Inspecting Informing Improving

The final declaration
Important information for trusts

March 2006

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Introduction

In October 2005, all NHS trusts submitted to the Healthcare Commission a draft declaration of their compliance with the Department of Health's core standards. This process was intended to test the Healthcare Commission's new approach to assessing the performance of NHS trusts.

In May 2006, trusts will be required to submit a final declaration to the Healthcare Commission. The final declaration is a statement of each trust's level of compliance with the core standards from April 1st 2005 to March 31st 2006. The declaration is not a 'snapshot' of compliance at the end of the year. It must cover the entire year.

In June and July, our regional teams will be visiting some trusts to assess the adequacy of evidence that they have used to assure themselves of their compliance with the core standards for the final declaration. This assessment will be based on the elements set out in *Criteria for assessing core standards* (April 2005).

About this document

We have now completed our review of the submission of draft declarations by trusts, taking account of the feedback we have received from trusts, patient organisations and other bodies.

This document provides important information to help NHS trusts to prepare for the submission of final declarations by May 4th 2006. In particular, it provides new guidance on our assessment and scoring, and clarifies key aspects of our previous guidance. Appendix A provides details of the learning from our review of the process for draft declaration.

Key dates

Wednesday, March 6th 2006

- final declaration form available on the Healthcare Commission's website

Monday, April 3rd 2006

- trusts can begin to submit their completed declarations to the Healthcare Commission

Noon, Thursday, May 4th 2006

- deadline for submission of final declarations to the Healthcare Commission
- not submitting a declaration by this date will result in a score of 'not met

Friday, May 12th 2006

- each trust should have made their final declaration available to the public

Friday, June 30th 2006

- deadline for reporting information from internal auditors

Trusts will need to consider the information provided in this document when completing their final declaration. It should be read in conjunction with the previous guidance that is available from our website at **www.healthcarecommission.org.uk/annualhealthcheck**. Where there is any contradiction between this document and our previous guidance, the advice in this document takes precedence.

1 New information relating to the final declaration

We have made some important changes to the process for the final declaration, based on our review of the process for the draft declaration. In this section, we provide new information on the process for the final declaration, particularly in relation to:

- the paper copy of the final declaration
- the relationship between the draft declaration and the final declaration
- the reporting of information from internal and external auditors
- trusts with more than one overview and scrutiny committee
- final declarations by NHS foundation trusts

Paper copies of the final declaration

Trusts will not need to submit a paper copy of their final declaration to the Healthcare Commission. The final declaration will be submitted electronically.

We continue to recommend that all members of a trust's board 'sign off' the declaration. This will indicate that the whole board has reflected on its responsibilities in relation to core standards. As a minimum, we require an appropriate officer(s), with delegated authority, to 'sign off' the declaration prior to submission. The declaration will be 'signed off' when the name(s) and position(s) of the relevant individual(s) has been recorded in the online declaration form. We do not require trusts to provide scanned signatures.

The relationship between the draft declaration and the final declaration

Each trust will receive a score for the assessment of compliance with core standards, based on the final declaration and any subsequent qualifications made by the Healthcare Commission. We will not use the content of the draft declarations in the calculation of trusts' scores.

We understand that a trust's final declaration may differ from the draft declaration that was submitted in October 2005. This could occur for a number of reasons, for example:

- a trust may conclude, based on new information available after October, that a lapse reported in the draft declaration is not actually a 'significant' lapse
- a trust, having previously declared that there was 'insufficient assurance' for a particular standard, may declare that it is 'compliant' with the standard in its final declaration based on additional assurance for the entire year

If a trust has misunderstood the requirements of the assessment when completing its draft declaration, it may be appropriate for it to change the relevant details in the final declaration. For example, in light of this guidance, a trust may now consider that it had incorrectly determined that there was a significant lapse for a standard between April 1st 2005 and September 30th 2005.

Information from auditors

Trusts will not be in a position to include the required information from internal and external auditors in their final declarations by the deadline for submission. Instead, we require the following:

- for 'internal audit opinion'
  We require trusts to submit this information by exception only. This means that a trust need only notify the appropriate regional team from the Healthcare Commission if the opinion of the head of internal audit includes negative commentary on the design and operation of its 'assurance framework' and associated processes, and/or the auditor provides an overall opinion of 'no assurance' in relation to its systems of internal control. This notification must be sent by June 30th 2006. We will issue a reminder to all trusts closer to this deadline
- for 'external audit opinion'
  NHS trusts - in accordance with the principles of the Concordat, the local appointed auditors will raise and discuss any issues of significance with our regional teams as they arise. The trust's local appointed auditors will, after the issue of the audit opinion, notify the appropriate regional team of any exceptions relating to a trust's statement on internal control (SIC). This will take place between July and August 2006 and may, in exceptional circumstances and following discussion with the local appointed auditors, result in a selective inspection by the Healthcare Commission of the trust concerned
  NHS foundation trusts – we require NHS foundation trusts to submit this information by exception only. This means that these trusts will need to inform the relevant regional team of any exceptions relating to its statement on internal control when this information is available. We will issue a reminder to all NHS foundation trusts closer to the relevant time. We are working with Monitor to identify mechanisms by which this information can, in the future, be obtained from a central source.

Overview and scrutiny committees

A trust may have more than one overview and scrutiny committee in its area. Our previous guidance recommended that trusts contact their 'relevant' overview and scrutiny committees. A trust should determine which committees are the most relevant to its work based on, for example, the distribution of the population it serves.

It is for each trust to decide how many and which committees it will invite to comment on its final declaration. However, trusts must invite at least one relevant overview and scrutiny committee to comment. A trust may wish to use arrangements for joint working, where they exist, to elicit comments from its overview and scrutiny committees. If an overview and scrutiny committee has not been invited to comment, it can still ask to comment on the performance of a trust in relation to the core standards. These comments must be included with the final declaration.

Final declarations by NHS foundation trusts

In response to feedback, there is now an optional section in the declaration form for NHS foundation trusts. This section can be used to record comments from the board of governors on performance in relation to core standards, in the same manner as

other third parties. NHS foundation trusts need to indicate in their declarations if their board of governors did not want to comment. As with other comments from third parties, if the board of governors does not wish to comment, this will not be taken as a criticism of the trust's performance in relation to core standards.

2 Clarifying key aspects of the process for the final declaration

The Healthcare Commission has previously provided guidance to trusts in relation to the assessment of compliance with core standards. The following information should be read in conjunction with our previous guidance.

Defining 'reasonable assurance'

Our assessment of compliance with core standards is based on a declaration that states that "the trust board has received reasonable assurance that the trust has complied with the core standards without significant lapses".

Reasonable assurance, by definition, is not absolute assurance. Conversely, reasonable assurance cannot be based on assumption. Reasonable assurance is based on documentary evidence that can stand up to internal and external challenge. In determining what level of assurance is reasonable, trusts must reflect that the core standards "are not optional" and "describe a level of service which is acceptable and which must be universal".[1] Our expectation is that each trust's objectives will include compliance with the core standards. This will be managed through the trust's routine processes for assurance.

Identifying 'significant lapses'

In previous guidance[2], we stated that "it is for trust boards to decide whether a given lapse is significant or not. However, in making this decision, we anticipate that boards will consider the extent of risk to patients, staff and the public, and the duration and impact of any lapse. The declaration is not intended as a medium for reporting isolated, trivial or purely technical lapses in respect of the core standards".

There is no simple formula by which to determine what constitutes a 'significant lapse'. A simple quantification of risk, such as the loss of more than £1million or the death of a patient, *cannot* provide a complete answer. Determining what constitutes a significant lapse depends on the standard that is under consideration, the circumstances in which a trust operates (such as the services they provide, their functions and the population they serve), and the extent of the lapse that has been identified (for example, the level of risk for patients, the duration of the lapse and the range of services affected).

In appendix A, we provide some examples of 'significant lapses' for trusts to consider.

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[1] *National Standards, local action*, Department of Health 2004
[2] *Guidance on the assessment of core standards*, published in *April* 2005

Categories of 'compliant', 'not met' and 'insufficient assurance'

As with the draft declaration, trusts will have to indicate whether they are 'compliant', 'not met', or if they have 'insufficient assurance' to declare their compliance with each core standard.

Compliant – a declaration of 'compliant' should be used where a trust's board determines that it has had 'reasonable assurance' that it has been meeting a standard, without significant lapses, from April 1st 2005 to March 31st 2006.

Not met – a declaration of 'not met' should be used where the assurances received by the trust's board make it clear that there have been one or more significant lapses in relation to a standard during 2005/2006.

Insufficient assurance – a declaration of 'insufficient assurance' should be used where a lack of assurance leaves the trust's board unclear as to whether there has been a significant lapse. That is, the trust does not know whether they have or have not been meeting a standard during 2005/2006.

Completing the action plans

If the final declaration by a trust reports that it is 'not met' or there is 'insufficient assurance' to declare compliance with a particular standard, the trust must complete the following four fields of the declaration form:

1. Start date
   The date at the start of the period for which the trust has:

   - identified a lack of assurance to determine whether there have been any significant lapses
     or
   - identified one or more significant lapses which means that the trust has not met the standard

2. End date (planned or actual)
   The date by which the trust had or plans to have:

   - assurances in place to enable it to determine compliance with the standard
     or
   - addressed the issues identified as one or more significant lapses(s)

3. Issue
   A statement detailing:

   - why the trust did not have assurance to determine their level of compliance
     or
   - the details of the significant lapse(s) that have been identified

4. Action plan
   An outline of the steps the trust is taking, or has taken, to:

   - address an issue of 'insufficient assurance' (that is, the actions in place to gain assurances of whether or not the trust is meeting the standard)

   or

   - address an issue of 'not met' (that is, the actions in place to address the significant lapses)

Assessing the different functions of primary care trusts (PCTs)

As outlined in *Criteria for assessing core standards* and *Briefing note to PCTs* (September 2005), our assessment of compliance with core standards applies to all services and functions provided by PCTs, including services provided by independent contractors and services that have been commissioned by the PCT. When completing the final declaration, PCTs should consider:

- whether they have 'reasonable assurance' that the services they provide directly are meeting the core standards
- whether they have taken reasonable steps to ensure that services provided by their independent contractors are meeting the core standards
- whether they have appropriate mechanisms through which they could identify and, where appropriate, respond to any significant concerns with regard to the core standards that arise from the services that they have commissioned

Each PCT must decide whether any failure to address these three aspects constitutes a 'significant lapse'. We encourage PCTs to revisit our previous guidance when completing their final declaration.

Eliciting comments from third parties

Trusts should include comments from third parties in the final declaration, as they did in the draft declaration. In particular, trusts must seek comments from their statutory patient and public involvement forums and from relevant overview and scrutiny committee(s).

All trusts, with the exception of NHS foundation trusts, must also seek comments from their strategic health authorities. We continue to encourage NHS foundations trusts to seek comments from their strategic health authority.

Requests for resubmitting the final declaration

The Healthcare Commission will allow all trusts to submit one request for resubmission of the final declaration. Rules for resubmission will be available on the Healthcare Commission website by the beginning of April. Trusts should refer to these rules before submitting their request. Requests for resubmission of the final declaration can be made up until midday on May 4th 2006.

Regional teams will authorise resubmissions by trusts. Resubmission will need to be made within five working days of authorisation, or before 5pm on May 8th 2006 (whichever is earlier).

Publication of the final declaration by trusts

Final declarations by trusts, including any comments from patient and public involvement forums, overview and scrutiny committees and, where relevant, the strategic health authority or board of governors, should be made available to the local community as well as the Healthcare Commission.

We suggested previously that trusts share the final declaration during the public part of a board meeting prior to submission, and further publicise it locally. Trusts' boards not scheduled to meet between April 1st 2006 and May 4th 2006 will need to make alternative arrangements for sharing their declaration with the local community. This may be achieved by publication on the trust's website and/or a combination of:

- local publicity, for example, through local briefings or at public meetings
- sharing copies of the final declaration with relevant local voluntary and community groups

We expect trusts to make their final declarations available to the public by May 12th 2006. If a trust does not meet this deadline, we will publish the declaration on our website and will indicate that it was not shared with the local community.

The completion of final declarations by trusts that have merged by April 1st 2006

A final declaration should be submitted for each NHS body (legal entity) that was in operation during April 1st 2005 to March 31st 2006. For example, the boards of new trusts, which have been formed by the merging of a number of PCTs and will become a legal entity on April 1st 2006, will need to submit a declaration for each of the former PCTs for the period from April 1st 2005 and March 31st 2006.

The process for cross-checking

The Healthcare Commission will cross check the final declarations by trusts to identify the 10% of trusts that we consider at greatest risk of having an undeclared significant lapse. These trusts, and another 10% of trusts selected at random, will receive a selective inspection focusing on five core standards.

The process for cross-checking uses a range of data that is nationally available and information from other regulators and bodies. This process enables us to target our inspections where we think there is the greatest risk of undeclared non-compliance with the core standards. It does not directly contribute to the score that a trust will receive for the assessment of compliance with core standards.

Selective inspection

Selective inspections by our regional teams will look at the adequacy of the documentary evidence that a trust relied upon when it made its final declaration. The adequacy of evidence will be assessed by reference to the elements published in *Criteria for assessing core standards*.

The starting point for our inquiries will be any summary of evidence used to inform those responsible for 'signing off' the final declaration. The regional team will wish to explore the detailed information that was used to inform such a summary. For

example, if a board received a report that a given standard was met throughout the year, the regional team will assess the adequacy of the documentary evidence that was the basis of the report. Similarly, if a board maintains a structured ‘assurance framework’, the regional team will assess the adequacy of the documentary evidence underlying this framework.

3 Scoring of the final declaration

Each NHS trust in England will receive a score of 'fully met', 'almost met', 'partly met' or 'not met' for their assessment of compliance with core standards. The score will be determined from the content of a trust's final declaration, taking account of any qualifications resulting from our selective inspections.

This section describes the method by which the Healthcare Commission proposes to award this score. Please note: the rules for scoring, and the thresholds to which they refer, are subject to approval by the Secretary of State for Health. The Healthcare Commission is currently discussing these proposals with the Department of Health. The information below remains provisional at this stage.

The purpose of the score

The methodology for scoring trusts on their compliance with core standards aims to:

- reflect the extent of a trust's compliance with core standards for the entire year
- encourage insight and honesty in the declarations submitted by trusts
- reward trusts that improve their level of compliance with core standards during the year

The basis of the score

The score is based on a calculation that reflects the proportion of core standards for which there is compliance. For this purpose, the Healthcare Commission considers there to be 44 standards (for example, C4a and C4b are considered as separate standards).

Please note: C7a and C7c are considered as one standard, as are C22a and C22c. Some standards have been excluded because they are not part of this assessment – standard C7d will be measured through our assessment of the use of resources, and C7f and C19 will be measured by reference to existing national targets.

Only 42 of the 44 core standards apply to ambulance trusts. C15a and C15b (relating to the routine provision of food to patients) do not apply.

The thresholds presented below apply to all types of trusts. For further detail, please refer to *Criteria for assessing core standards*.

The effect of selective inspection on a trust's score

A selective inspection may result in the qualification of a trust's declaration. A qualification by the Healthcare Commission will apply where we have concluded that a trust's final declaration of 'met' for one or more standards was not supported by adequate evidence. For each of these standard(s), the qualification will record whether the evidence assessed by our regional teams could support a more limited statement of compliance – that is, that the standard had been met by March 31st 2006.

Any standards to which the qualification applies will be counted twice in the calculation of a trust's score. That is, any one failing identified through selective inspection will be considered equivalent to two failings. Example 4 (page 14) illustrates how this rule will work.

Any trust that receives a qualification will be limited to a maximum score of 'almost met'.

Calculating the score

The score for each trust will be calculated in two steps:

- step 1 - considers the level of compliance across the entire year to calculate the maximum score that a trust can achieve.
- step 2 - considers the level of compliance at the end of the year to calculate the actual score achieved

Step 1

Table 1 provides the thresholds for the number of standards categorised as 'not met' or 'insufficient assurance' in the final declaration by a trust, taking account of any qualification made by the Healthcare Commission

Table 1: Thresholds to determine the maximum score a trust can achieve

Number of standards categorised as 'not met' or 'insufficient assurance'	**Maximum score**
0 to 4	Fully met
5 to 8	Almost met
9 to 13	Partly met
14 or more	Not met

To calculate the maximum score a trust can achieve:

1.1 Count the number of standards recorded in the final declaration as 'not met' or 'insufficient assurance'

1.2 If there has been a qualification to the declaration, count the number of standards to which it applies. Double this number and add it to the total calculated in 1.1

1.3 Compare the total calculated in 1.2 with the ranges listed in table 1. The range in which the total falls identifies the maximum score that the trust can achieve

1.4 If there has been a qualification, and the maximum score identified in 1.3 is 'fully met', then this maximum will be reduced to 'almost met'

Step 2

Table 2 shows the thresholds for the number of standards categorised as 'not met' or 'insufficient assurance', where the underlying significant lapse(s) or gap(s) in assurance have not been corrected by March 31st 2006. The timing of any such correction will be defined by the relevant 'end date' of non-compliance or insufficient

assurance in the final declaration, again taking account of any qualification made by the Healthcare Commission

Table 2: Thresholds to determine the actual score a trust can achieve	
Number of standards categorised as 'not met' or 'insufficient assurance', where the significant lapse(s) or gap(s) in assurance have not been corrected by March 31st 2006	**Actual score**
0	Fully met
No more than 4	Almost met
No more than 8	Partly met
9 or more	Not met

To calculate the actual score achieved:

2.1 Count the number of standards recorded in the final declaration as 'not met' or 'insufficient assurance', excluding any where the relevant 'end dates' in the declaration indicate that the significant lapse(s) or gap(s) in assurance have been corrected by March 31st 2006

2.2 If there is a qualification, count the number of standards to which it applies, excluding any for which it was concluded that the evidence that was assessed could support a statement that the standard had been met by March 31st 2006. Double this number and add it to the total calculated in 2.1

2.3 The actual score achieved cannot be higher than the maximum score defined in step 1. Compare the total from 2.2 with the remaining thresholds listed in the left column of table 2. The threshold that corresponds to the total from 2.2 identifies the actual score achieved by the trust

Examples

The following examples illustrate how the scoring will be applied.

Example 1

A trust declares that it has 'not met' seven standards in its final declaration. For four of these standards, the trust has corrected the significant lapses by March 31st 2006, as indicated by the relevant 'end dates' in the declaration. The trust does not receive a selective inspection.

The trust's score will be calculated as follows.

1 Calculate the maximum score that the trust can achieve (table 1)

1.1 The trust recorded seven standards in its final declaration as 'not met'

1.2 No qualification applies to the trust's declaration because a selective inspection has not been carried out. The trust's total remains 7

1.3 The total falls within the range of '5 to 8' in table 1, which means that the maximum score the trust can achieve is 'almost met'

1.4 This step does not apply because a selective inspection has not been carried out

2 Calculate the actual score achieved (table 2)
   2.1 Of the standards recorded as 'not met', three had not been corrected by March 31st 2006
   2.2 No qualification applies to the trust's declaration because a selective inspection has not been carried out. The trust's total remains three
   2.3 The maximum score the trust can achieve is 'almost met'. The total falls within the threshold of 'no more than 4' in table 2, which means that the trust achieves a score of 'almost met'

Example 2

A trust declares that it is 'not met' or has 'insufficient assurance' for 14 standards in its final declaration. For eight of these standards, the trust has corrected the significant lapses or the gap(s) in assurance by March 31st 2006, as indicated by the relevant 'end dates' in the declaration. The trust does not receive a selective inspection.

The trust's score will be calculated as follows.

1 Calculate the maximum score that the trust can achieve (table 1)
   1.1 The trust recorded 14 standards in the final declaration as 'not met' or 'insufficient assurance'
   1.2 No qualification applies to the trust's declaration because a selective inspection has not been carried out. The trust's total remains 14
   1.3 The total falls within the range of '14 or more' in table 1, which means that the maximum score the trust can achieve is 'not met'
   1.4 This step does not apply because a selective inspection has not been carried out

Table 2 does not apply because the trust can only achieve a maximum score of 'not met' in table 1. The actual score achieved by the trust is 'not met'.

Example 3

A trust declares that it has 'insufficient assurance' for four standards in its final declaration. For three of these standards, the trust has corrected the gap(s) in assurance by March 31st 2006, as indicated by the relevant 'end dates' in the declaration.

The trust's score will be calculated as follows.

1 Calculate the maximum score that the trust can achieve (table 1)
   1.1 The trust recorded four standards in its final declaration as 'insufficient assurance'
   1.2 No qualification applies to the trust's declaration because a selective inspection has not been carried out. The trust's total remains four
   1.3 The total falls within the range of '0 to 4' in table 1, which means that the maximum score the trust can achieve is 'fully met'
   1.4 This step does not apply because a selective inspection has not been carried out

2 Calculate the actual score (table 2)
  2.1 Of the standards recorded as 'not met', one had not been corrected by March 31st 2006
  2.2 No qualification applies to the trust's declaration because a selective inspection has not been carried out. The trust's total remains one
  2.3 The maximum the trust can achieve is 'fully met'. The total falls within the threshold of 'no more than 4' in table 2, which means that the trust achieves a score of 'almost met'

Example 4

A trust declares that it has 'insufficient assurance' for four standards in the final declaration, but indicated, by the relevant 'end dates' in the declaration, that the gaps in assurance for these standards had been corrected by March 31st 2006. The trust receives a selective inspection and the regional team concludes that the evidence used by the trust did not adequately show that three of the standards that were declared as 'compliant' in the final declaration had been met during or by March 31st 2006.

The trust's score will be calculated as follows.

1 Calculate the maximum score the trust can achieve (table 1)
  1.1 The trust recorded four standards in the final declaration as 'insufficient assurance'
  1.2 A qualification applies to three standards. Doubling this number gives six. This number is then added to the total in 1.1, giving a total of 10
  1.3 This total falls with the range of '9 to 13' in table 1, which means that the maximum score the trust can achieve is 'partly met'
  1.4 This step does not apply because the maximum score that the trust can achieve, taking account of the qualification, is already less than 'fully met'

2 Calculate the actual score (table 2)
  2.1 All of the standards recorded as 'insufficient assurance' had been corrected by March 31st 2006, giving the trust a total of 0
  2.2 A qualification applies to three standards. Of these standards, it was not concluded that the evidence assessed could support a statement that the standard had been met by March 31st 2006. Doubling this number gives six. This is added to the total in 2.1, giving a new total of six
  2.3 The maximum score the trust can achieve is 'partly met'. The total falls within the threshold of 'no more than 8'. The trust achieves an actual score of 'partly met'

Appendix A: Learning from the draft declaration

In this appendix, we highlight some of what we, and others involved in the process for the draft declaration, have learnt.

1 Submission of draft declarations in October 2005

The process for the submission of draft declarations

All trusts submitted their draft declarations before October 31st 2005. Many trusts did not report any specific concerns with regards to this process. However, we received feedback from a number of trusts that reported difficulties with the online declaration form and the process for submission. Some of the issues reported by trusts regarding the online submission form included:

- difficulties navigating the form, particularly when trying to save pages or when looking back at other pages – for example, the form did not allow trusts to 'jump' to a domain or standard that required updating
- difficulties changing their declaration from 'not met' to 'compliant' for individual standards, and removing details of action plans
- difficulties generating a printable (PDF) copy of the declaration, particularly because of the automatic inclusion of blank sections in the fields in the action plan or third party comments. This meant that some trusts had to present a 30-page document to their board. A number of trusts reported that this was unsatisfactory but manageable; others said that it was unacceptable for their boards, and they had to develop a separate document for the board
- a small number of trusts did not receive a copy of their declaration after submission and were concerned that their data had been lost

Our response:

A revised online declaration form is now available, although trusts will not be able to submit their completed declarations until Monday, April 3rd 2006.

Significant lapse

We received a range of feedback about the definition of a significant lapse. Some trusts were happy to devise or adapt their own criteria to help them to consider whether lapses were significant. Other trusts asked for more definitive guidance from the Healthcare Commission, such as a standardised scoring tool for each standard to determine whether it has had a significant lapse. We have provided additional guidance on identifying significant lapses on page 6. Below are some examples that trusts may also find helpful.

Example 1

Standard C14a: Healthcare organisations have systems in place to ensure that patients, their relatives and carers have suitable and accessible information about, and clear access to, procedures to register formal complaints and feedback on the quality of services.

A PCT, which is a provider of learning disability services, is considering their compliance in relation to standard C14a. The PCT knows that it provides a standard complaints leaflet through its website and at its sites. The PCT has not assessed whether it provides information on its complaints procedure in a suitable form for the population that it serves. The PCT has never had a request to provide the information in other forms or languages nor have they assessed whether those who use learning disability services are able to access their complaints procedures.

Is this a significant lapse?
The Healthcare Commission would expect the PCT to declare this as “insufficient assurance”, as there is no evidence that the PCT has sufficient information to determine whether there has been a significant lapse. The standard requires the PCT to ensure that “patients, their relatives and carers have suitable and accessible information about, and clear access to” complaints procedures, yet the PCT does not have information which demonstrates that they know that this is happening. In addition, given that the PCT provides services for people with learning disabilities, we would expect the PCT to have assessed whether this group of patients had clear access to complaints procedures.

Example 2
Standard C11b: Healthcare organisations ensure that staff concerned with all aspects of the provision of healthcare participate in mandatory training programmes.

An acute trust has declared that they are ‘not met’ for standard C11b because their figures show that 87% of staff have received mandatory training during 2005/2006, and the Healthcare Commission’s element states that “all staff participate in relevant mandatory training in accordance with the Management of Health and Safety at Work Regulations 1999”.

Is this a significant lapse?
Clearly, the trust has not achieved 100% compliance with the element, which constitutes a ‘lapse’ in terms of their compliance. The question for the trust is whether this lapse is ‘significant’. This is not something that can be answered against a threshold that is universally applicable. In one local context, 87% may be acceptable. In another, 13% may pose a highly significant risk. It is important to consider which groups of staff have received mandatory training, the relevance of this training to the roles they carry out, and what are the risks to patients, staff and the organisation.

These are the kinds of considerations we are expecting trusts to take into account when reaching a decision for each standard. In the event of a selective inspection, it is these decisions that we will wish to understand in order to be satisfied that the trust has ‘reasonable assurance’.

Example 3
Standard C4d: Healthcare organisations keep patients, staff and visitors safe by having systems to ensure that medicines are handled safely and securely.

A PCT has declared that it is not meeting standard C4d (medicines management) because the results of the latest audits on its process for medicines management

have not been reported to the medicines management board. The PCT's action plan states that the audit report will be presented at the next monthly meeting.

Is this a significant lapse?
This does not appear to be a significant lapse because the element for standard C4d does not state that all audits must be presented to this committee. Of course, we would expect the trust to consider any major issues raised by the audit relating to standard C4d in determining their level of compliance.

Getting 'sign off' from trust boards

Many trusts were positive about the level of involvement of trusts' boards in the process for the draft declaration. Some non-executive directors welcomed the opportunity to become involved in the process because it enhanced their focus on the safety and quality of care provided by their trust. Many draft declarations were signed by the entire board. Some boards of PCTs delegated authority for 'sign off' to their professional executive committee.

Our regional teams reviewed the paper copies of the draft declarations and checked that they had been signed. Early indications from our follow up visits suggest that draft declarations were more insightful and robust when members of the boards had been engaged in the process for sign off.

However, many trusts reported that the process for gaining signatures on paper was complicated and time consuming. Some trusts reported that it was difficult to get the members of their board to sign the declaration by the deadline. In some cases, this was because of delays between submission of their online declaration form and the return of the paper copy by the Healthcare Commission.

Our response:
Trusts will not have to submit a paper copy of the final declaration. However, this does not alter the accountability of trusts' boards for the standards of care provided by their trusts.

Comments from third parties

The Healthcare Commission has received some extremely positive feedback from trusts and third parties involved in this part of the process. For example, some patient and public involvement forums reported that the process had run smoothly, reflecting their existing relationships with trusts. Other patient and public involvement forums reported that the process had helped their trusts to engage with them in a more formal manner and to identify opportunities for engagement in the future.

Patient and public involvement forums and overview and scrutiny committees
We have already provided some feedback to patient and public involvement forums and overview and scrutiny committees about their role in the process for the draft declaration. These documents are available on our website. In particular, we found that:

- 388 trusts received comments from their patient and public involvement forums as part of the process for the draft declaration. Of the forums that did not comment, many indicated that they would contribute to the final declaration

- 322 trusts received comments from at least one overview and scrutiny committee, and many committees commented that they would contribute to the final declaration

Table 3 highlights some of the issues raised by third parties and trusts.

Table 3: Issues raised by third parties and trusts

Issues	Response
Some third parties have asked to provide their comments directly to the Healthcare Commission rather than to the trusts for inclusion in declarations.	We do not wish to receive comments submitted by third parties directly. We continue to require trusts to receive comments from their third parties and to submit comments verbatim within their declaration. This is because we wish to encourage local engagement between trusts and their third parties. We expect that, over time, this part of the process will develop into an ongoing dialogue about the areas covered by the core standards.
Some requests for a template for third parties to record their comments.	We have not provided a standard template for third parties to complete when submitting their comments to a trust. We recognise the independence of overview and scrutiny committees and patient and public involvement forums. Third parties can present their comments in the form that is most suitable for them. It may be, for example, that the forum/committee wishes to submit a formal letter, or to provide their comments as bullet points in an email. We will analyse all such comments provided in final declarations, regardless of the form in which they are presented.
Some patient and public involvement forums and overview and scrutiny committees reported that they had not been invited to comment on their trust's draft declaration, or that the trust had not given them enough time to comment (for example, two weeks notice).	Trusts must seek comments from their statutory patient and public involvement forums and relevant overview and scrutiny committees. Clearly, trusts must do so early enough to allow the forum/ committee(s) adequate time to respond. If the patient and public involvement forums and overview and scrutiny committees have not been contacted in a timely fashion, they can, of course, approach the trust to clarify the situation.
A small number of patient and public involvement forums have reported that they were asked by the trust to change the comment they had formally submitted.	Trusts must reproduce verbatim the comments submitted by their patient and public involvement forum.
Some forums and overview and scrutiny committees reported that the process	If an overview and scrutiny committee or a patient and public involvement forum does not wish to, or is unable to provide comments for a trust's final declaration it would be

Table 3: Issues raised by third parties and trusts	
Issues	**Response**
was burdensome and asked for further guidance on the detail of the core standards.	helpful if they could submit a comment to this effect to the trust. If a forum or committee does not comment, this will be accepted and the trust will not be criticised for this. We do not expect members of overview and scrutiny committees and patient and public involvement forums to have in depth, expert knowledge about all of the core standards or indeed to comment on all 24 standards.
Trusts and third parties both asked for the opportunity to share learning from the process for the draft declaration.	We are planning to work with the new patient and public resource centre to provide support on the detail of the core standards and on the process for assessing compliance with core standards.

Strategic health authorities

All NHS trusts (except NHS foundation trusts) included comments from their strategic health authorities in the draft declaration. From these comments, the Healthcare Commission was able to extract information from 410 draft declarations by trusts, which resulted in the incorporation of more than 4,000 distinct pieces of information into our process for cross-checking.

Strategic health authorities have generally taken one of two approaches when commenting on the draft declaration by trusts. They have:

- provided comments that reflect the information and intelligence that the strategic health authority already holds on each of its trusts. These strategic health authorities did not request additional information from trusts and did not request to see the trust's draft declaration before providing their comments
- provided comments based on a provisional view of a trust's draft declaration or after reviewing the additional information that it had requested from trusts

The level of detail provided by strategic health authorities varied. Some strategic health authorities provided detailed comments on each of the core standards for which they had information. Others simply provided a high level statement, generally endorsing the declaration by the trust. The Healthcare Commission has found it more difficult to code and analyse the latter style of comments.

Box 1: A positive approach

One strategic health authority approached the process for the draft declaration by:

- reviewing the existing information they already held on each of their trusts
- identifying where this information was relevant to specific core standards
- submitting information to the relevant trust

This approach helped to direct our attention to the relevant aspects of performance.

Our response:
The declaration provides third parties with an opportunity to comment on a trust's performance in relation to the core standards. It is not intended to imply any obligation on the trust to share the contents of their declaration with third parties prior to submission. Of course, where trusts wish to share the contents of their declaration before submission they are able to do so.

Use of 'general statement of compliance'

A blank section on 'general statement of compliance' was provided in the draft declaration form. The Healthcare Commission's analysis of the use of this section found that trusts used it in one or more of the following ways:

- to provide an overview of their level of assured compliance, such as 'with the exception of standards x, y, z, detailed below the board has reasonable assurance that the core standards have been in place since April 1st 2005'
- to describe the process of assurance that they used to inform their decision for each standard
- to describe some of the discussions they have had with members of the board – for example, one trust described how members of the board had challenged decisions relating to particular standards
- to respond to comments provided by third parties, particularly patient and public involvement forums – for example, one trust used this section to welcome the comments provided by their patient and public involvement forum and to acknowledge the work that was being carried out to develop their relationship with the forum
- to detail further information on standards that had been reported as 'not met' or 'insufficient assurance'. Unfortunately, in some cases, this approach contradicted details provided elsewhere in the declaration, resulting in inconsistencies

Our response:
The final declaration is a public document. To allow trusts to use the general statement of compliance to provide an accessible summary of the detail of the declaration, this is now the first section of the declaration form. It is important for the statement to be consistent with the detail presented in the rest of the declaration.

Use of 'not met' and 'insufficient assurance'

Our analysis of draft declarations showed that there was some confusion regarding the categories of 'insufficient assurance' and 'not met'.

The category 'insufficient assurance' should be used where a trust is unclear about whether there have been significant lapses – that is, they do not know whether they have been meeting a standard during 2005/2006.

We would expect any related action plan to correspond with this definition. It should, under 'issue', explain why a trust is unable to judge its level of compliance with a standard, and the actions should show how a trust plans to be in, or has reached, a position to understand their level of compliance with a standard. In many cases, the category of 'insufficient assurance' was selected, but the description that was provided in the action plan reflected a declaration of 'not met'.

Box 2: 'Insufficient assurance' and 'not met'

The example below shows details from two draft declarations for standards C8b. Given the details of the issue outlined in its action plan, we would have expected trust B to have reported 'not met' as trust A has done.

Trust A – declared 'not met' for standard C8b and detailed the issue as: "The trust does not have a robust programme in place to ensure that all staff will receive a personal development review."

Trust B – declared 'insufficient assurance' for the same standard and detailed the issue as: "The trust does not have a fully rolled out appraisal and PDP system for all staff, although appraisals are in place for managers."

Our response:
Trusts will need to consider and assign, for each standard, one of the following categories:

- that they have 'reasonable assurance' that they have met a standard for 2005/2006
- that they do not know whether they have met the standard during 2005/2006 ('insufficient assurance')
- that they know there have been one or more significant lapses in 2005/2006 ('not met')

Action plans presented in the draft declarations

We had some concerns regarding the quality of action plans in draft declarations.

Some trusts were unclear about how to complete the 'start date' and 'end date' – for example, whether start dates could precede the 2005/2006 or which end date they should select where they have a number of action plans in place for a given standard.

In some cases, trusts did not provide appropriate details of the issue(s) that had led to a declaration of 'not met' or 'insufficient assurance'. Instead, they repeated the wording of the standard or inserted the wording from the Healthcare Commission's consultation material (the prompts). In addition, the details provided in action plans were not always clear – sometimes action plans presented an outcome rather than the steps that the trust was taking or had taken to address an issue.

Box 3: Unclear 'issues' in action plans

Examples of unclear 'issues' provided in draft declarations:

- "system and documentation to be put in place by February 28th 2006"
- "further development of existing systems including identification of resources"
- "will improve existing systems by March 2006"

Table 4 shows two action plans, which provide reasonable details of the actions in place to address significant lapses identified in the draft declaration. These examples provide specific actions for each significant lapse. Example 1 also provides dates and milestones.

Table 4: Actions to rectify a significant lapse

Example 1: Not met	**Example 2: Insufficient assurance**
Actions identified by a trust for meeting standard C5a • introduction of a system for identifying new NICE guidance relevant to the PCT. First priority will be technology appraisals. Target date: October 2005 • identified technology appraisals will be discussed at the PCT's clinical effectiveness and audit committee, with identification of leads, on an ongoing basis. Target date: ongoing • development of mechanisms to communicate decisions made relating to NICE guidance. Target date: January 2006 • identification, by services, of training needs and costs associated with implementation. Target date: February 2006 • systems for monitoring implementation to be agreed. Target date: March 2006	**Actions identified by a trust to provide assurance for standard C13a** The following actions are in place, under the leadership of the director of nursing, to establish the trust's position with regard to standard C13a: • executive team to receive an update from clinical leads regarding Essence of Care action plans in place within their departments to provide assurance • the trust's diversity and equality committee has been re-convened with representatives from across the trust to provide central reporting of equality and diversity issues, the group will also include patient representatives • complaints will continue to be analysed to identify any issues relating to dignity, equality and diversity issues, and monitoring is presented to quarterly • roll out of indicators identified by the lead nurses group within services to help monitor dignity and respect • a clinical governance group has been established by the division for elderly care to provide information relating to dignity and respect

Our response:
The final declaration will be a public document and it will be important for trusts to explain clearly the significant lapse or gap that has been identified and the actions that they have taken or plan to take in response.

Assessing the functions of primary care trusts

We have previously issued guidance on the application of the assessment of compliance with core standards to independent contractors and commissioned services. These documents are available on our website.

We require PCTs to be able to demonstrate that they have taken 'reasonable steps' to satisfy themselves that their independent contractors meet the core standards, and to demonstrate that they have taken the core standards into account for their commissioned services. The process for the draft declaration indicated that not all PCTs were able to demonstrate that they had done this.

Independent contractors

With regard to independent contractors, some PCTs:

- went beyond the requirement by putting in place, for example, new processes to collect information from each independent contractor to determine whether they were meeting the standards
- have, in line with the guidance, used, or in some cases strengthened, existing mechanisms to ensure that they understand how their independent contractors are meeting the standards
- fell short of the requirement by failing to consider all of their independent contractors when completing their draft declarations – for example, some PCTs were unable to provide any evidence of the 'reasonable steps' they had taken in respect of dentists, optometrists or pharmacists

Commissioned services

With regard to commissioned services, some PCTs:

- went beyond the requirement by requesting information from each of their commissioned services in order to determine the level of compliance that has been achieved in relation to each of the core standards
- met the requirement by using existing forums, and reviewing information that they already held on their commissioned services, to understand whether their commissioned services were meeting the standards. In addition, some PCTs were revising their service level agreements and related mechanisms for monitoring to include reference to the core standards. Such developments, where appropriate, could certainly contribute to a comprehensive approach to meeting the requirements of our assessment of compliance with core standards
- fell short of the requirement by failing to consider how they could identify any issues regarding the quality of the services they commission

The guidance we published in September 2005 provided some examples of the sorts of mechanisms we would expect PCTs to use to ensure that they meet the requirements of the assessment of compliance with core standards. We would encourage PCTs to revisit this guidance when considering their final declarations.

2 The process for cross-checking

We cross-checked the draft declarations to identify the 10% of trusts we considered at greatest risk of having undeclared significant lapses. We checked the draft declarations against our analysis of a wide range of information that is centrally available. The process for cross-checking does not mean that the Healthcare Commission disagrees with a trust's declaration, only that we wish to explore with the trust the basis on which they have declared 'compliant' for a selected number of standards.

The information used to cross check draft declarations by trust included:

- measures of outcome, output and process derived from a range of data that is nationally available
- the results of the Healthcare Commission's surveys of patients and the NHS survey of staff
- intelligence from our own NHS second stage review of complaints, investigations into serious failures of services
- information obtained from other regulators and review agencies
- comments from third parties that accompanied the draft declarations

We used our analysis to identify 60 trusts, which subsequently received a 'risk based' follow-up visit.

We used the widest possible range of data available at the time of the draft declaration. However, we are continuing to build on this data in preparation for our analysis of final declarations in May 2006. We are also continuing to refine our methodology for analysing and combining different sets of data. This includes incorporating, more systematically, the information held by our regional offices ('local intelligence') about individual trusts.

We have not been able to share this information with trusts as effectively as we would have wished. We have found it difficult to achieve a succinct and meaningful presentation of the process because of the hundreds of items of information used. We are currently working with a number of trusts to test different and useful ways of presenting our analysis. We will aim to share our analysis as part of the follow-up of final declarations.

3 Selective inspection

Our regional teams carried out selective inspections in approximately 120 trusts between November 21st 2005 and February 17th 2006. Most trusts involved were positive about the visits from our regional teams and some commented that it provided a useful opportunity to learn about the process for our assessment. In this section, we provide an overview of the process for selective inspection and the emerging findings from these inspections.

The process for selective inspection

Trusts were selected in two ways:

- 'risk based' – selected through our process for cross-checking
- 'random' – selected by a random number generator

Five standards were reviewed during each selective follow-up visit, from those that the trust had declared 'compliant'. For each standard, the regional team focused on the adequacy of the evidence relied upon by the trust when making its draft declaration.

Six of the trusts that were selected at random received an unannounced inspection from the Healthcare Commission. Our regional teams wrote to all other individual trusts detailing the date of the visits and the five standards that had been selected.

The structure of visits varied, depending upon the organisation, although generally the approach involved:

- an initial discussion with the person leading on core standards for the trust, and/or the chief executive or other executive director, focusing on the trust's approach to assurance for the draft declaration

- an examination of the documentary evidence that the trust used to determine the category of 'compliant' for each of the five standards (either paper documents were presented or teams reviewed electronic documents provided by the trust)

- follow-up interviews with key personnel from the trust, where necessary, to address any queries concerning the documentary evidence presented

A number of merging trusts were included in the selective inspections. In some cases, our regional teams looked at only one of the trusts involved in the merger. In other visits, we assessed five standards in each trust. This was determined by the information used in our process for cross-checking or by random selection.

Evidence presented during the selective inspections

Our selective follow-up visits focused on the adequacy of the evidence that the trust had used to inform their declaration for the five standards that had been selected. The regional teams used an inspection guide to direct their inquiries for each element of a standard. The majority of trusts that received a selective inspection were able to provide the information that had formed the basis of their declaration. Most trusts provided this evidence electronically. Those that could not provided paper copies of the evidence. Many trusts were using tools to organise their evidence for the assessment, such as:

- the adaptation or augmentation of existing tools – for example, one trust had built upon the framework for Improving Working Lives because they were in the process of an Improving Working Lives practice plus review

- bespoke spreadsheets, often structured around consultation material provided by the Healthcare Commission ('the prompts'), with traffic light assessments and dynamic links to documents related to the standards
- off the shelf 'commercial' software packages, used to log and organise evidence related to each standard
- an 'assurance framework'[3], detailing risks, controls and assurances that are relevant to the core standards

In a number of visits, trusts presented regional teams with vast quantities of evidence. In some cases, it was not always apparent that some of the information presented to the regional team had been used to inform the draft declaration. Trusts were also not always able to explain how the evidence had been brought together to provide the grounds for the trust to declare 'compliant' for a standard.

By contrast, a few trusts failed to provide any documentary evidence and instead offered interviews with relevant staff. This made it difficult for our regional teams to understand the basis on which the declaration had been agreed. The Healthcare Commission expects to see the documentary evidence that supports the trust's statement of 'compliant' for a given standard. However, as highlighted in box 4, evidence that simply documents the process of assurance is unlikely to be judged as adequate by our regional teams.

Some of our regional teams were presented with documents that were dated after the submission deadline for the draft declaration. The teams were unable to consider this information when reviewing a standard, as the information could not have been available for the trust to consider when determining their level of compliance.

Trusts were generally able to provide 'controls based' information relating to a standard, such as policies, procedures, and structures for reporting. However, most standards require particular outcomes for patients, staff or the public. In such cases, evidence of a process being in place will not generally be sufficient. We will expect trusts to also provide evidence that the outcomes have been achieved. Box 5 focuses on a standard where particular outcomes are required.

Box 4: Example of inadequate documentary evidence

A regional team undertook a selective follow-up visit, which included reviewing a trust's statement of compliance for standard C5b, element 1 (clinical supervision).

The information provided to the team was a minute of the director of nursing's update to the trust board that clinical supervision was in place across the trust. The regional team reviewed the minute but was unclear on what basis this assurance had been given.

The team followed this up during an interview with the director of nursing to ascertain what information had informed his update to the board. During the conversation the director of nursing stated that he could not provide any documentary evidence to support his assurance to the board, but that, to the best of his knowledge, clinical supervision was in place in the trust.

[3] *Building an assurance framework: a practical guide for NHS boards*, Department of Health 2003

Box 5: Evidence presented by two trusts for standard C4d

Standard C4d requires that "systems are in place to ensure that medicines are handled safely and securely".

The following 'controls based' evidence relating to C4d was provided by trust A:

- terms and reference for medicines management committee (January 2004)
- overarching medicines management policy July 2005 (draft)
- safe and secure handling of medicines policy (no date)

This information alone does not demonstrate that the trust has *ensured* that medicines are handled safely and securely.

The following evidence provided by trust B for the same standard, however, is more likely to demonstrate that the required outcomes have been achieved:

- minutes of medicines management committee (April, June and August 2005)
- safe and secure handling of medicines policy (revised January 2005)
- report of audit of storage procedures for controlled drugs (report May 2005)
- report to board: summary of review of staff competencies (February 2005)
- clinical governance newsletter detailing summary of reported incidents (includes medication errors) and key learning (September 2005)
- report to board: summary of review of staff competencies (February 2005)

Our response:
Selective inspections for the final declaration will focus on the adequacy of the documentary evidence a trust relied upon when it made its final declaration. This means that:

- regional teams will assess the adequacy of a trust's evidence by reference to the elements (published in *Criteria for assessing core standards)*, using inspection guides
- the starting point of the inquiries by the regional teams will be any summary of evidence used to inform those responsible for 'signing off' the final declaration. Often, the regional team will wish to explore the more detailed information that has informed this summary

To reiterate, the prompts have no formal status in our assessment of core standards. The elements are the formal criteria used in our assessment.

Trusts should be satisfied that they have an appropriate and effective audit trail of evidence that they have used as a basis for their declaration. The Healthcare Commission does not prescribe how trusts should store this evidence. Should a trust receive a selective inspection relating to its final declaration, we will assess this evidence and take copies for the purposes of our evaluation. We do not require

trusts to provide printed copies of documents if they are available to us electronically. We will continue to accept evidence in whatever form it is available.

If a trust has considered a large number of documents when determining their declaration, our regional teams will want to be taken through these documents by the trust during the inspection. The selective inspection provides trusts with the opportunity to highlight the information that has led to a conclusion of ‘compliant’ for a given standard.

Appendix B: Independent evaluation of the assessment of compliance with core standards

The Healthcare Commission is committed to evaluating the costs of inspection and regulation and for ensuring these are justified in terms of the benefits provided. As part of this strategic goal, the Commission has commissioned an independent evaluation of the 2005/2006 assessment of compliance with core standards assessment.

Aim

The project aims to evaluate the costs, benefits and overall impact of the assessment of compliance with core standards and its various stages.

Method

The evaluation includes several phases of fieldwork with NHS trusts including:

- 12 in-depth case studies involving face to face and telephone interviews with trusts, as well as some strategic health authorities, overview and scrutiny committees and patient and public involvement forums, and monthly diaries
- face to face and telephone interviews with random samples of NHS trusts at various stages of the cycle of assessment
- a Delphi study to clarify and expand on the interim findings of the evaluation with NHS trusts

All data supplied by interviewees is being analysed in anonymised form and is confidential.

Findings

It is still very early for the evaluation to report substantive findings. However, preliminary findings from the process for the draft declaration suggest that it may be possible to distinguish a broad 'typology' in the way that different NHS trusts have approached self-assessment with implications for cost and impact. This is the subject of current analysis and will be a focus of subsequent phases of fieldwork. In addition, the evaluation has generated a rich picture of the challenges and opportunities presented by the draft declaration and early lessons on the process have fed into the Commission's learning.

Publication of results

The Healthcare Commission will receive the full findings by the end of 2006. We intend to feed back earlier results to the NHS as they become available.

We would like to take this opportunity to thank the NHS trusts that have volunteered their time to participate in the evaluation. We are committed to ensuring that we consider the findings and continuously improve our methods. We intend to follow up this first stage by commissioning further independent evaluation covering future cycles of the annual health check.