Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

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those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG33.

1 Guidance

This document replaces previous guidance on percutaneous pancreatic necrosectomy (interventional procedure guidance 33).

1.1 Current evidence on the safety and efficacy of percutaneous retroperitoneal endoscopic necrosectomy is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 The procedure should only be carried out by a team experienced in the management of complex pancreatic disease.

2 The procedure

2.1 Indications and current treatments

2.1.1 Pancreatic necrosis (also called necrotising pancreatitis) is a serious complication of acute pancreatitis that can occur in some patients. It is associated with significant morbidity, requiring prolonged hospitalisation, and high mortality.

2.1.2 Traditionally pancreatic necrosis has been treated by open necrosectomy via laparotomy, but image-guided drainage or laparoscopic drainage may also be used.
2.2 Outline of the procedure

2.2.1 Percutaneous retroperitoneal endoscopic necrosectomy aims to remove necrotic tissue under direct vision. The procedure is less invasive and may improve prognosis compared with traditional open surgery. Percutaneous drainage may be attempted as part of the management prior to the procedure.

2.2.2 With the patient under general anaesthesia, an endoscope (which may be rigid or flexible) is inserted via a posterolateral approach into the retroperitoneal space to visualise the area of necrosis. Dead tissue is removed, for example using suction, lavage or forceps, and debrided where necessary using forceps. Drains may be placed for irrigation in the postoperative period. The procedure may be repeated if required.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3 Efficacy

2.3.1 A randomised controlled trial (RCT) of 88 patients treated by a step-up protocol involving drainage followed-up as required by percutaneous retroperitoneal endoscopic necrosectomy versus primary open necrosectomy, reported mortality rates of 19% (8/43) and 16% (7/45) respectively (p = 0.70) (patients in this study were followed-up for up to 6 months from hospital discharge). In the group randomised to drainage followed as required by percutaneous retroperitoneal endoscopic necrosectomy 60% (26/43) of patients underwent the procedure, 35% (15/43) of patients required drainage alone and 5% (2/43) of patients with multiple organ failure were too unstable for the procedure and underwent endoscopic transgastric drainage.

2.3.2 A non-randomised controlled study of 189 patients treated by the procedure or open pancreatic necrosectomy reported mortality rates of 19% (26/137) and 38% (20/52) respectively (p = 0.009) (follow-up not
2.3.3 A non-randomised controlled study of 30 patients treated by the procedure or open necrosectomy reported in-hospital mortality rates of 7% (1/15) and 40% (6/15) respectively (p = 0.08).

2.3.4 The non-randomised controlled study of 30 patients treated by the procedure or open necrosectomy reported postoperative multiple organ failure in 13% (2/15) and 67% (10/15) of patients respectively (p = 0.008).

2.3.5 The RCT of 88 patients comparing drainage followed as required by percutanenous retroperitoneal endoscopic necrosectomy with primary open necrosectomy, reported a composite rate of major complication or death in 40% (17/43) and 69% (31/45) of patients in either group respectively (p = 0.006) (follow-up of up to 3 months from hospital discharge).

2.3.6 The Specialist Advisers listed key efficacy outcomes as a reduction in mortality and morbidity, reduction of requirement for postoperative critical care, number of interventions required and length of hospital stay.

2.4 Safety

2.4.1 The RCT of 88 patients comparing percutanenous retroperitoneal endoscopic necrosectomy with primary open necrosectomy, reported fistula formation or perforation requiring intervention in 33% (14/43) and 22% (10/45) of patients respectively (p = 0.32) (patients in this study were followed-up for up to 6 months from hospital discharge).

2.4.2 Bowel perforation occurred in 7% (1/15) of patients treated by the procedure and in 13% (2/15) of patients treated by open necrosectomy in the non-randomised controlled trial of 30 patients (p = not significant). In the same study, pancreatic fistula developed in 13% (2/15) of patients and 0% (0/15) of patients respectively (p = not significant; follow-up not stated).

2.4.3 The RCT of 88 patients reported that bleeding requiring intervention occurred in 16% (7/43) of patients treated in the percutanenous
retroperitoneal endoscopic necrosectomy group and in 22% (10/45) of patients treated by open necrosectomy ($p = 0.48$).

2.4.4 The Specialist Advisers stated that adverse events reported in the literature include incomplete drainage and/or sepsis control, iatrogenic injury to the kidney or spleen, colonic necrosis, pseudocyst formation, venous thrombosis and death.

3 Further information

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

It updates and replaces NICE interventional procedure guidance 33.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

2 January 2012: minor maintenance.
Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.
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