NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Endoscopic transluminal pancreatic necrosectomy (913/2)**
Name of Specialist Advisor:	**Christopher Halloran**
Specialist Society:	**Association of Upper Gastrointestinal Surgeons**
Please complete and return to:	azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

1 Do you have adequate knowledge of this procedure to provide advice?

X Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

X Yes.

☐ No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

X Yes.

☐ Is there any kind of inter-specialty controversy over the procedure?

☐ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

It is now understood that adequate treatment of pancreatic necrosis requires a multi-modal approach

The next two questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure please answer question 2.2.2.

2.2.1 If you are in a specialty which does this procedure, please indicate your experience with it:

X I have never performed this procedure.

☐ I have performed this procedure at least once.

☐ I perform this procedure regularly.

Comments:

This procedure is undertaken by either intervention radiologists or gastroenterologists; however most acute pancreatitis is managed by surgeons. I have instigated this technique in my unit and managed the patients.

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

X I take part in patient selection or refer patients for this procedure regularly.

Comments:

Where appropriate; I will ask our intervention team to undertake this procedure.

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

☐ I have undertaken bibliographic research on this procedure.

☐ I have undertaken research on this procedure in laboratory settings (e.g. device-related research).

☐ I have undertaken clinical research on this procedure involving patients or healthy volunteers.

X I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

X Established practice and no longer new.

☐ A minor variation on an existing procedure, which is unlikely to alter that procedure's safety and efficacy.

☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

3.2 What would be the comparator (standard practice) to this procedure?

There are no standard comparators as units differ in their experience and volume. High volume units will have better surgical outcomes data, hence will probably prefer that option.

The main trial (PANTER) which advocates a step up approach, using surgery only for bail out is significantly flawed (composite end points when dissected do not show meaningful differences – mortality is unaffected and is more effective on fluid collections, which don't require surgery). I am unconvinced by these data.

3.3 Please estimate the proportion of doctors in your specialty who are performing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

X 10% to 50% of specialists engaged in this area of work.

☐ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

Few surgeons will undertake this, but working as a multi-disciplinary team, members will use this technique.

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Theoretical adverse events

Haemorrhage, visceral perforation, untreated infected necrosis. Bail out salvage surgery is often required.

2. Anecdotal adverse events (known from experience)

Bleeding, requirement for early re-intervention and slipping of irrigation tube (this is major as the cavity requires continuous flushing to ensure infection does not persist).

3. Adverse events reported in the literature (if possible please cite literature)

Not reviewed, but broadly similar. Also includes grumbling sepsis and recurrent abscess formation.

4.2 What are the key efficacy outcomes for this procedure?

This procedure has the advantages that open or minimal access surgery is not required; therefore reducing post-operative SIR's.

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

This is a niche procedure and is NOT accepted as standard of care in many units. It is popularised by a number of poor studies in European and US health care systems where acute pancreatitis is not predominantly looked after by surgeons (rather by gastroenteritis's).

UK experience is fragmented – however it is fair to say that in a small number of selected cases it has advantages: i.e. poor access routes for retroperitoneal access or in patients deemed unfit for open necrosectomy.

The major draw backs:1) Large number of repeat interventions, often every 2-3 days – which is huge institutional drain and lack of access to 24hr endoscopy if the irrigation becomes dislodged and 2) Failure to adequately clear the cavity of necrosis.

4.4 What training and facilities are required to undertake this procedure safely?

Requires 24hr endoscopy with consultant cover. Training should be part of a National fellowship scheme.

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

There are really only small series or under-powered RCTs. PANTER trial advocates a step up approach incl. trans grastric necrosectomy. Furthermore:

PENGUIN: *JAMA.* 2012;307(10):1053-1061. doi:10.1001/jama.2012.276.

Context Most patients with infected necrotizing pancreatitis require necrosectomy. Surgical necrosectomy induces a proinflammatory response and is associated with a high complication rate. Endoscopic transgastric necrosectomy, a form of natural orifice transluminal endoscopic surgery, may reduce the proinflammatory response and reduce complications.

Objective To compare the proinflammatory response and clinical outcome of endoscopic transgastric and surgical necrosectomy.

Design, Setting, and Patients Randomized controlled assessor-blinded clinical trial in 3 academic hospitals and 1 regional teaching hospital in the Netherlands between August 20, 2008, and March 3, 2010. Patients had signs of infected necrotizing pancreatitis and an indication for intervention.

Interventions Random allocation to endoscopic transgastric or surgical necrosectomy. Endoscopic necrosectomy consisted of transgastric puncture, balloon dilatation, retroperitoneal drainage, and necrosectomy. Surgical necrosectomy consisted of video-assisted retroperitoneal debridement or, if not feasible, laparotomy.

Main Outcome Measures The primary end point was the postprocedural proinflammatory response as measured by serum interleukin 6 (IL-6) levels. Secondary clinical end points included a predefined composite end point of major complications (new-onset multiple organ failure, intra-abdominal bleeding, enterocutaneous fistula, or pancreatic fistula) or death.

Results We randomized 22 patients, 2 of whom did not undergo necrosectomy following percutaneous catheter drainage and could not be analyzed for the primary end point. Endoscopic transgastric necrosectomy reduced the postprocedural IL-6 levels compared with surgical necrosectomy (P = .004). The composite clinical end point occurred less often after endoscopic necrosectomy (20% vs 80%; risk difference [RD], 0.60; 95% CI, 0.16-0.80; P = .03). Endoscopic necrosectomy did not cause new-onset multiple organ failure (0% vs 50%, RD, 0.50; 95% CI, 0.12-0.76; P = .03) and reduced the number of pancreatic fistulas (10% vs 70%; RD, 0.60; 95% CI, 0.17-0.81; P = .02).

Conclusion In patients with infected necrotizing pancreatitis, endoscopic necrosectomy reduced the proinflammatory response as well as the composite clinical end point compared with surgical necrosectomy.

To me this is unconvincing and clinically unuseful

-Clin Res Hepatol Gastroenterol. 2014 Dec;38(6):770-6. doi: 10.1016/j.clinre.2014.06.016. Epub 2014 Aug 19.
Endoscopic transgastric versus surgical necrosectomy in infected pancreatic necrosis.
Tan V, Charachon A Lescot T Chafaï N Le Baleur Y, Delchier JC Paye F

Surgical necrosectomy, is still associated with a high morbidity. Indications of the endoscopic route, a new less invasive technique are not defined yet. To compare characteristics and clinical outcome of patients treated by the two techniques, a bi-centric retrospective comparison of 21 patients treated by **surgical necrosectomy in one center (group S)** with **11 patients treated in another center by endoscopic transgastric necrosectomy (group E)** was performed. **Clinical severity scores were significantly higher in group S** although CT severity score did not differ between groups. Acute postoperative complications including pancreatic fistula occurred more frequently in group S (86% vs. 27%, P=0.002). ICU and hospital length of stay were higher in group S (84 vs. 4 days; P=0.008 and 58 vs. 15 days; P=0.005 respectively). **Long-term complication did not differ between groups.** Compared to surgery, endoscopic necrosectomy exhibited lower rate of complications and reduced hospital length of stays. Endoscopic transgastric necrosectomy appears as a safe and effective procedure and has to be included in the therapeutic algorithm of infected pancreatic necrosis.

Again this is unconvincing as the 2 groups are clearly different

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, e.g. PUBMED? (This can include your own work). If yes, please list.

Mostly case series

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

See above

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

5.1 Outcome measures of benefit (including commonly used clinical outcomes – both short and long-term; and quality of life measures):

Mortality
SIRS
Critical care days
Overall hospital stay
Pancreatic enzyme replacement use

5.2 Adverse outcomes (including potential early and late complications):

Mortality
SIRS
Critical care days
Overall hospital stay
Whether surgical bail out was required
Pancreatic fistula rate

6 Trajectory of the procedure

6.1 In your opinion, what is the likely speed of diffusion of this procedure?

This procedure is part of good multi-modal treatment for infected or walled off "symptomatic" pancreatic necrosis. IT will not replace current surgical modalities, but will complement them.

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

☐ Most or all district general hospitals.

☐ A minority of hospitals, but at least 10 in the UK.

X Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

Not all HPB centres have either an interest in or experience of management of complications of acute severe pancreatic necrosis. Those who have well developed methodology, already have procedures of choice; if transgastric endoscopic necrosectomy is not one of them it is unlikely to overtake current preferences.

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

☐ Major.

☐ Moderate.

X Minor.

Comments:

Niche procedure, which will complement current treatment as opposed to replace it.

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

8 Data protection and conflicts of interest

8.1 Data protection statement

The Institute is committed to transparency. As part of this commitment your name and specialist society will be placed in the public domain, in future publications and on our website (www.nice.org.uk) and therefore viewable worldwide. This information may be passed to third parties connected with the work on interventional procedures.

A copy of the completed Specialist Adviser advice will be sent to the Specialist Society who nominated the Specialist Adviser.

Specialist Advisers should be aware that full implementation of the Freedom of Information Act 2000 may oblige us to release Specialist Advice from 2005. The Freedom of Information Act 2000 favours the disclosure of information however requests will be considered on a case by case basis. If information is made available, personal information will be removed in accordance with the Data Protection Act 1998. In light of this please ensure that you have not named or identified individuals in your comments.

8.2 **Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee**

Please state any potential conflicts of interest, or any involvements in disputes or complaints, relevant to this procedure. Please use the "Conflicts of Interest for Specialist Advisers" policy (attached) as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

[1] 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐ **YES** **X NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐ **YES** **X NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐ **YES** **X NO**
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐ **YES** **X NO**
Investments – any funds which include investments in the healthcare industry	☐ **YES** **X NO**
Do you have a **personal non-pecuniary** interest – eg have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	☐ **YES** **X NO**

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry	☐ **YES** **X NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☐ **YES** **X NO**

If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.

Comments:

Thank you very much for your help.

Professor Bruce Campbell, Chairman, Interventional Procedures Advisory Committee

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

February 2010

Conflicts of Interest for Specialist Advisers

1 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.

1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

2 **Personal pecuniary interests**

2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'** or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples are as follows.

2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.

2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place.

2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

2.2 No personal interest exists in the case of:

2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where

the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 Personal family interest

3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.

3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.

3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).

3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)

3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

3.2 No personal family interest exists in the case of:

3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

3.2.2 accrued pension rights from earlier employment in the healthcare industry.

4 Personal non-pecuniary interests

These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration

4.4 other reputational risks in relation to an intervention under review.

5 Non-personal interests

5.1 A non-personal interest involves payment that benefits a department or organisation for which a Specialist Advisor is responsible, but that is not received by the Specialist Advisor personally. This may either relate to the product or service being evaluated, in which case it is regarded as **'specific,'** or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as **'non-specific'**. The main examples are as follows.

5.1.1 **Fellowships** – the holding of a fellowship endowed by the healthcare industry.

5.1.2 **Support by the healthcare industry or NICE** – any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:

- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Endoscopic transluminal pancreatic necrosectomy (913/2)**
Name of Specialist Advisor:	**Manu Nayar**
Specialist Society:	**Pancreatic Society of Great Britain and Ireland**
Please complete and return to:	azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

1 Do you have adequate knowledge of this procedure to provide advice?

☒ Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

☒ Yes.

☐ No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

☒ Yes.

☐ Is there any kind of inter-specialty controversy over the procedure?

☐ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

The next two questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure please answer question 2.2.2.

2.2.1 If you are in a specialty which does this procedure, please indicate your experience with it:

☐ I have never performed this procedure.

☐ I have performed this procedure at least once.

×☐ I perform this procedure regularly.

Comments:

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

×☐ I take part in patient selection or refer patients for this procedure regularly.

Comments:

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

☐ I have undertaken bibliographic research on this procedure.

☐ I have undertaken research on this procedure in laboratory settings (e.g. device-related research).

×☐ I have undertaken clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

× ☐ Established practice and no longer new.

☐ A minor variation on an existing procedure, which is unlikely to alter that procedure's safety and efficacy.

☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

3.2 What would be the comparator (standard practice) to this procedure?

ENDOSCOPIC NECROSECTOMY PERFOMED VIA THE TRADIITONAL ENDOSCOPIC ROUTE /PERCUTANEOUS NECROSECTOMY/OPEN NECREOSECTOMY

3.3 Please estimate the proportion of doctors in your specialty who are performing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

× ☐ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Theoretical adverse events

10 – 155 INCLUDES BLEEDING, PERFORATION, INFECTION

2. Anecdotal adverse events (known from experience)

STENT MIGRATION, SEDTION RELATED ADVERSE REACTIONS

3. Adverse events reported in the literature (if possible please cite literature)

THE ABOVE FROM OUR PUBLICATION IN THE JOURNAL ENDOSCOPY THIS YEAR

4.2 What are the key efficacy outcomes for this procedure?

1. RESOLUTION OF NECROTIC CAVITY
2. MINIMISE COMPLCATIONS
3. REDUCE HDU/ITU STAY
4. QUALITY OF LIFE

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

OPTIMAL TECHNIQUE; TIMING OF REPEAT PROCEDURES

4.4 What training and facilities are required to undertake this procedure safely?

SHOULD ONLY BE PERFORMED IN A HGIH VOLUME CENTRE WITH A ROBUST MULTIDISCIPLINARY PANCREATIC TEAM INCLUDING SURGENS, HPB PHYSICIANS, INTERVENTIONAL RADIOLOGIST, DIETICIAN AND TRAINED NURSING STAFF.

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

NO BUT WOULD LIKE TO SET ONE UP AS THE LARGEST UNIT PERFROMING THESE PROCEDURES.

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, e.g. PUBMED? (This can include your own work). If yes, please list.

Endoscopic drainage of walled-off pancreatic necrosis using a novel self-expanding metal stent. Huggett MT, Oppong KW, Pereira SP, Keane MG, Mitra V, Charnley RM, **Nayar MK.** Endoscopy. 2015 Oct;47(10):929-32.

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

TIMING OF PROCEDURE
MANAGEMENT TEAM
TECHNIQUE
TIMING OF REPEAT PROCEDURES

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

5.1 Outcome measures of benefit (including commonly used clinical outcomes – both short and long-term; and quality of life measures):

RESOLUTION OF CAVITY
COMPLICATIONS
QUALITY OF LIFE

5.2 Adverse outcomes (including potential early and late complications):

BLEEDING
PERFORATION
SEPSIS
STENT MIGRATION
SEDATION RELAETD COMPLICATIONS

6 Trajectory of the procedure

6.1 In your opinion, what is the likely speed of diffusion of this procedure?

MAJOR ADVANCE IN ENDOSOCPIC TREATMENT OF PANCREATIC NECROSIS. I FORESEE WIDER USE OF THIS PROCEDURE BUT ONLY IN LARGE VOLUME CENTRES. SINCE THE INTRODUCTION OF THIS PROCEDURE OPEN NECROSECTOMY HAS ALMOST BECOME OBSOLETE.

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

☐ Most or all district general hospitals.

☐ A minority of hospitals, but at least 10 in the UK.

×☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

I REITERATE THAT THIS SHOULD ONLY BE PERFORMED IN UNITS WITH A ROBUST MDT OF WHICH THERE ARE < 10.

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

☐ Major.

×☐ Moderate.

☐ Minor.

Comments:

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

A FEW PUBLICATIONS WHICH MIGHT BE USEFUL

8 Data protection and conflicts of interest

8.1 Data protection statement

The Institute is committed to transparency. As part of this commitment your name and specialist society will be placed in the public domain, in future publications and on our website (www.nice.org.uk) and therefore viewable worldwide. This information may be passed to third parties connected with the work on interventional procedures.

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8.2 **Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee**

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Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	**YES**
	× ☐	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐	**YES**
	× ☐	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	× ☐	**NO**
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐	**YES**
	× ☐	**NO**
Investments – any funds which include investments in the healthcare industry	☐	**YES**
	× ☐	**NO**
Do you have a **personal non-pecuniary** interest – eg have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	☐	**YES**
	× ☐	**NO**

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry	☐	**YES**
	× ☐	**NO**

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[1] 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☐	**YES**
	☒	**NO**

If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.

Comments:

Thank you very much for your help.

Professor Bruce Campbell, Chairman, Interventional Procedures Advisory Committee

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

February 2010

Conflicts of Interest for Specialist Advisers

1 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.

1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

2 **Personal pecuniary interests**

2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'** or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples are as follows.

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These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

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- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Endoscopic transluminal pancreatic necrosectomy (913/2)**
Name of Specialist Advisor:	**Robert Sutton**
Specialist Society:	**Pancreatic Society of Great Britain and Ireland**
Please complete and return to:	azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

1 Do you have adequate knowledge of this procedure to provide advice?

☒ Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

☐ Yes.

☒ No. If no, please enter any other titles below.

Comments:

Endoscopic transgastric pancreatic necrosectomy

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

☒ Yes.

☒ Is there any kind of inter-specialty controversy over the procedure?

☐ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

This procedure requires a highly skilled expert therapeutic upper gastrointestinal endoscopist to be working in a specialist tertiary centre attracting referrals of patients with complicated acute pancreatitis from other hospitals. There remains controversy about the selection of patients for this procedure and the appropriateness of the alternatives as well as uncertainty as to comparative outcomes.

The next two questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure please answer question 2.2.2.

2.2.1 If you are in a specialty which does this procedure, please indicate your experience with it:

☒ I have never performed this procedure.

☐ I have performed this procedure at least once.

☐ I perform this procedure regularly.

Comments:

I work in a specialty that selects and/or refers patients for the procedure.

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

☒ I take part in patient selection or refer patients for this procedure regularly.

Comments:

We have a multidisciplinary approach to the management of patients with acute necrotising pancreatitis although the predominant management is undertaken under the care of and by consultant pancreatic surgeons.

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

☒ I have undertaken bibliographic research on this procedure.

☒ I have undertaken research on this procedure in laboratory settings (e.g. device-related research).

☒ I have undertaken clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

☐ Established practice and no longer new.

☐ A minor variation on an existing procedure, which is unlikely to alter that procedure's safety and efficacy.

☒ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

There has been one high quality randomised trial comparing the procedure with surgical necrosectomy (including minimally invasive and open surgery), but other reports are case reports (including air embolus) as well as case series.

3.2 What would be the comparator (standard practice) to this procedure?

Minimally invasive transabdominal pancreatic necrosectomy

3.3 Please estimate the proportion of doctors in your specialty who are performing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

☒ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

The number is restricted to one or two consultants in a proportion of the ~25 tertiary specialist pancreatic centres.

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Theoretical adverse events

Gastrointestinal and/or retroperitoneal haemorrhage; splenic vein thrombosis with portal hypertension and oesophageal varices; gas embolus; gastrointestinal perforation; creation of false tract; introduction and/or exacerbation of infection; exacerbation of organ dysfunction and/or failure; prolongation of hospital stay with multiple procedures; migration of any stent inserted; dislodgement of nasogastric tube with irrigation; fluid overload; failure requiring adoption of an alternative approach; death

2. Anecdotal adverse events (known from experience)

Prolonged hospital stay

3. Adverse events reported in the literature (if possible please cite literature)

Death:

Bonnot B, Nion-Larmurier I, Desaint B, Chafai N, Paye F, Beaussier M, Lescot T. Fatal gas embolism after endoscopic transgastric necrosectomy for infected necrotizing pancreatitis. Am J Gastroenterol. 2014 Apr;109(4):607-8. doi: 10.1038/ajg.2013.473. PubMed PMID: 24698875.

4.2 What are the key efficacy outcomes for this procedure?

Visible clearance of cavity on subsequent endoscopy and/or CT scanning with absence of recurrence of collection typically with infection. Absence of complications of gastrointestinal function or from any stent inserted into necrosis through gastric wall. Full recovery from acute pancreatitis.

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

Need for recurrent debridement; difficulty with continuous irrigation of cavity; inability to clear all necrosis.

4.4 What training and facilities are required to undertake this procedure safely?

Tertiary referral pancreatic centre with multidisciplinary team managing acute pancreatitis with most advanced level therapeutic endoscopic capability

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

Not known apart from RCT reported:
Bakker OJ, van Santvoort HC, van Brunschot S, Geskus RB, Besselink MG, Bollen TL, van Eijck CH, Fockens P, Hazebroek EJ, Nijmeijer RM, Poley JW, van Ramshorst B, Vleggaar FP, Boermeester MA, Gooszen HG, Weusten BL, Timmer R; Dutch Pancreatitis Study Group. Endoscopic transgastric vs surgical necrosectomy for infected necrotizing pancreatitis: a randomized trial. JAMA. 2012 Mar 14;307(10):1053-61. doi: 10.1001/jama.2012.276. PubMed PMID: 22416101.

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, e.g. PUBMED? (This can include your own work). If yes, please list.

No

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

Yes, includes who should do this, where and when, in which patients, and when alternatives are more appropriate.

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

5.1 Outcome measures of benefit (including commonly used clinical outcomes – both short and long-term; and quality of life measures):

Opiate usage; nutritional deficit and/or need for supplementation; C-reactive protein; serum albumin; haematocrit; neutrophil count; sequential organ failure assessment scores; CT or MRI scanning; length of stay; patient reported outcome e.g. on a scale of 0 to 10 with 0 being bed bound and 10 back to normal, where are you?

5.2 Adverse outcomes (including potential early and late complications):

A classification incorporating all the 'theoretical adverse events' listed in 4.1

6 Trajectory of the procedure

6.1 In your opinion, what is the likely speed of diffusion of this procedure?

Slow to moderate pace restricted to specialist centres

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

☐ Most or all district general hospitals.

☒ A minority of hospitals, but at least 10 in the UK.

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

Potentially in all tertiary specialist pancreatic centres

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

☐ Major.

☒ Moderate.

☐ Minor.

Comments:

Acute pancreatitis is the commonest gastrointestinal cause of emergency hospital admission, but only one in five patients with acute pancreatitis might be considered for this procedure (currently very much fewer undergo it).

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

It is recommended that NICE should include in the review comparison with alternative approaches to pancreatic necrosis, including minimally invasive transabdominal pancreatic necrosectomy, which is the nearest equivalent.

8 Data protection and conflicts of interest

8.1 Data protection statement

The Institute is committed to transparency. As part of this commitment your name and specialist society will be placed in the public domain, in future publications and on our website (www.nice.org.uk) and therefore viewable worldwide. This information may be passed to third parties connected with the work on interventional procedures.

A copy of the completed Specialist Adviser advice will be sent to the Specialist Society who nominated the Specialist Adviser.

Specialist Advisers should be aware that full implementation of the Freedom of Information Act 2000 may oblige us to release Specialist Advice from 2005. The Freedom of Information Act 2000 favours the disclosure of information however requests will be considered on a case by case basis. If information is made available, personal information will be removed in accordance with the Data Protection Act 1998. In light of this please ensure that you have not named or identified individuals in your comments.

8.2 **Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee**

Please state any potential conflicts of interest, or any involvements in disputes or complaints, relevant to this procedure. Please use the “Conflicts of Interest for Specialist Advisers” policy (attached) as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

[1] ‘Family members’ refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

Consultancies or directorships attracting regular or occasional payments in cash or kind	☒ **YES** ☐ **NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐ **YES** ☐ **NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐ **YES** ☐ **NO**
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐ **YES** ☐ **NO**
Investments – any funds which include investments in the healthcare industry	☐ **YES** ☐ **NO**
Do you have a **personal non-pecuniary** interest – eg have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	☐ **YES** ☐ **NO**

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry	☐ **YES** ☐ **NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☒ **YES** ☐ **NO**

If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.

Comments:

I am a consultant for multiple pharmaceutical companies but all payments made for this work are received by my employing Trust and are used in support of research for patient benefit. Support from the National Institute for Health Research for the NIHR Liverpool Pancreas Biomedical Research Unit.

Thank you very much for your help.

Professor Bruce Campbell, Chairman, Interventional Procedures Advisory Committee

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

February 2010

Conflicts of Interest for Specialist Advisers

1 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

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