinical trial outcomes fail to translate into benefits for patients (adapted from Heneghan et al, 2017)

### *7.5.1 Choosing the 'wrong' outcomes at the design stage*

Heneghan et al. highlighted the issue of choosing inappropriate outcomes before a trial has even begun, echoing Chalmers's and Glazsiou's review of research waste (see Chapter 1) which discussed how 'the outcomes that researchers have measured have not always been those that patients regard as most relevant'.(27) They cited an example of patients participating in rheumatoid arthritis research which revealed that fatigue was the most important outcome to patients, rather than pain (as the researchers had assumed).(204)

Heneghan et al. discussed the use of outcomes that lack relevance to patients and/or decision makers, postulating that researchers – with their individual areas of expertise, career agendas, external influences and personal biases – may have different views from other stakeholders about which outcomes are most relevant, and that the outcomes they are interested in may not align with those patients value. For example, a systematic review of patient-reported outcomes in cardiovascular trials published in leading medical journals found that 'important outcomes for patients were reported in only 23% of the 413 included trials.'(205)

### *7.5.2 Choosing surrogate outcomes*

Another of Heneghan's criticisms was the use of surrogate outcome measures – where a certain biomarker or endpoint is chosen as a proxy for the 'true' outcome of interest. Surrogate endpoints are usually encountered where the true outcome is difficult, slow or expensive to observe, and where the surrogate is believed to correlate closely enough with the relevant clinical outcome to be a valid alternative. For example, in oncology trials, the success or failure of new cancer therapies may be assessed by measuring cancer biomarker levels (for example, prostate-specific antigen levels for prostate cancer) because they are often an early indicator of cancer recurrence. However, these biomarkers are surrogates for the true clinical outcome of interest, i.e. 'cancer recurrence' or 'cancer progression'. In fact, these outcomes in turn are arguably themselves surrogates for the principal important outcome, namely 'overall cancer survival' and/or 'cancer-related quality of life'.

Other examples of surrogate outcomes in research include measuring cortisol plasma levels as a marker for psychological stress, or blood pressure reduction as a proxy for risk of cardiovascular disease. While the pragmatic advantages of surrogate outcomes may allow research studies to be completed more quickly and cheaply than if purely clinical outcomes were used, several commentators have argued that they are overused, and often correlate poorly with the true outcome of interest.(206) Furthermore, many trials that use surrogate outcomes do not explicitly discuss possible limitations regarding their validity as a predictor of the true outcome.(207)

A review by Fleming and DeMets discussed several mechanistic reasons (see Figure 7) why surrogate endpoints may be imperfect proxies for clinical outcomes.(208) They summarised these as follows: ‘a) The surrogate is not in the causal pathway of the disease process; b) Of several causal pathways of disease, the intervention affects only the pathway mediated through the surrogate; c) The surrogate is not in the pathway of the intervention's effect or is insensitive to its effect; d) The intervention has mechanisms of action independent of the disease process.’

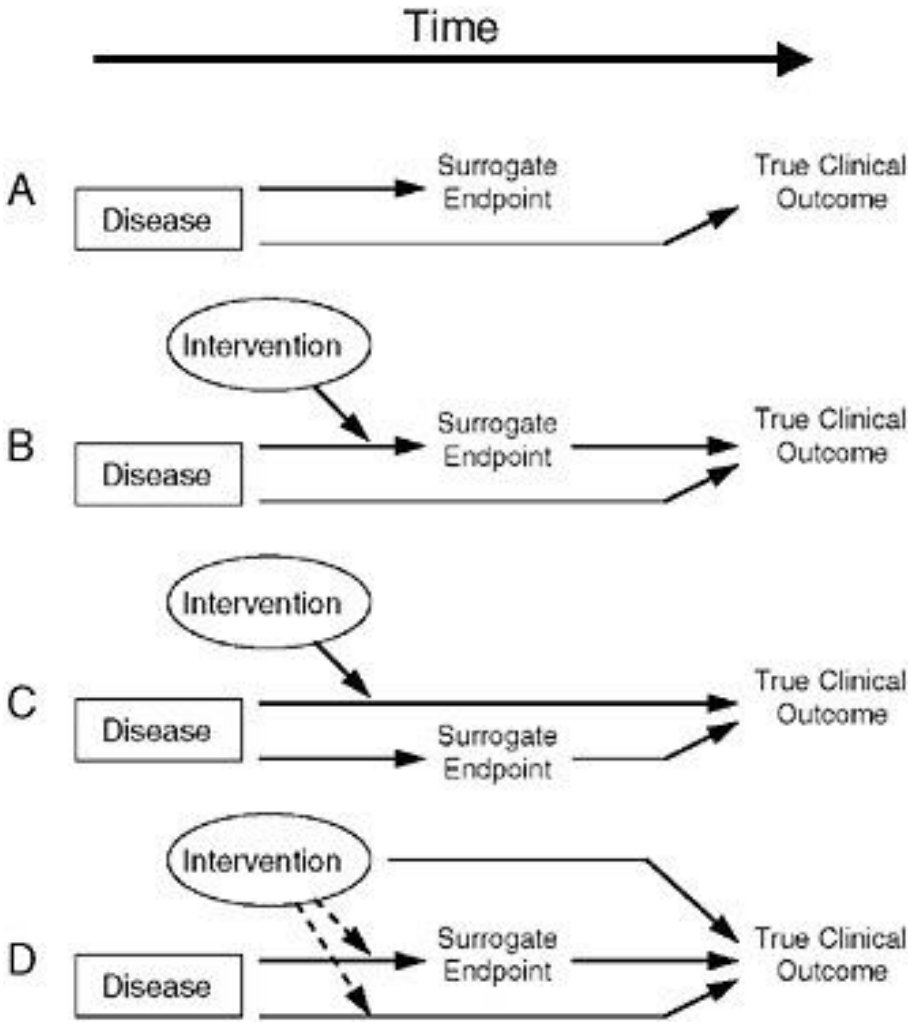


**Figure 7.** Reasons for failure of surrogate end points (Fleming & DeMets, 1996)

### *7.5.3 Composite outcomes*

The use of composite outcomes in clinical trials has also attracted criticism. A composite outcome is one where several (usually adverse) distinct outcomes are combined, such that a patient who suffers any one of these would be counted. Composite outcomes can increase the power of a study to detect differences between groups, because combining several individually rare outcomes into one composite outcome increases the event rate, and thus reduces the sample size required to detect a significant difference between groups. Another strength of composite outcomes is to provide a succinct quantitative overview of the overall effect of an intervention, by amalgamating separate adverse outcomes into one – such as death, dependency, or poor neurological function, which are commonly reported as a composite outcome in stroke trials.(162)

However, composite outcomes obscure the detail of the individual components and may be misleading if the component outcomes are not similar in both severity and incidence. If one complication within the composite outcome occurs much more frequently than the others, the overall rate of the composite outcome will merely approximate the rate of that particular complication.(209)

Montori et al propose that for a composite outcome to be valid, it must fulfil three criteria:(210)

- The components of the composite endpoint must be of similar clinical importance to patients
- The frequency of the occurrence of the components over the same time period must be similar; otherwise, the effect on the composite will be largely determined by the predominant event
- The effect of the treatment must be similar for each component of the composite

The limitations of composite outcomes were succinctly highlighted by Freemantle et al in a systematic review of 167 RCTs that reported a composite primary outcome incorporating all-cause mortality.(211) They found that 63 trials (38%) found no significant difference for either the primary endpoint or the mortality component;  60 (36%) reported significant

results for the primary outcome measure, but not for mortality; six (4%) were significant for mortality but not the primary composite outcome; and only 19 trials (11%) were significant for both. They concluded that composite outcomes may lead readers to 'overestimate' the true effect, and/or to infer that the results apply to the individual components of the composite outcome rather than only to the overall composite.

### *7.5.4 Heterogeneous, inconsistent and poorly defined outcomes*

Many authors have lamented the lack of precise and/or consistent definitions used to decide whether a particular outcome has occurred. If twenty trials reporting rates of myocardial infarction (MI) each used different definitions for an MI, or measured it at different timepoints, or used different measurement methods, then comparing their results becomes challenging, and combining those data in a meta-analysis is clearly impossible.

While authors of systematic reviews usually attempt to estimate the degree of heterogeneity of outcome measurement between the included studies, this severely limits the quantitative pooling of data in meta-analyses. At best, such heterogeneity diminishes confidence in the pooled estimates of an intervention's effect.(212) At worst, it may preclude any quantitative pooling of data within a systematic review, and thereby substantially undermine the value of individual trials and the utility of the combined evidence base.

The problem of inconsistent outcome reporting has long been recognized in various healthcare disciplines. Twenty years ago, a large systematic review of stroke outcome measures complained that 'there is little consistency in the measurement of outcome in acute stroke trials, and this may complicate interpretation of the results and reduce the likelihood of detecting worthwhile drug effects.' (213) Poorly defined or inconsistent outcome measures have also been highlighted in research for conditions as diverse as panuveitis,(214) chronic pain and bipolar disorder.(215) Moreover as the sheer volume of research published grows every year, the lack of consistent outcome measurement between similar trials makes appraisal of the evidence base all the more difficult. The issue has prompted efforts to agree consensus outcome definitions and/or standards in several areas of health research, which I shall explore later when discussing the concept of core outcomes.

### *7.5.5 Inadequate attention to measurement instrument or technique*

Related to variation in how outcomes are defined, concerns have been raised regarding the precise methods used to measure outcomes in the clinical setting. Trials rarely report every detail of how and when data was collected, yet complex multidimensional outcomes such as pain severity, or subtle changes in (for example) visual acuity, fatigue, or breathlessness may depend in part on how, when and where the outcome is measured, and by whom. This is particularly true for diseases with a well-recognised affective and/or emotional component to how patients experience them.(216, 217) To take the example of pain, there is evidence that even the act of measuring or asking about pain may affect patients' perceptions and experiences.(218)

In a variety of conditions, poor correlation has been observed between clinician-reported outcomes and patient-reported outcomes.(219-221) In other words, the method used to gather information affects the output. This may explain why, despite a wealth of research seeking to validate countless different pain measurement instruments, there is no universally accepted 'gold standard' tool. The virtual impossibility of separating out subjective, emotional and affective aspects of patients' multifaceted pain experiences necessarily renders the measurement of pain context-specific.(222) Even for research in chronic diseases where symptoms and signs are arguably more objective, multifaceted outcomes still require well-validated metrics with precise definitions in order to be interpretable by an external audience.

### *7.5.6 Selective outcome reporting*

The problem of selective reporting of trial outcomes – i.e. reporting different outcomes from those specified in the registered trial protocol, or failing to report all outcomes that were actually measured in a research trial, or emphasising the 'newsworthy' or statistically significant ones whilst omitting or downplaying the non-significant ones – is likewise well documented. The issue has received most publicity in industry-sponsored trials, with various egregious instances of pharmaceutical companies with a clear financial interest in demonstrating a significant benefit from a new trial drug neglecting to report safety outcomes or negative trial results.(223-225)

However, selective reporting is not confined to industry sponsored drug trials. Several reviews also provide strong evidence that statistically significant, or 'positive' outcomes have a higher likelihood of being fully reported than non-significant outcomes.(226, 227) Discrepancies between the outcomes listed when a trial is registered, and those actually reported when the trial is published, have been widely documented.(228) Nor is the problem restricted to secondary outcomes: differences between the primary outcome measures reported in trial publications and those originally planned have been found in myriad areas of health research, from cystic fibrosis to reconstructive dentistry to assisted human reproduction.(229-231)

To reduce bias in medical research from selective outcome reporting, the International Committee of Medical Journal Editors (ICMJE) introduced mandatory trial registration guidelines in 2005. Thereafter, in theory at least, member journals required prospective registration of trial protocols as a condition of publication, thus forcing researchers to abide by their own methodological rules. However, these rules have unfortunately not eliminated selective outcome reporting: several authors have described ongoing discrepancies between trial outcomes registered and those reported.(232) A review of trials published in ICJME-member psychiatry journals between 2009 and 2013 found that only a third had been prospectively registered with clearly defined primary outcome measures.(233) Mandatory trial registration is therefore not a panacea for preventing selective outcome reporting.(234)

Moreover, the effects of outcome reporting bias can be profound. In 2010, Kirkham et al conducted a methodological review of recently published Cochrane reviews: they found that the majority did not include full data for the primary outcome, with more than half the potential data missing in 25% of the reviews examined. Almost a fifth (19%) of the meta-analyses with a statistically significant result became non-significant after adjustment for outcome reporting bias, while 26% would have overestimated the treatment effect by $\geq$20%. They concluded that 'outcome reporting bias is an under-recognised problem that affects the conclusions in a substantial proportion of Cochrane reviews.'(235)

## 7.6 Outcome measurement controversies in Anaesthesia and Perioperative Medicine research

Many of the outcome measurement debates described above have been echoed in Anaesthesia and Perioperative medicine (APOM) research. I shall briefly visit these here before discussing different approaches to perioperative outcome measurement.

### *7.6.1 Choosing the 'right' outcomes to begin with: Which outcomes should anaesthesia and perioperative research trials measure?*

Agreeing which outcomes should be collected after major surgery is – as well as being a focus of this thesis – an area of increasing debate within the perioperative literature. Salih et al questioned whether the traditional outcome measures described in section 6.3 (postoperative mortality, morbidity and resource utilization) are sufficiently detailed to capture every nuance of a patient's experience after major surgery. They proposed more systematic measurement of perioperative outcomes and greater use of patient-reported outcome and experience measures.(161) Shulman and Myles have also called for greater emphasis on reporting clinically relevant and patient-centred outcomes alongside traditional perioperative outcomes like postoperative mortality and morbidity.(236) Ladha and Wijeysundera similarly suggested that patient-centred outcomes should be measured in tandem with clinical outcomes in order to 'identify important changes in postoperative function that impact patients without discernible complications, and ensure that the definition of success after surgery is more meaningful to all relevant stakeholders'.(237)

Other commentators have likewise highlighted the multifaceted nature of recovery after major surgery. A review by Lee at al entitled 'What does it mean to really "recover" from an operation?' called for 'a shift in the emphasis of outcome reporting from audit measures to longer-term patient- and recovery-centric measures'.(185) Miller and Mythen similarly suggested that 'recovery after anaesthesia and surgery is a complex process… [which] involves multiple domains, including physical, psychological, and social aspects. There is no standard definition or measure'.(238)

Overall, then, there appears to be emerging agreement that outcome measurement in perioperative trials needs to move beyond traditional clinical and resource use outcomes, because these do not fully capture the impact of major surgery on patients. Measuring

patient-centred outcomes and experience is necessary to provide a complete picture. Indeed, various studies seeking to address this deficit by reporting both traditional clinical outcomes and multidimensional patient-centred outcomes are already in progress, such as the UK-wide Perioperative Quality Improvement Initiative (PQIP).(239)

### *7.6.2 Surrogate outcomes in APOM research*

The use of surrogate endpoints in APOM research is widely recognised. Examples include postoperative troponin elevation as a marker for myocardial injury after surgery (MINS), the clinical significance of which is still unclear.(240, 241) Myles argues that past research has focused too little on patient-centred outcomes (defined as 'those that the patient actually experiences') and that surrogate endpoints (such as biochemical abnormalities or physiological derangements) should only be used if they result in patient distress, illness, disability, or death.(242) Meanwhile Kalkman views outcome measures as lying on a spectrum, from the entirely surrogate (e.g. postoperative troponin rise) to the partially patient-centred (e.g. postoperative myocardial infarction) to the wholly patient-centred (e.g. disability-free survival).(243)

### *7.6.3 Composite outcomes in APOM research*

Composite outcomes in APOM research are also reported, often where a particular outcome occurs only rarely (such as perioperative cardiac arrest, which might be included in a composite outcome of 'major adverse cardiovascular events') or where similar outcomes – perhaps with a shared underlying mechanism or aetiology – are grouped together. For example, 'airway complications' have been reported in a number of anaesthesia trials, often with multiple different events of dissimilar severity included under the catch-all of airway complications.(244, 245) These may range from 'inability to ventilate and/or oxygenate the patient' (leading to the patient's death, or irreversible brain damage) to 'traumatic airway injury' (which might simply mean a minor lip laceration or postoperative sore throat that resolves within a few days) or pulmonary aspiration of gastric contents.

Similarly, abstracts of perioperative research trials might report the overall incidence of ‘postoperative complications’ in each group, perhaps as a headline comparator that succinctly summarises the main observed differences.(159, 246, 247) However, such outcomes tell the reader little about the exact nature and severity of the component events that occurred, and may therefore falsely imply a significant difference in clinical outcome (or, conversely, disguise a significant difference between severe and mild complications) that only becomes apparent in the full text report.

Kalkman’s discussion of patient-centred endpoints highlights the pitfalls of combining several possible adverse outcomes of differing severities into one composite. For example, postoperative major adverse cardiac events (MACE) commonly includes several components that are clearly not equivalent to the patient, from death and cardiac arrest to non-fatal myocardial infarction and (often entirely asymptomatic) myocardial injury.(243) Finally, composite outcomes are patently impossible to interpret in the context of the existing literature if their component inputs vary between trials.(248)

### *7.6.4 Heterogeneous, inconsistent and unclear outcome definitions*

As in other spheres of medical research, variation and heterogeneity in outcome reporting have been widely noted across the perioperative literature.(249) Examples include Martin et al’s descriptions of ‘inconsistent complication reporting… in hospitals and in the surgical literature’;(250) Blencowe et al’s observation that ‘outcome reporting after esophageal cancer surgery is heterogeneous and inconsistent, and lacks methodological rigor’;(251) Cooper et al’s conclusion that ‘heterogeneity makes it difficult to compare outcomes across studies and to accurately extrapolate outcomes to clinical practice’ in spine surgery trials;(252) and O’Donnell et al’s finding of ‘the scale of the inconsistencies in reported outcomes across 32 studies, making evaluation in a standardized manner very difficult’ in hip fracture trials.(253)  Virtually all such studies bemoan the challenges posed by such heterogeneity for comparing results of similar trials, and for interpreting new trial data in the light of the existing evidence base.

### *7.6.5 Selective outcome reporting*

Various authors have drawn attention to the prevalence of incomplete or selective outcome reporting in the APOM literature, noting the frequent absence of prospective trial registration, and the reporting of primary outcomes that differ from those specified in the registered trial protocol.(232, 254-257). The issue is a particularly emotive one in APOM research since the widely publicised ‘Carlisle method’ was used to expose several egregious examples of anaesthesia research fraud.(258, 259) Allegations of selective outcome reporting therefore imply more than just sloppy scientific method: they may also cast doubt on the scientific integrity and honesty of the researchers involved.

A recent example of controversy over alleged selective outcome reporting, and the questions it raised regarding the scientific integrity of authors on both sides, involved the GAS trial.(260, 261) This multicentre RCT sought to provide the first RCT evidence addressing the still-unresolved debate about whether exposure to general anaesthesia in early life may adversely affect subsequent neurocognitive development. The GAS trial compared neurodevelopmental and cognitive outcomes in infants who underwent inguinal hernia repair under either general or spinal anaesthesia. An interim analysis, published in 2016, reported preliminary findings for one of the pre-specified secondary outcomes;(260) the authors were then accused by the COMPare group of ‘reporting outcomes that are different to those initially registered on ClinicalTrials.gov’.(262) The authors defended their prospectively planned interim report of these secondary outcomes, but conceded that ‘COMPare's inaccurate conclusions do highlight the issue that trial registries often do not request or have space for sufficient detail about secondary outcomes’.(263)

## 7.7 Standardising outcome measurement

The issues with outcome measurement and reporting highlighted above have prompted several efforts to lay down formal guidance and standardised methods for measuring outcomes.(264) An early initiative in cancer research was led by the World Health Organisation (WHO), which in the late 1970’s held two international conferences entitled ‘Standardization of Reporting Results of Cancer Treatment’, at which the WHO Handbook for Reporting Results of Cancer Treatment was produced.(265) In the 1990’s, the

international Outcome Measures for Rheumatology (OMERACT) collaboration developed a similar initiative for rheumatology research. OMERACT aims to ‘improve [rheumatology] outcome measurement through a data driven, iterative consensus process involving relevant stakeholder groups’ and holds regular consensus conferences to agree and update its outcome measurement guidance, with patients involved at every stage.(266) A similar approach was adopted by the chronic pain research community to develop its IMMPACT recommendations.(267)

### *7.7.1 Core Outcome Sets*

More recently, the concept of Core Outcome Sets (COS) has gained traction in a wide range of health research disciplines. A COS is defined as ‘an agreed set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care research.’(268) The Core Outcome Measures for Effectiveness Trials (COMET) Initiative, which was launched in 2010, and whose methodological principles were followed in the Core Outcome Measures for Perioperative and Anaesthetic Care (COMPAC) project, has led the way in promoting COS development, including collating all published and ongoing COS work in a regularly updated online database.

To keep track of the rapid growth of core outcome sets across the many diverse areas of medical research, the COMET group also conducts an annual systematic review of published core outcome sets. The latest update, published in January 2021, found 370 published COS’s spanning a multitude of specialties and disease areas.(269)

The philosophy underpinning COSs is to achieve consensus across researchers in a particular health or disease research area regarding which outcomes are most important, and to agree standardised approaches to measuring those outcomes. Of note, a COS is not intended to restrict the measurement of other additional outcomes that may be relevant in a particular trial. Thus the aim of COS is not a ‘one-size-fits-all’ approach to outcome measurement and reporting for research trials in a particular field, but merely to define a set of universally important outcomes that should be included *as a minimum* (or at least considered) in published reports of research studies in that field. The Core outcomes movement seeks to highlight outcomes of such fundamental importance that trial

investigators should automatically consider including them, while not having their hands tied when choosing other relevant outcomes.

The COMET initiative highlights several potential benefits from mandating COS reporting and the use of consistent, standardised methods for measuring and reporting research outcomes. The main benefit is to minimise the previously-described inconsistency and heterogeneity currently observed in health research outcome reporting, and thus enable results from different trials to be easily compared, contrasted, and combined in meta-analyses. When outcomes are measured and reported consistently between different trials, their results can reliably be pooled in meta-analyses to provide a more precise estimate of an intervention's true effect. Consistent outcome reporting also facilitates comparison of different trials' results, because any uncertainty about whether differences between studies are due merely to using different outcome definitions or measurement methodologies, rather than true clinical effects, are minimized.

### *7.7.2 Core Outcome Set development methodology*

An important aspect of the COMET Initiative's work in promoting COS development and dissemination involves quality control. While there is no universally accepted method for selecting appropriate trial outcomes, and indeed the most suitable outcome measures for a particular trial may be context-specific (i.e. dependent on the population, trial design, local healthcare context etc),(270) the COMET Initiative has published comprehensive guidance for COS development. These include the regularly updated COMET handbook,(271) and explicit standards for appraising a published COS.(272, 273) COMET Initiative guidance has been adopted by many diverse COS development groups, and enshrines key principles similar to those for research priority setting, namely:

- Methodological transparency
- Inclusivity and equal representation of all relevant stakeholders
- A robust consensus process to generate a COS reflecting the full breadth of stakeholder views.

### *7.7.3 Standardising outcome measurement in APOM research*

To our knowledge, there has to date been only one published report of an APOM-related initiative to harmonise outcome measurement in perioperative research, from a joint task force of the European Society of Anaesthesiology and the European Society of Intensive Care Medicine.(274) However, this collaboration did not specifically incorporate patient or clinician viewpoints; furthermore the absence of a COS for APOM prompted the NIAA Research Council to decide that a Core Outcome Set, based on wider stakeholder consensus, was warranted.

The next section of this thesis describes the 'Core Outcome Measures for Perioperative and Anaesthetic Care' (COMPAC) project, in which a COS for APOM trials was developed.

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# *Chapter 8. The Core Outcome Measures for Perioperative and Anaesthetic Care (COMPAC) initiative: Overview*

## 8.1 Introduction

The Core Outcome Measures for Perioperative and Anaesthetic Care (COMPAC) project was originally conceived by the NIAA Health Services Research Centre (HSRC), borne out of concerns among the UK perioperative research community that APOM research would benefit from greater consistency in outcome reporting and relevance to end users.

Concerns about inconsistent outcome measurement and reporting were also echoed in the global perioperative literature. Discussions with perioperative research colleagues in Australia fomented a parallel BJA-sponsored international collaboration alongside COMPAC, the 'Standardized Endpoints for Perioperative Medicine' (StEP) Initiative. Its remit was to develop explicit, consensus-based endpoints and/or definitions for measuring perioperative outcomes.

Unlike COMPAC, the StEP Initiative was an expert-led consensus-based collaboration between perioperative researchers and HCPs from several countries, with subgroups each tasked with agreeing specific definitions for specific domains. For example, the respiratory subgroup agreed definitions for endpoints such as postoperative pneumonia. While the StEP Initiative will not be described further in this thesis, it is mentioned here to clarify the remit and limits of the COMPAC initiative. In essence, COMPAC sought to recommend 'what' to measure, while StEP sought to agree 'how'.

COMPAC emphasised collaborative participation of service users and HCPs at every stage. The project followed the COMET Initiative's recommended methodological principles for Core Outcome Set (COS) development, as described in its handbook and the 'Core Outcome Set–Standards for Development (COS-STAD) and Reporting (COS-STAR)' recommendations.(271, 272) COMPAC comprised three consecutive phases, as summarised in Figure 8.

- Evidence-gathering phase: assessing current outcome measurement practice in perioperative and anaesthetic research through a systematic review (SR) of outcome measurement and reporting in high impact anaesthetic and perioperative RCTs. This SR provided a comprehensive overview of how outcomes are measured and reported in existing research.

- Stakeholder consultation phase: exploring patients', researchers' and HCPs' views regarding important outcomes in perioperative research. Gathering and incorporating the views of relevant stakeholders is a fundamental principle of COS development: this phase therefore sought to maximise stakeholder engagement and ensure their viewpoints were represented in the final COS.

- Final consensus phase: invited stakeholder representatives took part in a modified Delphi process involving iterative online surveys and a face-to-face workshop. Starting from a longlist of 'candidate' outcomes derived from the outputs of the first two phases, contributors participated in an iterative consensus process to nominate the most important outcomes for inclusion in the final COS.

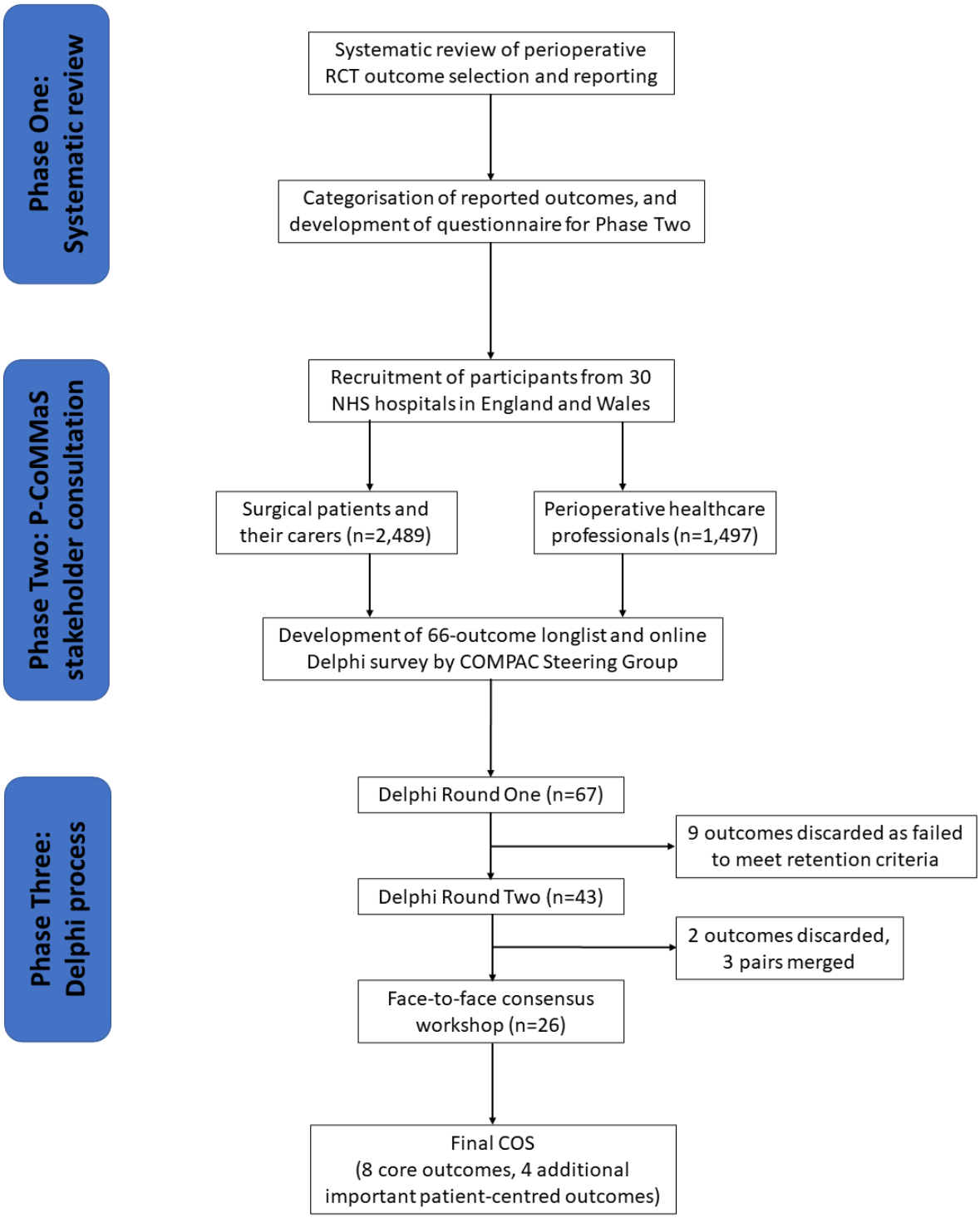


**Figure 8.** COMPAC process flow diagram: stages in development of the COMPAC core outcome set

**Previous/existing work:**

Several core outcome sets (COS) have recently been developed, or are being developed, for specific types of surgery or groups of surgical patients.(275-280) Core outcome sets relevant to anaesthesia for certain groups of surgical patients have also been published or are in progess, for example pertaining to anaesthesia for hip fracture patients,(276) recovery after Caesarean section,(281) regional anaesthesia and paediatric perioperative care.(282, 283)

However at the time COMPAC began, there was no COS spanning the breadth of APOM research. The previously mentioned ESA/ESICM consensus recommendations for standardised perioperative outcomes definitions was an important early milestone in improving consistency and standardisation in perioperative outcome measurement with relevance across the spectrum of surgical intervention,(274) but the COMPAC initiative is still – to our knowledge, at least – the only core outcome set with relevance for all APOM trials.

### *8.1.1 COMPAC objectives*

The agreed objectives of the COMPAC initiative were:

1. To develop a Core Outcome Set (COS) for clinical effectiveness trials in Anaesthesia and Perioperative Medicine (APOM)

2. To inform future recommendations regarding ‘what should be reported’ as a basic minimum in APOM research trials.

## 8.2 COMPAC scope and terms of reference

The COMPAC project was prospectively registered on the COMET Initiative database, and all phases were overseen and coordinated by the COMPAC Steering Group (SG). The SG members were:

- A UCL Perioperative Research Fellow (OB, author of this PhD)
- Three internationally-recognised perioperative and anaesthetic research leaders (Professors Ramani Moonesinghe, Mike Grocott, Paul Myles)
- Two invited members of the RCoA Lay Committee (Ms Irene Leeman and Ms Lynne Smith)

The COMPAC SG agreed the scope of COMPAC to be 'all clinical effectiveness trials recruiting participants undergoing major surgery requiring anaesthesia and/or perioperative care'. The following definitions were used throughout:

**Stakeholders:**

Anyone with a legitimate interest in the processes and outcomes of surgery, anaesthesia and perioperative care, classified into two overarching groups:

1. **Service users** (patients and carers): any patient with experience of having major surgery themselves, or carer with experience of looking after a friend or relative following major surgery.
2. **Healthcare professionals (HCPs)**: any clinician involved in the delivery of surgical, anaesthetic or perioperative care (both hospital and community-based), and academic researchers working in the fields of anaesthesia and perioperative medicine.

For simplicity, participants falling into both groups (i.e. HCPs with personal experience as patients and/or carers) were categorised as HCPs, based on the APoC-PSP findings that views from this group of participants were more closely aligned with those of HCPs than service users.

**Anaesthesia and Perioperative Care:**

All aspects of patient care around a surgical episode, both inpatient and outpatient, from the time surgery is first considered until discharge from hospital and beyond, excepting aspects that pertain directly to the surgery itself (such as choice of surgical scalpel).

**Major surgery:**

Any non-obstetric surgical procedure requiring any type of anaesthetic for which the patient is admitted to hospital overnight (i.e. non-ambulatory surgery).

Obstetric surgery – though frequently requiring an overnight stay – was excluded because it usually involves two (or sometimes more) patients, with fetal outcomes generally considered fundamental alongside those of the mother. As fetal outcomes do not apply in non-obstetric major surgery, the SG agreed that obstetric outcome measurement should be considered separately from outcomes in non-obstetric major surgery.

**Outcome:**

An outcome or endpoint was defined as ‘any variable used by trial investigators to evaluate, measure or quantify the end result (outcome) of the intervention under investigation’ (based on definitions used by the World Health Organisation and the USA’s Agency for Healthcare Research and Quality).(284, 285)

All ‘generic’ perioperative outcomes, i.e. outcomes or endpoints that may impact any patient undergoing major surgery, were included as eligible core outcomes. Thus ‘mortality’ was classed a generic outcome (since a patient may die after any operation), whereas bile duct leak was not (since this is a surgery-specific complication of hepatobiliary surgery). Outcomes which, though clearly associated with certain types of surgery (for example, venous thromboembolism after pelvic surgery, or arrhythmia after thoracic surgery) may potentially affect *any* patient undergoing major surgery, were included.

**Terms of reference:**

The remit of COMPAC was to produce a COS to guide future outcome reporting in APOM research. However, as there was no *a priori* expectation that the ensuing COS would be mandated or enshrined in research standards, COMPAC did not produce written terms of reference. As described above, a COS is intended to encapsulate a *minimum* set of outcomes for reporting in all future trials in a particular field. COMPAC similarly sought to

define a set of universally important outcomes for all future APOM trials, without imposing constraints on measurement and reporting of additional outcomes.

In the next three chapters, I describe the methods, results and conclusions of each of the three phases of the COMPAC project. They are described consecutively because each phase was informed by the results of the previous phase.

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# *Chapter 9. COMPAC Phase 1: Systematic review of outcome reporting in perioperative and anaesthesia research trials*

## 9.1 Introduction

We conducted a systematic review to gain a comprehensive insight into how outcomes are currently reported in APOM research trials, and where possible to evaluate the 'quality' of outcome reporting by reference to three pre-specified 'quality' criteria for outcome reporting. The review's pre-specified objectives were:

**Objectives**

1. To describe and collate outcome measures reported in the recent randomised controlled trial (RCT) literature in surgery, anaesthesia and perioperative medicine

2. To assess the quality of perioperative outcome measurement and reporting against the following 'quality' criteria: a) explicit timeframe described; b) explanation of definitions or criteria used to measure an outcome; c) incorporating a measure of clinical severity and/or patient impact.

3. To quantify the frequency of reporting of different outcome measures.

## 9.2 Methodology

Four online research databases (OVID Medline, EMBASE, Web of Science and the Cochrane Library) were searched for publications reporting RCTs that recruited adult patients undergoing major surgery. Searches were conducted by the lead author (OB), using the search strategies described in Appendix 2, between February and May 2016; 12th May 2016 was the last date searched.

Initial scoping searches across these databases were conducted to refine search strategies and inclusion criteria. Given the breadth and volume of published research

across surgery, perioperative medicine and anaesthesia, the COMPAC SG agreed to use search limits to filter out uncommon outcome reporting practice, exclude small and/or low impact publications, and thereby maximise the focus on 'mainstream' outcome reporting practice in high quality, widely influential research trials. The following inclusion criteria and limitations were therefore applied:

### *9.2.1 Inclusion criteria:*

**Types of study**

Only prospective RCTs were considered for inclusion, on the basis that these are the traditional 'gold standard' of clinical effectiveness trials. We also considered that outcomes reported in RCTs – which are prospectively chosen – would better reflect 'ideal' outcome measurement than those reported in observational trials or retrospective studies, which may be determined by pragmatic or logistical considerations.

**Participants and interventions**

We considered all trials which recruited adult participants (aged ≥18) undergoing any kind of major surgery (elective and/or emergency), other than obstetric, requiring hospital admission. Major surgery was defined as any procedure requiring a surgical incision, for which most patients were admitted to hospital for at least one night. Trials involving only endoscopic procedures were generally excluded; trials where a major surgical intervention was compared with an endoscopic or endovascular one were included.

**Additional restrictions:**

To restrict our focus to outcome reporting in high impact RCTs published in high impact journals, the following restrictions were applied:

- Only RCTs from the four highest impact journals for general medicine, surgery and anaesthesia were considered, which at the time of conducting the searches were:

- ***General Medicine:*** The Lancet; The New England Journal of Medicine (NEJM); The Journal of the American Medical Association (JAMA); The British Medical Journal (BMJ)
- ***Surgery:*** Annals of Surgery; The British Journal of Surgery (BJS); JAMA Surgery (formerly Archives of Surgery); The Journal of the American College of Surgery (JACS)
- ***Anaesthesia:*** The British Journal of Anaesthesia (BJA); Anaesthesia and Analgesia (A & A); Anaesthesia, Anesthesiology

- Only RCTs recruiting ≥100 participants
- Only RCTs published between 1st January 2005 and 31st December 2014.

To meet the aim of providing a comprehensive, wide-ranging overview of outcome reporting practice in high quality journals, we also set a prospective minimum target of ≥300 included RCTs. We agreed in advance that if this target was not met, we would relax either the participant number or date restrictions described above.

Searches were not extended by reviewing bibliographies of included trials, nor by performing grey literature searches, since we were only searching for large trials published in the major journals described above; additional searching was therefore considered unlikely to retrieve additional trials not already found in the four databases searched.

### *9.2.2 Exclusion criteria*

We did not record reasons for excluding trials which on full text review did not meet our inclusion criteria, since searches were sufficiently broad to retrieve a large number of non-relevant trials. However the commonest reasons for exclusion were:

- Not a prospective RCT
- Ambulatory, minor, or obstetric surgery, or non-surgical intervention
- Recruited only paediatric patients
- Fewer than 100 participants recruited
- No generic outcomes reported

- Duplicate trial (i.e. already retrieved via search of other database)

### *9.2.3 Assessment of quality / risk of bias*

We did not conduct formal assessments of quality or risk of bias for each included trial, since the review's aim was not to synthesise evidence regarding a clinical question, but to describe *common* outcome reporting practices in influential, high impact journals. The review was also primarily concerned with quality of outcome reporting based on the 'desirable' characteristics of perioperative outcome measurement discussed in chapter seven.(162, 236, 286) We therefore assessed quality of outcome reporting within each RCT – but not other aspects of methodological quality – using the following criteria:

- **Timeframe:** Where relevant, was the outcome measure reported with reference to a specified timeframe / timepoint?
- **Clear definition +/- reference to existing standards/ definitions:** Was the outcome measure clearly defined? If so, was a published standard, criteria or definition used? (e.g. international definition of myocardial infarction)(287)
- **Reflecting clinical severity and/or patient impact:** Where available, was a published scoring system or classification used to quantify the outcome's clinical severity and/or impact on the patient? If not, was the outcome's clinical severity and/or patient impact otherwise incorporated in its measurement? (e.g. 'Acute kidney injury requiring renal replacement therapy', 'bleeding requiring return to theatre', rather than merely 'acute kidney injury' or 'postoperative haemorrhage')

### *9.2.4 Data extraction*

The full text of all eligible trials was retrieved and reviewed. The following data was extracted and recorded for all included RCTs:

- Article title, authors, journal, date of publication
- Number of participants recruited, number of recruiting centres

- All ‘generic’ endpoints and outcome measures, including verbatim definitions, criteria or descriptions where available. (Where definitions or explanations of each outcome were absent, this was also noted).

Surgery-specific endpoints and outcome measures were not extracted. Where doubt existed about whether an outcome measure was generic or not, it was included, or discussed with a second author. Where outcome measures were vague or not specifically defined, we did not contact authors for clarification, since the aim of our review was to evaluate how outcomes are reported in the published literature, rather than how they were actually measured during the conduct of the trial.

### *9.2.5 Data synthesis*

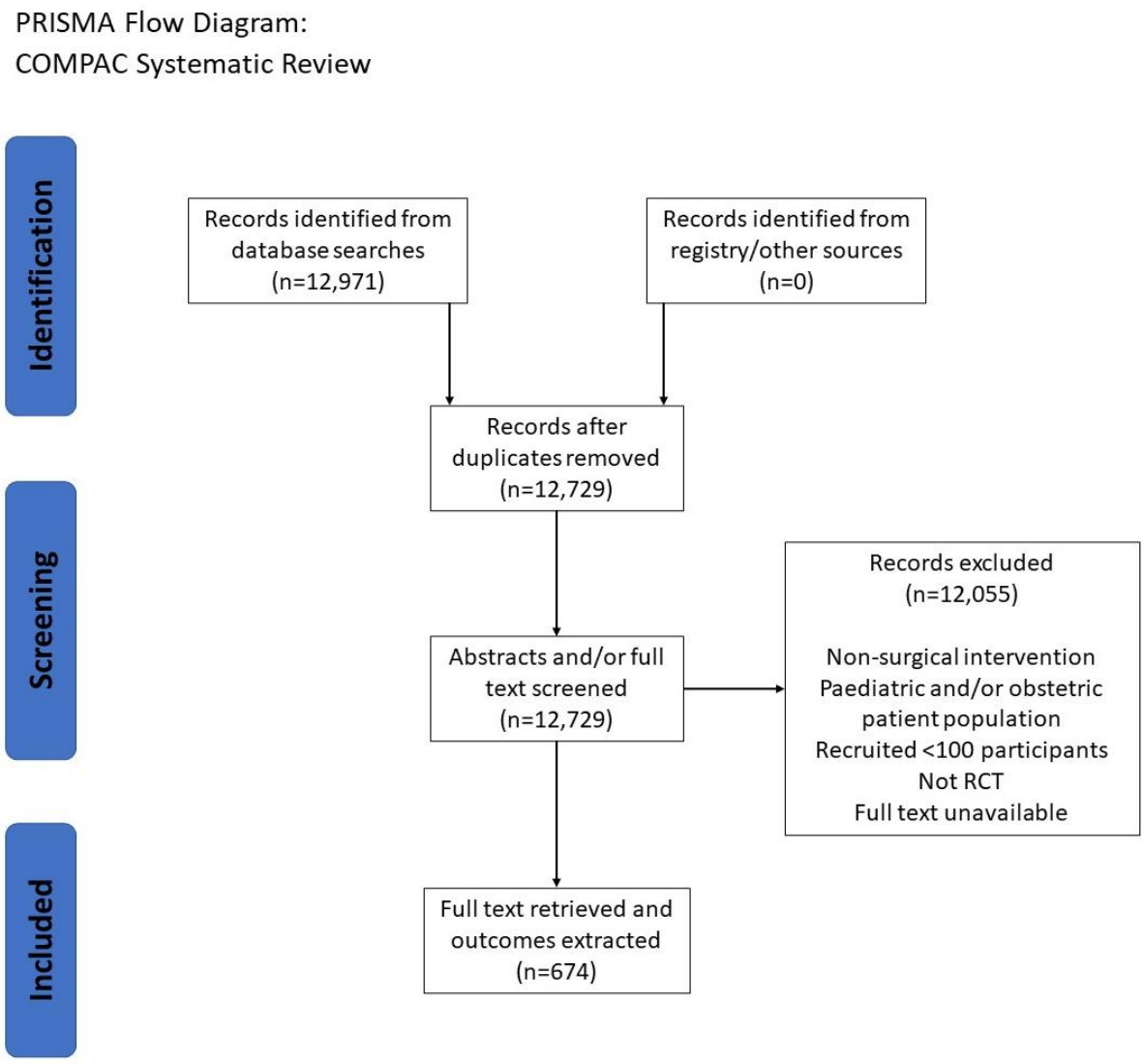
A frequency table of endpoints and outcome measurement variables was produced. For ease of reporting the findings, outcome measures were categorised into seven domains, based on existing outcome measurement classifications:(285)

- Mortality and survival measures
- Measures of perioperative morbidity, complications, and adverse events
- Composite outcome measures
- Healthcare resource use measures
- Patient comfort / recovery measures (variables reflecting any aspect of short-term patient comfort or discomfort in the postoperative period, including overall measures of postoperative recovery)
- Patient-reported outcome measures of health-related quality of life (HR-QoL)
- Medium to long-term measures of treatment success or failure

Descriptive statistics were used to summarise the different outcome measures within each domain, their respective frequency of reporting, and to describe trends in whether/how these outcome measures were defined.

## 9.3 Results

Our searches yielded a total of 12,971 RCTs, of which 674 were deemed eligible on full text review (see figure 9). The number of trials included and total number of participants from each journal is shown in Table 21.




*From:* Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

**Figure 9.** PRISMA flow diagram showing identification, screening and inclusion process for database searches. (PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses)

| Journal name | Impact factor (2015 JCR) | No. of RCTs retrieved | Total participants in retrieved trials |
|---|---|---|---|
| New England Journal of Medicine (NEJM) | 59.558 | 80 | 121,607 |
| The Lancet | 44.002 | 82 | 123,192 |
| Journal of the American Medical Association (JAMA) | 37.684 | 50 | 60,896 |
| British Medical Journal (BMJ) | 19.697 | 17 | 10,035 |
| Annals of Surgery | 8.569 | 95 | 35,679 |
| JAMA Surgery | 5.661 | 32 | 14,524 |
| British Journal of Surgery (BJS) | 5.596 | 75 | 32,908 |
| Journal of the American College of Surgeons (JACS) | 4.257 | 22 | 8,520 |
| British Journal of Anaesthesia (BJA) | 5.616 | 53 | 27,472 |
| Anesthesiology | 5.555 | 56 | 61,992 |
| Anesthesia and Analgesia | 3.827 | 82 | 27,124 |
| Anaesthesia | 3.794 | 30 | 11,478 |
| TOTALS | N/A | 674 | 535,427 |

**Table 21.** COMPAC systematic review: number of RCTs retrieved from each journal with total participant numbers

### *9.3.1 Mortality and survival outcome measures:*

At least one measure of mortality and/or survival was reported in 419 trials (62%). 317 (47%) reported at least one short-term mortality endpoint (defined as up to one year postoperative), while 164 (24%) reported at least one longer-term survival endpoint (defined as beyond a year postoperative).

**Short-term mortality reporting (n=317)**

The two commonest variations in short-term mortality reporting were the timepoint at which mortality was measured, and the attributed cause. Timepoints were mostly described in days, but some trials reported mortality in weeks or months postoperatively.

Overall, 30-day mortality was the commonest metric reported across all trials (Table 22).

| Mortality endpoint | Number of RCTs reporting this endpoint (%) |
|---|---|
| No timepoint specified | 11 (3.5%) |
| In-hospital / inpatient | 120 (38%) |
| 28 day / 4 week | 12 (3.8%) |
| 30 day / 1 month | 145 (46%) |
| 60 day | 11 (3.5%) |
| 90 day / 3 month | 31 (9.8%) |
| 12 month / 1 year | 53 (17%) |
| Other timepoint | 43 (14%) |

**Table 22.** Frequency of reporting of different short-term mortality endpoints

While 21 trials (6.6%) reported mortality attributable to a specific disease or cause – such as ‘mortality from cardiovascular causes’ – and 69 (22%) explicitly reported ‘all-cause’ mortality, the vast majority (227 trials, i.e.72%) did not provide details of mortality causation. These trials generally appeared to have reported mortality from any cause, but the inference was left to the reader rather than being explicitly stated by the authors. Terminology also varied between trials, with ‘death rate’, ‘death’, ‘mortality’, ‘survival’ all used to denote mortality; ‘perioperative’ and ‘postoperative’ were similarly used interchangeably; and all-cause mortality was reported using various different terms (e.g. ‘all-cause’, ‘total’, ‘due to any cause’ and ‘overall’).

**Long-term survival measures (n=164)**

Of 164 trials reporting long-term survival, 157 (98%) reported overall survival, with most authors providing details regarding frequency and duration of patient follow-up post-enrolment. 'Disease-specific' long-term survival was reported in 122 trials (76%); however terminology varied widely, with some trials reporting long-term mortality rates attributable to the disease or condition under investigation (e.g. 'breast-cancer mortality'); others reported survival without the disease under investigation (e.g. 'breast cancer-free survival'). Even within a single journal (the Lancet), we found varying terminology across different trials for long-term disease-specific survival. These included 'disease-free survival', 'progression-free survival', 'biochemical progression-free survival', 'clinical progression-free survival', 'recurrence-free survival', 'invasive-disease-free-survival', 'relapse-free survival', 'metastasis-free survival', and 'event-free survival' (defined as 'without recurrence or chemotherapy-related death').

### *9.3.2 Perioperative morbidity, complications and adverse events:*

Postoperative morbidity outcomes were reported in 412 (61%) RCTs. The precise outcome(s) reported varied widely between trials, depending on each trial's principal aims or research questions. Similarly, the level of detail and breakdown of reporting varied widely. Some reported 'overall' complications; others reported complications classified by organ system, or divided into (for example) early and late, infectious and non-infectious complications, local or systemic, or surgical and non-surgical complications. Some authors provided a full breakdown of the specific complications sought and reported; however, few provided precise definitions or criteria for how specific complications were measured or 'counted'. Several authors reported 'pre-defined' complications, which generally referred to an *a priori* decision about which complications would be sought, rather than the use of a standardised definition or criteria to attribute the presence or absence of a specific complication.

Alongside the varying level of detail described above, there was wide variation in reporting of the incidence of complications. Some authors reported the number of *patients* suffering from complications in each group, or the number of patients suffering from (for example) cardiac or infectious complications, depending on the trial intervention being studied – in preference to the incidence of complications themselves. In one such example, Bassi et al

reported the total (cumulative) number of complications observed in each group, the number of patients with complications, the number of patients with single versus multiple complications, and the individual incidence of specific complications.(288)

Meanwhile while most authors reported the occurrence of complications within a given timeframe (e.g. up to 30 days postoperatively), some reported the point prevalence of postoperative morbidity at a specific timepoint (e.g. 10 days postoperatively). Thus a postoperative chest infection that arose on day 3 but had resolved by day 7 would be included under the first system but missed by the second. This difference in how complications are measured – effectively, cumulative incidence of complications over a given period versus prevalence at a specific timepoint – unsurprisingly had a profound effect on the overall reporting of complications.

Some trials reported only ‘major’ complications or ‘serious’ adverse events (with/without further explanation of what was included as a major complication), or classified complications as major, moderate or minor. One common approach was to define the severity of postoperative morbidity by the therapeutic interventions required: for example, acute kidney injury (AKI) requiring renal replacement therapy (RRT), respiratory failure requiring invasive or non-invasive ventilatory support; bleeding requiring transfusion, ileus requiring total parenteral nutrition (TPN) etc. This approach to grading postoperative morbidity based on clinical impact and/or resource use, although clearly pragmatic, nevertheless depends on clinician judgment and thresholds for commencing a particular intervention.

With regard to the pre-specified quality criteria, the vast majority of retrieved trials (387 RCTs, 94%) specified a timepoint or timeframe when reporting perioperative morbidity outcomes. Most trials (359 RCTs, 87%) specified which complications were counted or measured; however less than a third (130 RCTs, 32%) used a standardised definition or criteria for judging a complication present or absent. The complications for which a standardised definition was most commonly referenced were stroke (35 RCTs), myocardial infarction (29), surgical site infection (24), pancreatic fistula (14), and acute kidney injury (13).

Most trials (354 RCTs, 86%) also incorporated an implicit assessment of clinical severity and/or patient impact – such as the level of clinical intervention required – when reporting perioperative morbidity outcomes, but less than a quarter (90 RCTs, 22%) used a

recognised grading system or classification to quantify clinical severity and/or patient impact. The most commonly encountered grading systems were Clavien-Dindo (23 RCTs), the National Cancer Institute Common Terminology Criteria for Adverse Events (8 RCTs), neurological outcome grading systems such as the Rankin, modified Glasgow Outcome Scale or Barthel Index (12 RCTs), and the Postoperative Morbidity Survey (5 RCTs).

### *9.3.3 Composite outcome measures:*

One hundred and four trials (15%) reported at least one ‘composite’ outcome, meaning a combined outcome incorporating several possible adverse perioperative endpoints. While most authors had defined their own ‘bespoke’ composite outcome, the majority included death/mortality (89 RCTs, 86%). Other commonly reported composite outcomes were major adverse cardiovascular or cerebrovascular events (MACCE, 33 RCTs) and major adverse cardiovascular events (MACE, 20 RCTs) – though there was no consistency regarding how these composites were defined between different trials.

Nineteen trials (18%) included only ‘serious’ or ‘severe’ adverse events within their composite, with varying degrees of rigour. For example, one RCT reported a ‘weighted’ composite outcome, with adverse events graded by group consensus from 0 (no harm) to 10 (death). However other trials reported endpoints of clearly unequal magnitude within their composite outcomes – for example, ‘death or an inability to walk across a room without human assistance’, and ‘death or loss of kidney function >20% at 1 year’.

### *9.3.4 Resource use outcome measures:*

One or more measure of healthcare resource use was reported in 348 RCTs (52%). By far the most common was ‘Hospital length of stay’ (250 RCTs, 72%); however other commonly encountered outcome measures were ‘Intensive Care (or Critical Care) length of stay’ (73 RCTs, 21%), ‘duration of surgery’ (52 RCTs, 15%), ‘need for unplanned re-operation or return to operating theatre’ (81 RCTs, 23%), and ‘unplanned hospital readmission’ (51 RCTs, 15%).

While the timeframe for measurement was implicit in virtually all of these outcome measures, they were rarely precisely defined. For example, only two RCTs described the

methods for deciding the start and end of surgery with reference to ‘duration of surgery’. Few authors described how ‘hospital length of stay’ was measured (though some specified measurement in hours or days); several trials also reported ‘time to readiness for discharge’ or a similar outcome (though again without clear definitions or further explanation).

Widespread variation was also observed in the reporting of outcomes. For example, some authors only included unplanned returns to theatre for a particular reason (e.g bleeding), or within a specified timeframe (e.g. up to 30 days postoperatively); others included all returns to theatre or need for re-operation, usually with no timepoint specified. Unplanned hospital readmission was also sometimes restricted to those admissions for a specific reason (e.g. wound infection or dehiscence), or within a particular period after hospital discharge. Even hospital length of stay was occasionally reported as a ‘total time in hospital’ outcome (i.e. including the index admission, plus any subsequent planned or unplanned admissions, such as for reversal of stoma) rather than referring solely to a patient’s index surgical admission.

Finally, authors variably reported certain outcomes as either continuous or dichotomous. For example, the requirement for postoperative mechanical ventilation (MV) was variously described in different RCTs using the mean (or median) duration of MV, or the proportion of patients requiring prolonged postoperative MV, or the proportion requiring prolonged MV beyond a specific duration (e.g >48 hours). Similarly, perioperative blood transfusion requirements were variably reported as the mean volume of red cells transfused per patient, or mean number of red cell units transfused, or proportion of patients requiring any perioperative transfusion of allogeneic blood products, multiple transfusions, etc.

In RCTs where financial costs of care were reported, a trend was observed towards reporting either the costs of the index hospital admission (32 RCTs), or of outpatient postoperative follow-up (10 RCTs), or the total costs of all healthcare attendances, interventions and investigations for the surgical problem in question (18 RCTs). The authors’ decisions about which outcomes to report generally appeared to be disease-specific (for example, a trial of endovascular versus open repair of abdominal aortic aneurysm might include both hospital admission and outpatient follow-up costs, whereas a trial of enhanced recovery for colorectal surgery might focus purely on the costs of the index admission).

### *9.3.5 Postoperative patient comfort and short-term recovery measures*

Two hundred and forty RCTs reported at least one measure of short-term patient recovery and/or postoperative comfort, ranging from postoperative pain (124 trials), postoperative nausea and/or vomiting (99 trials) and other physical symptoms (66 trials), to recovery of gut function (43 trials), psychological wellbeing (22 trials), overall quality of postoperative recovery (13 trials), and wound healing (7 trials). Several trials also reported how long patients spent in the post-anaesthetic care unit ('PACU') and/or time to satisfying criteria for PACU discharge, or measures of resuming postoperative physical activity such as 'time to mobilisation', time to return to normal activities (or 'activities of daily living'), or 'time to full recovery'.

The timeframe and/or timepoint for measuring these patient comfort and recovery measures was reported in almost all trials (226, 94%); similarly, they were defined in 232 (97%) of the 240 RCTs, with implicit or explicit assessment of clinical severity and/or patient impact in 227 (95%). However, the timeframes and definitions used varied significantly between different trials, as I shall explore in the following paragraphs.

**Pain outcome measures**

Of the 124 trials that reported postoperative pain, the vast majority (117, 94%) reported at least one measure of pain severity, mostly using one of the following measurement instruments:

- Visual analogue scale ('VAS'), usually 0-100 or 0-10: 82 RCTs
- Verbal rating scale ('VRS'), usually mild/moderate/severe 18 RCTs
- Numerical rating scale ('NRS'), usually 0-10 or 0-100 17 RCTs
- Summed Pain intensity difference (SPID) 6 RCTs

94 RCTs (76%) also reported the amount of painkiller required postoperatively for patients in each group. The precise method of measuring and reporting this outcome varied between trials, however: some reported total analgesic use (usually in morphine equivalents); others reported the mean or median length of time patients required

postoperative analgesia, and/or the cumulative analgesic use up to a particular timepoint; while others reported the number of patients needing rescue analgesia, or total doses of rescue analgesia required.

The timepoints at which pain was measured, and analgesic consumption recorded, similarly varied widely between trials, as did the method of measuring pain. Some authors reported pain at rest; others reported pain on movement, or coughing, or mobilising, or during specific movements relevant to the surgical population (e.g. knee flexion in knee arthroplasty patients). Other measures of pain intensity and/or impact reported that were infrequently reported included pain-related awakenings at night; unpleasantness or degree of distress caused by pain (i.e. the affective component), or pain intensity during specific procedures (e.g. wound dressing changes).

Meanwhile some authors reported postoperative pain at multiple timepoints, thereby describing its longitudinal trajectory (for example, comparing the analgesic efficacy of two different non-steroidal anti-inflammatory drugs), while others reported pain at only one timepoint (such as pain scores on day one post-laparotomy after different regional anaesthetic blocks).

**Nausea and vomiting outcome measures**

Of the ninety-nine trials that reported postoperative nausea and/or vomiting (PONV), 37 (37%) simply reported the incidence of any PONV, while 62 (63%) reported PONV severity. The commonest methods for measuring PONV severity were:

- Numerical (0-3) or verbal (none/mild/moderate/severe) rating scale 31 RCTs
- Visual analogue scale (VAS, usually 0-10 or 0-100) 14 RCTs
- PONV recorded as presence of nausea, vomiting, or both 9 RCTs
- ‘Severe PONV’ reported separately from overall PONV incidence 3 RCTs

58 RCTs (59%) also reported the need for rescue antiemetic, though as with analgesia requirement, this was variously reported as total antiemetic use, mean number of doses required, or the proportion of patients requiring any rescue antiemetic. Some trials further categorised postoperative vomiting severity according to the number of vomiting episodes,

or described retching and vomiting separately. Other variations observed in the reporting of PONV outcomes included:

- Thirteen RCTs (13%) divided PONV into early (variously defined as occurring 0-2 hours, 0-6 hours or 0-12 hours postoperatively) and late PONV
- Some trials reported PONV occurring in the post-anaesthetic recovery area as recorded by the nurse looking after the patient, whereas some specified patient-reported PONV incidence and/or severity (with the implicit assumption that assessment occurred once the patient was sufficiently recovered from anaesthesia to respond to questions). Most trials did not specify whether PONV was clinician-assessed or patient-reported, however.
- Seventeen RCTs (17%) reported 'complete PONV response'. While this was generally defined as a complete absence of nausea, vomiting, retching, or need for rescue antiemetic within a specific postoperative timeframe, some trials defined complete response as 'no emesis or antiemetic use'.

**Other postoperative symptoms**

Sixty-six RCTs reported other postoperative adverse physical symptoms, including excessive sedation (21 RCTs), itching or pruritus (20), sore throat (15), dizziness (14), shivering (10), headache (8), hoarseness (8), drowsiness (5), dysphagia and dysphonia (both 4). 'Opioid side effects' were reported collectively in fourteen RCTs. The level of detail of reporting generally varied according to whether the outcome was directly relevant to the trial intervention. Meanwhile twenty-two RCTs reported adverse psychological symptoms, such as anxiety (10 RCTs), depression (9), sleep disturbance (7), fatigue (3), restlessness and hallucinations (both 2). Some RCTs merely reported the overall incidence of these symptoms; others used a VAS, NRS or VRS to quantify severity; a minority used a validated measurement tool, such as the State Trait Anxiety Inventory.

**Gastrointestinal recovery**

Forty-three RCTs – mostly involving patients who had undergone gastrointestinal surgery – reported at least one measure of recovery of gut function. A wide range of outcome

measures was encountered, including ‘time to first flatus’ (17 RCTs), ‘time to first bowel movement’ (20), ‘time to tolerating oral or solid diet’ (19), ‘time to tolerating liquid diet’ (4), ‘duration of total parenteral nutrition’ (2), and ‘duration of postoperative ileus’ (3). Two trials also reported composite outcome measures (e.g. GI-2, encompassing ‘time taken to pass first stool and tolerate oral intake’). In almost all cases, definitions of what constituted ‘tolerating’ a particular diet were absent.

**Multidimensional Quality of Recovery scores**

Thirteen RCTs reported ‘quality of recovery’ (QoR) scores using a validated questionnaire.(289, 290) Six reported the full forty-question QoR-40 score, while five used the abbreviated QoR-9 and one the QoR-15.

**Post-anaesthesia recovery**

Early postoperative recovery traditionally takes place in a dedicated Post-Anaesthesia Care Unit (PACU) or ‘Recovery’ area, with most hospitals having strict PACU discharge criteria, often based on the Aldrete score.(291) Twelve RCTs reported ‘time to readiness for PACU discharge’ as a proxy for post-anaesthesia recovery (though without specifying PACU discharge criteria); eight reported ‘time to Aldrete score $\geq$9’; five reported total time spent in the PACU.

**Other measures of short-term recovery**

Eighteen RCTs reported at least one measure of short-term functional recovery after surgery. These included measures of mobility (such as return to walking, or sitting out of bed, or previous mobility levels), measures of functional ability (resumption of normal life activities, or ‘activities of daily living’), resumption of normal roles (e.g. time off work), and ‘time to full recovery’, which was not specifically defined. A few trials specifically measured the time taken for the patient to achieve their *full* preoperative level of function or mobility; most did not detail how they judged a patient’s return to normal activities. Furthermore few

trials explained how such assessments were conducted (for example, via patient questionnaire, outpatient or telephone follow-up, etc.)

Finally, nine trials reported an outcome related to successful surgical wound healing. Of note, these positive wound healing outcomes were reported far less commonly than 'failures of wound healing' or wound complications, which were reported in 140 RCTs. These included wound infection (reported in 120 trials), wound dehiscence (31), wound haematoma (27) and wound seroma (17 RCTs).

### *9.3.6 Patient-reported outcome measures of longer-term health-related quality of life (HRQoL)*

Two hundred and six (31%) RCTs reported at least one outcome describing patients' medium-to-long term HRQoL. As such measures are necessarily more nuanced and complex than outcomes such as mortality, I shall explore these in detail below.

#### Generic HRQoL measures

Generic or global HRQoL measures, i.e. those designed to measure HRQoL across several domains, were reported in 105 RCTs. The 36-Item Short Form Survey (SF-36), developed by RAND Health Care as part of the USA's Medical Outcomes Study,(292) was the most frequently reported (48 RCTs), while the European EQ-5D questionnaire developed by the EuroQoL group in the 1980's, which measures HRQoL across five domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression),(293) was reported in 34 trials. Other generic HRQoL measures encountered included the SF-12 (8 RCTs), EQ-VAS (6 RCTs), and SF-8 (1 RCT).

#### Disease-specific HRQoL measures

Meanwhile disease-specific HRQoL measures – i.e. those designed to evaluate HRQoL in specific patient groups – were reported in 72 trials. The most common examples were cancer-related, the vast majority of which used the well-validated European Organisation of Research and Treatment of Cancer (EORTC) quality of life questionnaires (QLQ's) for

different groups of cancer patients. The most frequently encountered were the generic EORTC QLQ C-30, which measures HRQoL in all cancer patients, reported in 19 RCTs, and the QLQ CR-38 (for colorectal cancer patients, 5 RCTs), QLQ BR-23 (breast cancer, 3 RCTs), and QLQ OV-28 (ovarian) and QLQ STO-22 (gastric), each reported in one RCT.

Three RCTs measured HRQoL in cancer patients using the Functional Assessment of Cancer Therapy (FACT) questionnaires, developed by the FACIT group.(294) As with the EORTC QLQ's, the FACT assessment tools include a generic, core questionnaire for all cancer patients and several separate ones for patients with specific cancers.

Forty-five non-cancer RCTs also used various disease-specific instruments to measure HRQoL in particular patient groups. Examples included the Oswestry Disability Index and the Roland-Morris Disability Questionnaire, both used principally for patients with lower back pain,(295) and each reported in five RCTs in this review. The Gastrointestinal Quality of Life Index (GIQLI) was reported in six RCTs,(296) and other gastro-oesophageal reflux disease-specific questionnaires such as the Visick and Reflux Disease Questionnaires (297) in a further six RCTs. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) were used in two RCTs,(75) and the Vascular Quality of Life Questionnaire in one trial.(298)

### Chronic pain

Twenty-two trials reported the prevalence and/or severity of postoperative chronic pain (i.e. patients with pain persisting more than three months beyond their surgery) in the medium to long-term. Ten RCTs used a VAS, three used a VRS; most others used a chronic pain specific questionnaire such as the Brief pain inventory, McGill or DN4.

### Psychological wellbeing and/or mental health outcomes

Twenty-eight trials reported psychological and/or mental health outcomes, most commonly relating to depression and/or anxiety. Five RCTs used the Hospital Anxiety and Depression Scale (HADS), while eight others reported the incidence of depression and/or anxiety (either using a different measurement instrument, or not specifying how measured). Body image and cosmetic outcomes were reported in eleven trials, most

commonly asking patients to score their cosmetic satisfaction using a VAS. Psychological wellbeing was reported in two RCTs, as was postoperative sleep quality. Postoperative chronic fatigue and/or lethargy was reported in seven RCTs, with five using a VAS.

**Functional status and long-term recovery**

Eighty trials (12%) reported several different measures of patients' functional status. These outcome measures broadly fell into four categories:

1) Mobility-related outcomes (fifteen RCTs). These included the ability to walk, walking distance, need for mobility aids, ability to perform specific movements (such as knee flexion), or formal clinical tests of mobility such as the shuttle walk test or timed-up-and-go test.

2) Outcomes assessing patients' capacity for performing their usual activities of daily living (ADLs). Eighteen RCTs reported patients' resumption of ADLs as an outcome, though how these assessments were conducted was unclear in over half of these trials.

3) Outcomes assessing time taken and/or patients' eventual ability to return to their usual life roles (such as work – reported in 20 RCTs), and/or usual place of residence (four RCTs). These also included outcomes quantifying cognitive impairment and/or disability (29 RCTs), for which the commonest measures were the Rankin score (11 RCTs), Glasgow Outcome Scale (six RCTs), and the Barthel Index (three RCTs).

4) Outcomes assessing patients' symptoms and/or functional capacity relative to baseline before surgery (eight RCTs), and/or assessing the extent of postoperative recovery at a particular timepoint such as 30 days postoperatively (seven RCTs). Some used a Likert scale or VRS (such as 'much better, better, about the same, worse, much worse'); however in most RCTs the tools used for these various assessments was unclear.

Across the eighty trials purporting to describe functional status, there was often little or no detail of how these outcomes were collected. Only a minority described and/or justified the assessment tool used, or how and when it was administered. In the vast majority, these outcomes were used to evaluate between-group differences, rather than for comparison with other trials.

**Patient satisfaction**

Fifty trials (7.4%) reported at least one outcome describing patient satisfaction. Several asked patients specifically to describe their satisfaction with a particular aspect of their care (e.g. postoperative analgesia, 12 RCTs; anaesthesia, 7 RCTs; antiemetic treatment, 4 RCTs); others asked patients about their overall satisfaction (8 RCTs). Fifteen trials asked patients to rate their satisfaction using a scoring system (e.g VAS, Likert, VRS or NRS); five asked about their willingness to have the same treatment again, or whether they regretted their choice, but none used the Decision Regret Scale or other validated instrument for evaluating regret and/or satisfaction.

Eighteen trials merely reported ‘patient satisfaction’, with no details of how it was assessed, or which aspects of the care process or surgical results the patient was being asked about. Moreover the majority of RCTs did not specify at what timepoint(s) the assessments of satisfaction were conducted.

### *9.3.7 Long-term treatment success/failure*

Two hundred and fifty-seven RCTs reported outcomes reflecting the overall success or failure of treatment in the medium to long term (i.e. over months-years). Most RCTs reporting these outcomes recruited patients having surgery for chronic, progressive or potentially recurring diseases, for example various types of cancer, coronary artery disease, peripheral vascular and cerebrovascular disease, hip and knee osteoarthritis, gastro-oesophageal reflux disease (GORD), and obesity.

**Disease progression and/or recurrence**

Cancer trials were those most likely to report treatment failure, defined as disease progression and/or recurrence. Ninety RCTs reported cancer recurrence or progression; most (59) reported any recurrence (i.e. both local or regional recurrences, and/or distant metastases), but 20 reported only local recurrences. Fifty-four non-cancer trials also reported disease recurrence over the medium-long term: the commonest were GORD (six RCTs) and cerebrovascular disease, coronary artery disease, and hernia recurrence (all in

five RCTs). Symptom recurrence (i.e. as reported by patients) was also collected as a marker of treatment failure in 41 RCTs: the vast majority (39) were non-cancer trials.

All trials retrieved provided details of the timeframe of patient follow-up, though some reported cumulative incidences of treatment failure (e.g. cumulative disease recurrence over the follow-up period) while others used a set cut-off (most commonly five years for cancer recurrence outcomes, and one year for cardiovascular disease recurrence).

### Side effects, adverse events and toxicity

The most commonly reported measures of treatment failure were treatment side effects, adverse events or toxicity. These were reported in 102 RCTs, 56 of which were cancer RCTs which reported recognised complications of adjunctive (i.e. non- surgical) cancer treatments such as chemotherapy, radiotherapy and immunotherapy. Half of these (28 RCTs) used the American National Cancer Institute Common Toxicity Criteria (NCI CTC) framework for categorising side effects and grading their severity, and three RCTs each used the WHO toxicity criteria or other classification system developed by a national Oncology Group (for example, the Japanese Clinical Oncology Group, used in one RCT). Five RCTs reported only ‘moderate or severe’ side effects (with no other details of how these were classified); 17 cancer trials did not specify a classification system or other criteria for toxicity events.

Forty-six non-cancer trials also reported safety or adverse event outcomes. Definitions for these were variable (or in some cases absent), though nineteen trials (41%) incorporated an assessment of patient impact and/or severity (for example, only major bleeding events were counted, or only those requiring clinical intervention).

### Further surgery/other interventions

The need for repeat surgery and/or other intervention was also commonly reported as a marker of treatment failure. Forty-eight trials reported proportions of patients requiring further intervention(s) over the follow-up period; however no RCT in this review assessed the impact on patients of needing to have further interventions.

## 9.4 Discussion

This systematic review summarised patterns and trends in outcome reporting across a broad range of RCTs published in high impact international journals. Nearly 700 RCTs, with over half a million patients in total, were included. The major finding was widespread heterogeneity across the range of outcome reporting, albeit with notable exceptions identified where standardised or accepted definitions for particular outcomes already appear to exist.

Perhaps unsurprisingly, the degree of heterogeneity was generally greater for complex, multidimensional outcomes (such as postoperative short-term recovery) than for simpler outcomes like mortality. However, our findings illustrate how even a binary outcome such as mortality can be difficult to interpret unless the timeframe and explicit details of whether all deaths were counted, or just those due to a specific cause(s), are reported.

### *9.4.1 Consequences of ambiguity in outcome measurement and reporting*

We have already explored how variation or ambiguity in definitions of specific outcomes between trials prevents easy comparison of outcomes between RCTs. The example of postoperative surgical site infection (SSI), which was reported in nearly 200 RCTs, illustrates the effects of such ambiguity. While a minority of trials defined their criteria for the presence of an SSI, the majority did not, creating uncertainty for readers wishing to compare the incidence of postoperative SSI between these various trials.

This ambiguity may be a factor in explaining the apparently conflicting evidence from different RCTs regarding the effect of perioperative oxygen supplementation on the incidence of SSIs. Whereas some trials have demonstrated a reduction in the incidence of SSI's from perioperative hyperoxia, others have found no benefit.(299-301) Commentators have speculated that differences in trial methodology or participants recruited may account for these contradictions between different trials, but using inconsistent criteria for SSI provides another obvious source of uncertainty in explaining the discrepancy.

Secondly, variation in timing of outcome measurement also affects the incidence of any given outcome. Considering again the example of SSI, a wide range of timeframes was observed between different RCTs in surveillance for SSI's, from only 72 hours up to 90

days postoperatively. Such variation calls into question whether an observed difference in SSI incidence between two similar trials genuinely exists, or is merely a methodological artefact attributable to their using different timeframes.

These ambiguities were further highlighted by isolated examples of outcome measures for which a standardised consensus definition appeared to be widely used and accepted. The International Study Group for Pancreatic Surgery (ISGPS) definition for pancreatic fistula is one such example. By using clear criteria for defining a postoperative pancreatic fistula, the incidence of this potentially devastating complication can be easily compared between RCTs investigating different surgical innovations. Similarly, the standardised National Cancer Institute's Common toxicity criteria allows quantification and comparison between trials of the varying complications that may ensue from different cancer treatments.

### *9.4.2 Recommendations for outcome measurement and reporting*

The results of this systematic review provide compelling evidence of how ambiguity in trial outcome reporting may cast doubt on the trial's findings. When researchers assume that an outcome measure is somehow self-explanatory, or simply neglect to precisely define and describe the measurement of a particular outcome, they introduce methodological uncertainty which undermines their findings. Because 'trials are only as credible as their outcomes',(302) several authors have therefore called for mandatory reporting of the selection process, definition, measurement, and analysis of a trial's primary outcomes.(51, 303, 304)

In a similar vein, recently published extensions to the CONSORT guidelines for reporting RCTs are a step in the right direction towards improving reporting of outcomes in RCTs. One of these – CONSORT PRO – sets out standards for RCTs using patient-reported outcomes (PROs).(305) As noted in our review, trials which report PROs in surgical patients often fail to provide details of the measurement tool used, or precisely how and when the PRO was measured: these guidelines should hopefully help to address this shortcoming. The planned development of an extension to the CONSORT and SPIRIT guidelines – the 'Instrument for reporting Planned Endpoints in Clinical Trials (InSPECT)' – should also improve details of outcome reporting in RCTs.(306)

### *9.4.3 Comparison with other trials*

A recurring theme in this review was RCTs whose main purpose appeared to be finding a difference in outcomes between groups within the trial. Omitting precise details of how outcomes were chosen, defined and measured may therefore appear unimportant as long as the intervention, group allocation and measurement of outcomes was consistent throughout the trial. If other RCTs report different findings, this is purely because they are different experiments with different methodologies and other (different) real world variables, even if the controlled variable is similar or even identical.

Nevertheless, while most RCT authors focus principally on finding any between-group difference in primary outcome within their trial, they are usually simultaneously eager to demonstrate how their findings are generalisable to other (similar) contexts and populations. Such generalisability is clearly hampered, however, if outcomes are poorly defined and/or reported. A highly significant difference in primary outcome risks losing much of its newsworthy impact if readers are unsure how comparable the finding is with other trials that measured ostensibly the same outcome. Conversely, precise reporting of primary outcome details may reassure other researchers that any difference is genuine.

## 9.5 Conclusions

This systematic review demonstrated the significant extent of heterogeneity and ambiguity in perioperative outcome reporting, whilst also determining the most frequently reported outcome measures across the most influential journals in perioperative research. Certain perioperative outcome domains – generally those which are complex and multifaceted, and therefore harder to measure, such as postoperative recovery – were particularly characterised by highly variable approaches to measuring and reporting; however the lack of detail in many trials made the true degree of variation between trials difficult to quantify.

In the next chapter, I describe a multicentre observational study which sought to obtain views from a wide range of patients, carers and clinicians regarding which outcomes are most important to patients who have major surgery.

# *Chapter 10. COMPAC Phase 2: Patient-Centred Outcome Measures for Major Surgery (P-COMMaS)*

## 10.1 Introduction

The next phase of the COMPAC initiative comprised a stakeholder consultation process, which sought to explore the views of surgical patients, their carers, and perioperative healthcare professionals (HCPs) about important outcome measures for patients having major surgery. We undertook a multicentre cross-sectional study in which eligible participants were invited to complete a short survey asking them to rate the importance of commonly reported outcome measures encountered in our systematic review, and to suggest any additional outcome measures they considered important for reporting in APOM research.

We hypothesised, based on the findings of the APoC-PSP, that we would observe significant differences between HCPs' and service users' ratings for the outcome measures under consideration.

### Objectives

1. To identify outcome measures of greatest importance to COMPAC stakeholders – patients undergoing major surgery, their carers, and HCPs looking after them.
2. To identify similarities and differences between the views of service users and HCPs regarding the importance of different outcomes.

### Null hypothesis

There is no difference between service users' and HCPs' views regarding important outcomes after major surgery.

## 10.2 Methodology

P-COMMaS was a prospective cross-sectional study exploring service user and HCP views about important outcomes after major surgery.

### *10.2.1 Study setting*

Participants were recruited from NHS hospitals across England and Wales. Before joining, each study team appointed a Principal Investigator (PI) and agreed local strategies for recruiting surgical patients, their carers, and HCPs. Study teams at each site were encouraged to approach participants in whichever settings and using whichever methods they considered most effective for their local context.

Several methods for approaching and recruiting participants were employed across the different study sites. For patients and carers, approaches included:

- At postoperative surgical outpatient clinic appointments
- In discharge lounges while waiting to be discharged from hospital during their index admission for surgery
- In GP surgeries and other outpatient settings postoperatively
- Email invitations to contributors to the APoC-PSP described earlier
- Via publicising the study on the NIHR Involve website
- Via the RCoA Lay Committee and ‘Patient, Carer and Public Involvement and Engagement’ (PCPIE) Group

HCPs were mostly recruited locally in study sites, for example in surgical outpatient clinics, hospital theatre suites and pre-assessment clinics. Some also learned of the study through membership of professional organisations such as the RCoA, or the RCS (Eng), or publications such as Anaesthesia News and the RCoA Bulletin.

### *10.2.2 Participants*

Eligible participants included all stakeholders with a potential interest in deciding which outcomes are important after major surgery, defined as follows:

- Patients with experience of having major surgery
- Their carers (relatives with significant direct experience of caring for a patient after major surgery)
- Healthcare professionals (HCPs) whose professional role entails caring for major surgical patients at any stage of their perioperative patient journey

Inclusion and exclusion criteria for service users (patients and carers) were as follows:

**Inclusion criteria**

- Age ≥18 years
- Direct experience of any kind of non-obstetric major surgery (either themselves, or as carers for a relative)

**Exclusion criteria**

- Unable to understand the study (e.g. due to learning difficulties, dementia or other cognitive impairment, language barrier)
- Experience of obstetric surgery only (e.g. Caesarean section)
- Experience of minor/ambulatory surgery only, not requiring inpatient admission

Inclusion and exclusion criteria for HCPs were as follows:

**Inclusion criteria**

- Direct involvement in providing clinical care for adult patients having major non-obstetric surgery, at any stage of their perioperative patient journey

**Exclusion criteria**

- Professional role does not involve providing care for major surgical patients
- Role involves obstetric or paediatric patients only

### *10.2.3 Intervention*

Eligible participants were invited to take part by local research team members. Those who expressed an interest were provided with an information sheet and a copy of the survey (either on paper, or online, see Appendices 3 and 4). They provided consent by ticking a box at the start of the survey; those completing it online also ticked another box at the end confirming that they agreed to submit the information they had entered.

The survey was only available in English, and asked respondents to rate the importance of seven different potential outcomes after major surgery on a scale of 1 to 10, and to suggest any other important outcomes in a free text section asking ‘Are there any other outcomes not mentioned above that you think are important after an operation?’ They also provided demographic information and details of their experience of surgery and perioperative care (whether as a patient, carer, or HCP). Finally, participants were asked whether they would be willing to participate in the final Delphi consensus phase of COMPAC, and if so, to provide their contact details.

When designing the P-COMMaS study, we originally planned to conduct semi-structured telephone interviews of a small subset of participants to further explore their views about important perioperative outcomes. However after the survey had closed and all responses had been collated, the COMPAC SG collectively agreed – in view of the participant numbers and range of free text comments and suggestions received – that semi-structured interviews would be unlikely to uncover new outcomes and might unnecessarily prolong the completion of COMPAC. The SG therefore concluded that semi-structured interviews would not significantly alter the overall results of the P-COMMaS consultation, and any benefits would be more than outweighed by the delay to the COMPAC process.

### *10.2.4 Outcomes*

The primary outcome was the proportion of respondents in each group who judged each outcome domain ‘critically important’, based on three categories of importance prospectively agreed by the COMPAC SG as follows: ‘critically important’ (a score of 8 out of 10 or higher); ‘fairly important’ (5 to 7), and ‘not very important’ (4 or lower).

The salient themes raised in respondents' free text comments and suggestions, and their respective frequencies, was the other main outcome of interest.

### *10.2.5 Data analysis*

#### Quantitative survey data

Online survey data was collected via surveymonkey, while completed paper questionnaires were returned from each study site to the NIAA via recorded delivery. All data was then entered by the study coordinator (OB) in a secure database hosted at University College London (UCL). Descriptive statistics were used to summarise participants' importance ratings for each candidate outcome, and to explore differences between service users' and HCPs' ratings, as well as trends and associations with different types of surgery and demographic variables such as age and professional group.

#### Qualitative free text data

For the free text comments and suggestions, a qualitative content analysis was performed using an inductive, content-driven approach (i.e. without any pre-existing framework or theoretical model). Comments were first entered into an Excel spreadsheet and re-read several times to gain a general sense of common ideas and themes. An initial thematic analysis was then performed, where each comment was coded with themes and ideas expressed either explicitly or implicitly. Service user comments and HCP comments were analysed as two separate datasets.

As the analysis progressed, new themes emerged, existing themes were adjusted or reworded to encapsulate comments that referred to similar ideas in slightly different ways, and (occasionally) similar themes were merged where a high degree of overlap existed. By the end of exploring each dataset, around thirty themes had emerged. While there was considerable overlap in themes between each dataset, some were found predominantly in one group. Each dataset was then re-analysed from beginning to end, to check each comment for the presence of themes that had appeared mainly within the other dataset, and to double-check the accuracy of themes that had been applied during the initial thematic analysis.

By the end of this analysis process, most comments had therefore been coded with several themes. No new themes emerged during the second analysis, and there was considerable overlap between themes, which reassured us that no themes had been overlooked. As with the APoC-PSP free text comments, a proportion of coded comments was reviewed by a second qualitative research expert, and any disagreements discussed with the main author who conducted the primary analysis (OB).

Similar or overlapping themes were then grouped into overarching, higher order categories. The overall frequency of each category and the themes contained within it was then described, using specific examples from the data. Most themes spanned several stages of perioperative care, reflecting the complex and variable nature of different patients' perioperative journeys. To illustrate this point, the code 'Information and communication' was assigned to all comments that touched on any aspect of information exchange or communication between patients and healthcare providers (or between different healthcare providers), whether explicitly or implicitly, and whether pre- or postoperatively. This code was therefore applied to all the following comments, because they all made reference to perioperative information exchange and/or communication:

*'Contacting family ASAP post-op to let them know pt is ok'*

*'Expectations after surgery… to be discussed pre-op'*

*'Being informed of plan and outcome. Info about rehab with clear instructions'*

*'Communication between theatres and the ward just after the operation'*

## 10.3 Results

A total of 4,104 participants completed the survey, of whom 2,582 were service users and 1,522 were HCPs. One hundred and eighteen responses (93 service user, 25 HCP) were excluded because of incomplete or unclear answers, leaving 3,986 valid survey responses from 2,489 service users (62%) and 1,497 HCPs (38%).

Almost 99% (3,939) were recruited from 29 acute NHS hospital study sites in England and Wales spanning 25 NHS Trusts or Welsh Health Boards. Meanwhile 47 participants (21

service users, 26 HCPs) responded to the survey online. The geographical distribution of the 29 study sites, and the numbers recruited from each, are shown in Figure 10 and Table 23.

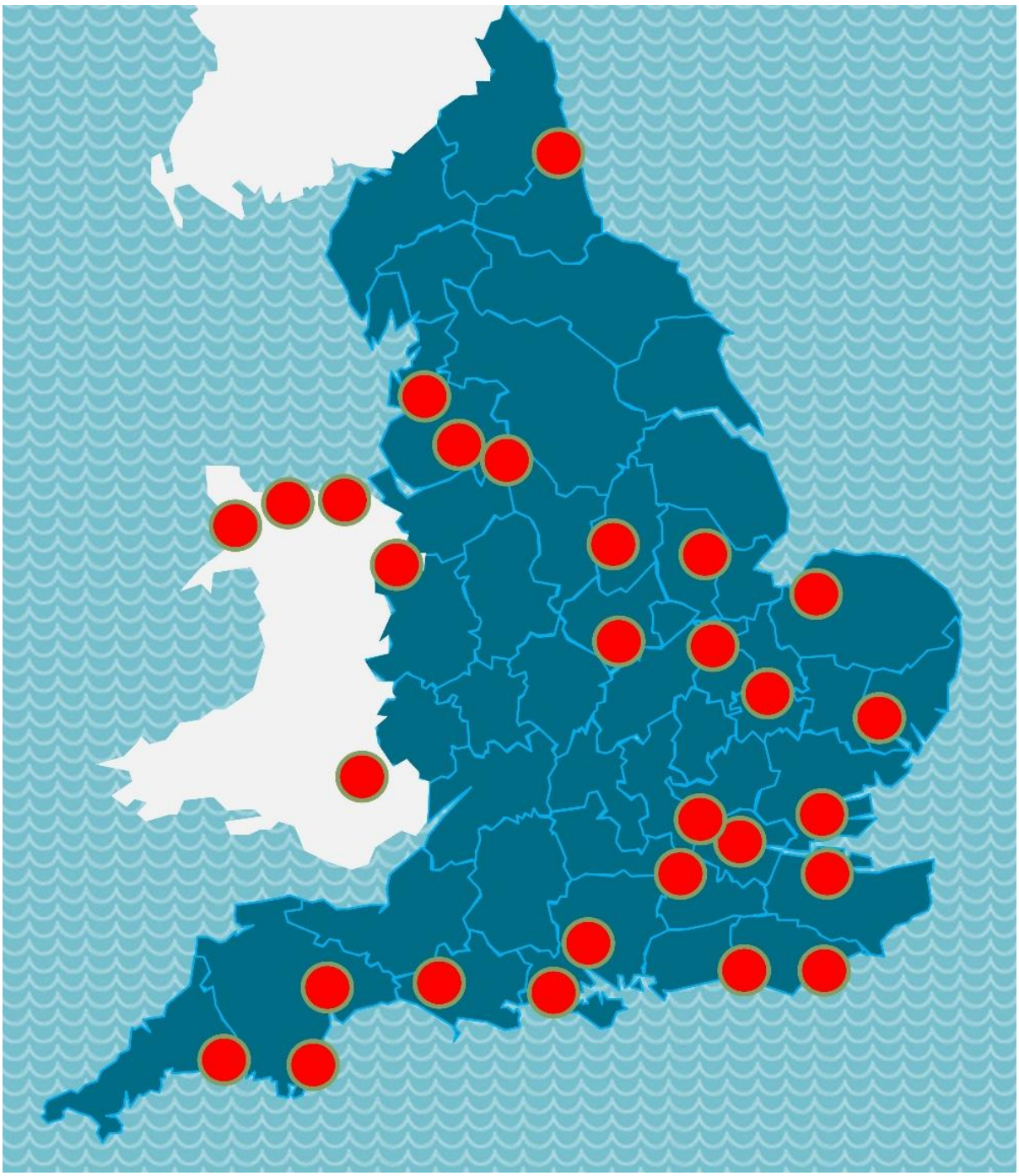


**Figure 10.** Geographical distribution of the 29 study sites in England and Wales from which P-COMMaS participants were recruited

| Site name | HCP | Service users | Total participants recruited |
|---|---|---|---|
| Llandudno General Hospital | 0 | 4 | 4 |
| Dorset County Hospital | 24 | 21 | 45 |
| Online | 26 | 21 | 47 |
| Royal Sussex County Hospital | 35 | 13 | 48 |
| Royal Devon & Exeter Hospital | 8 | 44 | 52 |
| Rotherham Hospital | 21 | 33 | 54 |
| Medway Maritime Hospital | 22 | 33 | 55 |
| Royal Victoria Infirmary | 36 | 19 | 55 |
| Derriford Hospital | 43 | 12 | 55 |
| Salford Royal Hospital | 30 | 42 | 72 |
| Royal Bolton Hospital | 44 | 35 | 79 |
| Lincoln County Hospital | 12 | 83 | 95 |
| Nevill Hall Hospital | 74 | 21 | 95 |
| Queen Elizabeth Hospital King's Lynn | 58 | 42 | 100 |
| University Hospitals Southampton | 48 | 52 | 100 |
| Pilgrim Hospital Boston | 14 | 87 | 101 |
| Torbay Hospital | 43 | 59 | 102 |
| Hinchingbrooke Hospital | 15 | 113 | 128 |
| Watford General Hospital | 88 | 44 | 132 |
| Royal Bournemouth Hospital | 60 | 74 | 134 |
| West Suffolk Hospital | 106 | 30 | 136 |
| Tameside General Hospital | 52 | 92 | 144 |
| Conquest Hospital | 61 | 119 | 180 |
| Ysbyty Gwynedd | 15 | 179 | 194 |
| University College Hospital | 98 | 103 | 201 |
| Peterborough City Hospital | 86 | 134 | 220 |

| | | | |
|---|---|---|---|
| Glan Clwyd Hospital | 67 | 197 | 264 |
| East Surrey Hospital | 149 | 124 | 273 |
| Basildon University Hospital | 55 | 229 | 284 |
| Wrexham Maelor Hospital | 107 | 430 | 537 |
| TOTAL | 1497 | 2489 | 3986 |

**Table 23.** P-COMMaS study sites and total number of participants recruited from each site

### *10.3.1 Participant demographics*

Participants' demographic data is summarised in Table 24. Service user respondents were overall older and less ethnically diverse than HCPs. Almost half (1,170 respondents, 47%) were aged ≥65, compared with less than 1% of HCPs (11 respondents). Likewise almost half of service users (1,175, 47%) were retired. Almost two-thirds of respondents were female, with a larger female majority among HCPs (68%) than service users (61%, p <0.001, Chi-squared), reflecting the female skew in the NHS workforce overall.(307) Finally, only 4% of service users described themselves as being from a non-white ethnic background, compared with 22% of HCPs (p <0.001, Chi-squared).

Table 25 summarises participants by stakeholder group with details of employment status and surgical or perioperative experience.

| | **All respondents (n=3,986)** | **Service users (n=2,489)** | **HCPs (n=1,497)** |
|---|---|---|---|
| **Age category** | | | |
| 18-25 | 130 (3.3%) | 49 (2.0%) | 81 (5.4%) |
| 25-34 | 538 (13%) | 138 (5.5%) | 400 (27%) |
| 35-44 | 649 (16%) | 214 (8.6%) | 435 (29%) |
| 45-54 | 779 (20%) | 389 (16%) | 390 (26%) |
| 55-64 | 708 (18%) | 528 (21%) | 180 (12%) |

| | | | |
|---|---|---|---|
| 65-74 | 684 (17%) | 673 (27%) | 11 (0.73%) |
| Over 75 | 497 (12%) | 497 (20%) | 0 (0%) |
| **Gender** | | | |
| Female | 2,549 (64%) | 1,530 (61%) | 1,019 (68%) |
| Male | 1,434 (36%) | 958 (39%) | 476 (32%) |
| **Ethnicity** | | | |
| White | 3,555 (89%) | 2,389 (96%) | 1,166 (78%) |
| Asian | 276 (6.9%) | 39 (1.6%) | 237 (16%) |
| Black | 54 (1.4%) | 24 (0.96%) | 30 (2.0%) |
| Mixed | 51 (1.3%) | 16 (0.64%) | 35 (2.3%) |
| Other | 7 (0.18%) | 19 (0.76%) | 24 (1.6%) |

**Table 24.** P-COMMaS participants' demographic data

| **Service users (n=2,489)** | | **HCPs (n=1,497)** | |
|---|---|---|---|
| Patients | 2,336 (94%) | | |
| Carers | 153 (6.2%) | | |
| **Employment status** | | **HCP role** | |
| Retired | 1,175 (47%) | Nurse | 702 (47%) |
| Employed (<40h/wk) | 574 (23%) | Doctor | 517 (35%) |
| Employed (≥40h/wk) | 277 (11%) | AHP* | 135 (9.0%) |
| Self-employed | 171 (6.9%) | CSW** | 125 (8.4%) |
| Unemployed | 27 (1.1%) | | |
| Carer role(s) | 89 (3.6%) | | |
| Other not seeking work (disabled, student etc) | 158 (6.3%) | | |
| **Experience of surgery** | | | |
| 1 operation | 1,085 (44%) | | |

| | | | |
|---|---|---|---|
| 2 operations | 598 (24%) | | |
| ≥3 operations | 806 (32%) | | |
| **Commonest type of surgery experienced** | | **Types of surgical patients cared for** | |
| Orthopaedic/trauma | 1,637 | Orthopaedic/trauma | 692 |
| General surgery | 1,405 | General surgery | 1,040 |
| Gynaecological, breast, urological | 1,220 | Any other specialty | 765 |

**Table 25.** P-COMMaS participants categorised by stakeholder group, employment status and surgical/ perioperative experience. *AHP = Allied Health Professional (e.g. Operating Department Practitioner, physiotherapist, dietitian.) **CSW = Clinical Support Worker (e.g. Theatre Support worker, Healthcare Assistant, Assistant Practitioner)

### *10.3.2 Outcome importance ratings*

Table 26 shows respondents' mean 'importance rating' out of ten for each outcome domain by stakeholder group, while table 27 shows the proportion of each group that rated each outcome 'critically important' (i.e. a score ≥8/10 as specified previously). Each table also reports the absolute between-group differences and their statistical significance. Figure 11 shows the between-group differences graphically.

Over 90% of both groups rated four of the seven outcomes under consideration as critically important. These were 'The operation being successful', 'Avoiding temporary postoperative complications', 'Avoiding permanent postoperative complications', and 'Not dying after the operation'. For the first two of these outcomes, a small but statistically significant absolute difference was noted between the groups, though 93% of HCPs still rated the avoidance of temporary complications as critically important. Overall, we observed strong support from almost all respondents regarding the critical importance of these four outcomes.

Respondents' support for the remaining three outcomes was less universal, however. Less than 90% of each group rated 'Being comfortable after the operation', 'Getting out of hospital as soon as possible', and 'Returning to normal activities as soon as possible' critically important. Furthermore, there was a more noticeable (and statistically significant)

divergence of opinion between service users and HCPs, with proportionally fewer HCPs rating these three outcomes as critically important than service users. Overall, these arguably more patient-centred outcomes received less support as critically important outcomes, especially among HCPs.

| Outcome domain | Mean importance rating (SD) | | | Absolute difference (service users vs HCPs) | P value (t-test) |
|---|---|---|---|---|---|
| | All respondents (n=3,986) | Service users (n=2,489) | HCPs (n=1,497) | | |
| The operation being successful | 9.67 (0.87) | 9.73 (0.83) | 9.56 (0.93) | 0.17 | <0.001 |
| Being comfortable after the operation | 8.96 (1.45) | 9.08 (1.43) | 8.77 (1.46) | 0.31 | <0.001 |
| Getting out of hospital ASAP | 7.99 (2.13) | 8.16 (2.16) | 7.72 (2.04) | 0.44 | <0.001 |
| Returning to normal activities ASAP | 8.19 (1.93) | 8.33 (1.98) | 7.96 (1.83) | 0.37 | <0.001 |
| Avoiding temporary postoperative complications | 9.48 (1.00) | 9.58 (0.94) | 9.30 (1.06) | 0.28 | <0.001 |
| Avoiding permanent postoperative complications | 9.83 (0.53) | 9.87 (0.47) | 9.76 (0.61) | 0.11 | <0.001 |
| Not dying after the operation | 9.65 (1.09) | 9.68 (1.12) | 9.59 (1.05) | 0.09 | 0.01 |

**Table 26.** P-COMMaS participants' mean importance ratings of each outcome domain by stakeholder group

| Outcome domain | Proportion rating the outcome 'critically important' | | | Absolute difference (service users vs HCPs) | P value (Chi-square test) |
|---|---|---|---|---|---|
| | All respondents (n=3,986) | Service users (n=2,489) | HCPs (n=1,497) | | |
| The operation being successful | 96.6% | 97.2% | 95.7% | 1.57% | 0.0077 |
| Being comfortable after the operation | 86.7% | 88.6% | 83.6% | 4.96% | <0.001 |
| Getting out of hospital ASAP | 66.6% | 70.6% | 60.0% | 10.6% | <0.001 |
| Returning to normal activities ASAP | 71.1% | 74.4% | 65.5% | 8.88% | <0.001 |
| Avoiding temporary postoperative complications | 94.6% | 95.6% | 93.1% | 2.53% | <0.001 |
| Avoiding permanent postoperative complications | 99.3% | 99.4% | 99.0% | 0.44% | 0.11 |
| Not dying after the operation | 95.2% | 95.5% | 94.7% | 0.82% | 0.24 |

**Table 27.** Proportion of P-COMMaS participants by stakeholder group who rated each outcome domain as critically important (i.e. >8/10)

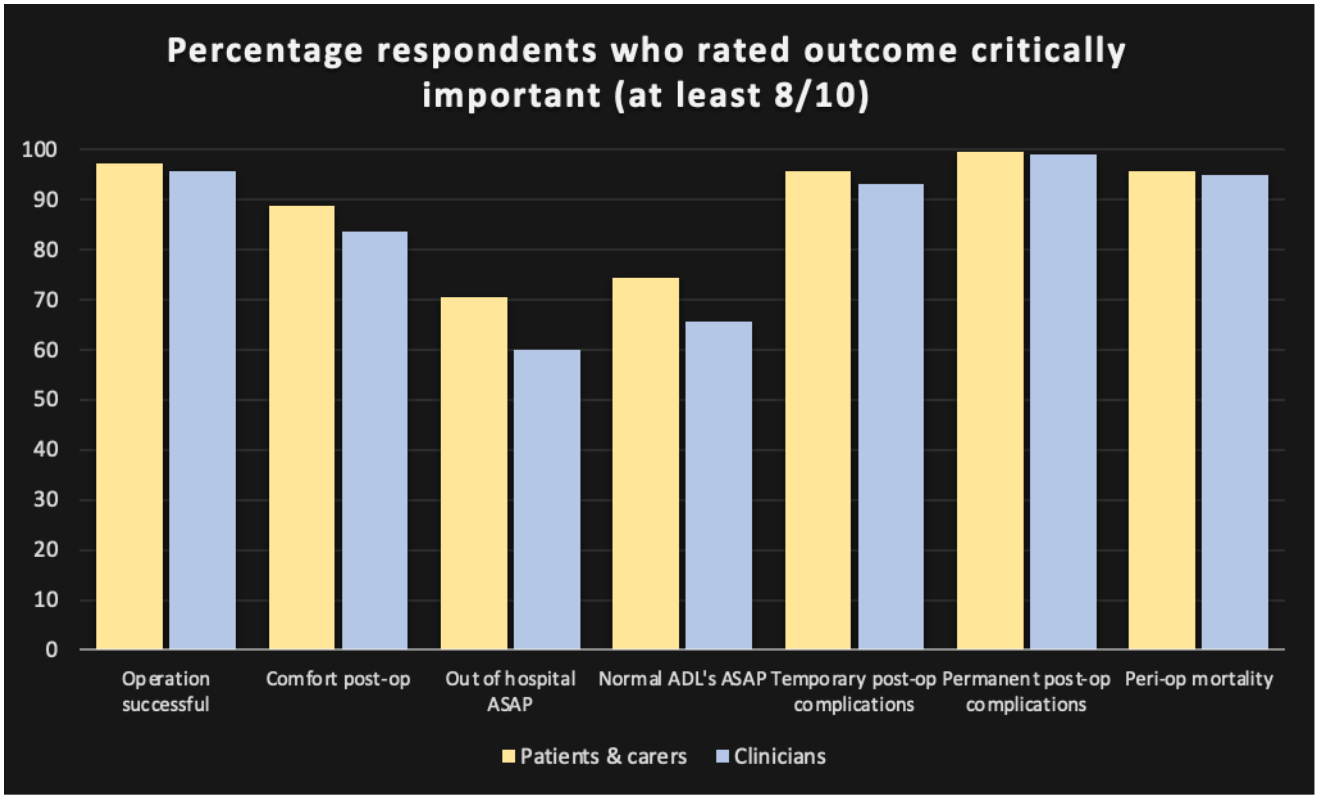



**Figure 11.** Proportion of P-COMMaS participants who rated each outcome as critically important (i.e. >8/10), divided by stakeholder group

### *10.3.3 Free text comments:*

Slightly over a third of respondents (1,389, or 35%) submitted free text responses to the question, 'Are there any other outcomes not mentioned above that you think are important after an operation?'. Overall, 871 comments came from service users (63%) and 518 from HCPs (37%), with similar proportions of each group submitting comments (871, or 35%, of the 2,489 service users, versus 518 of the 1,497 HCPs, also 35%).

Most comments were fairly short (mean length 76 characters), with a similar mean length for service users and HCPs (75 and 77 characters respectively). Over a third of respondents (38%) wrote 50 characters or less, again with similar proportions between service users (38%) and HCPs (37%). Only 44 respondents (3.2%) wrote comments

extending to ≥200 characters, again with similar proportions between groups (27 service users, 3.1%, vs 17 HCPs, 3.3%).

As described above, similar or overlapping themes appearing in these comments were grouped into overarching categories. The number of comments from each group that contained themes within each category is summarised in Table 28. Service users were significantly more likely than HCPs to bring up themes categorised under 'Information and communication' in their comments ($p<0.001$, Chi-square test). HCPs' comments, by contrast, were significantly more likely to discuss themes categorised under 'Wellbeing', 'Health-related quality of life' ($p<0.001$) and 'Impact on family/next of kin' ($P=0.013$).

| Category | Number of comments (%) | | | P value (Chi-square test) |
|---|---|---|---|---|
| | From all respondents (n=1,389) | From service users (n=871) | From HCPs (n=518) | |
| Information and communication | 557 (40%) | 438 (50%) | 119 (23%) | <0.001 |
| Postoperative care and support | 508 (37%) | 330 (38%) | 178 (34%) | 0.187 |
| Healthcare environment, staff attitudes | 466 (34%) | 307 (35%) | 159 (31%) | 0.0823 |
| Wellbeing | 288 (21%) | 127 (15%) | 161 (31%) | <0.001 |
| Health-related quality of life (HR-QoL) | 272 (20%) | 106 (12%) | 166 (32%) | <0.001 |
| Impact on family/next of kin | 124 (8.9%) | 65 (7.5%) | 59 (11%) | 0.013 |

**Table 28.** P-COMMaS survey results: number of free text comments submitted by each stakeholder group containing themes within each category

The main themes identified during the qualitative content analysis of respondents' comments were as follows:

#### 10.3.3.1 Information and communication

Five hundred and fifty-seven respondents (40% of all comments) highlighted the importance of information provision by HCPs and their communication with patients, and/or between different HCPs. Of note, over three quarters of these comments (79%) came from service users. Respondents described how important they considered good communication and information at all stages of the perioperative journey – between surgeons and patients before an operation, between nursing staff and patients after their operation while still in hospital, or with primary care teams after hospital discharge.

Some comments simply asserted the value of good communication and/or information in general (for example, *'Good communication from staff while you're in hospital'; 'Drs/nurses keeping me informed of advice, results, any further info I might need'; 'More info - knowing what's happening, info about how long you'll be in hospital etc'; 'Not to focus so much on stats - more communications with the actual patients, their thoughts and feelings*'). However, several comments highlighted specific aspects of information and/or communication; the most frequently encountered themes, with examples of each, within this category included:

**Patient expectations** (116 comments)

- *'When [patients] can start E[ating] & D[rinking]; whether they'll be able to cope at home; pain relief on discharge; getting back to normal sleeping patterns'*
- *'Whether further treatment will be needed (eg chemo); how patient will manage at home post-discharge; impact on normal life (eg stoma)'*
- *'Appropriate discussion of benefits and risks - including projection of recovery; collecting info prospectively to inform this discussion'*

**Patient understanding** (94 comments)

- *'Understanding balance of risks and benefit; proper informed consent; likely restrictions to normal life post-op'*
- *'Communication/info from surgical team about how op went, what they did. Often pts feel that they would like to see the surgeon'*
- *'Clearer language from some consultants, esp with elderly patients'*
- *'A companion/relative when being given important information'*

**Continuity of care** (43 comments)

- *'Minimise number of different people you have to see - familiar faces builds confidence'*
- *'Having a key community person to contact after discharge for continuity of aftercare. Better access to hospital notes for clinicians after discharge would help'*

**Shared decision making, empowering and involving patients in their own care** (71 comments)

- *'Being part of discussions about any future treatment, rather than just being told what will happen'*
- *'Important to listen to an individual's needs - we're not all the same and won't react the same way'*
- *'Information about what's normal and what to be concerned about, to help patients take care of themselves during recovery'*

**Consistency of information** (25 comments)

- *'Drs & anaesthetists [should] liaise at all levels. Dr said risk of valve op was 3-5%. Anaesthetist in hospital said 50-50'*
- *'Communication between the multidisciplinary team to prevent confusion and contradictory info'*

#### 10.3.3.2 Postoperative care and support

Five hundred and eight respondents (37%) mentioned the importance of good aftercare following major surgery. These comments covered the full spectrum of postoperative care, from soon after leaving the operating theatre to ward-based hospital care to support after discharge. They also covered not only physical recovery, but aspects of psychological, emotional and cognitive recovery.

There was considerable overlap with other themes. For example, many comments referred to how patients can be supported and empowered through this process, often touching on the 'Shared decision making' theme described earlier. Continuity of care also featured heavily in this category, as did the themes of waiting, patient understanding and expectations, and consistency of care. Several comments mentioned the importance of robust post-discharge follow-up and ongoing access to HCPs in the event of worries or complications, which overlapped significantly with comments tagged with themes relating to 'Information and communication'.

Examples of themes noted within the category of postoperative care and support included:

**Issues regarding postoperative in-hospital care and/or discharge** (46 comments)

- *'Regular checks by nursing staff once back on ward. Explanation and info about each procedure after the op eg removal of catheter or drains etc'*
- *'Not being pushed too fast too soon after the op - make sure pt is ready to walk freely on their own if able, but extra support if feeling weak etc'*
- *'Making sure physio, OT, social care are all involved in discharge process'*
- *'I feel I was sent home too early. I came out on the 3rd day but was readmitted within 24h with infection'*

**Outpatient aftercare and follow-up** (250 comments)

- *'Continued checkups and good dialogue with your surgeon, esp for any post-op complications. Must be free & open and constructive'*

- *'Organised aftercare for wound healing. Point of contact for any probs post-discharge'*
- *'Ensure follow-up is actually carried out as planned/explained. Support post-op eg via phone call from specialist nurse'*
- *'Care & follow-up after operation, which was excellent and helped my recovery. Support team nurses helped enormously with possible mental battle, easing anxiety and help with moving on'*
- *'How [patients] are going to cope on discharge especially if they live alone and family aren't living nearby'*

**Continuity of care** (43 comments)

- *'Home care/community nursing/GP visit (I wasn't monitored and felt anxious). Once I was discharged there was no communication between hospital and GP'*
- *'Post-op care continuity, incl, psychological assessments & support'*
- *'Having a point of contact (ie specialist nurse) if any probs or q's post-op. Receiving results from the surgery quickly (ie pathology report) in order to continue treatment pathway'*

**Consistency** (25 comments)

- *'Aftercare after discharge - I had wonderful care while in hospital but found there was no aftercare'*
- *'For all patients to have the same level of care & support post-op (eg occ therapist, physio) - at the moment some patients get and others don't'*

**Ignorance or uncertainty about results, follow-up plans and/or future treatments** (55 comments)

- *'Being informed about results - v frustrating when waiting and nobody knows what's going on'*
- *'Pts should be able to contact CNS post-surgery for support - waiting to see consultants can be worrying and minor problems can be resolved quickly'*

#### 10.3.3.3 Healthcare environment and staff attitudes

Four hundred and sixty-six respondents (34%) described the impact of HCPs' attitudes and demeanours on surgical patients, and/or aspects of the hospital environment they considered important. Several different points in patients' perioperative journeys were referenced, with the commonest recurring theme across this category being trust and/or confidence in HCPs and healthcare institutions (167 comments). Of note, the majority of positive comments praising personal experiences of perioperative healthcare referred to the idea of trusting HCPs and/or particular hospitals, for example: *'This is my 4th op at … in the past 10 years; always best care and recommend … to all family & friends'; 'the care was exemplary and I owe my current state of health & recovery to the staff'; 'Feeling safe, confident and well looked after - esp. when patient feeling vulnerable'.*

Other frequent themes in this category included:

**Staff empathy and kindness/compassion** (121 comments)

- *'Kind, understanding, supportive staff with sense of humour - happy staff = happy patient'*
- *'Compassionate attitude of staff. Efficiency is reassuring but nothing replaces that listening, empathetic approach of staff'*
- *'Nursing staff being friendly and approachable and communicate well with every patient'*

**Sufficient time for patients** (108 comments)

- *'Staff to be more caring and understanding. To have more time to talk to pts and listen to them'*
- *'Chance to discuss with consultant / medical team about the operation and aftercare'*
- *'Although staff on wards are very busy, they need to be sympathetic to people's needs, listening and caring'*
- *'Staff numbers - staff member not always available when you need them'*

**Hospital environment** (125 comments)

- *'Having better wards to recover on. The ward I was on after my mastectomy was very noisy esp. at night - poor sleep.'*
- *'When the patient is confined to bed it's very important they're looked after well by staff and given basic items eg fresh water'*
- *'Ward hygiene. Ward staff who act professionally; ward sister who acts with military precision and control'*

**Waiting for things to happen and/or updates from staff** (57 comments)

- *'Discharge day is full of mixed emotions (good and bad). Mine was chaos, I was left stressed and angry. 7 hrs of waiting and communication scarce. There really needs to be one person in charge of it all from start to finish'*
- *'Staff numbers - staff member not always available when you need them'*
- *'When you are in pain that staff respond quickly'*

**Maintaining patients' dignity, privacy and treating them with respect** (29 comments)

- *'Being able to obtain a bedpan when unable to get to the loo, without feeling a nuisance or having to wait so long the ordeal of bedwetting. So so humiliating…'*
- *'Being treated with respect & dignity. To be fully informed about all stages of post-op recovery, why certain aspects of care are needed etc'*

### 10.3.3.4 Holistic recovery from surgery – emotional, psychological and personal wellbeing

The importance of promoting patient wellbeing after surgery in the most holistic sense was reflected in comments from 288 respondents (21%), with HCPs significantly more likely to submit comments discussing wellbeing themes than service users. Most of these comments implicitly recognised that recovery from surgery is multifaceted, often

subjective, and entails more complexity than merely the medical or physical aspects of postoperative healing. Anxiety or fear of surgery and its aftermath, and the emotional and/or psychological impact of having major surgery, were also reflected in many of these comments.

Responses also frequently highlighted the impact of surgery on a patient's body image, sense of self and interpersonal relationships, as well as the significant impact on loved ones when a close relative undergoes major surgery. Respondents described not only significant emotional stress, but also practical changes in lifestyle, new or increased caring needs, and financial consequences that may arise after major surgery.

Several respondents suggested the potential benefits of psychological and/or emotional support or therapy before and/or after major surgery, and the importance of a positive mindset in promoting recovery. Adjusting to stomas, new scarring or other change of body image were specifically mentioned by several respondents – for example *'Change of body image. Change of functional abilities and impact on life(style)'*. Most comments implicitly emphasised the patient's own perception of their postoperative wellbeing as the most important outcome, rather than objective clinical measures of surgical recovery.

Specific themes noted within this category and further examples of comments where those themes appeared are summarised below:

**Perioperative psychological support** (42 comments)

- *'Post-op support team nurses helped enormously with possible mental battle, easing anxiety and help with moving on'*
- *'It's important to have support before and after surgery from a professional such as a Macmillan nurse'*
- *'Mental / psychological support from pre-admission through surgery and post-op care'*

**Postoperative mental health, wellbeing and peace of mind** *(134 comments)*

- *'Feeling healthy and more comfortable within yourself'*

- *'Mental health outcomes eg stress of operation; anxiety about recovery; processing any loss associated with the op (eg loss of limb, organ, level of previous fitness etc)'*
- *'Psychological recovery: being back to normal from perspective of memory, affect etc'*
- *'Peace of mind that everything will be ok. That I'm not the only person with this. It's not the end of the road. So in short, look after the mental side as well'*

**Body image, changes in sense of self** *(62 comments)*

- *'Psychological & emotional effects of having surgery. Impact on relationships / children. Body image changes / acceptance and how it affects relationship with partner etc'*
- *'Body image / scarring / disfigurement etc'*
- *'Scar - site, size etc. Need for a catheter. Loss of perceived dignity eg stoma'*

**Patient satisfaction** *(18 comments)*

- *'Overall feeling that operation was "worth it" because life is better than it was beforehand'*
- *'Quality of life post-op. Feeling confident you made correct decision to have surgery.'*

**Family/next of kin and/or peer support** *(36 comments)*

- *'Psychological effects of being acutely unwell / on ITU. Amount of time relatives can spend with pt post-op'*
- *'Support from friends & family – improves patient motivation for recovery'*
- *'Support and sharing of experiences with other pts who have had same op eg colostomy formation'*

### 10.3.3.5 Long-term health-related quality of life

In a similarly holistic vein, many respondents (272 comments, 20%) cited the importance after major surgery of overall quality of life, returning to normal function, and/or regaining independence. These comments generally implied a medium- to long-term perspective,

and an emphasis on regaining autonomy, the ability to perform usual life roles (such as work or caring roles), enjoy life's pleasures, and other aspects of life that 'make life worth living' for the individual. We noted that HCPs were significantly more likely than service users to submit comments relating to themes under this category.

Specific topics mentioned included food (resuming a normal diet, regaining normal taste sensation, gaining pleasure from food), childcare, driving, return of normal sleep patterns, sexual activity and/or physical intimacy, effects on fertility, looking after pets, return of normal bowel/bladder function or continence, normal cognitive function, and regaining previous mobility and/or fitness. Avoiding chronic pain and other long-term side effects of surgery were also highlighted, as was the avoidance of needing repeat surgery or other further treatments.

Examples of these comments included:

- *'Getting back to work, normal activities or just things which give the individual pleasure and a good quality of life are very important, but to me these things don't have to happen 'as quickly as possible.' I don't think we provide enough attention to rehabilitation services after major surgery beyond a very simple level of mobility and activities of daily living. Some countries provide much better more holistic rehabilitation.'*
- *'In elderly patients, loss of independence is often cited as very important'*
- *'Not to have any long-lasting disability. Not being restricted in activities of daily living. Getting back to work. Looking after children / grandchildren'*
- *'Functional symptoms & side effects resulting from surgery (eg gastrectomy - GI consequences)'*
- *'Psychological and cognitive recovery: being back to normal from perspective of memory, affect etc'*
- *'As a sufferer of recurrent kidney stones over 38 yrs, I'd like to the time between occurrences to be as long as possible (ie years not months ideally)'*
- *'Getting mobile quickly; being able to manage stairs (so can sleep upstairs); getting home for dog'*
- *'Being allowed to eat what / when you want. Getting back to hobbies (cricket / horses). Long-term management of ongoing conditions. Being able to make informed decisions / dictate own path'*

#### 10.3.3.6 Impact on family/next of kin, and patients' interpersonal relationships

Finally, 124 respondents (8.9%) referred to the importance of minimising the adverse impact of major surgery on patients' loved ones. Again HCPs were significantly more likely than service users to submit comments under this category, touching on not only the emotional impact on family members of having a sick relative going into hospital for a major operation, but also pragmatic consequences for patients and their families, such as needing additional support with daily activities, coping at home, rearranging work or care responsibilities, financial stresses, and burdens associated with travelling to/from hospital.

Several comments also alluded to guilt and/or anxiety felt by patients about being a burden, or the impact a patient's illness might have on family members, as well as the longer-term impacts on their relationships with family members. On a more positive note, other respondents highlighted the potential benefits of contact with loved ones in the postoperative period, such as encouraging a positive mindset in recovering patients, facilitating their return to normal interactions and life roles, and reassuring/empowering family members.

In summary, these comments provided rich insights into the multifaceted upheaval that major surgery may bring about for patients and their families. Examples of specific aspects mentioned included:

**'Not knowing' – relatives' anxiety about a loved one's condition, lack of updates and/or understanding** (43 comments)

- *'Letting relatives know when patient back from theatre as they worry'*
- *'Families and friends being kept informed where any complications do arise - information sharing and communication is as important as the care itself'*
- *'Communication & explanation of treatment & prognosis with patient & family'*
- *'Seeing family ASAP after the op – as a mother I would want to reassure them myself that I was ok'*

**Importance of family visits/contact with loved ones in promoting post-op recovery** (30 comments)

- *'Having family and friends around giving encouragement and being positive'*
- *'Involving relatives in post-op care and making sure they can see the patient as soon as possible'*
- *'Support from friends & family. Patient motivation for recovery'*

**Support for loved ones while patient is in hospital and/or after discharge**

- *'Ensuring any required home care is in place and to a good standard before hospital discharge. Carer should receive clear specific info'*
- *'Family - caring for family, pets, other dependents'*
- *'Making it easy for family to visit (car parking, access to hospital etc)'*
- *'Adapting lifestyle after life-changing procedures. How family / carers will cope, and patient's perception of this'*

## 10.4 Discussion

### *10.4.1 Main findings*

Over 4,000 contributors submitted their views to the P-COMMaS study. They were recruited from a wide range of NHS hospital trusts across England and Wales, and included a diverse range of patients, carers and HCPs. Our data provides robust evidence confirming the fundamental importance of 'traditional' clinical outcome measures such as postoperative mortality, postoperative complications and surgical success to virtually all service users and HCPs, with >90% of respondents rating these outcomes critically important. Moreover, this finding was consistent across a wide range of patient and carer demographics and types of surgery, and healthcare professional backgrounds.

However, we found lower levels of consensus regarding the critical importance of more patient-centred outcome measures, namely postoperative comfort, getting out of hospital

as soon as possible, and resuming normal activities. Fewer than 90% of respondents judged these outcomes critically important, and although ‘Being comfortable after the operation’ was deemed critically important by 87% of respondents, support for ‘Getting out of hospital as soon as possible’ and ‘Resuming normal activities as soon as possible’ as outcomes of critical importance reached only 67% and 71% respectively. Regarding these patient-centred outcomes, we also noted a significant difference between stakeholder groups, with consistently lower ratings among HCPs than service users.

### *10.4.2 Additional findings from free text comments*

Free text comments from slightly over a third of respondents also highlighted several other aspects of perioperative care that stakeholders consider important. These included issues relating to information and communication, postoperative care and support, the healthcare environment and staff attitudes, and longer-term patient wellbeing, health-related quality of life and the impact on family/next of kin. Again, differences were noted between stakeholder groups: service users’ comments were significantly more likely to bring up themes relating to ‘Information and communication’, but HCPs were more likely to highlight themes under the categories of ‘Wellbeing’, ‘Health-related quality of life’ and ‘Impact on family/next of kin’.

What might explain these observed between-group differences? While it is tempting to theorise that HCPs do not adequately prioritise communication with their patients (perhaps because they find it less rewarding than the clinical aspects of care), or that service users are too focused on the immediate aftermath of surgery to contemplate the long-term consequences, the data is not sufficiently rich to generate such theory. As already highlighted, over 95% of these free text comments were shorter than a 240-character tweet. While they may provide glimpses of aspects of perioperative care that service users and HCPs feel strongly about, they do not allow exploration of their views or clear insights into why they hold their beliefs. More in-depth qualitative research is needed to explore these findings further.

### *10.4.3 Strengths and limitations*

The number and breadth of respondents was the main strength of P-COMMaS. The service users spanned a wide range of ages, surgical experiences, and areas of England and Wales; moreover the service users sampled in this study were broadly reflective of the UK surgical population in terms of age and types of procedure. HCPs similarly included a wide range of different perioperative healthcare workers across multiple surgical specialties, with representation from virtually all relevant professional groups and perioperative healthcare contexts.

Limitations include the under-representation of ethnic minorities among service user respondents compared with the overall UK surgical population. This finding may have been at least partly due to the location of most study sites outside major urban centres, and the availability of the survey in English only, but other well-recognised barriers to participating in research faced by black and minority ethnic (BME) patients and carers likely also contributed to their under-representation. These barriers were not explicitly considered and addressed at the design stage, and this oversight likely limits the generalisability of our results to BME perioperative service users.

The generalisability to Scotland and Northern Ireland, and indeed to other healthcare systems internationally, is also questionable in view of having recruited only from NHS trusts in England and Wales. Nonetheless, it is likely that many of the priorities highlighted in our results reflect those of service users and clinicians in other jurisdictions. For example, the importance to surgical patients of good information and communication, healthcare environment and staff attitudes have all previously been reported in several non-UK contexts.(153, 308, 309)

The decision not to conduct in-depth interviews to explore the study question may also be considered a limitation; however as described previously, the large number of free text responses was felt to provide adequate qualitative insight, and the COMPAC SG agreed that the modest benefit of further qualitative data would not justify the additional burden to respondents of a telephone interview, or the time and resources required to collect it.

Finally, the data collection context may have affected both the service user and HCP perspectives obtained. Almost all participants were recruited in hospital settings, in environments such as outpatient clinics, discharge lounges, surgical wards, theatre suites and coffee rooms. Participants' survey responses are likely to have been influenced at least in part by this acute hospital context: conducting the same survey in GP surgeries or

other community-based healthcare settings might arguably have yielded different results, notwithstanding the additional challenges to recruitment this would likely have entailed.

## 10.5 Conclusions

The close agreement between HCPs' and service users' ratings of the clinical outcomes considered in this study support our original hypothesis from the beginning of this chapter, namely that there is no difference between service users' and HCPs' views regarding important outcome measures for assessing the quality of perioperative care. Moreover, both groups almost unanimously agreed that these outcomes are critically important in perioperative research.

However, the hypothesis was not supported for the patient-centred outcome measures under consideration. Both groups rated the patient-centred outcomes as less important overall than the clinical ones, and a significant difference was also noted between stakeholder groups' respective ratings, with HCPs rating them significantly lower in importance than service users.

In conclusion, while both service users and HCPs demonstrated strong agreement that clinical outcomes are fundamentally important for perioperative research, both groups exhibited less conviction about the importance of patient-centred outcomes.

# *Chapter 11. COMPAC Phase 3: A modified Delphi process to develop the COMPAC Core Outcome Set*

## 11.1 Introduction

The third phase of COMPAC involved a collaborative consensus process, whereby the results of the systematic review (Phase 1) and P-COMMaS stakeholder consultation process (Phase 2) were used to develop a longlist of candidate outcome measures. Simultaneously, stakeholder representatives (service users and HCPs who had contributed to P-COMMaS) were invited to participate in the COMPAC consensus process. Those who accepted then took part in a 3-stage modified Delphi consensus process to agree a final 'Core Outcome Set' from the longlist of candidate outcomes.

Delphi methodology – which is based on the principle that the decisions and judgements of a structured group are more valid than those of unstructured groups or of individuals – was developed at the beginning of the Cold War to forecast the impact of technology on warfare.(310) Its aim is to achieve group consensus in subject areas of limited knowledge or research, promoting expert consensus by ensuring participant anonymity, allowing experts to share differing views without confrontation, and then allowing them to reconsider their views without losing face.

There is no single, standardised methodology for conducting a Delphi process, but the usual approach entails gathering a group of suitable experts or stakeholders, and then conducting repeated 'rounds' of surveys or questionnaires within the group asking their views regarding a particular issue. After each round, the collated results are shared with participants, and the survey is then repeated, allowing participants to revise their opinions after considering the prevailing majority viewpoint.

For the COMPAC Delphi process, we sought to include a broad range of participants from our two stakeholder groups, namely service users (patients who have had major surgery and their carers) and healthcare professionals (anyone whose professional role involves caring for patients undergoing major surgery). At all stages, we sought to achieve a roughly even balance of representation from these two groups. Delphi methodology also relies on members of one stakeholder group being shown the views and/or scores of other stakeholder group(s) to inform their own views, as described later in this chapter.

The starting point for the COMPAC Delphi consensus process was a longlist of 'candidate' outcome measures, produced by the COMPAC SG based on the findings of the systematic review and the P-COMMaS stakeholder consultation study described earlier.

## 11.2 Methodology

### *11.2.1 Outcome longlist creation*

A longlist of potential, or 'candidate', core outcomes was compiled by the COMPAC SG following the methods recommended in the COMET handbook:(271)

- Outcomes from the systematic review were compiled in an Excel spreadsheet.
- Outcome measures which were described or defined slightly differently between trials, but which all related to the same endpoint, were combined into a single outcome
- All outcomes were then categorised into overarching 'outcome domains', based on the systematic review, the P-COMMaS survey results, and the outcomes taxonomy recommended by the COMET Initiative.(311)

The COMET Initiative's generic taxonomy of outcomes – which is based on the 'Outcome Measures Framework' used by the U.S. Department of Health's Agency for Healthcare Research and Quality,(312) the Cochrane Library's proposed classifications of outcomes, and the COMET Initiative's own systematic review of Core Outcome Set development processes (313, 314) – categorises outcomes into five domains: mortality/survival; clinical/physiological outcomes (subcategorised by organ system); life impact; resource use; and adverse events/effects. The COMPAC SG adapted this generic taxonomy for the context of perioperative outcomes to produce the following six domains:

- Mortality/survival
- Perioperative complications
- Resource use

- Short-term recovery from surgery
- Medium to long-term recovery from surgery
- Overall success/failure of surgery

Outcomes were phrased in lay terms, with ‘medical’ explanations added in brackets if necessary. The final longlist, and the wording/phrasing of the included outcomes, was discussed and agreed by the COMPAC SG, and sense-checked by a small sample of non-medical colleagues to ensure clarity and ease of understanding of the terms used.

The longlist was then used to create an online survey which asked respondents to rate the importance of each candidate outcome on the longlist using a five-point scale (from ‘1= not at all important’ to ‘5= very important’). The survey was initially piloted among a small sample of stakeholders and non-clinicians for ease of understanding, and to elicit feedback regarding the clarity of its explanations about the concept of core outcome sets. The five point Likert-type scale was chosen for its relative simplicity while retaining adequate discriminatory potential. Similar scales have been shown to be an appropriate shortlisting method in several other COS Delphi processes.(315, 316) The survey was also designed to be as short and user-friendly as possible to minimise the burden to participants and encourage completion. The final survey (Appendix 5) consisted of 69 questions, of which 64 were candidate outcome measures which respondents were asked to rate.

### *11.2.2 Modified Delphi process*

**Delphi Round One:**

Email invitations for the COMPAC Delphi process were sent to a selection of around 150 of the nearly 1,000 respondents to the P-COMMaS study who indicated their willingness to participate in the final phase of COMPAC. Those invited were purposively sampled by the COMPAC SG, i.e. non-randomly selected with the aim of maximising the diversity of stakeholder representation and to meet the following criteria:

- An even balance of service users and HCPs

- Maximum diversity of representation in terms of age, gender, ethnicity, and surgical experience (i.e. service users with diverse surgical experience, and HCPs with diverse professional and/or research backgrounds, including nurses, surgeons, anaesthetists, intensivists, and allied health professionals).
- A total of 50-100 Delphi participants

Those selected were sent an email invitation containing a link to the online survey for the COMPAC Delphi consensus process, along with a Participant Information Sheet. Invited stakeholders were asked to complete the survey within four weeks; reminder emails were sent after three weeks to those who had not responded. Based on the number of complete survey responses received at that point, email invitations were sent to a further sixty P-COMMaS contributors, again purposively selected to maximise the balance and diversity of COMPAC Delphi participants.

Because the Delphi consensus process relies on thorough engagement of participants, only fully completed survey responses were included for analysis. Responses were then collated and analysed to produce mean and median scores out of five for each candidate outcome measure, both for all respondents, and separately for service users and HCP.

**Delphi Round Two:**

Outcomes were retained for the second round of the Delphi process if:

- $\geq$65% of respondents from **either** stakeholder group scored the outcome $\geq$4 (i.e. ‘important’ or ‘very important’), AND
- <20% of respondents from that stakeholder group scored the outcome $\leq$2 (i.e. ‘not that important’ or ‘not at all important’)

A second online survey invitation was sent out via email to the original survey’s respondents as soon as the first survey scores had been collated and analysed. In this second survey (reproduced in Appendix 6), respondents were again asked to rate the importance of each candidate outcome measure (minus those that did not reach the retention thresholds described above). However this time, respondents were shown the

mean ratings from Round One, including both the mean score for all respondents to the first survey, and the mean score for each stakeholder group.

Sharing of the collective group rating is an important feature of Delphi methodology, since it allows respondents to see whether their score was similar to the overall 'average' rating, or an outlier. Delphi methodology also allows respondents to view the extent of disagreement between stakeholder groups, and whether their own score was broadly in keeping with the average for their own stakeholder group. It also informs stakeholders about any outcomes that, while not rated highly by their own group, was highly valued by the other stakeholder group. For this second survey, we highlighted in orange the outcome measures where a major discrepancy between the mean ratings of HCPs and service users had been observed – defined as a difference in mean scores of >0.5 (out of 5). Those with a less marked but still notable difference (defined as a difference in means of >0.3 but <0.5) were highlighted in yellow.

This reiteration of the Delphi survey allows respondents to revise their initial scores in light of the mean group ratings. Respondents were again requested to complete the survey as soon as possible, and reminder emails sent to those who had not completed it before the deadline of three weeks after the initial email invitation (which was three days before the final consensus workshop).

Outcomes were retained for the final COMPAC workshop if:

- $\geq$65% of respondents from **both** stakeholder groups scored the outcome $\geq$4, AND
- <20% of respondents from **both** stakeholder groups score the outcome $\leq$2

After analysis of the second survey results, the COMPAC SG reviewed and refined the list of outcomes for consideration at the final consensus workshop in order to ensure the outcomes were as succinctly and clearly worded as possible, and could each be printed on one page for ease of viewing in small groups.

### *11.2.3 Final consensus workshop and ratification of the COS*

The final core outcome set was decided at a face-to-face stakeholder consensus workshop held on 25th February 2020 at the Royal College of Anaesthetists (RCoA). The

workshop was facilitated by two independent experts from the James Lind Alliance (JLA) with extensive experience of overseeing similar stakeholder workshops to decide healthcare research priorities and recommendations.

All those who had completed the first Delphi survey were invited to attend the workshop. As before, we aimed for an even balance of representation (i.e. roughly even numbers of service users and HCPs) and a range of different surgical experience, ages etc. Places were allocated on a 'first come, first serve' basis, up to a maximum of around 30 delegates, and subject to ensuring a diversity of stakeholder representation. Participants were offered £150 remuneration as a goodwill gesture plus travel expenses for their time and effort, in line with NIHR guidance regarding compensation for volunteers contributing to health research,(317) and confirmed their attendance via an online registration form.

The workshop consisted of repeated rounds of plenary discussion and small group discussion sessions. It began with an initial plenary session where participants introduced themselves, and the facilitators explained the purpose and format of the workshop. Participants were then divided into three pre-allocated small groups (with even representation of service users and HCPs) to discuss and debate the candidate outcome measures in the first two outcome domains (i.e. mortality/survival, and perioperative complications). These discussions were each led and moderated by one of the workshop's facilitators.

After 30 minutes of discussion, each group classified all the outcome measures under discussion as either 'definite' core outcomes (and placed them on a green pile, scoring one point), 'equivocal/no consensus' (yellow pile, no points), or 'definitely not' core outcomes (red pile, minus one point). The three groups then came together for a plenary session in which each group's scores for each outcome measure were combined, and their respective choices discussed among the whole group in order to arrive at an overall 'whole group consensus' regarding the outcome's inclusion in, or omission from, the final Core Outcome Set.

All outcomes with a total combined score (from the three small groups) of 0 or less were excluded from further discussion, while those with a total score $\geq 2$ were included as core outcomes. Outcome measures scoring 1 were discussed further, and – once everyone had had an opportunity to voice their opinions about the importance (or not) of the outcome measure being discussed – a vote was taken via a show of hands. (Facilitators reminded

participants during each plenary discussion that the overall aim of COMPAC was to recommend outcome measures for reporting in *all* perioperative and anaesthetic research – not just those which would be desirable in certain circumstances.)

The threshold for inclusion as a core outcome was set at ≥70% support; anything less than this was deemed insufficient to warrant its recommendation as a core outcome for all future anaesthetic and perioperative research. Thus all outcome measures under discussion were assigned a 'whole group consensus' as 'included', 'excluded' or 'desirable, but not meeting threshold for inclusion' in the core outcome set.

The process of small group discussions followed by a plenary session was repeated for outcomes categorised in the next two domains, and finally for the last two domains. For each small group discussion, groups were mixed up to reduce the possibility of any individual voice dominating one group's discussions, and to minimise the chance that any disagreement arising between participants could affect subsequent sessions. A final plenary session was then held to review the overall designation of outcome measures as 'included', 'excluded' or 'desirable, but not meeting threshold for inclusion', at which there was a final opportunity for delegates to revisit any of the 'desirable' ones, and/or repeat the vote for inclusion/exclusion as necessary. At the end of this final session, all outcomes designated 'included' were ratified by participants as the COMPAC Core Outcome Set.

## 11.3 Results

### *11.3.1 Delphi Round One*

Eighty-two stakeholders completed the first COMPAC Delphi survey, representing slightly over a third (39%) of the ~210 stakeholders who were sent an email invitation (though at least forty of those emails were never opened). The response rate was therefore likely closer to around fifty percent. Fifteen of the survey responses were incomplete and were therefore excluded, leaving 67 complete, valid responses included in the analysis.

Of these 67, forty respondents (63%) identified as service users and 27 (37%) as HCPs. Among service users, 37 (93%) had direct experience of being a surgical patient, while

three (7.5%) had experience as carers only. The 27 HCPs included ten anaesthetists and/or intensivists, four surgeons, three geriatricians, one GP, three trainee (junior) doctors, two clinical nurse specialists, one Advanced nurse practitioner and two nurses.

Respondent demographic data is summarised in Table 29.

| | **All respondents (n=67)** | **Service users (n=40)** | **HCPs (n=27)** |
|---|---|---|---|
| **Age category** | | | |
| 18-25 | 0 (0%) | 0 (0%) | 0 (0%) |
| 25-34 | 3 (4.5%) | 0 (0%) | 3 (11%) |
| 35-44 | 7 (10%) | 1 (2.5%) | 6 (22%) |
| 45-54 | 16 (24%) | 3 (7.5%) | 13 (48%) |
| 55-64 | 15 (22%) | 12 (30%) | 3 (11%) |
| 65-74 | 17 (25%) | 16 (40%) | 1 (3.7%) |
| ≥75 | 6 (9.0%) | 6 (15%) | 0 (0%) |
| Did not disclose | 3 (4.5%) | 2 (5.0%) | 1 (3.7%) |
| **Gender** | | | |
| Female | 40 (60%) | 26 (65%) | 14 (52%) |
| Male | 24 (36%) | 12 (30%) | 12 (44%) |
| Did not disclose | 3 (4.5%) | 2 (5.0%) | 1 (3.7%) |
| **Ethnicity** | | | |
| White | 53 (79%) | 32 (80%) | 21 (78%) |
| Asian | 6 (9.0%) | 2 (5.0%) | 4 (15%) |
| Black | 3 (4.5%) | 3 (7.5%) | 0 (0%) |
| Mixed | 0 (0%) | 0 (0%) | 0 (0%) |
| Other | 2 (3.0%) | 1 (2.5%) | 1 (3.7%) |
| Did not disclose | 3 (4.5%) | 2 (5.0%) | 1 (3.7%) |

**Table 29.** Demographic details of participants in the COMPAC first Delphi round

**Respondent survey ratings**

Forty-nine (77%) of the 64 candidate outcome measures in the survey were scored 4 or 5 (ie 'important' or 'very important') by over 65% of both groups, as well as receiving scores of 2 or less from under 20% of both groups. These 49 were therefore retained for the second Delphi round. Of the remaining fifteen outcomes, eight were scored 4-5 by >65% of service users (with less than 20% of service users scoring these outcomes ≤2); these eight were therefore also retained for round two, by virtue of being important to a large majority of service users. The remaining seven outcomes were rated 'important' or 'very important' by <65% of both groups, and therefore did not meet the criteria for retention.

The outcome ratings by group are summarised in Table 30.

| | **Outcomes rated ≥4 by ≥65% of HCPs** | **Outcomes rated ≥4 by <65% of HCPs** | **Total** |
|---|---|---|---|
| **Outcomes rated ≥4 by ≥65% of service users** | 49 (77%) | 8 (13%) | 57 (89%) |
| **Outcomes rated ≥4 by <65% of service users** | 0 (0%) | 7 (11%) | 7 (11%) |
| **Total** | 49 (77%) | 15 (23%) | 64 (100%) |

**Table 30.** Importance ratings (from 1='not at all important' to 5='very important') of the 64 outcome measures considered in the COMPAC first Delphi round

For the 57 candidate outcome measures retained for round two, the absolute difference between HCPs' and service users' mean scores was >0.5 for eight outcomes (14%), and >0.3 for 11 others (19%). For the second Delphi survey, these outcomes were therefore highlighted in orange and yellow respectively to alert respondents that these were the outcomes with lowest level of consensus after the first Delphi round.

### *11.3.2 Delphi Round Two*

Forty-six (69%) of the 67 who fully completed the first Delphi survey also completed the second survey; however three responses were only partially complete, leaving 43 that were included in the analysis. Twenty (47%) were from HCP participants (ten anaesthetists and/or intensivists, three surgeons, two geriatricians, three junior doctors, one clinical nurse specialist and one nurse) and 23 (53%) from service users (all of whom had experience as surgical patients, while six also had carer experience).

Respondent demographic data is summarised in Table 31.

| | **All respondents (n=43)** | **Service users (n=23)** | **HCPs (n=20)** |
|---|---|---|---|
| **Age category** | | | |
| 25-34 | 2 (4.7%) | 0 (0%) | 2 (10%) |
| 35-44 | 7 (16%) | 1 (4.3%) | 6 (30%) |
| 45-54 | 11 (26%) | 1 (4.3%) | 10 (50%) |
| 55-64 | 9 (21%) | 7 (30%) | 2 (10%) |
| 65-74 | 9 (21%) | 9 (39%) | 0 (0%) |
| ≥75 | 5 (12%) | 5 (22%) | 0 (0%) |
| Did not disclose | 0 (0%) | 0 (0%) | 0 (0%) |
| **Gender** | | | |
| Female | 26 (60%) | 15 (65%) | 11 (55%) |
| Male | 17 (40%) | 8 (35%) | 9 (45%) |
| Did not disclose | 0 (0%) | 0 (0%) | 0 (0%) |
| **Ethnicity** | | | |
| White | 36 (84%) | 20 (87%) | 16 (80%) |
| Asian | 4 (9.3%) | 1 (4.3%) | 3 (15%) |
| Black | 2 (4.7%) | 2 (8.7%) | 0 (0%) |
| Mixed | 0 (0%) | 0 (0%) | 0 (0%) |
| Other | 1 (2.3%) | 0 (0%) | 1 (5%) |

| | | | |
|---|---|---|---|
| Did not disclose | 0 (0%) | 0 (0%) | 0 (0%) |

**Table 31.** Demographic details of participants in the COMPAC second Delphi round

### Respondent survey ratings

Of the 57 candidate outcome measures under consideration in this second Delphi survey, 55 (96%) were scored ≥4 (i.e. 'important' or 'very important') by >65% of both groups, while also receiving scores of ≤2 from <20% of both groups. One outcome – 'Complications arising during the operation itself' – was deemed important by <65% of HCPs; and another – 'All complications and adverse events, divided into a) those causing permanent harm; b) those only causing a temporary delay in recovery' – was deemed important by <65% of service users. Both outcomes were therefore removed from further consideration as they did not meet the prespecified retention criteria.

### COMPAC SG final pre-workshop review

Following review by the COMPAC SG of all remaining outcome measures for clarity and ease of use before the final workshop, one outcome was abbreviated, and three pairs of similar/overlapping outcomes were also combined into one outcome for the final workshop. These changes are shown in Table 32.

| Outcome domain | Second Delphi survey outcome wording | Revised wording for final workshop |
|---|---|---|
| Longer-term recovery | *Overall recovery to pre-operative 'baseline' level (i.e. 'how they were' before the operation – e.g. complete recovery / partial recovery / worse than before)* | *Overall recovery to pre-operative 'baseline' (how they were before the operation)* |
| | *Long-term level of functional dependence (eg. better / about the same / worse)* | *Long-term level of functional dependence* |

| | | |
|---|---|---|
| | *Long-term impact on relatives and/or carers (eg. more / less care needs)* | |
| Overall success / failure of surgery | *Recurrence of the symptoms the operation was intended to treat (yes/no)* | *Recurrence of symptoms the operation was intended to treat* |
| | *Time to recurrence of symptoms (if yes)* | |
| | *Recurrence or progression of the disease the operation was intended to treat (yes/no)* | *Recurrence or progression of the disease the operation was intended to treat* |
| | *Time to recurrence or progression of disease (if yes)* | |

**Table 32.** Changes made by the COMPAC SG to the wording/presentation of candidate outcomes discussed in the COMPAC workshop

### *11.3.3 Final consensus workshop*

Twenty-six participants attended the COMPAC workshop in February 2020, of whom 13 were HCPs and 13 service users. The full list of 52 outcomes under consideration, and the combined score for each outcome resulting from the small group discussions (from -3, i.e. all groups judged the outcome insufficiently important for inclusion as a core outcome, to +3, i.e. all three groups deemed the outcome important enough to merit inclusion in the final COS) are shown in Table 33. (Those highlighted in green were included in the final core set, while those highlighted yellow were designated as 'additional important patient-centred outcomes').

| Outcome domain | Candidate outcome under consideration | Combined score |
|---|---|---|
| **Mortality/survival** | *Overall mortality (death rate) after an operation* | 2 |
| | *Mortality after an operation from specific causes (e.g. infection, blood clot)* | 0 |
| | *Overall long-term survival (e.g. after a cancer operation)* | 3 |

| | | |
|---|---|---|
| | *Long-term 'disease-specific' survival (i.e. not including deaths from other causes)* | 0 |
| **Perioperative complications** | *Major (serious) post-operative complications and adverse events* | 2 |
| | *All post-operative complications and adverse events (both major and minor)* | 1 |
| | *Complications and adverse events needing medical intervention/treatment* | 0 |
| | *Complications and adverse events causing permanent disability or harm* | 3 |
| **Resource use** | *Total number of days spent in hospital for the operation* | 3 |
| | *Total post-operative time spent in Critical Care Ward* | 0 |
| | *Total time on organ support in Critical Care Ward (e.g. mechanical ventilator)* | -3 |
| | *Total time until ready for hospital discharge* | 1 |
| | *Unplanned hospital, GP or other healthcare attendance within 30 days of operation* | 0 |
| | *Unplanned hospital readmission within 30 days of operation* | 2 |
| | *Total financial cost of in-hospital care* | -2 |
| | *Total financial costs of all peri-operative care (both in hospital and outpatient)* | 0 |
| **Short term recovery after surgery** | *Post-operative pain (incidence)* | 1 |
| | *Severity and/or duration of post-operative pain* | 1 |
| | *Total amount of painkiller required post-operatively* | -1 |
| | *Post-operative pain severe enough to delay hospital discharge* | 1 |
| | *Post-operative nausea +/- vomiting (incidence)* | 1 |
| | *Post-operative nausea +/- vomiting severe enough to delay hospital discharge* | 0 |
| | *Other post-operative physical symptoms (e.g. itching, shivering, sore throat, bloating)* | -3 |

| | | |
|---|---|---|
| | *Postoperative psychological symptoms (e.g. anxiety, confusion, sleep disturbance, depression)* | 1 |
| | *Time taken to get back to eating and drinking normally (patient's usual diet)* | 0 |
| | *Time taken to get back to usual level of mobility* | 1 |
| | *Time taken to get back to work, caring or other usual life roles* | 1 |
| | *Time taken for wound to be fully healed* | -2 |
| | *Time to getting 'back to normal' in all aspects of life* | 0 |
| | *Discharge destination from hospital (e.g. own home/rehab facility/care home)* | 1 |
| | *Short-term post-operative dependence on carers (less/same/more)* | 1 |
| **Longer-term recovery after surgery** | *Overall health-related quality of life* | 3 |
| | *Disease-specific quality of life (e.g. back pain/movement after back surgery)* | -2 |
| | *Functional status – 'what the patient is able to do'* | 0 |
| | *Overall extent of recovery to pre-operative 'baseline' (how they were before the operation)* | 1 |
| | *Physical recovery to pre-operative baseline* | 0 |
| | *Cognitive recovery (mental function) to pre-operative baseline* | -1 |
| | *Psychological and emotional recovery to pre-operative baseline* | 1 |
| | *Incidence of long-term chronic pain* | 0 |
| | *Incidence of other persistent, long-term side effects* | -1 |
| | *Incidence of severe scarring or altered body image* | -2 |
| | *Ability to return to usual place of residence* | 0 |
| | *Ability to resume work / caring / other usual life roles* | 1 |
| | *Long-term level of functional dependence* | 0 |
| | *Overall patient satisfaction with the results of their operation* | 1 |

| | | |
|---|---|---|
| | *Patient's satisfaction with their treatment ('Would you choose the same again?')* | 1 |
| **Overall success/failure of surgery** | *Extent of relief or improvement of symptoms (patient-reported)* | 1 |
| | *Extent of cure of underlying disease (surgeon-reported)* | 0 |
| | *Recurrence of symptoms the operation was intended to treat* | -1 |
| | *Recurrence or progression of the disease the operation was intended to treat* | 1 |
| | *Need for further follow-up, surveillance or tests after the original operation* | -2 |
| | *Need for further treatment and/or surgery after the original operation* | 0 |

**Table 33.** The full list of 52 outcomes under consideration in the COMPAC workshop, with combined scores for each outcome resulting from small group discussions

The results of the plenary group discussions were as follows:

**First plenary session (Mortality/survival** and **Peri-operative complications)**

There was widespread consensus regarding the fundamental importance of overall postoperative mortality and overall long-term survival after an operation as important outcomes for any perioperative trial, but not for the other two mortality outcomes.

Similarly, there was broad agreement that all perioperative trials should report major complications and adverse events, and that – where they did not exist already – standardised definitions of 'major' and 'minor' post-operative complications should be developed and used in future perioperative trials. Participants also voted to include 'complications and adverse events causing permanent harm or disability' as a Core outcome. These four outcomes were thus approved for Core Outcome set inclusion.

**Second plenary session (Resource use** and **Short-term recovery)**

A wide range of opinions were voiced among the 26 participants regarding outcomes within these domains. However, while some participants initially voiced support for almost all outcomes within these domains, by the end of the discussion, only two had widespread support for inclusion across all participants: 'Total number of days in hospital for the operation', and 'Unplanned hospital readmission within 30 days of operation'.

Strong support was also observed for 'Postoperative level of dependence' as an outcome that reflects the extent of postoperative recovery and is meaningful to patients, carers and HCPs. It was therefore agreed by the whole group to combine 'Discharge destination from hospital (e.g. own home/rehab facility/care home)' and 'Short-term postoperative dependence on carers (less/same/more)' into the following: 'Discharge destination from hospital (e.g. own home/rehab facility/care home), AND/OR level of dependence (need for carers)' for inclusion in the Core Outcome Set.

Finally, strong support was voiced among the group for outcomes measuring postoperative pain, nausea and vomiting, and postoperative mental, emotional and psychological wellbeing. While none reached the 70% threshold for core outcome inclusion, there was widespread agreement that they would be nonetheless important and desirable outcomes to report in a wide range of perioperative trials. Consensus was thus reached across the whole group to omit these from the final Core Outcome set, but to highlight them as 'Additional important patient-centred outcome measures.'

**Third plenary session (Longer-term recovery and Overall success/failure of surgery)**

Only one outcome reached the threshold of 70% support for inclusion in the Core set after virtually any major surgery, namely 'Overall health-related quality of life'. All participants also agreed that this multidimensional outcome should be measured with a well-validated instrument, hence the addition of 'using a validated scoring tool' in parentheses as a condition for this outcome.

In the discussions about surgical success or failure, there was general consensus that the most important metric was 'the extent to which the operation achieved its intended aims' However, delegates decided after further deliberation, that surgical success or failure was

'out of scope' for this Core Outcome Set, since such outcomes are often surgery-specific. Participants agreed that no single perioperative outcome measure could adequately capture surgical success or failure for all types of operation. However, the notion of patient satisfaction received broad support as a subjective measure of surgical success; following a round of voting, over 70% supported its inclusion as an 'additional important patient-centred outcome.' The final wording agreed was 'patient satisfaction with their operation, and/or willingness (with hindsight) to choose the same again'.

### *10.3.4 Final agreed Core Outcome Set*

The core outcomes agreed and ratified at the end of the final plenary session, along with the four outcomes deemed 'additionally important', are shown in Table 34.

| Outcome domain | Core Outcome(s) |
|---|---|
| **Mortality/survival** | Overall mortality (death rate) after an operation |
| | Overall long-term survival (e.g. after a cancer operation) |
| **Perioperative complications** | Major (serious) postoperative complications and adverse events (using accepted, validated definitions of major and minor complications) |
| | Complications and adverse events causing permanent disability or harm |
| **Resource use** | Total number of days spent in hospital for the operation |
| | Unplanned hospital readmission within 30 days of operation |
| **Short term recovery after surgery** | Discharge destination from hospital (e.g. own home / rehab facility / care home), AND/OR level of dependence (need for carers) |
| **Longer-term recovery** | Overall health-related quality of life (using a validated scoring tool) |
| **Overall surgical success/failure** | None |
| **Outcome domain** | **Additional important patient-centred outcomes** |
| **Short term recovery after surgery** | Pain (incidence/severity/duration) |
| | Nausea +/- vomiting (incidence/severity/duration) |

| | |
|---|---|
| | Mental, emotional and psychological wellbeing |
| **Overall surgical success/failure** | Patient satisfaction with their operation, and/or willingness (with hindsight) to choose the same again |

**Table 34.** The COMPAC Core Outcome Set (COS) as agreed and ratified at the COMPAC workshop

## 11.4 Discussion:

The COMPAC project successfully developed a Core Outcome Set (COS) for Anaesthesia and Perioperative Care through an iterative consensus process involving both HCPs and service users. These outcomes were developed using collaborative methods as recommended by the COMET Initiative, and in view of the wide range and number of participants who contributed to the process, these outcomes should be considered fundamentally important to all stakeholders in perioperative research.

### *11.4.1 Strengths and limitations of COMPAC methodology*

COMPAC's main strength was its focus on collaborative, transparent and equitable partnership between all stakeholders, and its adherence to the COMET Initiative's recommended methodology for COS development. Its other main strength was the number and diversity of contributors, with over 2,500 service users and 1,500 HCPs from across England and Wales participating in the P-COMMaS stakeholder consultation phase.

However, there are potential limitations of such a consensus process. Firstly, to be truly valid, a core outcome set must incorporate the views of all relevant stakeholders. Second, it must be developed using transparent and widely accepted methodology. Third, it must achieve sufficient investment and buy-in from participants to ensure engagement with the repeated rounds of outcome selection and elimination over a protracted time period. A trade off may therefore be required to recruit sufficient numbers of participants, and allow

sufficient time for them to contribute, without making the process overly drawn out and onerous on participants.

To take each of these in turn, the COMPAC process gave equal weight to all participants' views, and deliberately sought to maximise stakeholder diversity at every stage. While the diversity achieved was arguably suboptimal in terms of ethnic diversity, there was adequate representation at all stages from service users of different ages, genders and diverse surgical cohorts, reflecting of the breadth of the overall UK surgical patient population. Similarly all stages included contributions from a wide range of different HCPs involved in different aspects of the patient's perioperative journey.

Regarding the methodology, COMPAC followed widely-accepted and repeatedly endorsed set of guidelines for developing COSs, which have to date been followed by hundreds of core outcomes groups around the world in many different healthcare contexts. Transparency was maintained at all stages via the COMPAC SG, who conducted and oversaw each stage of COMPAC and made collective decisions about specific details of the process (for example, the refinement of the final longlist for the COMPAC workshop).

Finally, the proportion of contributors to P-COMMaS who said they would be prepared to further contribute to the COMPAC consensus process, and the reasonably low drop-out rate during the Delphi rounds, imply a good level of engagement from the stakeholder representatives who participated in either or both phases. However, the almost two-year delay between the end of P-COMMaS, and the start of the COMPAC Delphi consensus process, may have adversely affected the proportion of P-COMMaS contributors who responded to the invitation to participate in the Delphi process. Such a delay may have impacted participation levels for several reasons: illness, bereavement, loss of interest, financial hardship, changing email address, or other changes in life circumstances may all have affected participants' willingness to participate in the COMPAC Delphi process.

However, as discussed earlier in the context of the APoC-PSP, there is clearly a pragmatic middle ground for stakeholder participatory research projects such as COMPAC, between overly exhaustive and resource-intensive efforts to harness all stakeholder views, and insufficient stakeholder engagement leading to inadequate representation. Involving too many participants, and/or too many rounds, and/or too long between rounds, may be extremely time and resource intensive. An excessively onerous or repetitive process also

risks inducing fatigue or apathy in contributors, which in turn may lead to high drop-out rates, or incomplete or poorly considered responses.

In contrast, a process with too few participants, too few rounds and/or too brief a window for responses, has different limitations. While it may be easier to manage and less costly, less comprehensive approach may potentially miss views from important stakeholder groups. Mean/median ratings and scores, and the variance in scores between different stakeholders (i.e. the 'disagreement' between stakeholder groups) also become less reliable with very small sample sizes, and a process that feels rushed or poorly prepared may lead to contributors losing faith and/or dropping out.

The optimum duration of each phase for developing a COS, and numbers of participants required, is therefore an ongoing debate within the Core Outcomes community. A pragmatic approach based on resources available, and the diversity of stakeholders affected, therefore seems appropriate. Given the broad scope of this COS (i.e. its aim of capturing outcomes that matter to all kinds of surgical patients), and the wide range of potential stakeholders, the COMPAC SG sought to err on the side of 'too many' participants rather than too few.

In the final chapter, I shall further explore the overall impact of the APoC-PSP and the COMPAC Initiative on the APOM research agenda, and the impact of stakeholder collaborations in research more generally.

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# *Chapter 12. Conclusions: The impact of the APoC-PSP and COMPAC projects, and implications for the future*

## 12.1 Introduction

In this chapter, I shall examine the impact of the APoC-PSP and COMPAC initiatives on APOM research, and their implications for its future. I shall also discuss how the work in this thesis has impacted my own career and research interests.

I shall explore the impact of these initiatives with reference to the following questions:

1. What impact has each project had on APOM research since they were completed? How should their impact be assessed?
2. To what extent have they addressed the problem of 'research waste' outlined in the first chapter?
3. How should the findings inform future work to agree research priorities and/or appropriate outcomes for APOM research? What role should collaborative stakeholder partnerships play? How frequently should they be repeated?
4. What lessons do they hold for stakeholder collaboration and patient and public involvement (PPI) in APOM research more widely?

### *12.1.1 Impact assessment*

The APoC-PSP and COMPAC initiatives were both notably resource-intensive undertakings. The APoC-PSP took almost two years from inception to publication of its top ten priorities, with almost 2,000 contributors devoting unpaid time and effort, and hours of work from SG members and NIAA staff. Meanwhile COMPAC took almost five years to complete, similarly benefiting from the (largely unrewarded) time and goodwill of over 4,000 contributors, as well as the hard work and dedication of research teams in the P-COMMaS study sites and staff at the NIAA and UCL. Given the considerable time and resources expended, it is worth exploring the extent to which the APoC-PSP and COMPAC initiatives have influenced (respectively) the APOM research agenda and the reporting of APOM trial outcomes.

Assessing impact is vital to appraising the value of projects like the APoC-PSP and COMPAC initiatives that involve 'research on research', because their overarching aim is to improve future research rather than to produce valuable new scientific knowledge directly. A cancer RCT that demonstrates a significant survival benefit from promising new cancer treatment arguably does not need further justification, because the new information it generates is self-evidently of value to cancer patients and clinicians. In contrast, PSPs and Core Outcome Sets do not in themselves provide new information that is useful to end users, but instead seek to improve future research studies by sharpening their focus on (respectively) genuinely important research questions and outcomes that truly matter to stakeholders.

To provide context to my assessment of the impact of the APoC-PSP and COMPAC initiatives, I shall first explore how other PSPs and COS development efforts have been evaluated in the years following their completion.

## 12.2 Assessing the impact of the APoC-PSP

### *12.2.1 Influence of PSPs on subsequent research activity*

Evaluating the impact of any PSP's top ten priorities among HCPs and research funding bodies, and its influence on shaping future research, is challenging. Firstly, the impact is far from instantaneous: professional organisations, research funders and charities need time to decide what the research priorities mean to them, and how to respond to them. Commissioning research to address the priorities, or reviewing new grant applications in light of a PSP's research priorities, also occurs over a timeframe of months to years.

Furthermore, awareness and acceptance of these priorities occurs via multiple channels and processes involving both active dissemination efforts and passive 'diffusion' among the research community – processes which are often neither visible nor measurable, and which are themselves influenced by the contemporary socioeconomic and cultural landscape in which they occur. While there is therefore no agreed timeframe following the conclusion of a PSP for assessing its impact, the influence and penetration of its results will become clear only after years or even decades.

### *12.2.2 Professional endorsement of PSP outputs*

Endorsement or other official approval by professional bodies is a relatively straightforward metric to quantify a PSP's adoption by the relevant research community. Priorities from several PSPs have been endorsed by professional bodies within the field;(318, 319) similarly the APoC-PSP's priorities have been endorsed by the NIAA, RCoA, AAGBI (now AoA) and specialist Anaesthetic societies. Professional endorsement does not automatically translate into funded research studies, but where professional bodies are also funders of future research and/or reviewers of grant applications, a PSP's priorities are perhaps more likely to be funded.

### *12.2.3 Cause and effect: did a PSP's priorities lead to specific research being funded and/or conducted?*

While new research proposals may reference published research priorities as a justification, in the absence of a commissioned funding call it is difficult to determine whether a particular research proposal was conceived specifically to address a particular PSP's priorities, or if it was already planned anyway.

On a similar note, assessing a PSP's impact on the research agenda also presupposes a reliable means of identifying all new research undertaken in relation to the PSP. The majority of PSPs – including the APoC-PSP – are undertaken as standalone projects with a finite budget and timeframe: they therefore effectively conclude with the publication of their research priorities. Few have an explicit plan for regular post-hoc surveillance of all new research studies in the field and their possible influence by the PSP's priorities.

### *12.2.4 How have other PSPs assessed their impact?*

Perhaps understandably in view of the above challenges, there is considerable debate about what happens to a PSP's research priorities after its conclusion and what follow-up should occur, particularly with regard to maximising its impact on future research and how to evaluate that impact. The latest version of the JLA Guidebook recommends that 'Steering Groups should create a dissemination plan for the results, identifying their

audiences and how to reach them', and that 'dissemination at the end of the PSP should be a consideration throughout the PSP process'.(320) A report from the NIHR Oxford Biomedical Research Centre entitled 'More than a Top Ten' similarly argued that initial plans for a PSP should ideally include consideration of who 'owns' the outputs, a plan for dissemination, strategies for working with research funders to translate some or all of the priorities into funded research studies, and clear accountability for 'what happens next'.(321)

Given these difficulties in quantifying impact, it is perhaps unsurprising that few PSPs have undertaken formal impact evaluations. A recent qualitative review entitled 'What happens after JLA PSPs?' concluded that 'the history and context of a JLA PSP have a major influence on its impact... there is no universal formula for success, but greater resource and attention should be given to what happens after prioritisation.' The lack of recognised metrics or processes for evaluating the influence of PSPs on their respective research agendas and their role in reducing research waste is an area of continued debate both for the JLA and other promoters of PPI in health research.(68)

Currently, the commonest approach to evaluating impact appears to be ad hoc reports – usually by the organisation that funded the PSP – collating completed or ongoing research studies that address the PSP's research priorities.(322-324) Indeed, the most clearly impactful PSPs are those where a specific disease charity has funded a PSP, and then proceeded to champion its priorities and fund research proposals that specifically address them. For example, the Cystic Fibrosis Trust funded and led a PSP in 2017; a report into its impact, titled 'You said, we did: How the Cystic Fibrosis priorities have been addressed since they were agreed in 2017' described how 'For funders and researchers alike, this list of priorities became one of the 'guiding principles' in deciding which areas of Cystic Fibrosis to focus on. The Cystic Fibrosis Trust alone has provided over £10 million of research funding to address these priorities, leveraging an additional £13 million of co-funding from other research funders.'(325)

Another easily demonstrated area of direct impact occurs where funding organisations have undertaken a PSP, and then require funding applicants to demonstrate how their proposed research addresses the priorities identified. Diabetes UK and Cystic Fibrosis UK are two examples of research charities whose funding is targeted to priorities they have themselves highlighted in an earlier PSP. Meanwhile the National Cancer Research

Institute has formed partnerships with other research organisations (Macmillan Cancer Support, the Medical Research Council and the British Society for Immunology) for research studies addressing priorities from its ‘Living with Cancer and Beyond’ PSP in 2018.(326)

### *12.2.5 Indirect impact of PSPs*

However, a PSP may have intangible impact in several other respects. For example, its results may subliminally influence researchers, making them more mindful of the importance of research that addresses stakeholders’ shared priorities, even if their own immediate research endeavours do not directly address a PSP’s priorities. Raising the profile of a disease or particular research area, and increasing awareness among clinicians, patients, and/or the general public, may also be a useful benefit of conducting a PSP. Secondly, increasing public awareness may have indirect benefits for research in the disease/specialty, such as facilitating recruitment of trial participants. Thirdly, the very act of involving patients and carers may help increase public confidence in research.(327)

Finally, the positive personal impacts, educational benefits or skills development that participating in a PSP may bring to individuals have been highlighted. For example, a contributor to the Teenage and Young Adult Cancer PSP commented “I always say that I didn’t want my diagnosis to go to waste, and now something tangible came out here that could help other people in the future. That feels amazing.”(328)

### *12.2.6 The APoC-PSP*

Notwithstanding the challenges in measuring a PSP’s impact discussed above, I provide here some examples of how the APoC-PSP has positively influenced the APOM research agenda in the seven years since its priorities were published, as well as noting areas where its reach has been limited, and which might therefore benefit from prospective planning if the exercise were to be repeated.

**Successes**

As noted above, the APoC-PSP's priorities were endorsed by the major UK professional organisations, and have been approved by the NIAA Funders' Forum and NIAA Research Council (who are responsible for assessing grant applications and allocation of research funds). The NIAA website specifies that its grant allocations process 'is informed by the results from the JLA/NIAA Anaesthesia and Perioperative Care Priority Setting Partnership'. Whilst not mandated, the wording implies that the priorities do indeed influence funding decisions – although the minutes of NIAA Grant Committee meetings (available via the NIAA website) do not give any clues as to whether this is the case in practice. In a similar vein, the UK Perioperative Clinical Trials Network (POMCTN) also mentions consideration of the APoC-PSP's priorities when deciding which trials to adopt, without clarifying to what extent they influence its decisions.

While there remains a degree of uncertainty, then, about the extent to which the APoC-PSP's priorities influence research fund allocation by the NIAA's funding partners, we are aware of many examples of recently completed or ongoing studies that explicitly reference them in their study rationale. The BMJ Open website also reports that the original APoC-PSP publication has been cited over 100 times. Without providing an exhaustive list, major studies informed by the APoC-PSP priorities include a systematic review of chronic pain prevalence in the UK,(329) studies exploring the influence of anaesthetic technique on hip fracture outcomes;(276, 330) the VITAL study of volatile versus intravenous anaesthesia,(331) the OSIRIS study exploring shared decision-makIng for high-rIsk major surgery,(332) the SINFONIA trial of two different agents to reverse neuromuscular blockade, the Fluid Optimisation in Emergency Laparotomy (FLO-ELA) trial,(333) the PREPARE trial investigating the role of preoperative exercise in reducing postoperative complications and disability,(334) and an ongoing trial of trans-auricular vagus nerve stimulation to reduce perioperative pain and morbidity.(335) These and other trials answering APoC-PSP priorities are described in a page on the JLA website.(336)

Finally, the APoC-PSP was deemed sufficiently successful to serve as a model for a recent Anaesthesia PSP conducted in Canada, which closely mirrored the APoC-PSP process and for which members of the APoC-PSP SG provided methodological guidance and advice about accessing hard-to-reach participants groups.(133)

**Challenges**

The above examples illustrating the APoC-PSP's influence on APOM research do not, of course, imply maximum impact. One clear area in which its impact has been limited concerns commissioned funding calls to address its top ten priorities. A meeting was held soon after the APoC-PSP's completion between the JLA and the NIHR to discuss whether any of the identified research priorities might align with the NIHR HTA's commissioned calls for research, but no commissioned calls resulted from the meeting. The NIAA funding partners likewise decided against commissioning research explicitly addressing any of the priorities.

It was also noted among the NIAA Research Council members soon after the completion of the APoC-PSP that no formal strategy for promoting the research priorities had been agreed in advance either among APOM HCPs or the wider public. Although several articles were published in the RCoA Bulletin and Anaesthesia News (the main non-academic newspieces for Anaesthetists in the UK) soon after the APoC-PSP's conclusion, this was felt to be a missed opportunity, not just because of the potential lack of visibility of the priorities within the perioperative research community, but also because it seemed a good moment to publicise APOM in the mainstream media and raise the profile of UK perioperative research.

## 12.3 Assessing the impact of COMPAC

Turning now to the COMPAC initiative, how should we appraise COMPAC's impact on subsequent research? As discussed earlier, the overarching aim of a Core Outcome Set (COS) is to make research more relevant to end users. Providing researchers with a ready-made set of core outcomes that are unequivocally important to all stakeholders should theoretically save researchers time and effort when selecting trial outcomes, and prevent the research waste that may arise when trials report unimportant or irrelevant outcomes that neither patients nor clinicians are interested in.

### *12.3.1 Assessing COS uptake*

However, the impact of a COS clearly depends on its uptake. Various COS experts have therefore sought to quantify the use of COSs following their publication. Although there are sporadic disease areas where COS use appears well established (principally rheumatology – where a recent review described 81% of drug RCTs for rheumatoid arthritis using a COS to report their outcomes)(337) – they generally conclude that COS uptake is limited.(338, 339) Another recent review of COS use in clinical trials published in major medical journals found that only a small minority of triallists had used a COS even when a suitable published COS existed.(340) A recent assessment of COS uptake in Cochrane reviews,(341) and a review of COS use in hip fracture trials also reported similar findings.(342)

Meanwhile, although enthusiasm persists among healthcare researchers for COS development, with new COSs being published every year, only modest efforts are directed towards examining uptake. Hughes et al, in their recent review of COS uptake across all published COSs, found only 24 studies assessing COS uptake, addressing only seventeen, or 5%, of the 337 COSs that had been completed at the time of their review. They concluded that 'further studies are needed to assess whether COS have been implemented… and to explore the barriers and facilitators to COS uptake.' (339)

Several barriers have been noted to the adoption of COSs. These include lack of awareness, difficulties identifying a relevant COS, scepticism about the validity of the COS development process, unfamiliarity with how to use them in research trials, reluctance because a COS is viewed as not pragmatic or logistically feasible for a specific trial, and researchers' own biases and preferences for particular outcomes.(338, 343) These findings have led to recommendations for raising awareness, and more education and training about COS use, among researchers and funders.(343)

### *12.3.2 Professional endorsement*

Endorsement by professional and/or regulatory bodies is another important factor in encouraging COS uptake, as demonstrated by the example of rheumatoid arthritis research. A 2013 review of outcome reporting in rheumatoid arthritis trials over the previous 50 years found almost 70% of trials using the COS by the end of the study period, and noted a significant increase in COS uptake following its endorsement by the

US Food and Drug Administration in 1996, and European Medicines Agency in 1998.(344) In contrast, studies assessing the impact of other COSs which were not endorsed by a regulatory body reported much lower rates (4-20%) of COS adoption.(345-347)

However, COS endorsement does not automatically lead to increased COS uptake. For example, the NIHR Health Technology Assessment (HTA) Programme updated its funding application guidelines in 2012, recommending that 'where established Core Outcomes exist they should be included amongst the list of outcomes unless there is good reason to do otherwise.' However, a review of funding applications submitted to the NIHR HTA programme over the subsequent four years found that only 20% mentioned searching for a relevant COS. While most of the others did justify their choice of outcomes – and in many cases, no relevant COS had been developed at the time of application, which may partly explain the omission – the recommendation to use a COS was frequently overlooked by funding applicants and funders themselves.(348)

COS endorsement by systematic review groups such as the UK's Cochrane Collaboration, or the USA's Agency for Healthcare Research and Quality, may also help drive COS uptake. A recent commentary by Clarke and Williamson argued for 'greater involvement of systematic reviewers in the development and implementation of core outcome sets'. They highlighted two surveys of Cochrane reviews published in 2007, 2011, and 2013: a total 9,800 outcomes were reported across 1,227 newly published Cochrane reviews, of which precisely none cited a COS as influencing their choice of review outcomes.(349) The most recent version of the Cochrane Handbook for Systematic Reviews does, however, recommend using a COS (where one exists) when selecting outcomes for reporting.(350)

### *12.3.3 Recommendations for maximising COS uptake*

In summary, to achieve meaningful uptake, a COS requires sustained, multi-pronged efforts to maximise awareness and acceptance among triallists, endorsement by professional and regulatory bodies, and promotion by research funders. Williamson et al have published perhaps the most comprehensive recommendations to date for improving COS uptake across the target research community, with suggestions not only for COS developers but also for researchers, research funders, regulators and publishers (see Table 35). They recommend that 'COS developers should collaborate with key

organizations to identify specific uptake strategies for their health area and ensure consensus recommendations regarding how to measure the core outcomes are provided.'(338)

| | |
|---|---|
| **COS developers** | |
| 1. | Develop an implementation plan at the start of the COS development process. Include in the plan an assessment of COS uptake a few years after dissemination, with a request for feedback from trialists to assess implementation barriers and facilitators |
| 2. | After completing the 'what' stage, move on to the 'how' stage so that researchers are pointed to the tools that they could use to measure the core outcomes, which may require more support from the funders of COS development |
| 3. | Be more active around dissemination, for example, comment on relevant regulatory guidance consultations; enter into correspondence as new research appears in a journal, highlighting the need for use of the COS; and provide feedback or peer review on protocols, other plans for research, and reports of research |
| **Trialists** | |
| 1. | Search the COMET database for COS. If a relevant, high-quality COS is identified but will not be used, explain why not so that the COS developers may address this feedback. |
| 2 | When implementing a COS, provide feedback to the COS developers on any implementation barriers and facilitators. |
| 3. | Register for the COMET initiative alerts system, to receive information about newly initiated or published COS in your area of interest. |
| **Patient organizations** | |
| 1. | Register for the COMET initiative alerts system, to receive information about newly initiated or published COS in your area of interest. |
| 2. | Make public research partners aware that relevant COS exist and encourage them to champion the use of high-quality COS. |
| **Professional bodies** | |
| 1. | Provide information about COS and promote uptake at educational activities during annual meetings. |

| | |
|---|---|
| 2. | Professional bodies linked to clinical trials (e.g., Society for Clinical Trials) could have a particular emphasis in this activity and work closely with COS organizations to promote uptake. |
| **Research funders** | |
| 1. | Identify and implement effective strategies for encouraging the 'use of design, conduct, or methodological standards and guidelines' (https://evir.org/contact-us/), which would include COS. |
| 2. | Test active approaches (e.g., adding a specific question to the application form, adding the recommendation to consider COS in a funder's feedback letter), which may be more effective than passive ones (e.g., a recommendation in a funder's guidance document). |
| 3. | Evaluate strategies and share findings with other funders. |
| **Trial registries** | |
| 1. | Provide information about COS in guidance given to trialists registering their studies. |
| 2. | Improve the data recording format for outcomes to enable easier assessment of COS uptake. Consider adding fields for trialists to record any COS used. |
| **Regulators** | |
| 1.. | During the drafting of a new or updated guidance document, review the COMET database for evidence about relevant high-quality COS, with an accompanying recommendation appropriate to the scope of the guidance. |
| 2. | Engage with the COS development process, to help identify barriers and facilitators early on. |
| **Journal editors** | |
| 1. | Encourage authors of protocols of trials or systematic reviews to consider COS. |
| 2. | When editorials and commentaries accompany the results of trials or systematic reviews, refer to the benefits of using a relevant COS and the potential for research waste of not doing so. |
| **Systematic reviewers** | |
| 1. | Follow the recommendation in the Methodological Expectations of Cochrane Intervention Reviews standards to consider a COS when choosing outcomes for the review. If a relevant, high-quality COS is identified but will not be used, explain why not so that the COS developers may address this feedback. |

| | |
|---|---|
| 2. | Assess uptake of the COS, if one exists, in the studies in the review. Identify any challenges posed by outcome heterogeneity arising in the review and make recommendations about future use of the COS. |
| 3. | If no COS exists, and outcome heterogeneity is evident, include the need to develop a COS in the research recommendations arising from the review. |
| **Systematic review protocol registries (e.g., PROSPERO)** | |
| 1. | Provide information about COS in guidance provided to systematic reviewers registering their systematic review protocol. |
| 2. | Improve the data recording format for outcomes to enable an easier assessment of COS uptake. Consider adding fields for systematic reviewers to record any COS used. |
| **Clinical guideline development groups** | |
| 1. | Consider the use of a relevant high-quality COS, if one exists, for assessing the evidence in the development of clinical guidelines |
| **HTA and value assessment organizations** | |
| 1. | Consider the use of a relevant high-quality COS, if one exists, for health technology evaluations. |
| 2. | Evaluate the influence of such a policy of endorsing COS as a factor in determining access to and pricing of medical products. |

**Table 35.** Actions for consideration and subsequent evaluation in relation to improving COS uptake (from Williamson et al, 2022)

### *12.3.4 Assessing the impact of COMPAC*

In light of the gradual adoption of COSs generally observed over many years following their publication, it is perhaps premature to appraise the uptake of COMPAC's core outcomes barely a year since their publication. To our knowledge, two published studies to date have justified their choice of outcome measure with reference to COMPAC's COS,(351, 352) but as far as we are aware, no studies published to date have reported the COS in its entirety. However, the use of COMPAC's core outcomes has been promoted in editorials in the British Journal of Anaesthesia,(353, 354) and new COS development processes informed by COMPAC in specific subspecialty areas of APOM are

currently ongoing, specifically for regional anaesthesia, pain after Caesarean section, and paediatric surgery.(355)

Unfortunately, so far there has been little uptake or endorsement among professional bodies or relevant research funders. Unlike the APoC-PSP's priorities, the NIAA grant applications guidance makes no recommendations regarding the use of COMPAC's COS, nor any other guidance regarding the selection of appropriate trial outcomes. Similarly, none of the main Anaesthesia academic journals promote or encourage reporting of COMPAC's core outcomes, nor do they provide guidance for the selection and reporting of trial outcomes.

Notwithstanding the relatively recent publication of the COMPAC's initiatives COS, the lack of uptake to date is perhaps unsurprising given the absence of a prospective dissemination and promotion strategy. While COMPAC's results have been published,(356) presented at international conferences, and reported in the Royal College of Anaesthetists' monthly bulletin, no specific plan for publicising or implementing COMPAC's core outcomes in the longer term was developed at the outset of COMPAC. In light of the recommendations regarding successful COS uptake discussed above, such a strategy is urgently needed to encourage adoption of COMPAC's recommended outcomes. The widespread use of COMPAC's COS in APOM research will likely depend on ongoing dialogue and collaboration with perioperative researchers, funders, journal editors and regulatory bodies.

## 12.4 Strategies for maximising impact of future patient-clinician collaborations

In summary, both the APoC-PSP and COMPAC have demonstrated a frequently observed shortcoming of PSPs and COS initiatives, namely excessive focus on the planning and execution of the projects themselves, and not enough attention to publicising and disseminating the results. In fairness, disseminating research findings has long been highlighted as a particular challenge for participatory research with disparate target audiences,(357) and several other PSPs and COS initiatives have encountered similar

challenges with uptake.(358) Moreover the observed preference of researchers for conducting new research rather than promoting and publicising their existing research findings suggests that challenges with dissemination are not confined to PSPs and core outcomes initiatives.(359, 360)

As described above, maximising the impact of a PSP or COS initiative on future research requires explicit strategies for ongoing promotion, awareness and education among several audiences including researchers, research funding bodies, and regulators. There is growing interest among behavioural scientists in effective strategies for promoting COS uptake and understanding how to engage these various audiences effectively,(361) but the resources required for such ongoing efforts are rarely factored into the design and/or funding plans when PSPs or COS development groups are initially conceived.

Debates about the relative merits of prioritising new research versus the promotion and dissemination of existing research findings are encountered across all spheres of health research, and bring us back to the central question of reducing research waste and maximising research value. In the next section, I shall consider whether the APoC-PSP and COMPAC initiatives have meaningfully reduced waste in APOM research, and future opportunities to use their outputs to further maximise the value of future perioperative research.

## 12.5 Have the APoC-PSP and COMPAC initiatives helped reduce waste and maximise value in APOM research?

I shall begin with a brief reiteration of the underlying assumptions justifying stakeholder participatory research initiatives such as the APoC-PSP and COMPAC:

- Current research is not always relevant to its end users (i.e. service users, clinicians, researchers)
- This leads to a high proportion of wasteful research (i.e. research that does not produce useful new information)

- Collaborative research involving end users helps clarify what research topics they consider most important, and which outcomes they consider most meaningful
- Future research will then become more relevant to end users, thereby reducing research waste, by addressing these important research priorities, and measuring these important (core) outcomes.

Exploring how these initiatives have impacted the issue of APOM research waste might therefore involve measuring and comparing the degree of wastage before and after their completion. Unfortunately, there is no recognised method for quantifying waste across a specific time, geography and area of healthcare research. Furthermore, any differences in research waste before or after would not prove a causative link, since there are many other uncontrolled variables at play in the perioperative research community that might have led to the observed differences.

Chalmers and Glasziou made a rough attempt to quantify research waste in their 2009 review. Their estimate of 85% of research funding being wasted was based on a ballpark figure of around half of research being wasted at each of the four main stages where they highlighted research waste (failure to address important questions; failure to publish; failure to appraise existing evidence; and failure to adequately report study interventions and outcomes).

Estimating the degree of research waste attributable the first of these issues – which the APoC-PSP sought to address – is challenging, as it would require some objective yardstick for measuring the importance of any given research study. Estimating research wastage due to inadequate reporting of study outcomes is, however, at least theoretically possible, by comparing outcomes described in published trial protocols with those subsequently reported in trials publications. A ‘before and after’ comparison of inadequate outcome reporting could perhaps illuminate any impact from COMPAC’s COS on the quality of outcome reporting, but attributing any change observed to COMPAC would be problematic, even if an obvious ‘step change’ were observed.

Perhaps because of these challenges, and the impossibility of inferring causation even if a reduction in research waste were observed, the current state of play regarding research waste has more often been appraised in editorials and review articles than through original

research. Overall, then, it seems likely that collective opinion within a research community may be the best barometer of a PSP's or COS's contribution to reducing research waste.

In the final sections of this chapter, I shall discuss the implications of the APoC-PSP and COMPAC initiatives for future APOM priority setting and outcome selection, and their implications for APOM research more widely.

## 12.6 Implications for future priority setting and outcome selection in APOM research

The APoC-PSP and the COMPAC initiatives are, by virtue of their collaborative participatory approaches, products of the context in which they were conducted, providing a snapshot in time of participating stakeholders' views. They therefore reflect the prevailing social, economic and cultural norms in the UK, as well as the NHS-dominated healthcare landscape.

### *12.6.1 The dynamic nature of research priorities and COSs*

There are therefore several reasons why the outputs of both exercises might change over time and in different settings. Changes in UK healthcare infrastructure or NHS funding models could potentially render some of the APoC-PSP's research priorities and/or COMPAC's core outcomes obsolete: for example, the question 'How can we improve communication between the teams looking after patients throughout their surgical journey?' might lose importance in a more joined-up healthcare system with greater continuity of care. Similarly the core outcome 'short-term recovery after surgery' – measured by discharge destination and/or level of dependence – is highly dependent on contemporary hospital discharge processes.

Secondly, wider societal shifts might impact on stakeholders' views regarding important research questions and outcomes. For example, the increasing recognition of personal mental health and wellbeing could feasibly lead to the primacy of postoperative psychological health and wellbeing over traditional clinical outcomes. Thirdly, new

research may provide answers to current research priorities, or suggest new fundamentally important outcome measures. For example, the discovery of an anaesthetic agent with an ideal neurodevelopmental safety profile might render the question ‘What are the effects of anaesthesia on the developing brain?’ obsolete, just as the hypothetical discovery of a serum biomarker that accurately predicted postoperative complications might lead to its inclusion as a core outcome.

Changes in the structures and processes of conducting and funding research, as well as political and macroeconomic events (such as the UK’s departure from the European Union, or the climate crisis) may also affect research priorities and outcome reporting. In summary, there is no telling what societal and scientific developments may occur in the years following the completion of a PSP or COS process, and therefore no guarantee of their continuing relevance and/or validity.

### *12.6.2 Updating the APoC-PSP and COMPAC outputs*

Just as Cochrane systematic reviews undergo periodic updates to incorporate new evidence (and/or exclude old or discredited evidence), so too the research priorities and/or core outcomes agreed for a particular area of health research are likely to require regular updating. The changing nature of research priorities has been demonstrated in several fields, such as asthma and breast cancer,(362-365) where reiterations of research agenda setting have yielded new priorities. Repeated reiterations of COS development initiatives – such as for rheumatoid arthritis – have likewise led to the emergence of new core outcomes and refinements of existing ones.(266, 366)

The comparison in chapter 5 similarly demonstrated how research priorities evolve over time in APOM research, although more overlap was noted between the outputs of the two APOM research prioritisation exercises (RPEs) conducted six years apart than between the ICM RPEs conducted fourteen years apart. This finding calls into question how often research priority setting should be repeated. Repeating the exercise too often risks simply producing very similar results, inducing fatigue among stakeholders, and exacerbating research waste. Meanwhile appraising research agendas setting too infrequently risks current research priorities becoming obsolete and/or forgotten by the research community. While there is clearly no optimum interval for all areas of health research, in a relatively

new field like perioperative medicine the argument for more frequent initial iterations is compelling.

The same approach likely holds true for COS development. A first iteration of COS development may benefit from refining or updating a few years after its publication, to examine how it is used among the relevant research community, identify problems and suggest ways to improve its utility in research. A well-established, widely-used and endorsed COS may need reviewing only rarely. This recognition that a COS should evolve to meet the needs of its research community prompted the OMERACT group's biannual research conferences,(367) and in time COMPAC's core outcomes will likely benefit from similar review by the APOM research community to understand where, why and how they are used (or not used), and how to improve their utility to researchers and funders.

### *12.6.3 Lessons for future APOM research priority setting and outcome selection consensus processes*

In both the APoC-PSP and the COMPAC initiative, areas of close agreement between the views of HCPs and service users were noted (such as the fundamental importance of clinical perioperative outcomes), but also areas of diverging opinions. These included the relative importance of research to improve perioperative patient experience (prioritised to a greater extent by service users than by HCPs in the APoC-PSP), and the value of patient-centred postoperative outcomes (similarly rated significantly more important by service users than by HCPs in P-COMMaS).

Future initiatives to agree research priorities and core outcomes for APOM research will likely continue, therefore, to benefit from equitable collaboration between patients, carers and HCPs, in order to avoid neglecting views from certain stakeholder groups. While the two main strengths of the APoC-PSP and COMPAC initiatives were a) their transparent, inclusive and equitable consensus methodology, and b) the diversity of stakeholders who contributed to both processes, they also hold lessons for future APOM research initiatives involving collaborative stakeholder coproduction.

Firstly, the importance of formulating a clear plan at the design stage for publicising and disseminating the eventual findings. While the APoC-PSP has arguably had a reasonable impact on the APOM research landscape in the seven years since its publication, its

impact would likely have been greater, and certainly more immediate, had NIAA funders and/or the NIHR committed in advance to commission research to address its priorities, and/or if funders had been quicker to endorse the research priorities and mandate their use in justifying new grant applications. Likewise COMPAC's core outcomes may prove slow to gain traction without clearer support and/or endorsement from Anaesthesia's professional bodies, research funders, journal editors and systematic reviewers.

The second main lesson is regarding strategies to ensure effective stakeholder engagement and participation. While the APoC-PSP and COMPAC both achieved highly effective stakeholder participation in certain aspects, there were also clear areas for improvement, such as the relative paucity of minority ethnic participants in both initiatives, and the delay between the completion of P-COMMaS and the COMPAC Delphi process which likely adversely impacted levels of engagement and participation in the Delphi process. A robust, multifaceted strategy for encouraging participation of hard-to-reach stakeholder groups at the design stage – for example, making greater use of social media, or targeted outreach to specific communities – and a tight but realistic timetable for completing each stage of the process, would likely help improve both these aspects.

Finally, the relatively long time period for completion of both projects is an area for potential improvement. While the generally accepted consensus methodology involving several sequential stages has the advantage of being thorough and comprehensive, both the APoC-PSP SG and the COMPAC SG found it at times unwieldy and resource-intensive. In addition, the risks of stakeholder dropout – whether through unforeseen changes in life circumstances, or merely due to fatigue or disillusionment – are significantly increased over the course of a long drawn-out consensus process.

A shorter, leaner process would likely cost less, require less time and effort (both for participants and support staff), and maximise stakeholder buy-in whilst minimising stakeholder dropout. Specific aspects that could perhaps be conducted more quickly and efficiently in the future include the evidence synthesis stages (after the first APoC-PSP survey, and at the start of the COMPAC initiative) and the progress through the sequential survey rounds.

## 12.7 Implications for stakeholder collaboration and patient and public involvement (PPI) in future APOM research

The APoC-PSP and COMPAC initiatives have both demonstrated the feasibility and benefits of stakeholder collaboration in deciding APOM research priorities and core outcomes, by producing a clear set of research priorities, and a defined set of fundamentally important research outcomes, representing the views of all relevant stakeholders in APOM research.

However, stakeholder collaboration on the scale described here is neither feasible nor desirable for the majority of APOM research. Just as governments do not hold referenda on every policy issue, widespread stakeholder consultation for all APOM research studies is unnecessary and unrealistic. Instead, wide-ranging stakeholder collaboration across many regions should arguably be reserved for deciding major issues in future research APOM policy – of which research agenda setting is perhaps the most fundamental.

### *12.7.1 Lessons for PPI in future APOM research*

An important additional legacy of the APoC-PSP and COMPAC initiatives are their contribution to further understanding PPI activity in APOM research. Both initiatives demonstrated that service users have valuable insights and viewpoints to share with APOM researchers regarding how to maximise the relevance of APOM research to the public; both initiatives have increased our understanding of how to engage effectively with service users in APOM research, how to harness their views, and the importance of targeted strategies to reach all relevant stakeholder groups and thereby maximise the diversity of service user representation obtained.

## 12.8 Personal career development arising from this body of work

On a personal level, my work on the APoC-PSP and COMPAC initiatives has cemented my passion for patient-centred perioperative care, and has led me to develop my involvement in other efforts to promote collaborative approaches to perioperative research design involving service users and HCPs as active contributors. The first has been the NIAA's Patient, Carer and Public Involvement and Engagement (PCPIE) group, of which I am co-chair and which meets quarterly to provide feedback from a patient and public perspective on APOM research proposals. The PCPIE group comprises eight 'lay' members and two clinicians (of whom I am one), advising researchers on aspects like ease of understanding, burden to patients, potential ethical or information governance concerns, and making other recommendations regarding how a proposed study might be made more relevant to patients and the public, or more manageable for participants.

Thanks to my experience with the APoC-PSP and COMPAC initiatives, I have also been fortunate enough to join the recently launched NIHR Central London Patient Safety Research Collaboration (PSRC) as co-lead for patient and public involvement and engagement (PPIE). This NIHR-funded partnership between University College Hospital NHS Foundation Trust and University College London will deliver research addressing patient safety across the full range of APOM, acute and critical care health services. As with the APoC-PSP and COMPAC initiatives, incorporating contributions from a wide range of service users, and targeting our PPIE efforts to ensure a diverse breadth of PPIE representation, are key principles of maximising the public relevance and eventual impact of the PSRC's work, and involves similar challenges to those encountered in both initiatives described in this thesis.

Both for me personally, and for the evolution of PPI in APOM research more widely, the APoC-PSP and COMPAC initiatives have provided a blueprint for PPI in APOM research, demonstrating that PPI is both feasible and beneficial – even on a national scale – while providing novel insights into effective PPI methodology and efficient use of PPI resources.

## 12.9 Conclusion

An equitable, transparent and collaborative consensus process incorporating views from a wide range of service users, HCPs and researchers is currently considered the optimum approach for agreeing the fundamental 'starting points' for health research, including deciding which research questions are most pressing, and which outcomes are most meaningful. The work described in this thesis demonstrated the feasibility and benefits of stakeholder collaboration in agreeing research priorities and core outcomes for APOM research.

Future research agenda setting exercises in APOM, and/or initiatives to improve outcome measurement and reporting, should likewise seek engagement from a wide range of relevant stakeholders, and proceed according to established consensus methodology that gives equal weight to all stakeholders' views. They should specifically include a prospective plan for promotion and dissemination of their results among the research community, a targeted strategy for approaching underrepresented stakeholder groups to ensure maximum stakeholder diversity, and consideration to the pragmatic and resource implications of undertaking widespread stakeholder consultation.

Both the APoC-PSP and COMPAC initiatives clearly demonstrated the benefits of including all stakeholder views to ensure the legitimacy and relevance of future health research, and the risks of ignoring or neglecting specific stakeholder groups. They have respectively provided – through a collaborative participatory research approach involving service users and HCPs – the first set of APOM research priorities, and the first set of fundamentally important APOM Core Outcomes, that reflects the views of all stakeholders. These outputs will hopefully enable APOM researchers to minimise waste and maximise the value of their research, and fulfil the ever-growing ethical imperative to demonstrate the importance of their research to patients and wider society

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# Appendices

**Appendix 1.** Members of the Steering group of the Anaesthesia and Perioperative Care Priority Setting Partnership (APoC-PSP)

| Name | Role | Stakeholder organisation represented |
|---|---|---|
| **Maddy Bell** | Administrative support | Royal College of Anaesthetists (RCoA) |
| **Natalie Bell** | Terms of reference, protocol and administrative support | RCoA |
| **Oliver Boney** | Steering Group Coordinator (May 2014 onwards) | National Institute of Academic Anaesthesia (NIAA) |
| **Ann Conquest** | Healthcare professional member | Association for Perioperative Practice (AfPP) |
| **Marion Cumbers** | Non-clinician member | Royal National Orthopaedic Hospital Patient Group |
| **Sharon Drake** | Terms of reference, protocol, administrative support | RCoA |
| **Mike Galsworthy** | Steering Group Coordinator (prior to May 2014) | NIAA |
| **Jacqui Gath** | Non-clinician member | Independent Cancer Patients' Voice (ICPV) |
| **Mike Grocott** | Healthcare professional member | RCoA |
| **Emma Harris** | Non-clinician member | Kangaroo Club |
| **Simon Howell** | Healthcare professional member | British Journal of Anaesthesia (BJA) |
| **Anthony Ingold** | Non-clinician member | Oesophageal Patients Association |
| **Leanne Metcalf** | James Lind Alliance adviser and Steering group chair | James Lind Alliance (JLA) |
| **Mike Nathanson** | Healthcare professional member | Association of Anaesthetists of Great Britain and Ireland (AAGBI) |
| **Thomas Pinkney** | Healthcare professional member | Royal College of Surgeons (England) |

**Appendix 2.** Categorisation of the APoC-PSP interim prioritisation survey's 92 questions by domain(s) of healthcare quality addressed (clinical effectiveness, patient safety, or patient experience)

| Theme | Summary research question | Domain(s) of healthcare quality addressed in the question |
|---|---|---|
| **MATERNITY** | How can **pain relief during childbirth** be improved? | Clinical effectiveness<br>Patient experience |
| **MATERNITY** | How do epidurals affect **progress and outcomes** of labour (childbirth), and how can **adverse effects** be minimised? | Clinical effectiveness |
| **MATERNITY** | How can detection and management of **maternal bleeding** during childbirth be improved? | Clinical effectiveness<br>Patient safety |
| **MATERNITY** | How do anaesthetic interventions during pregnancy or around the time of birth **affect the baby**? | Patient safety |
| **MATERNITY** | How can anaesthesia for **Caesarean sections** be improved? | Clinical effectiveness<br>Patient experience |
| **MATERNITY** | What anaesthetic strategies can reduce complications and deaths in **higher risk pregnancies**? | Clinical effectiveness<br>Patient safety |
| **CHILDREN** | How can we reduce **pain after surgery** in children and newborns? | Clinical effectiveness<br>Patient experience |
| **CHILDREN** | How can we **reduce anxiety** in children undergoing surgery? | Patient experience |
| **CHILDREN** | What are the effects of anaesthesia on the **developing brain**? | Patient safety |
| **CHILDREN** | How can **pre-operative assessment** for children be improved? | Clinical effectiveness<br>Patient experience<br>Patient safety |
| **CHILDREN** | How can we improve outcomes through **better monitoring** of children around the time of surgery? | Clinical effectiveness |
| **CHILDREN** | What **intravenous fluids** should we give children having surgery? | Clinical effectiveness<br>Patient safety |
| **CHILDREN** | What are the **long-term effects** of anaesthesia in babies? | Patient safety |
| **CHILDREN** | What can we do to improve outcomes for **higher risk children** having surgery? | Clinical effectiveness |

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|---|---|---|
| **CHILDREN** | What is the best way to **organise anaesthetic and surgical services** for children? | Clinical effectiveness |
| **ELDERLY CARE** | How can the anaesthetic team improve outcomes for **hip fracture patients**? | Clinical effectiveness |
| **ELDERLY CARE** | How can we reduce the effects of anaesthesia on **brain function**, particularly in the elderly? | Patient safety |
| **ELDERLY CARE** | What are the consequences of **low blood pressure** around the time of surgery, particularly in the elderly? | Clinical effectiveness<br>Patient safety |
| **ELDERLY CARE** | How can we reduce the **risks** of anaesthesia in elderly patients? | Clinical effectiveness<br>Patient safety |
| **ELDERLY CARE** | How can we **improve recovery** from surgery for elderly patients? | Patient safety |
| **PERIOPERATIVE CARE DELIVERY** | How can protocols, guidelines, checklists and care pathways **improve the safety and effectiveness** of anaesthesia? | Clinical effectiveness<br>Patient safety |
| **PERIOPERATIVE CARE DELIVERY** | How can operating **theatre efficiency** be improved? | Clinical effectiveness |
| **PERIOPERATIVE CARE DELIVERY** | How can patient care around the time of **emergency surgery** be improved? | Clinical effectiveness<br>Patient safety |
| **PERIOPERATIVE CARE DELIVERY** | What is the best way to **organise specialist surgical services**? | Clinical effectiveness |
| **PERIOPERATIVE CARE DELIVERY** | How can **patient data** be used to improve perioperative care? | Clinical effectiveness |
| **PERIOPERATIVE CARE DELIVERY** | What **outcomes** should we use to **measure the 'success'** of anaesthesia and perioperative care? | Clinical effectiveness |
| **PERIOPERATIVE CARE DELIVERY** | How do we decide which **clinicians** should deliver the different elements of perioperative care? | Clinical effectiveness<br>Patient safety |
| **TRAINING** | How can we most effectively deliver training to improve **quality and safety** in anaesthesia and perioperative care? | Clinical effectiveness<br>Patient experience<br>Patient safety |
| **TRAINING** | Should anaesthetists receive more training on caring for patients with **specific medical problems** (eg Ehlers Danlos syndrome?) | Clinical effectiveness |
| **TRAINING** | Would greater use of **Physician's Assistants (Anaesthesia)** be beneficial? | Patient safety |
| **TRAINING** | What training or resources could improve perioperative care in **developing countries**? | Clinical effectiveness |

| | | |
|---|---|---|
| **PAIN** | How can anaesthesia and pain relief be improved for patients with **Ehlers Danlos Syndrome**? | Clinical effectiveness<br>Patient experience |
| **PAIN** | How can pain control be improved in patients with **longstanding medical conditions**? | Clinical effectiveness<br>Patient experience |
| **PAIN** | How can we better **predict the severity** of pain immediately after surgery? | Clinical effectiveness |
| **PAIN** | How can we improve our use of **drugs** to provide better pain relief before and after surgery? | Clinical effectiveness<br>Patient experience |
| **PAIN** | How can we use **non-drug therapies** to provide better pain relief before and after surgery? | Clinical effectiveness<br>Patient experience |
| **PAIN** | How can we better **assess perioperative pain** in adults and children? | Patient experience |
| **PAIN** | What are the risk factors for developing **chronic pain** after surgery? | Patient experience |
| **PAIN** | What can we do to stop patients developing **chronic pain** after surgery? | Clinical effectiveness<br>Patient experience |
| **PAIN** | What can we do to reduce the **side effects** of pain relief medications? | Clinical effectiveness<br>Patient safety<br>Patient experience |
| **REGIONAL ANAESTHESIA** | What are the risks and benefits of **epidural and spinal injections** for major abdominal surgery? | Clinical effectiveness<br>Patient safety<br>Patient experience |
| **REGIONAL ANAESTHESIA** | How can the effectiveness of **epidural and spinal injections** be improved? | Clinical effectiveness |
| **REGIONAL ANAESTHESIA** | How do we improve **involvement of patients** in decision-making about regional anaesthesia? | Patient experience |
| **REGIONAL ANAESTHESIA** | How can the **effectiveness** of regional (local) anaesthetic techniques (other than epidural and spinal injections) be improved? | Clinical effectiveness |
| **REGIONAL ANAESTHESIA** | For **which patients** does regional (local) anaesthesia give **better outcomes** than general anaesthesia? | Clinical effectiveness |
| **REGIONAL ANAESTHESIA** | How can the **risks and side effects** of regional (local) anaesthesia be minimised? | Clinical effectiveness<br>Patient safety<br>Patient experience |

| | | |
|---|---|---|
| **COMPLEMENTARY MEDICINE** | How can **acupuncture** be used to improve recovery from surgery? | Clinical effectiveness<br>Patient experience |
| **COMPLEMENTARY MEDICINE** | How can **hypnosis** help control anxiety and improve recovery around the time of surgery? | Patient experience |
| **COMPLEMENTARY MEDICINE** | How can complementary medicine **help with recovery** from surgery? | Patient experience |
| **COMPLEMENTARY MEDICINE** | How can **psychological techniques** improve post-operative patient outcomes and satisfaction? | Patient experience |
| **COMMUNICATION** | How can we improve communication **between the teams** looking after patients having surgery? | Clinical effectiveness<br>Patient safety |
| **COMMUNICATION** | How could we improve communication between **healthcare staff and patients** before and after surgery? | Patient experience |
| **COMMUNICATION** | How can we promote **compassion and empathy** among staff caring for patients having surgery? | Patient experience |
| **COMMUNICATION** | What are the benefits of increased **patient and carer involvement** in perioperative care? | Clinical effectiveness<br>Patient experience |
| **ACCIDENTAL AWARENESS** | What is the best method for monitoring the **depth of anaesthesia**? | Clinical effectiveness<br>Patient safety |
| **ACCIDENTAL AWARENESS** | How can accidental awareness under general anaesthesia be **detected and avoided**? | Clinical effectiveness<br>Patient experience |
| **ACCIDENTAL AWARENESS** | What is the best way to **reduce the harm** caused by accidental awareness under general anaesthesia if it occurs? | Clinical effectiveness<br>Patient experience |
| **LONG-TERM EFFECTS** | How can anaesthetic technique and perioperative care help reduce the risk of **cancer recurrence**? | Clinical effectiveness |
| **LONG-TERM EFFECTS** | What can be done to **speed up recovery** from anaesthesia? | Patient experience |
| **LONG-TERM EFFECTS** | What **long-term harm** may result from anaesthesia, in particular following **repeated anaesthetics**? | Patient safety |
| **ANXIETY / STRESS** | How can we **reduce** anxiety and stress **before** an operation? | Patient experience |
| **ANXIETY / STRESS** | How can we **reduce** anxiety and stress **at the start** of an anaesthetic? | Patient experience |
| **ANXIETY / STRESS** | How can we **reduce** a patient's anxiety and stress immediately **after** an operation? | Patient experience |

| | | |
|---|---|---|
| **ANXIETY / STRESS** | What can we do to help patients with **needle phobia**? | Patient experience |
| **ANXIETY / STRESS** | Should patients routinely be offered **sedation for minor procedures**? | Patient experience |
| **PATIENT EXPERIENCE** | How can the patient's experience **before** surgery be improved? | Patient experience |
| **PATIENT EXPERIENCE** | What should be **discussed with patients** before surgery, and what is the best **setting** for this discussion? | Clinical effectiveness<br>Patient experience |
| **PATIENT EXPERIENCE** | How can we better implement fasting guidelines to avoid **excessive pre-operative fasting** and improve the patient experience? | Clinical effectiveness<br>Patient experience |
| **PATIENT EXPERIENCE** | How can better information improve patients' **expectations of pain** after surgery? | Patient experience |
| **PREPARING FOR SURGERY** | What **fasting guidelines** should patients follow before surgery? | Clinical effectiveness<br>Patient experience |
| **PREPARING FOR SURGERY** | How can we improve medical assessment to determine the **risk of harm** after surgery? | Clinical effectiveness |
| **PREPARING FOR SURGERY** | How can **pre-operative assessment** for adults be improved? | Clinical effectiveness<br>Patient experience |
| **PREPARING FOR SURGERY** | How can **patient education programmes** improve outcomes after surgery? | Clinical effectiveness<br>Patient experience |
| **PREPARING FOR SURGERY** | How can **weight loss programmes** improve outcomes after surgery? | Clinical effectiveness |
| **PREPARING FOR SURGERY** | How can preoperative **nutritional modifications** improve outcomes after surgery? | Clinical effectiveness |
| **PREPARING FOR SURGERY** | How can preoperative **exercise or fitness training**, including physiotherapy, improve outcomes after surgery? | Clinical effectiveness |
| **PREPARING FOR SURGERY** | Does treating **pre-operative anaemia** improve outcomes after surgery? | Clinical effectiveness |
| **PREPARING FOR SURGERY** | How should a patient's **existing drug regime** be modified before and after surgery? | Clinical effectiveness<br>Patient safety |
| **ANAESTHETIC PRACTICE** | How can we minimise the **risk of physical injury** in patients undergoing anaesthetic? | Patient safety<br>Patient experience |
| **ANAESTHETIC PRACTICE** | How can the anaesthetist help reduce the risk of **complications after surgery**? | Clinical effectiveness |

| | | |
|---|---|---|
| **ANAESTHETIC PRACTICE** | What is the best choice of **intravenous fluids** to improve outcomes after surgery? | Clinical effectiveness<br>Patient safety |
| **ANAESTHETIC PRACTICE** | How can we better detect and treat **major bleeding**? | Clinical effectiveness<br>Patient safety |
| **ANAESTHETIC PRACTICE** | Does **cardiac output monitoring** improve outcomes after surgery? How can we improve cardiac output monitoring? | Clinical effectiveness |
| **ANAESTHETIC PRACTICE** | How can we make **airway management** safer? | Clinical effectiveness<br>Patient safety |
| **RECOVERING FROM SURGERY** | What causes **nausea and vomiting** after surgery? | Patient experience |
| **RECOVERING FROM SURGERY** | How can we **prevent nausea and vomiting** after surgery? What is the **best treatment** if it occurs? | Clinical effectiveness<br>Patient experience |
| **RECOVERING FROM SURGERY** | What is the **impact of nausea and vomiting** after surgery on a patient's overall recovery? | Patient experience |
| **RECOVERING FROM SURGERY** | How can we **reduce complications** (adverse events) after surgery? | Clinical effectiveness |
| **RECOVERING FROM SURGERY** | Does post-operative **intensive care** improve outcomes in **higher risk patients** having major surgery? | Clinical effectiveness<br>Patient safety |
| **RECOVERING FROM SURGERY** | How should we **plan discharge** from hospital after surgery, and what would help patients recover at home after discharge? | Clinical effectiveness<br>Patient safety<br>Patient experience |
| **RECOVERING FROM SURGERY** | How can we **improve patient recovery** from surgery? | Clinical effectiveness<br>Patient experience |
| **RECOVERING FROM SURGERY** | Do **enhanced recovery programmes** (fast track surgery to speed up patient recovery) improve short and long-term outcomes? | Clinical effectiveness |

**Appendix 3.** Members of the Steering group of the Core Outcome Measures for Perioperative and Anaesthetic Care (COMPAC) initiative

| Name | Role | Organisation represented |
|---|---|---|
| **Oliver Boney** | Steering group coordinator | National Institute of Academic Anaesthesia (NIAA) |
| **Mike Grocott** | Healthcare professional member | Royal College of Anaesthetists (RCoA) |
| **Irene Leeman** | Non-clinician member | RCoA Lay Committee |
| **Ramani Moonesinghe** | Healthcare professional member | NIAA |
| **Paul Myles** | Healthcare professional member | Australian and New Zealand College of Anaesthetists (ANZCA) |
| **Lynne Smith** | Non-clinician member | RCoA Lay Committee |

**Appendix 4.** COMPAC systematic review: example search strategy for the four databases searched (OVID Medline, EMBASE, Web of Science, Cochrane Library)

1 = surg$.mp. or exp General Surgery/ (1,559,324)

2 = an*esthesi$.mp. (243,773)

3 = exp Anesthesia, General/ or exp Anesthetics/ or exp Anesthetics, Intravenous/ or an*estheti*.mp. or exp Anesthesia, Obstetrical/ or exp Anesthesia/ (401,732)

4 = exp Perioperative Care/ or exp Perioperative Nursing/ or per*operati*.mp. or exp Postoperative Complications/ (569,728)

5 = postoperative.mp. or exp Postoperative Care/ or exp Postoperative Complications/ or exp Postoperative Period/ (677,006)

6 = exp Intraoperative Complications/ or exp Postoperative Complications/ or complication.mp. (598,323)

7 = 1 or 2 or 3 or 4 or 5 or 6 (2,323,509)

8 = dentist*.mp. or exp Dentists/ or exp Dental Care/ or exp Dental Caries/ (149,412)

9 = dental.mp. (367,761)

10 = exp Hearing Loss/ or exp Hearing Aids/ or exp Persons With Hearing Impairments/ or exp Hearing/ or hearing.mp. or exp Hearing Tests/ or exp Hearing Disorders/ (123,341)

11 = exp Ophthalmoplegia/ or exp Ophthalmology/ or exp Ophthalmologic Surgical Procedures/ or ophthalm*.mp. or exp Eye Diseases/ (531,875)

12 = exp Cataract Extraction/ or exp Cataract/ or cataract*.mp. (57,506)

13 = exp Cardiac Catheterization/ or cardiac catheter*.mp. (72,741)

14 = exp Coronary Angiography/ or exp Angioplasty, Balloon, Coronary/ or coronary angiogra*.mp. (82,928)

15 = exp Fertilization in Vitro/ or exp Fertility/ or fertili*.mp. or exp Oocytes/ (171,147)

16 = history of medicine.mp. or exp "History of Medicine"/ (22,626)

17 = 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 (1,389,470)

18 = 7 not 17 (2,089,379)

19 = limit 18 to (humans and yr="2005 - 2014" and "all adult (19 plus years)" and randomized controlled trial) (26,100)

20 = "new england journal of medicine".jn. (71,116)

21 = "journal of the american medical association".jn. (9,420)

22 = british medical journal.jn. (44,630)

23 = lancet.jn. (127,774)

24 = anesthesiology.jn. (21,489)

25 = anesthesia & analgesia.jn. (22,212)

26 = "british journal of anaesthesia".jn. (16,884)

27 = anaesthesia.jn. (17,625)

28 = "annals of surgery".jn. (16,512)

29 = "british journal of surgery".jn. (19,924)

30 = "journal of the american college of surgeons".jn. (5,941)

31 = "archives of surgery".jn. (15,455)

32 = jama surgery.jn. (596)

33 = 19 and 20 (147)

34 = remove duplicates from 33 (120)

**Appendix 5.** P-COMMaS survey (service user version)


# P-COMMaS Survey (patients & carers)

***WHAT?*** Our research group has recently completed a wide-ranging review of the last ten years of research on major surgery. We looked at which 'outcomes' researchers most commonly measure to decide if surgery has gone well or not.

***WHO?*** We are now surveying patients, carers and healthcare professionals to ask their views about the outcome measures we identified.

***WHY?*** Your answers will help ensure future research looks at outcomes that truly matter to patients.

The survey will take around 10 minutes. Thank you for being part of our study, and for helping make future research more relevant to patients.

I confirm I have read and understood the participant information sheet, and agree to take part in the survey ☐

| ***How important do you consider the following after an operation? Please enter a number from 1 (not at all important) to 10 (of utmost importance).*** | |
|---|---|
| 1. **The operation being successful** (i.e. cures the problem, doesn't need a repeat operation in the future) | |
| 2. **Being comfortable after the operation** (i.e. being free from pain, not feeling sick or dizzy etc) | |
| 3. **Getting out of hospital** as quickly as possible | |
| 4. **Getting back to work, or normal daily activities**, as quickly as possible | |
| 5. Avoiding post-operative complications **that might delay recovery** (e.g. a chest infection, blood clot, bleeding) | |

| | |
|---|---|
| 6. Avoiding post-operative complications **that might cause permanent disability** (e.g. a stroke, heart attack, nerve injury, loss of vision) | |
| 7. **Chances of dying** during or soon after your operation | |

| ***Are there any other outcomes not mentioned above that you think are important after an operation?*** *(Please outline below):* |
|---|
| |
| |
| |
| |
| |
| |

| ***1. How old are you?*** | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 18-24 | | 25-34 | | 35-44 | | 45-54 | | 55-64 | | 65-74 | | 75 or over | |

| ***2. Do you identify as*** | | | | | |
|---|---|---|---|---|---|
| Male | | Female | | Other | _____ |

| ***3. What is the highest educational level you have completed?*** | | | |
|---|---|---|---|
| None / incomplete primary | | Primary school | |
| Secondary school | | Tertiary (higher) education | |
| Postgraduate / higher professional | | Prefer not to say | |

| ***4. What ethnic group do you consider yourself?*** | |
|---|---|
| **White** (English / Welsh / Scottish / Northern Irish / British; Irish; Gypsy or Irish Traveller; other white background) | |
| **Mixed / multiple ethnic groups** (White and Black Caribbean; White and Black African; White and Asian; other mixed / multiple ethnic background) | |

| | |
|---|---|
| **Asian / Asian British** (Indian; Pakistani; Bangladeshi; Chinese; any other Asian background) | |
| **Black / African / Caribbean / Black British** (African; Caribbean; other Black / African / Caribbean) | |
| **Other ethnic group** (Arab; any other ethnic group) | |

***5. How would you describe your MAIN occupation?***

| | | | |
|---|---|---|---|
| Employed (over 40 hours / week) | | Looking after home / family | |
| Employed (1-39 hours / week) | | Retired | |
| Self-employed / freelance (over 40 hours / week) | | Disabled / long-term sick | |
| Self-employed / freelance (1-39 hours / week) | | Student / in education / training | |
| Unemployed (looking for work / waiting to start a job already obtained) | | Other _____ | |

***6. Would you describe yourself PRIMARILY as: (please tick one)***

| | | | |
|---|---|---|---|
| Patient | | Carer | |

***7. What operation(s) have you experienced – whether as a patient or carer (please list all operations and their respective dates)?***

*Operation:*_____*Date:*_____

*Operation:*_____*Date:*_____

*Operation:*_____*Date:*_____

*Operation:*_____*Date:*_____

*1. Would you be willing to take part in a phone interview with one of our research team to further explore your views on outcomes after surgery?* ***You will receive an Amazon gift voucher as a token of thanks.***

Yes, I am happy to take part in a phone interview ☐

*2. Would you like to receive notification when the results of P-COMMaS are published?*

Yes, I would like to be notified of the study's results ☐

*3. Would you be interested in contributing to the global **'Core Outcome Measures for Perioperative and Anaesthetic Care'** (COMPAC) initiative?* (Details at: http://www.niaa-hsrc.org.uk/HSRC-COMPAC )

Yes, I am interested in contributing to COMPAC ☐

If so, please provide an email address and/or phone number where our research team can reach you:

Name:_____

Email:_____

Telephone:_____

(Your contact details will not be used for any other purposes or shared with any third parties.)

***Thank you very much for completing the survey***

## *The P-COMMaS Research Team:*

| | |
|---|---|
| *Dr Ramani Moonesinghe (Chief Investigator)* | *University College Hospital, London* |
| *Dr Oliver Boney (Study Coordinator)* | *University College Hospital, London* |
| *Professor Mike Grocott (Co-Investigator)* | *University Hospital, Southampton* |
| *Ms Jacqui Gath (Patient expert)* | *Independent Cancer Patients' Voice* |
| *Ms Marion Cumbers (Patient expert)* | *Royal National Orthopaedic Hospital Patient Group* |


| | | |
|---|---|---|
| **Chief Investigator:** | Dr Ramani Moonesinghe | **Email:** rmoonesinghe@googlemail.com |
| **Study Coordinator:** | Dr Oliver Boney | **Email:** pcommas@rcoa.ac.uk |

**Appendix 6.** P-COMMaS survey (clinician version)


# P-COMMaS Survey (clinicians)

***WHAT?*** Our research group has recently completed a wide-ranging review of the last ten years of research on major surgery. We looked at which 'outcomes' researchers most commonly measure to decide if surgery has gone well or not.

***WHO?*** We are now surveying patients, carers and healthcare professionals to ask their views about the outcome measures we identified.

***WHY?*** Your answers will help ensure future research looks at outcomes that truly matter to patients.

The survey will take around 10 minutes. Thank you for being part of our study, and for helping improve the patient-relevance of future research.

I confirm I have read and understood the participant information sheet, and agree to take part in the survey ☐

| ***How important do you consider the following after a major operation? Please enter a number from 1 (not at all important) to 10 (of utmost importance).*** | |
|---|---|
| 1. **The operation being successful** (i.e. cures the problem, doesn't need a repeat operation in the future) | |
| 2. **Being comfortable after the operation** (i.e. being free from pain, not feeling sick or dizzy etc) | |
| 3. **Getting out of hospital** as quickly as possible | |
| 4. **Getting back to work, or normal daily activities**, as quickly as possible | |
| 5. Avoiding post-operative complications **that might delay recovery** (e.g. a chest infection, blood clot, bleeding) | |

| | |
|---|---|
| 6. Avoiding post-operative complications **that might cause permanent disability** (e.g. a stroke, heart attack, nerve injury, loss of vision) | |
| 7. **Chances of dying** during or soon after the operation | |

| ***Are there any other outcomes not mentioned above that you think patients consider important after a major operation?*** *(Please outline below):* |
|---|
| |
| |
| |
| |
| |
| |

| ***1. How old are you?*** | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 18-24 | | 25-34 | | 35-44 | | 45-54 | | 55-64 | | 65-74 | | 75 or over | |

| ***2. Do you identify as*** | | | | | |
|---|---|---|---|---|---|
| Male | | Female | | Other | _____ |

| ***3. What is the highest educational level you have completed?*** | | | |
|---|---|---|---|
| Secondary school | | Tertiary (higher) education | |
| Postgraduate / higher professional | | Prefer not to say | |

| ***4. What ethnic group do you consider yourself?*** | |
|---|---|
| **White** (English / Welsh / Scottish / Northern Irish / British; Irish; Gypsy or Irish Traveller; other white background) | |
| **Mixed / multiple ethnic groups** (White and Black Caribbean; White and Black African; White and Asian; other mixed / multiple ethnic background) | |

| | |
|---|---|
| **Asian / Asian British** (Indian; Pakistani; Bangladeshi; Chinese; any other Asian background) | |
| **Black / African / Caribbean / Black British** (African; Caribbean; other Black / African / Caribbean) | |
| **Other ethnic group** (Arab; any other ethnic group) | |

***5. What is your clinical role as a provider of care for surgical patients?***

| | | | | | |
|---|---|---|---|---|---|
| Surgeon | | GP | | Anaesthetist | |
| Intensivist | | Pre-assessment nurse | | Theatre / scrub staff | |
| ODP / ODA | | Recovery nurse | | Ward / ICU nurse | |
| Physiotherapist | | GP practice nurse | | Community nurse | |
| Other (please describe) | | | | | |

***What kinds of major surgery do you see most often in your patients?***

_____

_____

_____

_____

*1. Would you be willing to take part in a phone interview with one of our research team to further explore your views on outcomes after surgery?* ***You will receive an Amazon gift voucher as a token of thanks.***

Yes, I am happy to take part in a phone interview ☐

*2. Would you like to receive notification when the results of P-COMMaS are published?*

Yes, I would like to be notified of the study's results ☐

*3. Would you be interested in contributing to the global **'Core Outcome Measures for Perioperative and Anaesthetic Care'** (COMPAC) initiative?* (Details at: http://www.niaa-hsrc.org.uk/HSRC-COMPAC )

Yes, I am interested in contributing to COMPAC ☐

If so, please provide an email address and/or phone number where our research team can reach you:

Name:_____

Email:_____

Telephone:_____

(Your contact details will not be used for any other purposes or shared with any third parties.)

***Thank you very much for completing the survey***

## *The P-COMMaS Research Team:*


| | |
|---|---|
| *Dr Ramani Moonesinghe (Chief Investigator)* | *University College Hospital, London* |
| *Dr Oliver Boney (Study Coordinator)* | *University College Hospital, London* |
| *Professor Mike Grocott (Co-Investigator)* | *University Hospital, Southampton* |
| *Ms Jacqui Gath (Patient expert)* | *Independent Cancer Patients' Voice* |
| *Ms Marion Cumbers (Patient expert)* | *Royal National Orthopaedic Hospital Patient Group* |

| | | |
|---|---|---|
| **Chief Investigator:** | Dr Ramani Moonesinghe | **Email:** rmoonesinghe@googlemail.com |
| **Study Coordinator:** | Dr Oliver Boney | **Email:** pcommas@rcoa.ac.uk |

**Appendix 7.** COMPAC Delphi process first survey: longlist of candidate outcomes participants were asked to rate (on scale of 1-5)

| Outcome Measure |
|---|
| **1. Mortality and survival measures** |
| *These outcomes record the number of patients who do not survive after their operations. Often, researchers report short-term, ('perioperative') mortality soon after the operation. They may also report longer-term death rates or survival, especially for operations whose aim is to cure life-threatening conditions such as cancer or heart disease.* |
| **1. a Overall mortality (death rate) after an operation** |
| **1. b Mortality after an operation from specific causes (e.g. from a blood clot, infection, heart attack)** |
| **1. c Overall long-term survival (e.g. after an operation to treat cancer, heart disease or other medium to long-term condition)** |
| **1. d Long-term 'disease-specific' survival (i.e. discounting deaths from other unrelated causes)** |

| **2. Peri-operative complications (i.e. 'Things that can go wrong' after an operation)** |
|---|
| *These outcomes describe how often patients suffer unwanted complications or 'adverse events' after an operation. However, researchers might report all complications (whether minor or serious), or only serious ones, or only those they consider to be directly caused by the operation itself. Here we're asking you to decide which of these various categories of complications you think are most important.* |
| **2. a Major (serious) post-operative complications and adverse events** |
| **2. b All post-operative complications and adverse events (i.e. both major and minor complications)** |

| |
|---|
| **2. c Complications or adverse events that require medical intervention or treatment, and/or which prolong patient's stay in hospital** |
| **2. d Complications arising during the operation itself (e.g. cardiac arrest, anaphylaxis, haemorrhage)** |
| **2. e Complications that cause permanent disability or harm** |
| **2. f All complications and adverse events, divided into a) those causing permanent harm; b) those only causing a temporary delay in recovery** |

| **3. Time and/or resource use** |
|---|
| *Alongside the clinical results after an operation, researchers often measure how long patients were in hospital, how long they spent in different wards, or how much their hospital stay cost. These outcomes help researchers understand how quickly patients recover from their operations, and may help find new ways to speed up recovery, reduce costs and/or improve patient access to hospital care.* |
| **3. a Total number of days the patient spends in hospital for surgery (from admission to discharge)** |
| **3. b Duration of the patient's operation/procedure (minutes)** |
| **3. c Length of time patient spends in Post-Anaesthesia Recovery Area (minutes)** |
| **3. d Length of time patient spends in Critical Care Ward (hours-days)** |
| **3. e Length of time patient spends on organ support in Critical Care Ward, such as on a mechanical ventilator (hours-days)** |
| **3. e Length of time until the patient is ready for discharge from hospital** |
| **3. f Unplanned attendance at hospital, GP or other healthcare facility within 30 days of operation** |
| **3. f Unplanned readmission to hospital within 30 days of operation** |
| **3. f Total financial cost of in-hospital care** |

| |
|---|
| **3. g Total financial costs of all perioperative care (i.e. both in hospital and outpatient)** |

| **4. Acute (short-term) recovery and/or post-operative comfort** |
|---|
| *Many perioperative research trials look at how quickly – and how fully – patients recover from their operations. For example, they might measure physical symptoms, such as pain or sickness levels in the days following an operation, or how quickly (and to what degree) patients are able to return to previous activities, especially basic 'activities of daily living' like eating and drinking, going to the toilet, getting dressed, or being able to move around. Increasingly, they might also measure emotional and psychological wellbeing, and how having a major operation affects patients mentally as well as physically.*<br>*Please think about which of the following measures of patient recovery you consider most important, and rate them accordingly:* |
| **4. a Number of patients who experience post-operative pain** |
| **4. a(i) Severity and/or duration of post-operative pain** |
| **4. a(ii) Duration of post-operative pain** |
| **4.a (iii) Total amount of painkiller required** |
| **4.a (iv) Number of patients who experience pain severe enough to delay discharge from hospital** |
| **4. b Number of patients who experience post-operative nausea and/or vomiting** |
| **4. b(i) Severity and/or duration of post-operative nausea and/or vomiting** |
| **4. b(ii) Duration of post-operative nausea and/or vomiting** |
| **4. b(iii) Total amount of anti-sickness medication required** |
| **4. b(iv) Number of patients who experience post-operative nausea and/or vomiting severe enough to delay discharge from hospital** |
| **4. c Number of patients who experience other physical symptoms (e.g. itching, cold/shivering, sore throat, lethargy, bloating, or other new symptoms) that weren't there before the operation** |

| |
|---|
| **4. d Number of patients who experience psychological symptoms that weren't there before the operation (e.g. anxiety, confusion, sleep disturbance, depression, fatigue, lethargy)** |
| **4. e Time taken to get back to eating and drinking normally (i.e. patient's usual diet)** |
| **4. f Time taken to get back to normal level of mobility** |
| **4. g Time taken to get back to work or other usual daily life roles** |
| **4. h Time taken for wound to be fully healed** |
| **4. I Time taken to get 'back to normal' in all aspects of the patient's life** |
| **4. j Discharge destination from hospital (e.g. patient's previous home or residence, short-term rehabilitation facility, or long-term care facility)** |
| **4. k Short-term level of dependence or reliance on others for care needs (e.g. less dependent on others than before the operation / about the same / more dependent)** |
| **4. l Total days spent at home within 30 days of the operation (e.g. if patient leaves hospital 3 days after their operation and spends next 30 days at home, 'days at home' = 27)** |

| **5. Medium to long-term recovery from surgery and quality of life** |
|---|
| *As well as the immediate recovery period, perioperative research is increasingly looking at the longer-term consequences of having an operation. This may encompass several aspects of a patient's life in the months and years after surgery: their physical capabilities, their mental capacity or cognitive abilities, and their emotional wellbeing. Practical consequences – such as whether a patient can continue to live at home, or resume their previous life roles (such as work or caring roles) – may be another aspect of measuring medium to long-term recovery.* |
| **5. a(i) Overall health-related Quality of Life** |
| **5. a(ii) Disease-specific Quality of Life (e.g. assessment of bowel function after colon surgery, or back pain/movement after back surgery)** |
| **5. b(i) Functional status ('what the patient can do') – questionnaire to assess levels of daily activity** |

| |
|---|
| **5. b(ii) Functional status ('what the patient can do') – assessed using clinical tests e.g. on exercise bike ('cardiopulmonary exercise test')** |
| **5. c(i) Overall recovery to pre-operative 'baseline' level (i.e. 'how they were' before the operation – e.g. complete recovery / partial recovery / worse than before)** |
| **5. c(ii) Physical recovery to pre-operative baseline level (e.g. complete recovery / partial / worse than before)** |
| **5. c(iii) Cognitive recovery (i.e. mental function) to pre-operative baseline level (e.g. complete recovery / partial / worse than before)** |
| **5. c(iv) Psychological and emotional recovery to pre-operative baseline level (e.g. complete / partial / worse than before)** |
| **5. d(i) Incidence of chronic pain** |
| **5. d(ii) Incidence of other persistent, long-term side effects** |
| **5. d(iii) Incidence of severe scarring or altered body image (e.g. after breast reconstruction, stoma formation, limb amputation)** |
| **5. e(i) Ability to return to usual place of residence (i.e. back to previous home vs need for new care home facility)** |
| **5. e(ii) Ability to resume work/other usual life roles (fully able / partly able / unable)** |
| **5. e(iii) Long-term level of functional dependence (better / about the same / worse)** |
| **5. e(iv) Long-term impact on relatives and/or carers (more / less care needs)** |
| **5. f (i) Overall patient satisfaction with results of their operation** |
| **5. f(ii) Patient's satisfaction with their treatment decision (i.e. 'with the benefit of hindsight, would you choose the same treatment again?')** |
| **5. f(iii) Overall relative/carers' satisfaction with results of the operation** |

| |
|---|
| **6. Medium to long-term 'Overall success/failure' of the surgery** |

| |
|---|
| *While the intended benefits of surgery are not the same for all operations, most patients who have surgery hope either to improve their quality of life (e.g. by curing painful or troubling symptoms), or reduce the chances of dying prematurely (e.g. by removing a cancer, or curing another life-threatening condition), or sometimes both.*<br>*Surgeons will often tell their patients whether the operation was successful; however, patients themselves are usually the ultimate judge of their operation's success. Below are some potential outcome measures that may be used in perioperative research to assess the 'overall success or failure' of an operation. Please decide how important you consider each of these as a measure of the success of an operation.* |
| **6. a(i) Extent of relief or improvement of symptoms (assessed by the patient – complete improvement / partial / none / worse than before)** |
| **6. a(ii) Extent of cure of underlying disease (assessed by the surgeon – complete cure / partial / incurable / worse than before)** |
| **6. b(i) Recurrence of the symptoms the operation was intended to treat (yes/no)** |
| **6. b(ii) Time to recurrence of symptoms (if yes)** |
| **6. c(i) Recurrence or progression of the disease the operation was intended to treat (yes/no)** |
| **6. c(ii) Time to recurrence or progression of disease (if yes)** |
| **6. d(i) Need for further follow-up, surveillance or tests after the original operation** |
| **6. d(ii) Need for further treatment, hospital admissions and/or surgery after the original operation** |

**Appendix 8.** COMPAC Delphi process second survey: reduced longlist of candidate outcomes (after removal of those that did not meet retention threshold). Outcomes highlighted yellow where a marked difference between clinicians' and service users' mean scores was observed in the first survey (yellow ≥0.3 point difference, orange ≥0.5 point)

| Outcome Measure | | |
|---|---|---|
| **1. Mortality and survival measures** | | |
| *These outcomes record the number of patients who do not survive after their operations. Often, researchers report short-term, ('perioperative') mortality soon after the operation. They may also report longer-term death rates or survival, especially for operations whose aim is to cure life-threatening conditions such as cancer or heart disease.* | | |
| **1. a Overall mortality (death rate) after an operation** | | |
| *Overall = 4.76* | *Patients & carers = 4.75* | *Clinicians = 4.78* |
| **1. b Mortality after an operation from specific causes (e.g. from a blood clot, infection, heart attack)** | | |
| *Overall = 4.64* | *Patients & carers = 4.7* | *Clinicians = 4.56* |
| **1. c Overall long-term survival (e.g. after an operation to treat cancer, heart disease or other medium to long-term condition)** | | |
| *Overall = 4.55* | *Patients & carers = 4.5* | *Clinicians = 4.63* |
| **1. d Long-term 'disease-specific' survival (i.e. discounting deaths from other unrelated causes)** | | |
| *Overall = 4.27* | *Patients & carers = 4.28* | *Clinicians = 4.26* |

| **2. Peri-operative complications (i.e. 'Things that can go wrong' after an operation)** |
|---|

| | | |
|---|---|---|
| *These outcomes describe how often patients suffer unwanted complications or 'adverse events' after an operation. However, researchers might report all complications (whether minor or serious), or only serious ones, or only those they consider to be directly caused by the operation itself. Here we're asking you to decide which of these various categories of complications you think are most important.* | | |
| **2. a Major (serious) post-operative complications and adverse events** | | |
| *Overall = 4.76* | *Patients & carers = 4.65* | *Clinicians = 4.93* |
| **2. b All post-operative complications and adverse events (i.e. both major and minor complications)** | | |
| *Overall = 4.12* | *Patients & carers = 4.27* | *Clinicians = 3.89* |
| **2. c Complications or adverse events that require medical intervention or treatment, and/or which prolong patient's stay in hospital** | | |
| *Overall = 4.5* | *Patients & carers = 4.51* | *Clinicians = 4.48* |
| **2. d Complications arising during the operation itself (e.g. cardiac arrest, anaphylaxis, haemorrhage)** | | |
| *Overall = 4.49* | *Patients & carers = 4.62* | *Clinicians = 4.3* |
| **2. e Complications that cause permanent disability or harm** | | |
| *Overall = 4.79* | *Patients & carers = 4.7* | *Clinicians = 4.93* |
| **2. f All complications and adverse events, divided into a) those causing permanent harm; b) those only causing a temporary delay in recovery** | | |
| *Overall = 4.4* | *Patients & carers = 4.35* | *Clinicians = 4.48* |

| |
|---|
| **3. Time and/or resource use** |
| *Alongside the clinical results after an operation, researchers often measure how long patients were in hospital, how long they spent in different wards, or how much their hospital stay cost. These outcomes help researchers understand how quickly patients recover from their operations,* |

| | | |
|---|---|---|
| *and may help find new ways to speed up recovery, reduce costs and/or improve patient access to hospital care.* | | |
| **3. a Total number of days the patient spends in hospital for surgery (from admission to discharge)** | | |
| *Overall = 4.13* | *Patients & carers = 4.1* | *Clinicians = 4.18* |
| **3. d Length of time patient spends in Critical Care Ward (hours-days)** | | |
| *Overall = 4.03* | *Patients & carers = 4.10* | *Clinicians = 3.92* |
| **3. e Length of time patient spends on organ support in Critical Care Ward, such as on a mechanical ventilator (hours-days)** | | |
| *Overall = 4.2* | *Patients & carers = 4.36* | *Clinicians = 3.96* |
| **3. e Length of time until the patient is ready for discharge from hospital** | | |
| *Overall = 4.07* | *Patients & carers = 4.02* | *Clinicians = 4.15* |
| **3. f Unplanned attendance at hospital, GP or other healthcare facility within 30 days of operation** | | |
| *Overall = 4.18* | *Patients & carers = 4.16* | *Clinicians = 4.22* |
| **3. f Unplanned readmission to hospital within 30 days of operation** | | |
| *Overall = 4.46* | *Patients & carers = 4.45* | *Clinicians = 4.48* |
| **3. f Total financial cost of in-hospital care** | | |
| *Overall = 3.91* | *Patients & carers = 3.82* | *Clinicians = 4.04* |
| **3. g Total financial costs of all perioperative care (i.e. both in hospital and outpatient)** | | |
| *Overall = 3.86* | *Patients & carers = 3.76* | *Clinicians = 4.0* |

| **4. Acute (short-term) recovery and/or post-operative comfort** |
|---|
| *Many perioperative research trials look at how quickly – and how fully – patients recover from their operations. For example, they might measure physical symptoms, such as pain or sickness levels in the days following an operation, or how quickly (and to what degree) patients are able* |

| | | |
|---|---|---|
| *to return to previous activities, especially basic 'activities of daily living' like eating and drinking, going to the toilet, getting dressed, or being able to move around. Increasingly, they might also measure emotional and psychological wellbeing, and how having a major operation affects patients mentally as well as physically.*<br>*Please think about which of the following measures of patient recovery you consider most important, and rate them accordingly:* | | |
| **4. a Number of patients who experience post-operative pain** | | |
| *Overall = 4.06* | *Patients & carers = 4.28* | *Clinicians = 3.73* |
| **4. a(i) Severity and/or duration of post-operative pain** | | |
| *Overall = 4.37* | *Patients & carers = 4.46* | *Clinicians = 4.23* |
| **4.a (ii) Total amount of painkiller required** | | |
| *Overall = 3.88* | *Patients & carers = 4.21* | *Clinicians = 3.38* |
| **4.a (iii) Number of patients who experience pain severe enough to delay discharge from hospital** | | |
| *Overall = 4.35* | *Patients & carers = 4.41* | *Clinicians = 4.27* |
| **4. b Number of patients who experience post-operative nausea and/or vomiting** | | |
| *Overall = 3.77* | *Patients & carers = 3.82* | *Clinicians = 3.69* |
| **4. b(iii) Number of patients who experience post-operative nausea and/or vomiting severe enough to delay discharge from hospital** | | |
| *Overall = 4.06* | *Patients & carers = 4.03* | *Clinicians = 4.12* |
| **4. c Number of patients who experience other physical symptoms (e.g. itching, cold/shivering, sore throat, lethargy, bloating, or other new symptoms) that weren't there before the operation** | | |
| *Overall = 3.71* | *Patients & carers = 4.13* | *Clinicians = 3.08* |
| **4. d Number of patients who experience psychological symptoms that weren't there before the operation (e.g. anxiety, confusion, sleep disturbance, depression, fatigue, lethargy)** | | |

| | | |
|---|---|---|
| *Overall = 4.12* | *Patients & carers = 4.32* | *Clinicians = 3.85* |
| **4. e Time taken to get back to eating and drinking normally (i.e. patient's usual diet)** | | |
| *Overall = 4.03* | *Patients & carers = 3.95* | *Clinicians = 4.15* |
| **4. f Time taken to get back to normal level of mobility** | | |
| *Overall = 4.37* | *Patients & carers = 4.31* | *Clinicians = 4.46* |
| **4. g Time taken to get back to work or other usual daily life roles** | | |
| *Overall = 4.31* | *Patients & carers = 4.21* | *Clinicians = 4.46* |
| **4. h Time taken for wound to be fully healed** | | |
| *Overall = 3.94* | *Patients & carers = 4.21* | *Clinicians = 3.54* |
| **4. I Time taken to get 'back to normal' in all aspects of the patient's life** | | |
| *Overall = 4.27* | *Patients & carers = 4.26* | *Clinicians = 4.27* |
| **4. j Discharge destination from hospital (e.g. patient's previous home or residence, short-term rehabilitation facility, or long-term care facility)** | | |
| *Overall = 4.18* | *Patients & carers = 4.08* | *Clinicians = 4.35* |
| **4. k Short-term level of dependence or reliance on others for care needs (e.g. less dependent on others than before the operation / about the same / more dependent)** | | |
| *Overall = 4.17* | *Patients & carers = 4.05* | *Clinicians = 4.35* |

| **5. Medium to long-term recovery from surgery and quality of life** |
|---|
| *As well as the immediate recovery period, perioperative research is increasingly looking at the longer-term consequences of having an operation. This may encompass several aspects of a patient's life in the months and years after surgery: their physical capabilities, their mental capacity or cognitive abilities, and their emotional wellbeing. Practical consequences – such as whether a patient can continue to live at home, or resume their previous life roles (such as work or caring roles) – may be another aspect of measuring medium to long-term recovery.* |
| **5. a(i) Overall health-related Quality of Life** |

| | | |
|---|---|---|
| *Overall = 4.46* | *Patients & carers = 4.59* | *Clinicians = 4.27* |
| **5. a(ii) Disease-specific Quality of Life (e.g. assessment of bowel function after colon surgery, or back pain/movement after back surgery)** | | |
| *Overall = 4.51* | *Patients & carers = 4.67* | *Clinicians = 4.27* |
| **5. b(i) Functional status ('what the patient can do') – assessment of activity level** | | |
| *Overall = 4.35* | *Patients & carers = 4.33* | *Clinicians = 4.38* |
| **5. c(i) Overall recovery to pre-operative 'baseline' level (i.e. 'how they were' before the operation – e.g. complete recovery / partial recovery / worse than before)** | | |
| *Overall = 4.42* | *Patients & carers = 4.44* | *Clinicians = 4.38* |
| **5. c(ii) Physical recovery to pre-operative baseline level (e.g. complete recovery / partial / worse than before)** | | |
| *Overall = 4.4* | *Patients & carers = 4.41* | *Clinicians = 4.38* |
| **5. c(iii) Cognitive recovery (i.e. mental function) to pre-operative baseline level (e.g. complete recovery / partial / worse than before)** | | |
| *Overall = 4.54* | *Patients & carers = 4.64* | *Clinicians = 4.38* |
| **5. c(iv) Psychological and emotional recovery to pre-operative baseline level (e.g. complete / partial / worse than before)** | | |
| *Overall = 4.44* | *Patients & carers = 4.53* | *Clinicians = 4.31* |
| **5. d(i) Incidence of chronic pain** | | |
| *Overall = 4.51* | *Patients & carers = 4.59* | *Clinicians = 4.38* |
| **5. d(ii) Incidence of other persistent, long-term side effects** | | |
| *Overall = 4.31* | *Patients & carers = 4.41* | *Clinicians = 4.15* |
| **5. d(iii) Incidence of severe scarring or altered body image (e.g. after breast reconstruction, stoma formation, limb amputation)** | | |
| *Overall = 4.05* | *Patients & carers = 4.26* | *Clinicians = 3.73* |

| | | |
|---|---|---|
| **5. e(i) Ability to return to usual place of residence (i.e. back to previous home vs need for new care home facility)** | | |
| *Overall = 4.58* | *Patients & carers = 4.51* | *Clinicians = 4.69* |
| **5. e(ii) Ability to resume work/other usual life roles (fully able / partly able / unable)** | | |
| *Overall = 4.49* | *Patients & carers = 4.41* | *Clinicians = 4.62* |
| **5. e(iii) Long-term level of functional dependence (better / about the same / worse)** | | |
| *Overall = 4.38* | *Patients & carers = 4.31* | *Clinicians = 4.5* |
| **5. e(iv) Long-term impact on relatives and/or carers (more / less care needs)** | | |
| *Overall = 4.14* | *Patients & carers = 4.21* | *Clinicians = 4.04* |
| **5. f (i) Overall patient satisfaction with results of their operation** | | |
| *Overall = 4.31* | *Patients & carers = 4.38* | *Clinicians = 4.19* |
| **5. f(ii) Patient's satisfaction with their treatment decision (i.e. 'with the benefit of hindsight, would you choose the same treatment again?')** | | |
| *Overall = 4.49* | *Patients & carers = 4.51* | *Clinicians = 4.46* |

## 6. Medium to long-term 'Overall success/failure' of the surgery

*While the intended benefits of surgery are not the same for all operations, most patients who have surgery hope either to improve their quality of life (e.g. by curing painful or troubling symptoms), or reduce the chances of dying prematurely (e.g. by removing a cancer, or curing another life-threatening condition), or sometimes both.*

*Surgeons will often tell their patients whether the operation was successful; however, patients themselves are usually the ultimate judge of their operation's success. Below are some potential outcome measures that may be used in perioperative research to assess the 'overall success or failure' of an operation. Please decide how important you consider each of these as a measure of the success of an operation.*

**6. a(i) Extent of relief or improvement of symptoms (assessed by the patient – complete improvement / partial / none / worse than before)**

| | | |
|---|---|---|
| *Overall = 4.51* | *Patients & carers = 4.54* | *Clinicians = 4.46* |
| **6. a(ii) Extent of cure of underlying disease (assessed by the surgeon – complete cure / partial / incurable / worse than before)** | | |
| *Overall = 4.51* | *Patients & carers = 4.67* | *Clinicians = 4.27* |
| **6. b(i) Recurrence of the symptoms the operation was intended to treat (yes/no)** | | |
| *Overall = 4.4* | *Patients & carers = 4.54* | *Clinicians = 4.19* |
| **6. b(ii) Time to recurrence of symptoms (if yes)** | | |
| *Overall = 4.26* | *Patients & carers = 4.51* | *Clinicians = 3.88* |
| **6. c(i) Recurrence or progression of the disease the operation was intended to treat (yes/no)** | | |
| *Overall = 4.46* | *Patients & carers = 4.61* | *Clinicians = 4.23* |
| **6. c(ii) Time to recurrence or progression of disease (if yes)** | | |
| *Overall = 4.32* | *Patients & carers = 4.49* | *Clinicians = 4.08* |
| **6. d(i) Need for further follow-up, surveillance or tests after the original operation** | | |
| *Overall = 4.05* | *Patients & carers = 4.41* | *Clinicians = 3.5* |
| **6. d(ii) Need for further treatment, hospital admissions and/or surgery after the original operation** | | |
| *Overall = 4.26* | *Patients & carers = 4.51* | *Clinicians = 3.88* |