National Institute for Health and Care Excellence

Acute upper gastrointestinal bleeding
Quality Standard Consultation Comments Table
11 February – 12 March 2013

Row	Stakeholder	Section	Comments Please insert each new comment in a new row.	Response
1	University Hospitals Birmingham	Addition	I think there are important omissions. A) Patients whose bleeding was secondary to a duodenal ulcer should be offered helicobacter eradication and a 13C urea breath test in some weeks (6) off treatment. This is easily auditable as an outcome measure. B) Patients with gastric ulcers should have biopsies taken from the ulcer and a follow-up Endoscopy 2 months later to ensure that healing has taken place. If Aspirin or NSAIDs were not implicated at onset then they should also be offered Helicobacter eradication therapy and the breath test as in A. (Endoscopy units should already be auditing this)	We agree that these points are relevant to the topic but as the topic expert group considered this as standard practice it was not prioritised as an area for quality improvement. The topic expert group prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where there is potential to generate measurable indicators.
2	British Society of Interventional Radiology	Addition	The development of appropriate clinical networks is not expressly mentioned. These will be necessary to provide access to TIPS and to embolization in some cases. Established clinical networks would reduce risks associated with delayed transfer and ensure appropriate governance and provide equity of access.	We acknowledge that it may be necessary to develop clinical networks in order to achieve the care described in the quality standard. However, it is not within the remit of the quality standard to describe all developments that may be necessary in order to deliver the quality statements. It is expected that decisions about service configuration and commissioning arrangements will be made locally.

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3	British Society of Interventional Radiology	Addition	There is no express mention of surgery in this document though clearly it is part of the pathway.	We acknowledge that surgery is clearly a key part of the clinical pathway for this topic. However, the quality standard does not automatically cover the entire care pathway. It addresses the parts of the pathway prioritised by the topic expert group. As there have been no recent new developments in surgical practice, with the exception that interventional radiology is the first step following failed endoscopic therapy, the topic expert group did not prioritise this area. The topic expert group prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where there is potential to generate measurable indicators.

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4	British Society of Gastrointestinal and Abdominal Radiology	Addition	The option of surgery for the management of non-variceal bleeding is not clearly defined in this document.	We acknowledged that surgery is clearly a key part of the clinical pathway for this topic. However, the quality standard does not automatically cover the entire care pathway. It addresses the parts of the pathway prioritised by the topic expert group. As there have been no recent new developments in surgical practice, with the exception that interventional radiology is the first step following failed endoscopic therapy, the topic expert group did not prioritise this area. The topic expert group prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where there is potential to generate measurable indicators.
5	NHS Direct	General	NHS Direct welcome the quality standard and have no comments on its content.	Thank you for your response.
6	British Society of Gastroenterology	General	The BSG Endoscopy committee has looked at the draft guidelines and below is a précis of our areas of concern and suggestions re clarifying some aspects.	Thank you for your response.
7	British Society of Gastroenterology	General	These quality standards are generally very good and few concerns have been raised about most of them.	Thank you for your response.
8	British Society of Gastroenterology	General	Most concerns centred on the statements regarding emergency endoscopy for those with severe bleeding who are haemodynamically unstable.	Thank you for your response.

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9	British Society of Gastroenterology	General	How does one define severe acute upper gastrointestinal bleeding? It is not defined in the text.	Thank you for your comments. We have added some additional text to clarify the definition of acute upper gastrointestinal bleeding.
10	British Society of Gastroenterology	General	There are major areas of concern about practicality, necessity and evidence base for several of these measures. There does not seem an avenue for clinical decision making.	The topic expert group reviewed all measures in the draft quality standard and have prioritised and refined those they considered most important to measure the quality statements in the final standard. The measures have been revised for the final quality standard to improve clarity. It is not anticipated that these quality statements and measures be used as targets. The expectation is that quality statements and measures will be used and adapted at a local level.
11	British Society of Gastroenterology	General	I can't find any definition of what constitutes "People with severe acute upper gastrointestinal bleeding" within the text.	Thank you for your comments. We have added some additional text to clarify the definition of acute upper gastrointestinal bleeding.
12	British Society of Paediatric Gastroenterology Hepatology and Nutrition	General	Endoscopic training of paediatric trainees and maintaining skills among consultant paediatric gastroenterologists would point to some centralisation of services based on geography and critical mass of skills for on call rotas. Such a development could improve compliance with the QS, however at the cost of transporting patients early in their course and additional capital investment. It is not clear if outcomes would be improved.	We acknowledge that it may be necessary to develop services in order to achieve the care described in the quality standard. However, it is not within the remit of the quality standard to describe all developments that may be required in order to deliver the quality statements. It is expected that decisions will be made locally regarding what whether training and centralisation are necessary to facilitate achievement of the quality statements. This quality standard covers the management of acute upper gastrointestinal bleeding in adults and young

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				people (16 years and older). Whilst we acknowledge that some of the statements may be applicable to children it is outside of the remit of the standard to cover the management of this group.
13	British Society of Paediatric Gastroenterology Hepatology and Nutrition	General	BSPGHAN requests that NICE considers preparing a Quality Standard for children and young people under 16 years with acute upper gastrointestinal bleeding. The quality standard is necessary to ensure that formal networks are developed to provide a safe service for children who don't have access to adult centres for GI bleeding.	At present, NICE has not been referred children and young people under 16 years with acute upper gastrointestinal bleeding as a topic for quality standard development. Future health-related quality standard topics will be referred to NICE by NHS England and a process for feeding back new topics suggestions to NHS England is currently being formalised.
14	Royal College of Paediatrics and Child Health	General	Endoscopic training of paediatric trainees and maintaining skills among consultant paediatric gastroenterologists would point to some centralisation of services based on geography and critical mass of skills for on-call rotas. Such a development could improve compliance with the QS, however at the cost of transporting patients early in their course and additional capital investment it is not clear if outcomes would be	We acknowledge that it may be necessary to develop services in order to achieve the care described in the quality standard. However, it is not within the remit of the quality standard to describe all developments that may be required in order to deliver the quality statements. It is expected that decisions will be made locally regarding what whether training and centralisation are necessary to facilitate achievement of

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			improved.	the quality statements. This quality standard covers the management of acute upper gastrointestinal bleeding in adults and young people (16 years and older). Whilst we acknowledge that some of the statements may be applicable to children it is outside of the remit of the standard to cover the management of this group.
15	Royal College of Paediatrics and Child Health	General	RCPCH requests that NICE considers preparing a Quality Standard for children and young people under 16 years with acute upper gastrointestinal bleeding. The quality standard is necessary to ensure that formal networks are developed to provide a safe service for children who don't have access to adult centres for GI bleeding.	At present, NICE has not been referred children and young people under 16 years with acute upper gastrointestinal bleeding as a topic for quality standard development. Future health-related quality standard topics will be referred to NICE by NHS England and a process for feeding back new topics suggestions to NHS England is currently being formalised.

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16	University Hospitals Birmingham	Introduction	This is a bit disingenuous to the profession and is an repeat of stuff that has been written endlessly over the years However whilst it is true that mortality from acute GI bleeding may not have changed much over 50 years despite the introduction of anti-secretory drugs and endoscopic management there has been an extraordinary change in demographics (age of population) and the rise in variceal haemorrhage also plays a part. To imply that present medico-surgical management has had no effect on mortality rates is seriously flawed and indeed depressing for those involved in care of such patients –it is generally not a good idea to point out to people that they are wasting their time! While a significant rise in mortality rates would have been expected over this time for the reasons above this has not been seen so it is actually highly likely that management has provided significant benefits, but with a moving baseline this cannot be demonstrated. People are more likely to accept "standards" if this is acknowledged. The development of standards from which to assess whether a given unit is doing well or badly is welcome.	Thank you for your comments. The introductory text has been rephrased to take these comments into account.

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17	University Hospitals Birmingham	Quality statement 01	This shows some pretty woolly thinking in my opinion. There is excellent evidence that the Rockall score predicts outcome and that the Blatchford score can help aid decisions about who to discharge early or not admit. However, there is no evidence as far as I know that the knowledge of either score has any impact whatsoever on outcome – i.e. if not calculated patients are just as likely to die as if calculated. Yet it is the latter that this standard refers to! I think the panel wish to ensure that certain basic characteristics of the presentation of any given patient are recorded as a surrogate for making an assessment of how important any given bleed is. Surely the standard should be that blood pressure, pulse, ?respiratory rate, haemoglobin on arrival, urea clotting, history of collapse, presence of melaena, haematemesis and drug use and perhaps others are recorded in all cases. I can see how Blatchford score should also be done because there is an evidence base for deciding what to do next on that basis, but whether a Rockall score is recorded or not does not (as far as I know) determine outcome in any way so why would that be a quality standard? Significant aspects of the history and presentation could have been missed yet both scores recorded and the encounter could not then be deemed high quality. So for me this standard should be that a Blatchford score (or other validated score which has been shown to alter outcome or be decision aid) PLUS a series of baseline information is recorded on that first encounter – to include the features I mention above	Thank you for your comments. The concept of this statement is to assess the risk of further bleeding of patients, informing the best course of treatment and in some instances, identifying those appropriate for early discharge. A rationale section has been added to the quality standard to clarify this. It was felt that the capturing of the suggested data e.g. blood pressure, pulse etc, should already either be captured as part of standard practice, or as part of the risk assessment.

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18	British Society of Paediatric Gastroenterology Hepatology and Nutrition	Quality statement 01	Children's diseases and aetiologies are different to adults and children's lesser co-morbidities mean they tolerate bleeding better usually. There is no risk score validated for children and it is not clear if a risk score for adults works between 16 and 19 years of age. Service provision for under 16s has developed according to local availability between paediatricians, paediatric surgeons and adult gastroenterologists and surgeons. This service provision is variably applied to patients over 16 years. Those 16-19 should have the benefit of paediatric services if they are immature or pre-pubertal	The quality standard is designed to describe high quality care and does not typically describe commissioning processes. The topic expert group felt that in most instances people aged 16-19 would be accessing adult services.
19	Royal College of Paediatrics and Child Health	Quality statement 01	Children's diseases and aetiologies are different to adults and children's lesser co-morbidities mean they tolerate bleeding better usually. There is no risk score validated for children and it is not clear if a risk score for adults works between 16 and 19 years of age. Service provision for under 16s has developed according to local availability between paediatricians, paediatric surgeons and adult gastroenterologists and surgeons. This service provision is variably applied to patients over 16 years. Those 16-19 should have the benefit of paediatric services if they are immature or pre-pubertal.	The quality standard is designed to describe high quality care and does not typically describe commissioning processes. The topic expert group felt that in most instances people aged 16-19 would be accessing adult services.

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20	University Hospitals Birmingham	Quality statement 02	I am non-plussed by this 2h “target” which is arbitrary as far as I know. If imposed and these quality standards are treated as targets, then there are potentially serious implications – how to ensure that there is a skilled individual available effectively immediately (because they determine whether the Endoscopy unit/theatre is opened (if out of hours) or other patients delayed (in hours) to thus enable the procedure to happen within two hours). This group of endoscopists have to be available 24h a day and clearly could not be doing anything else at the times they were expected to deliver this target. The impact on their “ususal” work and that of the Endoscopy unit and staff could be substantial. This service would cost something (in some cases a lot depending on how many skilled endoscopists they have in the Trust) and surely NICE would want evidence that these costs produce benefit. I know of no evidence to suggest that 2h is better than 4h or 6h in these cases and the latter two are much more practical and would cost nothing to the average unit which presently provides a 24h service. I think 2h is too proscriptive and not evidence based.	The topic expert group discussed this timescale at length and concluded that 2 hours is a pragmatic and more measurable translation of "immediate" as referred to in the clinical guideline. It is not anticipated that these quality statements and measures be used as targets. The expectation is that quality statements and measures will be used and adapted at a local level.
21	British Society of Gastroenterology	Quality statement 02	There is no evidence base for endoscopy within 2 hours of resuscitation	The topic expert group discussed this timescale at length and concluded that 2 hours is a pragmatic and more measurable translation of "immediate" as referred to in the clinical guideline.

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22	British Society of Gastroenterology	Quality statement 02	When does the clock start for this 2 hours?	The statement has been updated to refer to within 2 hours of "optimal resuscitation", with a definition of this in the definitions section. This clarifies that local judgement should be used to define optimal resuscitation, balancing the risks inherent with endoscopy for unstable patients with the risks of delaying endoscopy.
23	British Society of Gastroenterology	Quality statement 02	Some patients with trivial bleeding may not need endoscopy at all.	This statement refers to only those patients who are haemodynamically unstable.
24	British Society of Gastroenterology	Quality statement 02	Auditing the time to endoscopy within 2 hours of resuscitation will be almost impossible.	The topic expert group reviewed all measures in the draft quality standard and have prioritised and refined those they considered most important to measure the quality statements in the final standard. The statement has been updated to refer to within 2 hours of "optimal resuscitation", with a definition of this in the definitions section. This clarifies that local judgement should be used to define optimal resuscitation, balancing the risks inherent with endoscopy for unstable patients with the risks of delaying endoscopy.

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25	British Society of Gastroenterology	Quality statement 02	Re *People with severe acute upper gastrointestinal bleeding who are haemodynamically unstable are offered endoscopy within 2 hours of resuscitation.Haemodynamically unstable patients are those with active bleeding whose blood pressure or pulse cannot be normalised.* So, these are just those who continue to bleed, not those who have had a big bleed but respond to initial resuscitation. But what do we mean by within 2h of resuscitation? Does the clock start at the start of the process? Presumably can't mean from time someone is resuscitated (i.e.haemodynamically stable) as these patients would be excluded by 2nd statement above. Needs to be made clear.	The topic expert group discussed this timescale at length and concluded that 2 hours is a pragmatic and more measurable translation of "immediate" as referred to in the clinical guideline. The statement has been updated to refer to within 2 hours of "optimal resuscitation", with a definition of this in the definitions section. This clarifies that local judgement should be used to define optimal resuscitation, balancing the risks inherent with endoscopy for unstable patients with the risks of delaying endoscopy.
26	British Society of Gastroenterology	Quality statement 02	Also, is there evidence underpinning 2h? If clock starts once resuscitation starts then waiting longer to stabilise someone might be preferable.	The topic expert group discussed this timescale at length and concluded that 2 hours is a pragmatic and more measurable translation of "immediate" as referred to in the clinical guideline.
27	British Society of Gastroenterology	Quality statement 02	Auditing this could be a nightmare.	The topic expert group reviewed all measures in the draft quality standard and have prioritised and refined those they considered most important to measure the quality statements in the final standard. The statement has been updated to refer to within 2 hours of "optimal resuscitation", with a definition of this in the definitions section. This clarifies that local judgement should be used to define optimal resuscitation, balancing the risks inherent with endoscopy for unstable patients with the risks of delaying endoscopy.

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28	British Society of Gastroenterology	Quality statement 02	In summary, good principle but not practical & might actually hamper appropriate care. Why not just record time from bleed to scope as auditable outcome instead (i.e. no standard)?	The topic expert group feel that this is an aspirational and safe statement. The statement has been updated to refer to within 2 hours of "optimal resuscitation", with a definition of this in the definitions section. This clarifies that local judgement should be used to define optimal resuscitation, balancing the risks inherent with endoscopy for unstable patients with the risks of delaying endoscopy.
29	British Society of Gastroenterology	Quality statement 02	The 2 hour standard is not only ambiguous but also lacking evidence. Clearly for ongoing sick / unstable patients urgent intervention is needed but this standard does not define those clearly enough. Similarly the 2 hour time frame is artificial and may not be appropriate. NCEPOD encouraged us all to move away from inappropriate surgical intervention done by the wrong people in the wrong environment.	The topic expert group discussed this timescale at length and concluded that 2 hours is a pragmatic and more measurable translation of "immediate" as referred to in the clinical guideline. The quality standard describes a selection of areas for quality improvement. It should be read in combination with the underpinning clinical guideline and the use of clinical judgement.
30	British Society of Gastroenterology	Quality statement 02	Re "people with severe acute upper gastrointestinal bleeding who are haemodynamically unstable are offered endoscopy within 2 hours of resuscitation")	Thank you for your response.
31	British Society of Gastroenterology	Quality statement 02	This could mean that we are expected to provide an emergency endoscopy, almost immediately, for every septic patient with a coffee ground vomit, every dehydrated and frightened young man (i.e. tachycardic and hypotensive) presenting with trivial Mallory-Weiss tear and every old person with dehydration, abdominal pain who take iron tablets.	The quality standard describes a selection of areas for quality improvement. It should be read in combination with the underpinning clinical guideline and the use of clinical judgement. The use of clinical judgement will clarify that people with sepsis, anxiety etc do not represent the group described in the quality statement.

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32	British Society of Gastroenterology	Quality statement 02	Re People with severe acute upper gastrointestinal bleeding who are haemodynamically unstable are offered endoscopy within 2 hours of resuscitation.....	Thank you for your response.
33	British Society of Gastroenterology	Quality statement 02	The comments about defining severe UGI bleed are noted; perhaps suggest a form of wording such as "as evidenced by medically confirmed large scale visible haematemesis or melaena" - that should exclude the septic UTI or worried MWT. The issue of haemodynamic instability is also unclear - if they are saying it can't be corrected then immediate endoscopy is required. If it can be corrected then how long to wait depends on a lot of circumstances. A young fit man with a brief drop in bp that corrects easily at 1am I would gladly observe carefully overnight and scope in the morning whereas a frail elderly patient with big drop in bp that was difficult to resuscitate should be done ASAP. Varices likewise. So I think this standard is currently tenuous and unachievable and we should advise something different such as - "arrangements are in place for immediate endoscopy for patients with significant ongoing haemodynamic instability" and leave this 2 hour target altogether	The quality standard describes a selection of areas for quality improvement. It should be read in combination with the underpinning clinical guideline and the use of clinical judgement. Additionally, the statement has been updated to refer to within 2 hours of "optimal resuscitation", with a definition of this in the definitions section. This clarifies that local judgement should be used to define optimal resuscitation, balancing the risks inherent with endoscopy for unstable patients with the risks of delaying endoscopy.

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34	Royal College of Radiologists	Quality statement 02	The RCR view on endoscopy within 2 hours for the unstable patient is that, "within" 2 hours is fine, in that it can be sooner. On the other hand for trauma bleeding we have a requirement to get on with treating within 60 minutes. I don't see why this should be any less important.	The topic expert group discussed this timescale at length and concluded that 2 hours is a pragmatic and more measurable translation of "immediate" as referred to in the clinical guideline. The topic expert group prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where there is potential to generate measurable indicators.
35	British Society of Paediatric Gastroenterology Hepatology and Nutrition	Quality statement 02	The timescale required in the QS point 2 are probably not consistently met by the service provisions developed according to local availability between paediatricians, paediatric surgeons and adult gastroenterologists and surgeons at present except in a few larger paediatric centres. It is not clear that this represents any risk to patients.	Thank you for your response. The topic expert group prioritised areas of care where they agreed that practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where there is potential to generate measurable indicators.
36	British Society of Paediatric Gastroenterology Hepatology and Nutrition	Quality statement 02	Patients under 16 and those over 16 with relationships to paediatric services are typically resuscitated in local emergency depts., transported if necessary, admitted to PICUs under the care either of a paediatric gastroenterologist or paediatric surgeon and endoscoped on an emergency list usually within 24 hours if stable. Those who continue to bleed would have emergency endoscopy and paediatric surgical support would be obtained.	The quality standard is designed to describe high quality care and does not typically describe service configuration or commissioning arrangements. It is expected that these will be agreed locally. The topic expert group felt that in most instances people aged 16-19 would be accessing adult services.

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37	British Society of Paediatric Gastroenterology Hepatology and Nutrition	Quality statement 02	Rare and difficult lesions are often managed with direct endoscopy input from adult gastroenterology services but this arrangement may not be possible in stand alone children's hospitals.	The quality standard is designed to describe high quality care and does not typically describe service configuration or commissioning arrangements. It is expected that these will be agreed locally. The topic expert group felt that in most instances people aged 16-19 would be accessing adult services.
38	British Society of Paediatric Gastroenterology Hepatology and Nutrition	Quality statement 02	2 hours is not currently a reasonable timeframe in paediatrics because of distribution of services, transport etc.. It is not clear if it is a necessary target aged 16-19 years. However, those who continue to bleed and are therefore unstable are scoped as soon as availability of facilities permit which might be over 2 hours.	The topic expert group discussed this timescale at length and concluded that 2 hours is a pragmatic and more measurable translation of "immediate" as referred to in the clinical guideline. The topic expert group felt that in most instances people aged 16-19 would be accessing adult services. The quality standard is designed to describe high quality care and does not typically describe service configuration or commissioning arrangements. It is expected that service developments required to achieve the care described in the quality standard will be agreed locally.
39	Royal College of Paediatrics and Child Health	Quality statement 02	The timescale required in this quality statement is probably not consistently met by the service provisions developed according to local availability between paediatricians, paediatric surgeons, adult gastroenterologists and surgeons at present except in a few larger paediatric centres. It is not clear that this represents any risk to patients.	Thank you for your response. The topic expert group prioritised areas of care where they agreed that practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where there is potential to generate measurable indicators.

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40	Royal College of Paediatrics and Child Health	Quality statement 02	Patients under 16 and those over 16 with relationships to paediatric services are typically resuscitated in local emergency departments, transported if necessary, admitted to PICUs under the care either of a paediatric gastroenterologist or paediatric surgeon and endoscoped on an emergency list usually within 24 hours if stable. Those who continue to bleed would have emergency endoscopy and paediatric surgical support would be obtained.	The quality standard is designed to describe high quality care and does not typically comment on service configuration or commissioning arrangements. It is expected that any service developments required to achieve the care described in the quality standard will be agreed locally. The topic expert group felt that in most instances people aged 16-19 would be accessing adult services.
41	Royal College of Paediatrics and Child Health	Quality statement 02	Rare and difficult lesions are often managed with direct endoscopy input from adult gastroenterology services but this arrangement may not be possible in standalone children's hospitals	The quality standard is designed to describe high quality care and does not typically comment on service configuration or commissioning arrangements. It is expected that any service developments required to achieve the care described in the quality standard will be agreed locally. The topic expert group felt that in most instances people aged 16-19 would be accessing adult services

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42	Royal College of Paediatrics and Child Health	Quality statement 02	2 hours is not currently a reasonable timeframe in paediatrics because of the distribution of services, transport etc. It is not clear if it is a necessary target for those aged 16-19 years. However, those who continue to bleed and are therefore unstable are scoped as soon as availability of facilities permits which might be over 2 hours.	The topic expert group discussed this timescale at length and concluded that 2 hours is a pragmatic and more measurable translation of "immediate" as referred to in the clinical guideline. The topic expert group felt that in most instances people aged 16-19 would be accessing adult services. The quality standard is designed to describe high quality care and does not typically describe service configuration or commissioning arrangements. It is expected that service developments required to achieve the care described in the quality standard will be agreed locally.
43	University Hospitals Birmingham	Quality statement 03	The 24h target I think is also an evidence free zone. There is evidence that a potential cause for bleeding is more likely to be found if the Endoscopy is done earlier, but to my knowledge there isn't evidence that that alters the outcome for patient. The strongest argument for 24h is that it probably identifies people who could be discharged from hospital and thus I believe it could be cost effective. However we should be clear what this quality standard is about – management of beds rather than outcomes for patients.	The timescale of 24 hours is taken from the clinical guideline. A rationale section has been added to the quality standard to clarify that the purpose of this statement is to help to avoid re-bleeding and to reduce length of hospital stay for the patient.
44	British Society of Gastroenterology	Quality statement 03	Standard 3 – all patients with a GI bleed should be scoped within 24 hours. Does not seem to allow for the many patients with trivial GI bleeding where clinical decision is not to scope or to discharge and scope electively. These patients would be marked as a fail on this quality standard.	The wording of this statement has been modified to clarify that this statement only refers to those who have been admitted with an acute upper gastrointestinal bleed.

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45	British Society of Gastroenterology	Quality statement 03	In a resource short NHS we should not be supporting measures that use unnecessary resources with no evidence that they improve patient care.	A rationale section has been added to the quality standard to clarify that the purpose of this statement is to help to avoid re-bleeding and to reduce length of hospital stay for the patient.
46	British Society of Paediatric Gastroenterology Hepatology and Nutrition	Quality statement 03	Paediatric services caring for people 16-19 years old may not consistently meet the standards of points 2 and 3. It is not clear that implies inferior care for this group as endoscopy would take place soon afterwards depending on organisational constraints.	Thank you for your response. Quality standards describe high quality, aspirational care. It is not anticipated that these quality statements and measures be used as targets. The expectation is that quality statements and measures will be used and adapted at a local level.
47	Royal College of Paediatrics and Child Health	Quality statement 03	Paediatric services caring for people 16-19 years old may not consistently meet the standards of points 2 and 3. It is not clear that implies inferior care for this group as endoscopy would take place soon afterwards depending on organisational constraints	Thank you for your response. Quality standards describe high quality, aspirational care. It is not anticipated that these quality statements and measures be used as targets. The expectation is that quality statements and measures will be used and adapted at a local level.
48	University Hospitals Birmingham	Quality statement 04	Agreed	Thank you for your response.

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49	University Hospitals Birmingham	Quality statement 04	I wonder how many are trained in this – centralization as for 5. Is fibrin not as good, perhaps too proscriptive without sufficient evidence?	Training is a presumed aspect of the statement. Quality standards describe high quality, aspirational care and it is possible that this may require additional training in order for this type of care to be achieved. The topic expert group identified the development sources they felt were most relevant to developing the standard, within the framework of the quality standards development process. The quality standard is based on evidence-based recommendations from national accredited guidance, i.e. the NICE acute upper GI bleeding clinical guideline. The quality standards do not seek to reassess or redefine the evidence base. Please refer to the full clinical guideline for detailed summary of the underpinning evidence base for the clinical recommendations on which the quality standard is based.
50	British Society of Gastroenterology	Quality statement 05	A second attempt at endoscopic therapy may be appropriate in some cases.	The quality standard describes a selection of areas for quality improvement. It should be read in combination with the underpinning clinical guideline and the use of clinical judgement.
51	British Society of Gastroenterology	Quality statement 05	Some patients may need to go straight to surgery rather than interventional radiology	We acknowledge that surgery is clearly a key part of the clinical pathway for this topic. However, the quality standard does not automatically describe the entire care pathway. It addresses the parts of the pathway prioritised by the topic expert group. The quality standard describes a selection of areas for quality improvement. It should be read in combination

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				with the underpinning clinical guideline and the use of clinical judgement.
52	University Hospitals Birmingham	Quality statement 05	Add “or repeat Endoscopy” where the evidence base is at least as good. I do think provision of interventional radiology is a problem and I presume that quality standards for it’s use should be developed – ie do they have something like the 2h target above. I do not believe that the majority of hospitals have sufficient radiologists skilled in this to offer a 24h service and thus centralization will be necessary. This comes with a series of problems and costs due to inter-hospital transfers and in the case of bad bleeding this transfer *could* negate any benefit. I wonder if there is a satisfactory evidence base to support this quality standard (and the cost efficacy data to go along?).	The quality standard describes a selection of areas for quality improvement. The quality standard is based on evidence-based recommendations from national accredited guidance, i.e. the NICE acute upper GI bleeding clinical guideline. Please refer to the full clinical guideline for detailed summary of the underpinning evidence base for the clinical recommendations on which the quality standard is based. The quality standard is designed to describe high quality care and does not typically describe service configuration or commissioning arrangements. It is expected that service developments required to achieve the care described in the quality standard will be agreed locally.
53	British Society of Interventional Radiology	Quality statement 05	It is essential that this standard remains. We, as it would seem were the topic expert group, are convinced of the value of IR in this patient group. This standard is achievable, though it will take some work. There has already been considerable work undertaken by the BSIR/ NHSI and the DOH IR project group to map and improve IR services particularly for OOH care. It is vital that given the clinical value of these treatments they remain in the standard and that they are commissioned appropriately.	Thank you for your comments.

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54	British Society of Interventional Radiology	Quality statement 05	Structure – we would suggest that this should be phrased local or established network provision.	Thank you for your comments. The topic expert group felt that the current measure was appropriate and therefore no amendments have been made to this section.
55	British Society of Interventional Radiology	Quality statement 05	Commissioners need to specifically commission this element of service and it should not be assumed that this will automatically be available from commissioning diagnostic services	The quality standard describes high quality clinical care but does not specifically discuss commissioning issues. The quality standard section: *Description of what the quality statement means for each audience* describes what commissioners need to do to achieve the care described in the statement. The NICE support for commissioning report which is published alongside the quality standard will also offer guidance to commissioners.
56	British Society of Interventional Radiology	Quality statement 05	Should the quality standard include a timeframe? Given the nature of this patient group a timeframe for consideration would seem appropriate, given that some of the service provision may be by network ; this may be in the order of 2- 4 hours.	The topic expert group felt that the most important concept to emphasise in this statement was that interventional radiology should be offered.
57	British Society of Interventional Radiology	Quality statement 05	We would suggest rewording the description of the procedure as it does not use blood clot to achieve haemostasis and this may unnecessarily alarm patients or even put some religious group off having the procedure. Suggested wording “A long plastic tube called a catheter is inserted into an artery and, under x-ray guidance, is then passed to the site of bleeding. After a small injection of x-ray dye to confirm that the tube is in the right place, the bleeding artery is blocked off using specially developed blood vessel occluders. A scan beforehand may be necessary if the earlier endoscopy has failed to identify the source of bleeding"	Thank you for your comments, this text has now been amended taking your suggestions into account.

Row	Stakeholder	Section	Comments Please insert each new comment in a new row.	Response
58	British Society of Gastroenterology	Quality statement 05	Standard 5 mandates that radiological intervention must be the next step after endoscopy – not allowing the next step to be surgery. This removes appropriate decision making.	The quality standard describes a selection of areas for quality improvement. It should be read in combination with the underpinning clinical guideline. Achievement of the statements is not mandatory. Quality standards are not intended to replace clinical judgement or appropriate decision making.
59	British Society of Gastroenterology	Quality statement 05	Under Draft Quality Statement 5, the explanation of interventional radiology is flawed: "People with acute upper gastrointestinal bleeding caused by stomach or duodenal ulcers whose blood pressure or pulse is unstable and who have more bleeding after treatment are offered interventional radiology. This procedure uses scans to identify where the bleeding is coming from. A long tube, called a catheter, is then placed at the site of the bleeding, and the bleeding is stopped with an artificial blood clot". It should read: .."This procedure uses a sterile catheter normally passed via an artery in the groin and steered via a network of arteries within the abdomen. Injection of dye (contrast) via this catheter can successfully localise bleeding points. Using this catheter, bleeding can be stopped in a variety of ways that include placement of coils or artificial blood clotting solutions directly into the bleeding artery or one of its feeding arteries".	Thank you for your comments, this text has now been amended taking your suggestions into account.
60	British Society of Gastroenterology	Quality statement 05	Also under this standard, I agree with others that repeat endoscopy may be considered before interventional radiology. Indeed in CG141 it is stated " • Offer a repeat endoscopy to patients who re-bleed with a view to further endoscopic treatment or emergency surgery.	The quality standard describes a selection of areas for quality improvement. It should be read in combination with the underpinning clinical guideline and the use of clinical judgement.

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61	Royal College of Radiologists	Quality statement 05	**Statement 5: No patient should die of <u>exsanguination</u> secondary to acute non variceal upper GI haemorrhage**	All suggestions for additional statements were discussed by the topic expert group who considered they were inappropriate for inclusion (for example, outside the scope of the quality standard), or already covered by existing statements. The topic expert group prioritised the areas of care they felt were most important for patients, based on the development sources listed. Areas of care were prioritised where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where there is potential to generate measurable indicators.
62	Royal College of Radiologists	Quality statement 05	**There is no mention of surgery as a 3rd option for non variceal bleeding**	We acknowledge that surgery is clearly a key part of the clinical pathway for this topic. However, the quality standard does not automatically cover the entire care pathway. It addresses the parts of the pathway prioritised by the topic expert group. As there have been no recent new developments in surgical practice, with the exception that interventional radiology is the first step following failed endoscopic therapy, the topic expert group did not prioritise this area.
63	Royal College of Radiologists	Quality statement 05	In the IR section I would suggest that "false clot" doesn't make sense, it would be better if it said that bleeding is stopped by blocking the artery which causing blood loss.	Thank you for your comments. This text has now been amended.

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64	Royal College of Radiologists	Quality statement 05	I do believe that access to Interventional Radiology should be part of the standard. Just because it's a bit difficult to achieve is not a good reason to remove it. These are guidelines to the best practice. In the briefing document it makes clear that open surgery carries a very high mortality. If Interventional Radiology/Embolisation is possible then I would want that available to all patients to reduce that mortality. I'm sure patients would too.	Thank you for your comments. The final quality standard includes a statement about interventional radiology.
65	British Society of Gastrointestinal and Abdominal Radiology	Quality statement 05	Quality statement 5: There are no suggested timeframes for either CT scanning or interventional treatment for people with non-variceal acute upper gastrointestinal bleeding who are haemodynamically unstable and who re-bleed after endoscopic treatment .	The topic expert group felt that the most important concept to emphasise in this statement was that interventional radiology should be offered.
66	British Society of Gastrointestinal and Abdominal Radiology	Quality statement 05	For those who are haemodynamically unstable after a re-bleed it would seem sensible to include a time limit for CT scanning and/or interventional treatment along similar lines to those recommended for initial endoscopy (eg within 2 hours).	The topic expert group felt that the most important concept to emphasise in this statement was that interventional radiology should be offered.
67	British Society of Gastrointestinal and Abdominal Radiology	Quality statement 05	The use of the term ‘scans’ in this statement is somewhat vague. I suggest that this should this be clarified as CT scan.	Thank you for your comment. The relevant section of the statement has been updated and now specifies CT scan.

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68	British Society of Gastrointestinal and Abdominal Radiology	Quality statement 05	Suggest that this quality statement should include timeframes for the provision of CT scanning and/or interventional treatment since it applies to patients who are haemodynamically unstable following a re-bleed after endoscopic treatment. Achievable timeframes for a locally provided service may be within 2 hours, but where transfer to a network provided IR service is required, realistically achievable timeframes are likely to be longer.	The topic expert group felt that the most important concept to emphasise in this statement was that interventional radiology should be offered.
69	British Society of Gastrointestinal and Abdominal Radiology	Quality statement 05	Description of what the quality statement means for each audience:	Thank you for your response.
70	British Society of Gastrointestinal and Abdominal Radiology	Quality statement 05	I agree with the BSIR's suggestion to reword this description to remove the reference to 'blood clots' in the description of ithe interventional radiology procedure. However, I suggest a slight alteration to the suggestion regarding the use of scans for the identification of the site of bleeding before proceeding. A CT scan can be useful if immediately available to identify the site of bleeding, particularly where 24/7 IR services are not locally available and require network transfer of the patient for appropriate interventional treatment, when the site of bleeding has not been identified at endoscopy or when a re-bleed following endoscopic treatment may have occurred from a different site. I therefore suggest the following revision to the description:	Thank you for your comments. This text has now been amended.

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71	British Society of Gastrointestinal and Abdominal Radiology	Quality statement 05	" People with acute upper gastrointestinal bleeding caused by stomach or duodenal ulcers whose blood pressure or pulse is unstable and who have more bleeding after treatment are offered interventional radiology. A CT scan may first be necessary to identify the source of bleeding if the earlier endoscopy has failed or an additional bleeding site is suspected. A long plastic tube called a catheter is then inserted into an artery and, under x-ray guidance, is passed to the site of bleeding. After a small injection of x-ray dye to confirm that the tube is in the right place, the bleeding artery is blocked off using specially developed blood vessel occluders."	Thank you for your comments. This text has now been amended.
72	British Society of Paediatric Gastroenterology Hepatology and Nutrition	Quality statement 05	Not all paediatric units have access to experience interventional radiology. Rare and difficult lesions are often managed with direct endoscopy input from adult gastroenterology services or interventional radiology services but this arrangement may not be possible in stand alone children's hospitals, who have developed their own effective organisational responses.	The quality standard is designed to describe high quality care and does not typically describe service configuration or commissioning arrangements. It is expected that these will be agreed locally. The topic expert group felt that in most instances people aged 16-19 would be accessing adult services.
73	Royal College of Paediatrics and Child Health	Quality statement 05	Not all paediatric units have access to experienced interventional radiology. Rare and difficult lesions are often managed with direct endoscopy input from adult gastroenterology services or interventional radiology services but this arrangement may not be possible in standalone children's hospitals, which have developed their own effective organisational responses.	The quality standard is designed to describe high quality care and does not typically describe service configuration or commissioning arrangements. It is expected that these will be agreed locally. The topic expert group felt that in most instances people aged 16-19 would be accessing adult services.

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74	Royal College of Radiologists	Quality statement 05	In the Draft quality standard for acute upper gastrointestinal bleeding **Page 13 "**People with acute upper gastrointestinal bleeding caused by stomach or duodenal ulcers whose blood pressure or pulse is unstable and who have more bleeding after treatment are offered interventional radiology. This procedure uses scans to identify where the bleeding is coming from. A long tube, called a catheter, is then placed at the site of the bleeding, and the bleeding is stopped with an artificial blood clot". Whilst appreciating that this is meant to explain the procedure to a lay person, it is simplistic and just plain wrong. Comments about blood clots will upset some people as blood clots are associated with pulmonary embolus and Jehovas witness will react as thay do when blood products are mentioned. Suggest : "A long plastic tube called a catheter is inserted into an artery and, under x-ray guidance, is then passed to the site of bleeding. After a small injection of x-ray dye to confirm that the tube is in the right place, the bleeding artery is blocked off using specially developed blood vessel occluders. A scan beforehand is only necessary if the earlier endoscopy has failed to identify the source of bleeding."	Thank you for your comments. This text has now been amended.
75	British Society of Interventional Radiology	Quality statement 05 and 09	Quality standards 5 and 9 are essential to improve the quality of access to Interventional Radiology techniques	Thank you for your comments.
76	University Hospitals Birmingham	Quality statement 06	Agreed	Thank you for your response.

Row	Stakeholder	Section	Comments Please insert each new comment in a new row.	Response
77	University Hospitals Birmingham	Quality statement 07	Agreed	Thank you for your response.
78	University Hospitals Birmingham	Quality statement 09	Agreed but issues over centralization as in 5.	Quality standards describe high quality, aspirational care and it is possible that this may require development of services in order for this type of care to be achieved. It is expected that these developments will be agreed locally.
79	British Society of Interventional Radiology	Quality statement 09	It may not be as clear cut as uncontrolled bleeding vs controlled bleeding. There is evidence that outcomes for patients with established cirrhosis (b/c) and variceal bleeding may be improved by early (within 72 hours) TIPS even if the bleeding is currently controlled. Garcia – Pagan et al N Eng J med 2010 Jun 24; 362 (25)2370-9	The topic expert group identified the development sources they felt were most relevant to developing the standard, within the framework of the quality standards development process. The quality standards are based on evidence-based recommendations from national accredited guidance, i.e. the NICE acute upper GI bleeding clinical guideline. The quality standards do not seek to reassess or redefine the evidence base. Please refer to the full clinical guideline for detailed summary of the underpinning evidence base for the clinical recommendations on which the quality standard is based.
80	British Society of Interventional Radiology	Quality statement 09	See above comments re early TIPS in patients with advanced cirrhosis. Certainly TIPS should be considered in those with continued uncontrolled bleeding. It may be clearer to phrase Following failed endoscopic therapy, people with uncontrolled acute upper gastro-intestinal bleeding from varices should be offered TIPS	Thank you for your comments. A rationale section has been added to this statement to clarify that the intention of the statement is for TIPS to be offered when variceal bleeding cannot be controlled with endoscopic treatment.

Row	Stakeholder	Section	Comments Please insert each new comment in a new row.	Response
81	British Society of Paediatric Gastroenterology Hepatology and Nutrition	Quality statement 09	The implication was not clear to me.	Thank you for your comments. Additional text has been added to highlight that this should only be attempted if the techniques described in statements 7 and 8 have been unsuccessful.
82	Royal College of Paediatrics and Child Health	Quality statement 09	The implication was not clear to me.	Thank you for your comments. Additional text has been added to highlight that this should only be attempted if the techniques described in statements 7 and 8 have been unsuccessful.
83	University Hospitals Birmingham	Quality statement 10	Agreed but surely should advise long-term use of a PPI in addition (BNF does!)	The quality standard describes a selection of areas for quality improvement. It is not within the remit of the quality standard to describe all elements of care relating to the quality statements. The quality standard should be read in combination with the underpinning clinical guideline and the use of clinical judgement. It remains important that other evidence-based guideline recommendations continue to be implemented.
84	Royal College of Radiologists	Quality statement 05 and 09	**Statements 5&9 because they re-inforce the need for a robust 24/7 IR service either provided locally or through a network which is being resisted by too many hospital trusts**	Thank you for your comments.
85	Royal College of Radiologists	Quality statement 05 and 09	**I think the standards in 5 & 9 should state that if IR services are not available locally suitable, previously defined transfer arrangements should be in place to an IR centre.**	The quality standard is designed to describe high quality care and does not typically describe service configuration or commissioning arrangements. It is expected that service developments required to achieve the care described in the quality standard will be agreed locally.

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86	Royal College of Radiologists	Quality statement 05 and 09	More: 7.1.2 "Given the absence of any good quality controlled evidence, CG141 considers the practical issues which would follow from any recommendation. It notes that some people were poor operative risks, for a variety of possible reasons, and that successful embolisation was potentially the safer procedure. There was a strong consensus view that this should be tried first (encompassing all professional groups and the patient representatives). However, at present not all hospitals can offer appropriate interventional radiology. **The guideline development group did not wish to make a recommendation which would prevent timely surgery when an appropriately skilled interventional radiologist was not available,** and formed a recommendation which emphasises the need for prompt action whichever treatment modality is to be employed"	The statement is reflective of the underpinning recommendation from the clinical guideline 141 that interventional radiology should be offered in the first instance. The definitions highlight that surgery should be offered if interventional radiology not promptly available.
87	Royal College of Radiologists	Quality statement 05 and 09	**If it were the other way round and appropriate surgery was not available in a hospital trust offering endoscopic therapy, would the guideline group be as sanguine as they appear to be about an absence of IR in the same trust. If as stated some patients are inappropriate surgical candidates how can the group accept a surgery only alternative to endoscopy? Surely a centre which offers an upper GI bleeding service should have all 3 available 24/7 or at least agreed transfer arrangements. NICE is sidestepping its responsibilities with this statement.**	The statement is reflective of the underpinning recommendation from clinical guideline 141 that interventional radiology should be offered in the first instance. The definitions highlight that surgery should be offered if interventional radiology is not promptly available. Quality standards describe high quality, aspirational care and it is possible that this may require development of services in order for this type of care to be achieved. It is expected that these developments will be agreed locally.

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88	Royal College of Radiologists	Quality statement 05 and 09	There is little or no mention of access to CT. In the IR section it mentions "scans" but that is about it. I would suggest that a centre should have immediate (or within 30 minutes) access to CT.	Thank you for your comments. Statement 5 has been updated and now makes reference to the potential requirement for a CT scan.
89	British Society of Gastrointestinal and Abdominal Radiology	Quality statement 05 and 09	Quality statements 5 and 9 because they have implications for the need for immediate access to CT, a local 24/7 interventional radiology service or suitable local transfer arrangements to an interventional radiology centre	Thank you for your response.
90	British Society of Paediatric Gastroenterology Hepatology and Nutrition	Quality statements 3,4, 6,7.8,9 and 10	Paediatric services are usually compliant. Most GI bleeding referred to paediatric units is in patients with portal hypertension and most of that is from patients who have known liver disease. They are already prepared with clear plans and management is along accepted and successful pathways to the 3 supraregional units	Thank you for your comments.
91	Royal College of Paediatrics and Child Health	Quality statements 3,4, 6,7.8,9 and 10	Paediatric services are usually compliant. Most GI bleeding referred to paediatric units is in patients with portal hypertension and most of that is from patients who have known liver disease. They are already prepared with clear plans, and management is along accepted and successful pathways to the 3 supra-regional units	Thank you for your comments.