

Rapid Response Report NPSA/2010/RRR010: Early detection of complications after gastrostomy

March 2010

Supporting Information

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Background

Gastrostomies can be inserted via endoscopic routes (*percutaneous endoscopic gastrostomy (PEG)* as single-stage buttons, under radiological guidance (*per-oral image-guided gastrostomy (PIG)* or *radiologically inserted gastrostomies (RIG)* (also referred to as *percutaneous radiological gastrostomy (PRG)*) or during surgery. Other abbreviations used include *laparoscopic insertion of gastrostomy (LIG)*, *laparoscopic assisted PEG (LAPEG)*, placement of a PEG with laparoscopic assistance into the jejunum (LAPEJ), and *percutaneous enteral access tubes (PEATs)*.

Gastrostomies are usually used as a medium-to-long term feeding strategy for patients with additional dietary needs or an inability to swallow. They are used as a medium-to-long term feeding strategy for children and adults with additional dietary needs or an inability to swallow, and may be inserted surgically, endoscopically or under radiological guidance. Decisions on whether they are the most appropriate intervention need to be taken with care, and has been the subject of recent guidance from the Royal College of Physicians¹. For inpatients receiving care for their presenting condition (e.g. stroke), gastrostomy insertion normally occurs in the endoscopy or radiology department, with patients returning to their original ward after immediate recovery from the procedure. For outpatients, the procedure may take place on a day case basis or as a short stay.

In the literature, serious complications from gastrostomy insertion are considered to be rare. However, estimates do vary between studies, with an older overview suggesting that from three to eight per cent of patients experience major complications² whilst more recent overviews report a procedure-related morbidity of nine to 17 per cent, with major complications occurring in only one to three per cent of cases, and a mortality rate of 0.5 per cent³. Conversely, Janes et al⁴ compared the outcomes for patients given gastrostomies in 1992 and 2002 in a single UK hospital and found an increased rate of complications over time, plausibly explained by patients with much more complex and serious conditions being referred for gastrostomy insertion. This study also outlines the difficulty of attributing mortality to gastrostomy insertion, as by 2002, 22 per cent of the patients studied were dying from their underlying illness within 30 days of gastrostomy insertion. Sanders et al⁵, undertaking a similar review in two district general hospitals, found an overall 30-day mortality rate of 28 per cent, with an increased mortality rate of 54 per cent for the subgroup of patients with dementia. Out of 361 cases reviewed, there were three fatalities from peritonitis and six of gastric haemorrhage, all resulting in death within 72 hours. Leeds et al⁶ compared post-procedure mortality for a large sample of patients receiving PEGs and PIGs and identified similar 30-day mortality rates from all causes of 10.7 per and 15.3 per cent. The Royal College of Physicians¹ has since issued advice on the issues of performing gastrostomies on patients unlikely to benefit.

The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) document, *Scoping our practice*⁷, included detail on PEG insertion which was later expanded on by Johnston et al⁸. As all the subjects in the NCEPOD study had died, their findings cannot be used to estimate the scale of the problem, but it is notable that 43 per cent of the deaths occurred in the first seven days post procedure, with aspiration pneumonias frequently implicated.

The complications most likely to result in serious illness or death in the **immediate period** after gastrostomy insertion based on Potack and Chokhavatia's literature review³ include the following:

Aspiration pneumonia

The level of sedation may contribute to aspiration risk during the procedure, and rates of around one per cent of insertions resulting in peri-procedure aspiration are reported. Whilst post-procedure aspiration resulting from refluxed gastric contents and tube feedings is thought to be even higher, levels attributable to the gastrostomy are difficult to assess given the high vulnerability of many patients undergoing these procedures to aspiration from other causes.

Colonic perforation

Colonic perforation during gastrostomy placement is a rare but not unknown complication in adults, but occurs more frequently in paediatric populations, at a rate of two to 3.5 per cent. Colonic perforation is also likely to lead to peritonitis and major surgery may be needed to identify and repair the perforation.

Haemorrhage

Haemorrhage may be caused during the procedure by the puncture of gastric wall vessels, or after the procedure if the gastric mucosa is too tightly compressed underneath the internal bumper and blood vessels erode. Haemorrhage may be primary haemorrhage (during or immediately after insertion), or secondary haemorrhage (which may occur 12-24 hours after gastrostomies placed under general anaesthetic in children as their blood pressure rises), or may occur several days after gastrostomy insertion (due to stomal necrosis). Whilst very minor external bleeding can be normal, significant external bleeding can indicate serious internal bleeding.

Wound infection

Localised wound infection, including with Methicillin-resistant *Staphylococcus aureus* (MRSA), can occur in five to 25 per cent of cases, despite the standard administration of prophylactic antibiotics. Given the very vulnerable nature of the patient group, some localised infections may proceed to bacteraemia.

Peritonitis

Peritonitis results from bacterial transmission across the stoma puncture site and complicates up to 2.3 per cent of procedures and carries a high mortality rate. Peritonitis manifests as abdominal pain, fever, and a raised white cell count in the initial days after placement. Transient external leakage of the stomach contents from the puncture canal can indicate a likelihood that internal leakage is also occurring. There can also be **chemical peritonitis** if enteral feed leaks across; this can manifest as pain on feeding. Many patients undergoing gastrostomy may be too ill or disabled to verbally express pain, and therefore signs of pain need to be recognised (for example, changes in vital signs, irritability, or restlessness).

Whilst the general symptoms of pneumonia, infection, and haemorrhage are well known, as they can occur after a range of procedures and operations, the symptoms of pain on

feeding and external leakage of gastric contents are specific to gastrostomies, and therefore may be less well known by staff without specific expertise.

Review of evidence of harm

Context of clinical activity levels

No firm estimates were found about the number of gastrostomy insertions in a UK setting. Scaling down American estimates³ to the population of England and Wales would lead to an estimate of 30,000 to 40,000 insertions annually, but this appears unlikely given Janes et al's⁴ description of around 100 PEGs inserted per year in a large UK teaching hospital (representing about 15,000 annually given 176 acute trusts in England and Wales, most of which would be smaller).

Evidence of harm from the Reporting and Learning System (RLS)

A key word search of the RLS and Strategic Executive Information System (STEIS) was made for incidents reported from October 2003 until 13 January 2010.

Twenty-two incidents were identified where serious complications occurring after gastrostomy insertion did not appear to be rapidly recognised and acted on. In 11 of these reports the patient died, and in 11 they apparently suffered severe harm (for example, needing emergency surgery or HDU/ITU admission). The complications involved were:

- nine cases of leakage of feed into the peritoneal cavity and/or peritonitis;
- two of colonic puncture;
- one related to haemorrhage;
- one involving both haemorrhage and colonic puncture;
- one septic shock secondary to aspiration;
- one of leakage of feed into thoracic cavity;
- one of surgical emphysema;
- six of unclear mechanism.

Of these 22 incidents, five affected children, and 17 were adults (aged 51-80 years). Four related to RIG insertion, with 12 related to PEG insertion and in six incidents the type of gastrostomy was not clearly described.

Examples included:

"The death of an adult after PEG insertion; vital signs were not well monitored and when deterioration was noted this was attributed to the use of controlled drugs, and peritonitis was not considered until three days post procedure. The patient died after a period of HDU treatment and the post-mortem identified chemical peritonitis."

"Emergency surgery and intensive care admission in an adult after RIG insertion. The RIG had been internally displaced, but this was not recognised until the patient became critically ill. The patient had been complaining of abdominal pain on feeding for several days."

"The death of an adult after PEG insertion; they remained an inpatient for two days after PEG insertion but were discharged despite abdominal pain and leakage of gastric contents from the gastrostomy site. They were readmitted four days later and internal leakage was confirmed. Despite corrective surgery and ITU care they died three weeks later."

"A parent made a series of phone calls because of concerns, including externally leaking gastric fluid, about their child who had a gastrostomy inserted as a day case the day before; day unit staff referred the calls on to a nurse specialist who found the message on their answerphone around the time the child died at home."

"The death of an older adult after PEG insertion on a Friday. Feeding commenced over the weekend. On the Monday ward round the patient was found to be pyrexial and tachycardic. A CT scan confirmed peritonitis and suggested feed had been leaking internally due to a loose fit of the tube. Despite surgery and ITU care, the patient died. Investigation highlighted that there was no guideline on observations or aftercare for the ward to refer to."

The incidents suggested that staff did not always realise that pain on feeding was a 'red flag' but treated it with pain relief or a change of feeding speed, rather than stopping the feed and urgently investigating the possibility that the pain was due to leakage of feed into the peritoneum. External leakage of gastric contents in the post-procedure sometimes appeared to be perceived as a minor skin care problem, rather than a sign that the gastrostomy site was not properly fixed and that therefore internal leakage into the peritoneum might also be occurring. Opportunities to detect general deterioration through making regular checks of temperature, pulse, blood pressure and respirations appeared to be missed.

Evidence of harm from NHS Litigation Authority (NHSLA) data

NHSLA data was searched from inception to June 2009 (approximately 10 years) for gastrostomy keywords. NHSLA reports are brief, but the details that could be determined suggested the pattern of harm was similar to that found in the RLS:

- Eight claims specified failure to monitor the patient and detect peritoneal leakage post gastrostomy, five fatal.
- Three delayed responses to external leakage from gastrostomy site (probably also indicating peritoneal leakage), one fatal.
- Four claims related to bowel perforation, one fatal.
- One haemorrhage after gastrostomy insertion.
- One fatal liver puncture during gastrostomy insertion.
- Six additional unspecified complications.

Four of these NHSLA reports involved children, one of which was a death, but most reports were too brief to determine if adult or child, for example:

"PEG into abdominal cavity leaked food into abdomen causing peritonitis leading to major organ failure and death. Failure to note vomiting as complication of PEG and failure to monitor."

“It is alleged that the gastrostomy operation was carried out incorrectly and the post-operation care severely lacking leading to the need to the surgery.”

Evidence of scale of harm in the literature

Using the most conservative estimates described above of major complications (one per cent) and procedure-related mortality (0.5 per cent) and the more conservative estimate of numbers of procedures undertaken in England and Wales (15,000), this would suggest a minimum of around 150 major complications and 75 procedure-related deaths might occur annually in England and Wales.

Evidence of harm during secondary procedures

Whilst the harm data appeared to relate to initial placement of gastrostomies, it should be noted that the same risks may arise when a PEG is being changed to a gastrostomy button, or after the change of a gastrostomy button, or during tube changes complicated by stenosis.

Evidence of harm during jejunostomies

Whilst the available evidence related to gastrostomies, jejunostomies are likely to involve similar risks.

National standards and best practice

Artificial nutrition support is a complex area of clinical practice, and specific complications and their symptoms inevitably make up a very small part of definitive guidance such as National Institute for Health and Clinical Excellence (NICE) Clinical Guideline 32⁹ and guidance from The European Society for Clinical Nutrition and Metabolism¹⁰.

Diagnosis of post-procedure complications which are not unique to gastrostomy (such as sepsis, aspiration pneumonia, and haemorrhage) is covered by a very wide a range of guidance and good practice and this Rapid Response Report (RRR) is intended solely to supplement these by increasing staff awareness of symptoms *specific* to life-threatening complications of gastrostomy.

Appropriate local adaptations

Local experts (for example, consultant gastroenterologists) will be well placed to advise on the clinical actions needed when serious complications are suspected, but these may include aspiration of stomach contents via the gastrostomy tube, placing the tube on free drainage, CT scanning or contrast study and surgical review. For children, the investigation of choice may differ and early contact with appropriate paediatric surgery advice may be critical.

This Rapid Response Report (RRR) does not attempt to identify what steps might be most appropriate in any individual case, but ensure that the appropriate senior advice is sought. Issues such as surgical referral, CT scanning, and contrast study are specifically mentioned in the RRR because these are helpful indications to frontline staff that senior specialist review and specific investigations are likely to be required.

We accept that local arrangements for emergency advice from specialists are likely to differ according to local circumstances and so have not been prescriptive on which department or service is used as an emergency advice point. The intention of the RRR is for local organisations to ensure effective local arrangements are agreed and communicated.

The requirement of the RRR that patients should have a senior review before discharge is included because some of the reported incidents suggested a decision to discharge had been made despite patients showing signs and symptoms of serious complications. A 'senior review' would include review by any person agreed as competent by the local organisation to promptly recognise and act on signs and symptoms indicating serious complications.

Conclusion

Gastrostomies are small stomas created between the stomach and the skin of the abdomen through which a feeding tube is inserted. They are used as a medium-to-long term feeding strategy for children and adults with additional dietary needs or an inability to swallow, and may be inserted endoscopically or under radiological guidance. Like any interventional procedure there is potential for complications but promptly recognising and acting on these complications reduces the risk of serious harm or death.

Reports to the RLS suggest that pain on feeding or external leakage of gastric contents were not always recognised as a potential 'red flag' symptom of peritoneal leakage of feed. Additionally, patients discharged shortly after gastrostomies are usually given the contact details of nurse specialists or dietetic departments for long-term support with feeding. In some cases, relatives or carers used these numbers when they had urgent concerns about the patient, but these services are not intended to respond to emergencies and are not usually available outside weekdays. Ensuring these key symptoms and their significance are known to all staff involved in the immediate aftercare of patients who have been given gastrostomies (including hospital staff, GPs and the patient and their carers) should reduce the risk of complications developing into critical illness or death.

Implementing this RRR would be expected to have only minor cost implications (for example revising local guidance, printing labels or purchasing rubber stamps).

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Useful resources for patients

NHS information for patients *Having a percutaneous endoscopic gastrostomy tube* (www.uhb.nhs.uk/pdf/PiHavingPegInserted.pdf)

Royal College of Radiologists *Information for patients undergoing a percutaneous gastrostomy* 2008 (www.rcr.ac.uk/docs/patients/worddocs/CRPLG_15.doc)

Appendix 1: Recommended labels format for aftercare of gastrostomy patients

LABELS

Suggested labels to temporarily highlight this risk can be downloaded at www.nrls.npsa.nhs.uk/alerts and will print on standard address label sheets. However, we would encourage organisations to review their aftercare advice to ensure it is permanently adapted to highlight these risks and adequately covers **all** potentially life-threatening complications in addition to long-term care of the gastrostomy.

Example ADULT inpatient documentation additional label (printable label sheets available separately) :

IF THERE IS PAIN ON FEEDING, OR PROLONGED OR SEVERE PAIN POST-PROCEDURE, OR FRESH BLEEDING, OR EXTERNAL LEAKAGE OF GASTRIC CONTENTS, STOP FEED/MEDICATION DELIVERY IMMEDIATELY. OBTAIN SENIOR ADVICE URGENTLY AND CONSIDER CT SCAN, CONTRAST STUDY OR SURGICAL REVIEW.



Example CHILD inpatient documentation additional label (printable label sheets available separately):

IF THERE IS PAIN ON FEEDING, OR SIGNS OF DISTRESS/PHYSIOLOGICAL INSTABILITY, OR PROLONGED OR SEVERE PAIN POST-PROCEDURE, OR FRESH BLEEDING, OR EXTERNAL LEAKAGE OF GASTRIC CONTENTS, STOP FEED/MEDICATION DELIVERY IMMEDIATELY. OBTAIN URGENT SENIOR ADVICE ON APPROPRIATE INVESTIGATIONS AND SURGICAL REVIEW.



GP discharge information additional label:

Patient and carer information additional label:

IF THERE IS PAIN ON FEEDING, OR EXTERNAL LEAKAGE OF GASTRIC CONTENTS, OR FRESH BLEEDING, ADVISE CARERS TO STOP FEED IMMEDIATELY AND URGENTLY REFER TO *[appropriate 24/7 local service]*



IF THERE ARE LEAKS OF FLUID AROUND THE TUBE, OR PAIN ON FEEDING, OR NEW BLEEDING STOP FEED IMMEDIATELY. AND TELEPHONE *[appropriate 24/7 local service]* FOR URGENT ADVICE



Printable label sheets are available separately at www.nrls.npsa.nhs.uk/alerts

Appendix 2: Summary of rationale for recommended actions

This table provides a summary of how the incident reports, local policy review, and literature explored above informed our recommended actions.

Action	Summary of rationale
<p>1. Distribute this Rapid Response Report (RRR) to relevant clinical staff, including nursing and medical staff in acute hospitals and GPs, community nurses and out-of-hours services in primary care.</p>	<p>Frontline staff who may be involved in the care of patients who have recently had a gastrostomy inserted need to be made aware of the risk of harm from failure to act</p>
<p>2. Local protocols specify the observations to be taken in the immediate recovery period (<i>for example, the frequency and duration of observations of blood pressure, pulse, respiration and pain score, alongside checks of the stoma site for bleeding, leakage of gastric contents or tube displacement</i>).</p>	<p>Regular observation is needed to detect early complications. Whilst there is no definitive guidance on the exact frequency and duration required, expert gastroenterologists consulted during this review suggested frequencies of around half-hourly for four hours, and hourly for four further hours, but adjustments to match local routines may be required.</p>
<p>3. They mark the patient's medical and nursing notes with a high-visibility warning that if there is pain on feeding, prolonged or severe pain post-procedure, or fresh bleeding, or external leakage of gastric contents, stop feed/medication delivery immediately, obtain senior advice urgently and consider CT scan, contrast study or surgical review*.</p>	<p>These symptoms are specific to gastrostomies and indicate potentially life-threatening complications, but RLS reports indicate some staff did not recognise the significance of these symptoms.</p> <p>Symptoms of other life-threatening complications of gastrostomy, such as aspiration pneumonia or sepsis, are common to many other procedures and clinical staff will be much more familiar with them.</p> <p>Whilst the need for a CT or contrast study is a matter for individual clinical decision-making, including these on the warning for adults helps convey the need for specific and urgent investigation of these symptoms. An alternative form of label wording for children is provided.</p> <p>Using the department that inserts the gastrostomy (whether endoscopy or radiology departments) to add warnings to each patient's notes at the point of carrying out the procedure is likely to be the most robust and sustainable way of ensuring this information is available after the patient's return to their home ward.</p>
<p>4. They add the equivalent warning to the preliminary discharge information that is communicated to the patients' GP and community nurses or care home nurses on discharge.</p>	<p>Post-discharge the GP is likely to be the patient's first point of contact. Using the department that inserts the gastrostomy (whether endoscopy, surgery, or radiology departments) to add warnings to the preliminary discharge letter at the point of carrying out the procedure is likely to be the most robust and sustainable way of ensuring this information is available to the GP.</p>

<p>5. Where patients are discharged within 72 hours (three days) of gastrostomy insertion:</p> <ul style="list-style-type: none"> a) systems are in place to ensure senior review before discharge (see supporting information); b) patients and their carers are warned that the signs listed above are danger signs that need urgent attention (verbally and through using the labels provided with this RRR, or an equivalent high visibility warning on local patient information) and are given an appropriate local contact number for urgent aftercare advice that is available overnight and at weekends; c) the staff answering this contact number understand that the signs listed above are symptoms that need an urgent response, and have local protocols to guide them on what actions to take. 	<p>Gastrostomies are carried out as day-case or short-stay procedures, and discharge may take place before feeding is successfully re-established. If the patient has been an inpatient for 72 hours post-gastrostomy insertion, serious complications would already have been expected to have become apparent.</p> <ul style="list-style-type: none"> a) The requirement of the RRR that patients should have a senior review before discharge is included because some of the reported incidents suggested a decision to discharge had been made despite patients showing signs and symptoms of serious complications. A 'senior review' would include review by any person agreed as competent by the local organisation to promptly recognise and act on signs and symptoms indicating serious complications. b) Patients and their carers will be able to seek help when these symptoms occur if they are given the right information. In some RLS reports, carers were not sure who to contact for urgent advice out-of-hours, and instead tried to contact nine-to-five services which would support them with non-urgent advice on feeding but were not set up to provide an urgent response. c) In some RLS reports, carers had contacted an urgent advice line (for example, surgical wards that take calls out-of-hours relating to problems post day case procedures) but the staff taking the call did not realise the significance of these symptoms.
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** These action points may need to be amended in light of local service provision and for children (e.g. for paediatric cases a surgical opinion may be obtained first followed by the locally available radiological investigation of choice, and some gastrostomy types in children may result in chronic external leakage of gastric contents).*

Appendix 3: Suggested compliance checklist

The table below gives suggested evidence that organisations may wish to use locally as assurance of compliance with this Rapid Response Report.

Action	Suggested evidence of compliance
<p>1. Distribute this Rapid Response Report (RRR) to relevant clinical staff, including nursing and medical staff in acute hospitals and GPs, community nurses and out-of-hours services in primary care.</p>	<p>Dated electronic or paper record of distribution.</p>
<p>2. Local protocols specify the observations to be taken in the immediate recovery period (<i>for example, the frequency and duration of observations of blood pressure, pulse, respiration and pain score, alongside checks of the stoma site for bleeding, leakage of gastric contents or tube displacement</i>).</p>	<p>A copy of the local protocol.</p>
<p>3. They mark the patients' medical and nursing notes with a high-visibility warning that if there is pain on feeding, prolonged or severe pain post-procedure, or fresh bleeding, or external leakage of gastric contents, stop feed/medication delivery immediately, obtain senior advice urgently and consider CT scan, contrast study or surgical review*.</p>	<p>A copy of the label, documentation, or rubber stamp used to mark patients' notes.</p> <p>Protocol or work instructions that clarify who in the gastrostomy department is responsible for attaching the warning information (including endoscopy department for PEG and radiology department for RIG and surgical department if relevant in the organisation).</p> <p>Results of audit of random sample of case notes of patients undergoing gastrostomy confirming appropriate high-visibility warnings included.</p>
<p>4. They add the equivalent warning to the preliminary discharge information that is communicated to the patients GP and community nurses or care home nurses on discharge.</p>	<p>A copy of the label, documentation, or rubber stamp used to mark preliminary discharge information.</p> <p>Protocol or work instructions that clarify who in the gastrostomy department is responsible for attaching the warning information (including endoscopy department for PEG and radiology department for RIG and surgical department if relevant in the organisation).</p> <p>Results of audit of random sample of preliminary discharge information of patients undergoing gastrostomy confirming appropriate warnings included.</p>

<p>5. Where patients are discharged within 72 hours (three days) of gastrostomy insertion:</p> <ul style="list-style-type: none"> a) systems are in place to ensure senior review before discharge (see supporting information); b) patients and their carers are warned that the signs listed above are danger signs that need urgent attention (verbally and through using the labels provided with this RRR, or an equivalent high visibility warning on local patient information) and are given an appropriate local contact number for urgent aftercare advice that is available overnight and at weekends; c) the staff answering this contact number understand that the signs listed above are symptoms that need an urgent response, and have local protocols to guide them on what actions to take. 	<ul style="list-style-type: none"> a) A copy of the local protocol including staff groups/roles considered competent to review patients post-gastrostomy before early discharge. b) A copy of the information provided to patients and carers including advice on these symptoms and an appropriate local contact number to be used for urgent concerns. c) A copy of the local protocol that guides staff responding to any calls from patients and carers reporting these symptoms post gastrostomy insertion.
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** These action points may need to be amended in light of local service provision and for children (e.g. for paediatric cases a surgical opinion may be obtained first followed by the locally available radiological investigation of choice, and some gastrostomy types in children may result in chronic external leakage of gastric contents).*