NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of TA71; Guidance on the use of coronary artery stents (recommendations 1.1 and 1.5)

This guidance was issued in October, 2003.

1. Recommendation

The guidance should be updated in a forthcoming guideline. That we consult on this proposal.

2. Original remit(s)

"As part of the planned review of guidance on coronary artery stents, to appraise the clinical and cost effectiveness of drug eluting stents compared with conventional stents for the primary prevention of restenosis following PTCA".

The above formed the footnote for the objective of the scope in TA71 which was “To assess the clinical effectiveness and cost effectiveness of coronary artery stents and the newer drug eluting stents, for the primary prevention of restenosis following percutaneous coronary interventions (PCI), and to update if and as necessary, guidance issued to the NHS in England and Wales (for ‘conventional’ stents) in May 2000[1]”

3. Current guidance

1.1 Stents should be used routinely where percutaneous coronary intervention (PCI) is the clinically appropriate procedure for patients with either stable or unstable angina or with acute myocardial infarction (MI).

1.5 This guidance specifically relates to the present clinical indications for PCI and excludes conditions (such as many cases of stable angina) that are adequately managed with standard drug therapy.

4. Rationale[1]

Because bare metal stents have been considered standard of care for several years, it is not considered useful to carry out an update of the still extant recommendations 1.1 and 1.5 of TA71 as a technology appraisal.

However, it would be beneficial for these recommendations to be updated when CG167 (Myocardial infarction with ST-segment elevation) and CG94 (Unstable angina and NSTEMI) are reviewed in July 2015 and September 2015 respectively. It

[1] A list of the options for consideration, and the consequences of each option is provided in Appendix 1 at the end of this paper

has previously been agreed to update the TA152 (drug eluting stents) in these clinical guidelines.

This would lead to all NICE's recommendations on the use of stents to be brought together within the entire context of clinical management of the conditions, which will allow for an analysis of the new technologies and ongoing research which compares drug-eluting stents and bare-metal stents. The clinical guidelines can also contextualise the use of stents with the use of CABG.

5. Implications for other guidance producing programmes

It is most useful if the recommendations in TA71 are updated in the forthcoming updates to the STEMI and NSTEMI guidelines. The reviews of CG167 on STEMI is scheduled to start in July 2015, and CG94 on NSTEMI in September 2015.

6. New evidence

The search strategy from the original assessment report was re-run on the Cochrane Library, Medline, Medline In-Process and Embase. References from January, 2002 onwards were reviewed. Additional searches of clinical trials registries and other sources were also carried out. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

7. Summary of evidence and implications for review

PCI with stent compared with PCI without stent

Two meta-analyses were identified that compared PCI with stenting and PCI with balloon angioplasty (Nordman et al., 2003 and Suwaidi et al., 2004). One meta-analysis (Suwaidi et al., 2004) did not include any new trials compared with TA71 and the other meta-analysis (Nordman et al., 2003) included only one additional study. The data for the additional study was taken from an abstract and has not been published as a full study report.

Ten trials were identified that have been published since the previous review proposal for TA71 (Braun et al., 2007; COMPASS; Dens et al., 2005; Gil et al., 2007; Hanekamp et al., 2004; Hausleiter et al., 2004; LASMAL I; LASMAL II; Panchavinnin et al., 2004; and PRISON). None of these trials have completed in the last 7 years.

None of the new trials reported the combined incidence of revascularisation, myocardial infarction or death, which was the main outcome considered in TA71. The results of the studies are summarised below.

Major adverse cardiac events

There were statistically significantly fewer major adverse cardiac events at 6 months (Gil et al., 2007) and at 9 months (LASMAL I) in patients who had PCI with stent than those who had PCI without stent. However, there was no statistically significant difference between the groups at 1 year (Hanekamp et al., 2004).

Restenosis and revascularisation

Patients treated with a stent had a statistically significantly lower restenosis rate at 30 days than those treated without stent (LASMAL II). At 6 months, a statistically significant difference between the groups was reported in 1 trial (Braun et al., 2007) but the difference was not reported to be statistically significant in 2 other trials (Hanekamp et al., 2004 and Panchavinnin et al., 2004). At 1 year, there was no statistically significant difference between the groups (COMPASS).

There was no statistically significant difference in revascularisation rates at 6 months (Braun et al., 2007 and Dens et al., 2005). At 1 year, a statistically significant difference between the groups was reported in 1 trial (Hausleiter et al., 2004), but the difference was not reported to be statistically significant in 2 other trials (COMPASS and PRISON).

It is unclear how the results of the new trials compare with the trials considered in TA71, as the main outcome considered in TA71 (the combined incidence of revascularisation, myocardial infarction or death) was not reported in the new trials. The results do appear to be in line with TA71 in that there is a statistically significant difference at shorter follow up periods, and that the size of the difference between the groups reduces with increasing follow up time.

PCI with stent compared with CABG

Six systematic reviews comparing PCI and CABG were identified in the literature search (Bakhai et al., 2005., Bravata et al., 2007; Chawla et al., 2010; Daemen et al., 2008; Kajimoto et al., 2012, and Takagi et al., 2008). The systematic reviews each included at least 1 trial that was already included in TA71. In addition, at least 1 of the systematic reviews included trials of PCI without stents in its comparison of PCI with CABG, which were not relevant to this RPP. Because of the potential for either including trials that have been previously considered or trials that are not relevant, the summary results of the systematic reviews are not described here and the results from the individual trials are summarised instead. Four trials which have reported since TA71 (Cisowski et al., 2004; Hong et al., 2005; MASS II; and MYOPROTECT) and 2 trials considered in TA71 that have reported new data since TA71 (ARTS [5 year data] and SOS [6 year data]) were identified from the systematic reviews and are considered in this RPP.

The literature search identified a further 8 studies that have been published since TA71 that compare PCI with stent and CABG (CARDia; FREEDOM; Kapur et al., 2010; MICASA; OCTOSTENT; SYNTAX; VA CARDS and Weintraub et al., 2004).

None of the new trials reported the combined incidence of revascularisation, myocardial infarction or death, which was the main outcome in TA71. The data from the new trials are summarised below.

Major cardiac adverse events and other combined outcomes

There were statistically significantly more major cardiac adverse events after PCI than after CABG at 6 months and at 2 years (Cisowski et al., 2004). There were also statistically significantly more incidences of major adverse cardiac or

cerebrovascular events after PCI than after CABG at 1 year (FREEDOM and SYNTAX), at 3 years (SYNTAX), and at 5 years (SYNTAX).

There were statistically significantly more incidences of death, stroke, or myocardial infarction after PCI than after CABG at 30 days (FREEDOM), however, there was no statistically significant difference at 1 year (CARDia), 3 years (SYNTAX), or 5 years (ARTS). The combined incidence of death, stroke, myocardial infarction, and revascularisation was statistically significantly higher at 1 year after PCI than after CABG (CARDia).

Stroke/cerebrovascular accident

Statistically significantly fewer patients experienced a stroke after PCI than after CABG at 30 days (FREEDOM) and at 1 year (SYNTAX), however, there was no statistically significant difference in the rate of stroke at 3 years (SYNTAX), 5 years (SYNTAX and MASS II) or 10 years (MASS II).

Myocardial infarction

There was no statistically significant difference in the number of myocardial infarctions after PCI compared with after CABG at 6 months (Hong et al., 2005) or 1 year (SYNTAX), however, there were statistically significantly more myocardial infarctions after PCI at 30 days (FREEDOM), 1 year (MICASA), 3 years (SYNTAX), and 5 years (SYNTAX).

There were statistically significantly more acute myocardial infarctions with PCI compared to CABG at 5 years and 10 years (MASS II). The same trial found no statistically significant difference in non-fatal myocardial infarctions at 5 years, but statistically significantly more non-fatal myocardial infarctions with PCI at 10 years.

Mortality

No statistically significant difference in the number of deaths between PCI and CABG was reported at 6 months (Hong et al., 2005), 1 year (MYOPROTECT; SYNTAX; MASS II), 5 years (ARTS; Kapur et al., 2010; MASS II; and SYNTAX), or 10 years (MASS II), however, there were statistically significantly more deaths reported after PCI than after CABG at 30 days (FREEDOM), 2 years (VA CARD), and 6 years (SOS). There were also statistically significantly more cardiac deaths after PCI at 5 years and 10 years (MASS II).

Need for revascularisation

There was a statistically significantly higher incidence of stent thrombosis (after PCI) compared to graft occlusion (after CABG) at 30 days (SYNTAX), but there was no statistically significant difference between the number of patients with stent thrombosis and those with graft occlusion in the same trial at 5 years.

There was no statistically significant difference in the number of patients needing revascularisation after PCI or CABG at 6 months (Hong et al., 2005), however, statistically significantly more patients needed revascularisation after PCI than after CABG at 1 year (SYNTAX and Weintraub et al., 2004), 3 years (SYNTAX), 5 years (SYNTAX, MASS II and ARTS), and 10 years (MASS II).

Quality of life and cost effectiveness evidence

There was no statistically significant difference in quality of life scores between PCI and CABG at 28 days (MYOPROTECT) or 1 year (MYOPROTECT). The QALY gain at 1 year was also not statistically significantly different (OCTOSTENT). This is in line with the evidence considered in TA71, which suggested that there was not a large difference in quality of life after PCI with stent compared with CABG.

The cost-effectiveness of PCI with stent compared with CABG was reported in 2 new studies. In a Dutch study, the cost-effectiveness ratio for stent implantation compared with CABG was €93,768 per QALY gained (OCTOSTENT). This was a result of fewer days in hospital and lower direct in-hospital costs with stent, as well as an increased in the quality of life at 1 month (although the difference in quality of life was not statistically significant at 1 year). A US study also reported that PCI with DES is more cost-effective than CABG (SYNTAX). This was a result of higher initial hospitalisation costs with CABG and a slightly higher quality-adjusted life expectancy with PCI.

TA71 states that stenting is considerably cheaper than CABG and is therefore more cost-effective, given that there was no statistically significant difference in quality of life after the 2 procedures. However, TA71 acknowledges that the Assessment Group's model for TA71 did suggest that CABG would be more clinically and cost-effective than stenting in patients who were eligible for both treatments. TA71 states that this suggestion was challenged at consultation by clinicians stating that previous studies had not reached this conclusion.

The cost-effectiveness results reported in the 2 new studies (OCTOSTENT and SYNTAX) support the existing TA71 guidance and the clinicians' view that stenting is considerably cheaper than CABG and is therefore more-cost effective, given that there was no statistically significant difference in quality of life after the two procedures. However, it is worth noting that the mortality data was inconsistent across the studies.

Ongoing trials

No ongoing trials comparing PCI with and without stent were identified.

Four trials are ongoing comparing PCI with CABG (EXCEL, FREEDOM, NOBLE, and PRECOMBAT). The 1 year results of the FREEDOM trial are already available and are included in the summary above and the 5 year mortality rates are expected in December 2018. The other trials are expected to complete in September 2014 (PRECOMBAT), December 2018 (NOBLE), and December 2021 (EXCEL).

Implications for review

PCI with stent compared with PCI without stent

The new data suggest that PCI with stent results in fewer major adverse cardiac events and a lower rate of restenosis compared to PCI without stent for at least the first year after treatment. These results do not suggest that a review of TA71 would affect the existing recommendation to use stents when PCI is undertaken.

PCI with stent compared with CABG

In TA71 the Committee considered that there were only data available for 3 years of follow up. The Committee considered that long-term cost-effectiveness models were needed because most patients who have stents fitted live longer than 5 years. TA71 included a recommendation for further research for data that would allow long-term outcomes to be compared. The Committee also acknowledged that its conclusions drawn from the longer-term cost effectiveness models (such as the 5 year extrapolations) depended critically on whether a survival advantage accrues to CABG. There are new data on mortality rates at 5 years (ARTS; Kapur et al., 2010; MASS II; and SYNTAX), 6 years (SOS), and 10 years (MASS II) that could enable a more accurate survival advantage, and therefore a more robust longer-term economic model, to be determined.

TA71 does not recommend when to use PCI with stent and when to use CABG.Therefore, it is unclear how an updated model would affect the existing recommendation within a technology appraisal. It would be appropriate to consider this new data in the updates of the clinical guidelines on STEMI and NSTEMI to allow all of NICE's recommendations on the use of stents to be brought together within the entire context of management of the conditions.

8. Implementation

A submission from Implementation is included in Appendix 3.

Based on the implementation submission, it appears that NICE guidance on using stents when PCI is performed is being adhered to.

9. Equality issues

There were no equality issues raised in the original guidance.

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Appendix 1 – explanation of options

When considering whether to review one of its Technology Appraisals NICE must select one of the options in the table below:

Options	**Consequence**	**Selected – 'Yes/No'**
A review of the guidance should be planned into the appraisal work programme.	A review of the appraisal will be planned into the NICE's work programme.	No
The decision to review the guidance should be deferred to [specify date or trial].	NICE will reconsider whether a review is necessary at the specified date.	No
A review of the guidance should be combined with a review of a related technology appraisal.	A review of the appraisal(s) will be planned into NICE's work programme as a Multiple Technology Appraisal, alongside the specified related technology.	No
A review of the guidance should be combined with a new technology appraisal that has recently been referred to NICE.	A review of the appraisal(s) will be planned into NICE's work programme as a Multiple Technology Appraisal, alongside the newly referred technology.	No
The guidance should be incorporated into an on-going clinical guideline.	The on-going guideline will include the recommendations of the technology appraisal. The technology appraisal will remain extant alongside the guideline. Normally it will also be recommended that the technology appraisal guidance is moved to the static list until such time as the clinical guideline is considered for review. This option has the effect of preserving the funding direction associated with a positive recommendation in a NICE technology appraisal.	No
The guidance should be updated in an on-going/forthcoming clinical guideline.	Responsibility for the updating the technology appraisal passes to the NICE Clinical Guidelines programme. Once the guideline is published the technology appraisal will be withdrawn. Note that this option does not preserve the funding direction associated with a positive recommendation in a NICE Technology Appraisal. However, if the recommendations are unchanged from the technology appraisal, the technology appraisal can be left in place (effectively the same as incorporation).	Yes

Options	Consequence	Selected – 'Yes/No'
The guidance should be transferred to the 'static guidance list'.	The guidance will remain in place, in its current form, unless NICE becomes aware of substantive information which would make it reconsider. Literature searches are carried out every 5 years to check whether any of the Appraisals on the static list should be flagged for review.	No

NICE would typically consider updating a technology appraisal in an ongoing guideline if the following criteria were met:

i. The technology falls within the scope of a clinical guideline (or public health guidance)

ii. There is no proposed change to an existing Patient Access Scheme or Flexible Pricing arrangement for the technology, or no new proposal(s) for such a scheme or arrangement

iii. There is no new evidence that is likely to lead to a significant change in the clinical and cost effectiveness of a treatment

iv. The treatment is well established and embedded in the NHS. Evidence that a treatment is not well established or embedded may include;

- Spending on a treatment for the indication which was the subject of the appraisal continues to rise
- There is evidence of unjustified variation across the country in access to a treatment
- There is plausible and verifiable information to suggest that the availability of the treatment is likely to suffer if the funding direction were removed
- The treatment is excluded from the Payment by Results tariff

v. Stakeholder opinion, expressed in response to review consultation, is broadly supportive of the proposal.

Appendix 2 – supporting information

Relevant Institute work

Published

Drug-eluting stents for the treatment of coronary artery disease Technology Appraisal TA152 Issued; July 2008 Reviewed: June 2012 Decision: to defer the review to allow for the results of clinical trials to be considered (estimated to be 2015).

Management of stable angina. Clinical Guideline CG126. Issued: July 2011. Anticipated review date: July 2014.

Unstable angina and NSTEMI: the early management of unstable angina and non-ST-segment-elevation myocardial infarction. Clinical Guideline CG94. Issued: March 2010. Expected review date: March 2013.

MI: secondary prevention: Secondary prevention in primary and secondary care for patients following a myocardial infarction. Clinical Guideline CG48. Published: May 2007. Recommended for update in February 2011.

SeQuent Please balloon catheter for in-stent coronary restenosis. Medical Technologies Guidance MTG1. Issued: February 2010.

Percutaneous laser coronary angioplasty. Interventional Procedure Guidance IPG378. Issued: January 2011.

Off-pump coronary artery bypass grafting. Interventional Procedure Guidance IPG377. Issued: January 2011.

Totally endoscopic robotically assisted coronary artery bypass grafting. Interventional Procedure Guidance IPG128. Issued: June 2005.

Myocardial infarction with ST-segment-elevation: the acute management of myocardial infarction with ST-segment-elevation. Clinical Guideline. Expected issue date: July 2013.

In progress

Technology Appraisal. Acute coronary syndrome - prasugrel with PCI (review TA182) [ID 648] Expected date of issue: August 2014

Technology Appraisal. Acute coronary syndrome - rivaroxaban [ID532] Referral date: May 2012 Expected date of issue: March 2015

Registered and unpublished trials

Trial name and registration number	Details
Coronary Artery Bypass Grafting Vs Drug Eluting Stent Percutaneous Coronary Angioplasty in the Treatment of Unprotected Left Main Stenosis (LeftMain/NOBLE) (NCT01496651)	Estimated Enrollment: 1200 Estimated Study Completion Date: December 2018
Bypass Surgery Versus Angioplasty Using Sirolimus-Eluting Stent in Patients With Left Main Coronary Artery Disease (PRECOMBAT) (NCT00422968)	Enrollment: 1454 Estimated Study Completion Date: September 2014
EXCEL Clinical Trial (NCT01205776)	Estimated Enrollment: 2600 Estimated Study Completion Date: December 2021

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Appendix 3 – Implementation submission

Review of NICE technology appraisal guidance No.71; Guidance on the use of coronary artery stents (recommendation 1.1 only)

Recommendation 1.1: stents should be used routinely where percutaneous coronary intervention (PCI) is the clinically appropriate procedure for patients with either stable or unstable angina or with acute myocardial infarction (MI).

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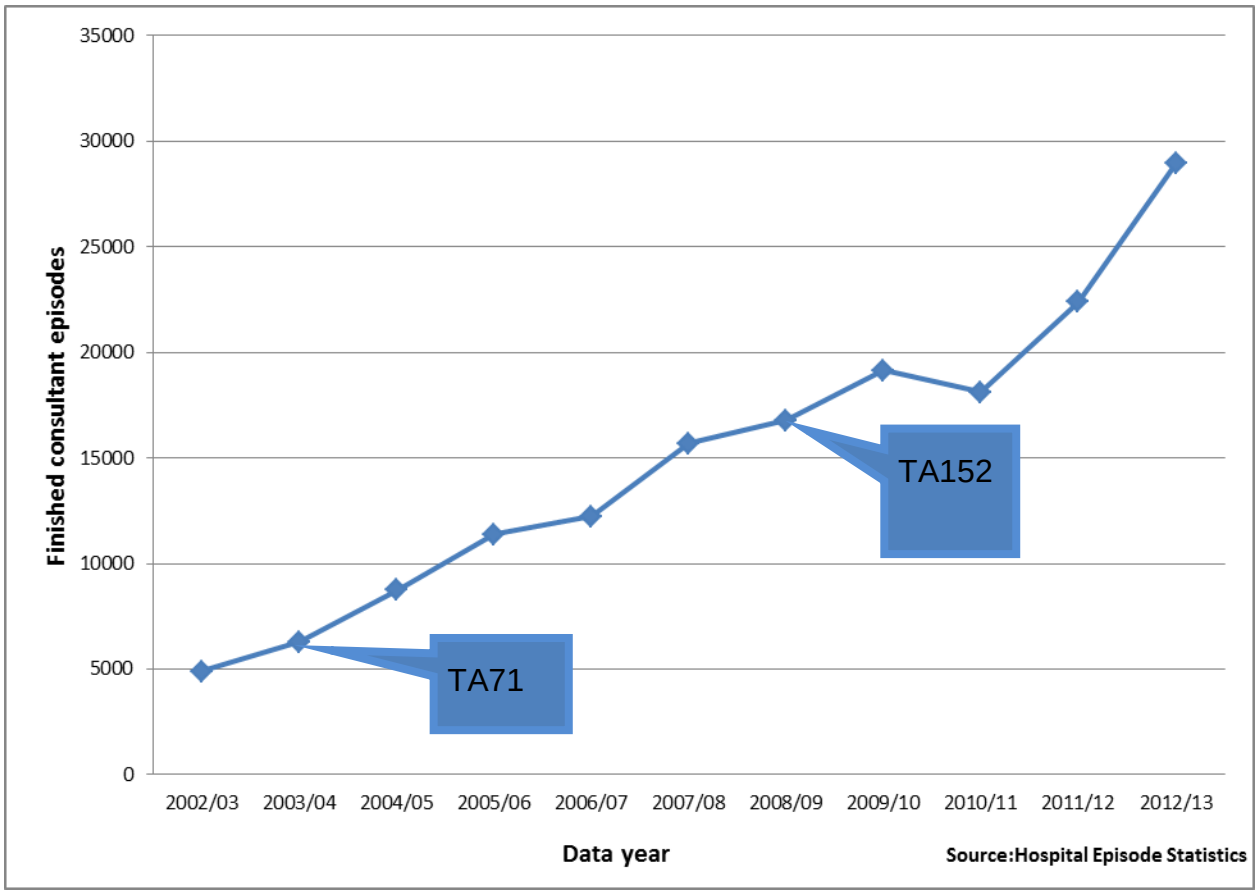
1. Routine healthcare activity data

1.1. Hospital Episode Statistics data

This section presents hospital episode statistics (HES) data for the number of finished consultant episodes with a primary diagnosis of angina or myocardial infarction (MI) and primary procedure of percutaneous transluminal balloon angioplasty and insertion of stent into coronary artery (see appendix B) conducted in England, between 2002/03 and 2012/13 (figure 1).

Figure 1: Number of finished consultant episodes with a primary diagnosis of angina or myocardial infarction (MI) and primary procedure of percutaneous transluminal balloon angioplasty and insertion of stent into coronary artery conducted in England



2. Implementation studies from published literature

Information is taken from the uptake database website.

2.1 The NHS Information Centre for Health and Social Care (2009) Audit of Angioplasty Procedures 2009

A UK wide audit performed by the British Cardiovascular Intervention Society (BCIS). Following concerns about the safety of drug eluting stents in September 2006, there was a fall in their use to 55 per cent across the UK. Data from 2008 suggest a gradual increase in their use now that safety issues are better understood. Research suggests that compliance with the NICE guidance would result in about 70 to 80 per cent of patients being treated with a drug eluting stent.

2.2 NHS Information Centre for Health and Social Care/ British Cardiovascular Intervention Society (2011) National audit of angioplasty procedures 2010

This audit aims to improve the care of patients who undergo percutaneous coronary intervention (PCI) procedures in the UK. Of 88 NHS PCI centres in the UK, all but 5 submitted data for procedures performed between 1st January and 31st December 2009. Results showed that overall use of stents remains high at 92%, with a gradual increase in the percentage of patients treated with drug eluting stents. In 2009 on average centres used drug eluting stents in 63.5% of cases.

2.3 National Institute for Cardiovascular Outcomes Research, University College London (2012) National Audit of Percutaneous Coronary Interventional Procedures: Annual Report 2011

This 2010 audit on Percutaneous Coronary Interventional Procedures (PCIs) included data submitted by 94 of 97 NHS PCI centres and 6 of 17 private hospitals in the UK. A total of 87,676 PCIs were performed, of which the results found that 92% involved stent insertion, as recommended by NICE for patients with angina or with acute myocardial infarction. It was noted that there has been a gradual increase in the percentage of patients treated with drug eluting stents.

2.4 National Institute for Cardiovascular Outcomes Research, University College London (2013) National Audit of Percutaneous Coronary Interventional Procedures: Annual Public Report January 2011 - December 2011

This 2011 UK audit on Percutaneous Coronary Interventional Procedures (PCIs) included data from 97/99 NHS PCI centres and 7/18 private hospitals. A total of 88,692 PCIs were performed, of which 92% involved stent insertion. Following concerns about the safety of drug eluting stents in September 2006, there was a fall in use to 55% across the UK. Data from 2011 suggest an increase in use (71%) now that safety issues are better understood. However there are large differences in usage across the UK.

2.5 Health and Social Care Information Centre (2013) NICE Technology Appraisals in the NHS in England 2012; Experimental Statistics - Innovation Scorecard

This experimental report presents data in the format of an interactive reporting spreadsheet, attempting to assess compliance with NICE TAs by NHS organisations. A total of 121 TAs are included, covering 88 medicines and 6 medical device technologies. For medicines, this Scorecard reports on the calendar year 2012 and considers medicines recommended before July 2012. The report describes data currently available and the limitations in using this data to assess compliance.

2.6 MINAP (2013) Myocardial Ischaemia National Audit Project: How the NHS cares for patients with heart attack. Annual Public Report April 2012 - March 2013

This 12th annual MINAP Public Report presents analyses from all hospitals and ambulance services in England, Wales and Belfast, that provided care for patients with suspected heart attack in 2012/13. Results found the proportion of all MINAP heart attack patients that received primary percutaneous coronary intervention (PCI) was 72% in England, and in Wales was 55%. Use of secondary prevention medication at discharge continues to exceed the national standards at 95%.

2.7 The NHS Information Centre for Health and Social Care (2009) Angioplasty and Stents to treat Coronary Artery Disease: The 2008 report of the National Audit of Percutaneous Coronary Intervention in the United Kingdom

he number of PCI centres in the UK was 1,269 per million population (pmp). The audit found that the great majority of procedures undertaken now involve stent insertion (95%) suggesting that this aspect of good practice is being met in line with NICE guidance. The audit found a fall in the use of drug-eluting stents to 55% across the UK following safety concerns. These concerns are now resolved and early data from 2008 suggests a return to usage levels in line with NICE guidance.

2.8 Dr Foster (2007) How healthy is your hospital?

Dr Foster asked NHS Trusts whether they followed NICE guidelines on the use of drug eluting stents. On average, 54% of trusts reported that they did. Regional variation is still considerable: only 24% of hospitals in the North West are likely to adhere to NICE guidelines about the use of drug eluting stents as opposed to 75% in south central.

2.9 Dr Foster Intelligence (2013) Fit for the future? Dr Foster Hospital Guide 2012

Dr Foster aims to help healthcare organisations improve their quality and efficiency by developing performance matrix for every hospital trust in England. This report shows variation in treatment levels within trusts according to age. Examples include: the rate of Percutaneous Coronary Intervention (PCI) treatment for aged 75 and older ranging from 65% to zero; and that 1/34 women aged over 75 has a breast reconstruction following a mastectomy compared with 2/3 women aged under 75.

3. Qualitative input from the field team

The implementation field team have recorded the following feedback in relation to this technology appraisal. It should be noted the feedback recorded below was recorded between 2006 and 2009, it is likely some of the comments will be in relation to TA152 (July 2008) - Coronary artery disease - drug-eluting stents, which replaced recommendations 1.2 – 1.4 of TA71.

- One organisation advised that they only use one type of non-eluting stents and pay one negotiated price so may find it contractually difficult to move away from this approach at present. The IC noted that this is a common finding across a number of trusts. Another trust suggested that procurement prices can affect cost effectiveness on some topics such as stents, and requested a 'cost calculator' be provided by NICE that showed the price needed for good value.

- One person suggested that NICE look at the evidence around stents, and ascertains whether or not the move from major cardiac surgery to radiologists undertaking procedures was clinically and cost effective. They also questioned whether there was evidence to suggest that the move from major invasive surgery to laparoscopic surgery was cost effective in view of the training and resource requirement.

- Two people from one organisation expressed criticism of individual pieces of guidance which included aortic stents.

- One trust (2006) reported hearing about issues with adverse incidents with drug eluting stents.

Appendix A: Healthcare activity data definitions

Hospital Episode Statistics (HES)

Hospital Episode Statistics (HES) are the national statistical data warehouse for England of the care provided by NHS hospitals and for NHS hospital patients treated elsewhere. HES are the data source for a wide range of healthcare analysis. It contains admitted patient care data from 1989 onwards.

The HES Interrogation System is an online version of the data. The NHS Information Centre maintains the system.

Finished Consultant Episode (FCE): The FCE is a period of admitted patient care under one consultant within one healthcare provider. The figures do not represent the number of patients, as a person may have more than one episode of care within the year.

Main operation: The main operation is the first recorded operation in the HES data set and is usually the most resource intensive procedure performed during the episode.

Secondary operation: As well as the main operative procedure, there are up to 19 secondary operation fields in Hospital Episode Statistics (HES) that show secondary or additional procedures performed on the patient during the episode of care.

Appendix B

It should be noted that the diagnosis and procedure codes used in this document have been sourced by the data analyst. While the coding is believed to be correct, to ensure they meet current national clinical coding/classification standards the NHS Classifications Service (National Clinical Classifications Helpdesk) should be consulted.

Diagnosis codes

Stable or unstable angina or acute myocardial infarction (MI) has been defined using the following ICD-10 procedure codes (table 1).

Table 1: ICD-10 procedure codes

Description	ICD-10 Code
Angina pectoris	I20
Acute myocardial infarction	I21
Subsequent myocardial infarction	I22

Procedure codes

Percutaneous transluminal balloon angioplasty and insertion of stent into coronary artery has been defined using OPCS4.2 – OPCS4.5 procedure codes (table 2).

Table 2: OPCS4 procedure codes for percutaneous transluminal balloon angioplasty and insertion of stent into coronary artery

OPCS4.2 Code	OPCS4.3 Code	OPCS4.4 Code	OPCS4.5 Code	OPCS4.6 Code	Description
(K49.1 + Y02.2) or (K49.2 + Y02.2)	K75.1	K75.1	K75.1	K75.1	Percutaneous transluminal balloon angioplasty and insertion of 1-2 drug-eluting stents into coronary artery
(K49.1 + Y02.2) or (K49.2 + Y02.2)	K75.2	K75.2	K75.2	K75.2	Percutaneous transluminal balloon angioplasty and insertion of 3 or more drug-eluting stents into

					coronary artery
(K49.1 + Y02.2) or (K49.2 + Y02.2)	K75.3	K75.3	K75.3	K75.3	Percutaneous transluminal balloon angioplasty and insertion of 1-2 stents into coronary artery
(K49.1 + Y02.2) or (K49.2 + Y02.2)	K75.4	K75.4	K75.4	K75.4	Percutaneous transluminal balloon angioplasty and insertion of 3 or more stents into coronary artery NEC
K49.8 + Y02.2	K75.8	K75.8	K75.8	K75.8	Other specified percutaneous transluminal balloon angioplasty and insertion of stent into coronary artery
K49.9 + Y02.2	K75.9	K75.9	K75.9	K75.9	Unspecified percutaneous transluminal balloon angioplasty and insertion of stent into coronary artery

Data for the period 2002/03 – 2005/06 were coded using OPCS4.2 procedure codes, these have been defined in this document as K49*+ Y02.2. From April 2006 onwards OPCS4.3 or above procedure codes were used, these have been defined in this document as K75*, the description of the K75* codes are included in table 2. The changes in clinical coding may have had an impact on data quality during that period.

[1] The Dept. of Health/National Assembly for Wales remit to the Institute is “As part of the planned review of guidance on coronary artery stents, to appraise the clinical and cost effectiveness of drug eluting stents compared with conventional stents for the primary prevention of restenosis following PTCA."