

Preoperative tests (update)

Routine preoperative tests for elective surgery

NICE guideline NG45

Appendix N: Research recommendations

April 2016

*Developed by the National Guideline Centre,
hosted by the Royal College of Physicians*

Disclaimer

Healthcare professionals are expected to take NICE clinical guidelines fully into account when exercising their clinical judgement. However, the guidance does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of each patient, in consultation with the patient and, where appropriate, their guardian or carer.

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Appendix N: Research recommendations

N.1 Glycated haemoglobin (HbA1c)

Research question: Does optimisation of HbA1c in patients with poorly controlled diabetes improve surgical outcomes?

Why this is important:

Diabetes is the most common metabolic disorder in the UK and patients with diabetes require an increased amount of surgical procedures. Moreover, diabetes leads to increased morbidity, length of stay and inpatient costs. Current evidence suggests that doctors often fail to identify high-risk patients before surgery and do not provide perioperative interventions to control HbA1c levels. However, the impact of optimising HbA1c levels prior to surgery has not been assessed in a randomised clinical trial.

Criteria for selecting high-priority research recommendations:

PICO question	<p>Population: Adult patients classified as ASA grade 2 or above undergoing:</p> <ul style="list-style-type: none">• Major or complex non-cardiac surgery <p>Exclusion criteria:</p> <ul style="list-style-type: none">• People with severe COPD (equivalent to NYHA IIIb)• People undergoing cardiac surgery (such as valve replacement and coronary artery graft)• People undergoing transplantation• People undergoing emergency surgery <p>Stratified analysis if data available for:</p> <ul style="list-style-type: none">• Surgery type or surgery grade (if specified)• ASA grade• Selected comorbidities: cardiovascular, respiratory and renal diseases, obesity, diabetes <p>Any studies including initial risk stratification of patients will be included.</p> <p>Intervention: Medical optimisation of HbA1c</p> <p>Comparator(s):</p> <ul style="list-style-type: none">• No optimisation of HbA1c (glycated haemoglobin) in patients with poorly controlled diabetes, defined as HbA1c >69 mmol/litre (8.5%)• Patients with well-controlled diabetes, defined as HbA1c <69 mmol/litre (8.5%) <p>Outcomes: Critical:</p> <ul style="list-style-type: none">• All-cause mortality• Health-related quality of life
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	<p>Important:</p> <ul style="list-style-type: none"> • Complications related to surgery or anaesthesia (for example arrhythmias, myocardial infarction, heart failure, respiratory failure, acute kidney failure, wound infection, post-operative lower respiratory tract infection, post-operative urinary tract infection, cerebrovascular accidents) • Length of post-operative hospital stay • Length of preoperative hospital stay • Hospital readmission • Intensive care unit (ICU) admission • Number of episodes of hypoglycaemia (CBG <4 mmol/litre) • Number of episodes of hyperglycaemia (CBG >12 mmol/litre) • Hospital-acquired DKA <p>Study design: Prognostic RCT</p> <p>Timeframe: To be completed</p>
<p>Importance to patients or the population</p>	<p>If it was demonstrated that optimisation of patients preoperatively improved outcomes, it would provide evidence to commissioners, patients and surgical staff that elective surgery should be postponed until optimisation had been achieved. An elevated HbA1c test result would allow resources to be anticipated and also ensure that patients were appropriately consented.</p>
<p>Relevance to NICE guidance</p>	<p>Research is essential to inform future updates of key recommendations in the guideline. Definitive evidence is required regarding the preoperative optimisation of patients with diabetes to achieve glycaemic control, rather than consensus recommendations.</p>
<p>Relevance to the NHS</p>	<p>The implications would be that all patients having elective surgery would need to achieve good glycaemic control before being listed for surgery. This may require further funding of diabetologists/DISNs/GPs with a specialist interest in diabetes management. Patients would need to be aware that they would not be a candidate for elective surgery until they had complied and achieved glycaemic control</p>
<p>National priorities</p>	<p>No relevant national priorities</p>
<p>Current evidence base</p>	<p>The current evidence base is only retrospective. Furthermore, whilst there appears to be an association between glycaemic control and outcome, it cannot be stated with certainty. Likewise, whilst the concept of pre-optimisation makes clinical sense, there are no prospective studies to demonstrate its efficacy. There are no relevant ongoing trials.</p>
<p>Equality</p>	<p>Perioperative management of patients with diabetes is often suboptimal, and further research offers the potential to improve outcomes in this population.</p>
<p>Feasibility</p>	<p>The proposed research can be carried out within a realistic timescale and the sample size required to resolve the question is feasible. There are no ethical or technical issues.</p>
<p>Other comments</p>	<p>There is an authoritative guideline¹ that already recommends preoperative testing of HbA1c and postponing surgery until glycaemic control is</p>

achieved, if the patient's diabetes is not well controlled.
As the life span of an erythrocyte is 120 days, pre-optimisation and subsequent assessment of adequate optimisation as assessed by glycosylated haemoglobin could be a lengthy and thus costly study.

N.2 Polysomnography

Research question A: Does preoperative screening of people who are at risk of obstructive sleep apnoea (OSA) with polysomnography identify those at higher risk of postoperative complications?

Research question B: Does treating OSA perioperatively improve outcomes?

Why this is important:

OSA is a common condition, particularly in obese patients, and is associated with adverse post-operative outcome. However, it is frequently undiagnosed prior to surgery. Work is ongoing to assess the association of OSA with a variety of post-operative outcomes (morbidity, mortality, quality of life) in specific surgical populations. However there is currently no robust evidence or ongoing trials studying whether preoperative diagnosis and assessment of OSA leads to preoperative intervention or improved post-operative outcomes.

PICO question	<p>Population: Adults with obesity undergoing major or complex elective non-cardiac non-bariatric surgery.</p> <p>Exclusion criteria:</p> <ul style="list-style-type: none">• People with a pre-existing diagnosis of obstructive sleep apnoea• People undergoing cardiac surgery (such as valve replacement and coronary artery graft)• People undergoing bariatric surgery• People undergoing transplantation <p>Stratification for:</p> <ul style="list-style-type: none">• Surgery type• Surgery grade• ASA grade <p>Intervention:</p> <ul style="list-style-type: none">• Polysomnography <p>Comparison:</p> <ul style="list-style-type: none">• Routine care <p>Outcomes:</p> <ul style="list-style-type: none">• Preoperative optimisation of therapy• Preoperative change in management• Post-operative morbidity• Intensive care unit admission• Length of stay• Post discharge functional outcome• Hospital readmission• Health-related quality of life
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Importance to patients or the population	It is anticipated that routine diagnosis and assessment of obstructive sleep apnoea in obese patients undergoing major or complex surgery will result in improved identification of high-risk patients, preoperative optimisation, improved clinical perioperative management, improved processes of care and improved clinician- and patient-reported outcomes.
Relevance to NICE guidance	Research in this area is essential to inform future updates of key recommendations in this guideline.
Relevance to the NHS	Research in this area would clarify the costs and benefits of investing in the preoperative diagnosis and assessment of severity of obstructive sleep apnoea in obese patients who are at risk of the condition and are undergoing major surgery. Such evidence may provide financial advantage and impact on service delivery if such a diagnostic tool could identify high-risk patients, result in change in clinical management and reduce risk of adverse post-operative outcome (patient, clinician and process related outcomes).
National priorities	No relevant national priorities
Current evidence base	Although there is some evidence that patients with obstructive sleep apnoea have worse post-operative outcomes, there is no robust evidence that routine preoperative polysomnography in obese patients undergoing major surgery results in change in perioperative clinical management or in improved post-operative outcomes. Furthermore there are no studies examining the cost-benefit of polysomnography.
Equality	None identified
Feasibility	The proposed research can be carried out within a realistic timescale and the sample size required to resolve the question is feasible. There are no ethical or technical issues.
Other comments	None

References

- 1 Dhatariya K, Flanagan D, Hilton L, Kilvert A, Levy N, Rayman G et al. Management of adults with diabetes undergoing surgery and elective procedures: Improving standards. NHS Diabetes, 2011