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A comparison of hospital episode statistics and traditional methods to identify outcomes in a randomized trial; a sub-study of HEAT-PPCI

Sarah R. Blake[1], Claire Roome[2], Adeel Shahzad[3], Ian Kemp[1], Christine Mars[1], Keith Wilson[1], Rod H. Stables[1]

[1]Institute of Cardiovascular Medicine and Science, Liverpool Heart and Chest Hospital, Thomas Drive, Liverpool L14 3PE, UK
[2]John Radcliffe Hospital, Headley Way, Headington, Oxford OX3 9DU, UK
[3]Manchester University NHS Foundation Trust, Southmoor Rd, Wythenshawe, Manchester M23 9LT, UK
Address correspondence to Sarah R. Blake, E-mail: sarahblake@outlook.com

ABSTRACT

Background This study aims to compare information from hospital episode statistics (HES) and traditional direct patient contact to identify readmission and clinical events in the follow-up of a randomized controlled trial (RCT).

Methods The study followed 1812 patients for 28 days using direct contact (DC). In addition, we obtained HES for this period. We examined medical records for all suspected readmissions and determined confirmed events by adjudication. We compared the ability of the individual DC and HES methods to determine readmission and the occurrence of trial-specific events, confirmed at adjudication.

Results In the ascertainment of readmission, compared to DC, HES demonstrated a trend towards better sensitivity (identifying 153/166 = 92.2% versus 144/166 = 86.7%; difference = 5.4%, 95% CI: 0.1–11.5%) and better specificity (1492/1492 = 100% versus 1426/1492 = 95.5%; difference = 4.4%, 95% CI: 4.2–5.6%).

An examination of HES coding does not identify rates for specific events that match those from adjudication, with limitations in both sensitivity and specificity.

Conclusion HES is effective in the ascertainment of readmission and is a useful tool in follow-up. Information from HES provides a reflection of a patient's course and associated cost, as perceived by the healthcare system. Future studies could modify outcome definitions to reflect episode coding.

Keywords cardiology intervention, hospital episode statistics, primary percutaneous coronary intervention, randomized controlled trials, trial follow up

Introduction

Loss to follow-up can compromise the external and internal validity of a trial. Traditional methods of follow-up are often expensive and time-consuming, involving direct contact with each study participant over a prolonged period. The use of novel methods of trial follow-up, such as electronic databases, may reduce the cost, avoid loss to follow-up and be more convenient for research staff and patients. Hospital episode statistics (HES) is a centralized database containing information for all patient care delivered in England in NHS facilities. HES is compiled from the coding data received from NHS trusts. Each episode of care is identified from the patients' hospital notes and recorded as a series of diagnostic codes taken from International Classification of Diseases 10th Revision (ICD-10). Each code in HES is

Sarah R. Blake, Cardiology Research Fellow
Claire Roome, Paediatric Speciality Registrar
Adeel Shahzad, Consultant Cardiologist
Ian Kemp, Research Nurse
Christine Mars, Research Nurse
Keith Wilson, Patient Ambassador
Rod H. Stables, Consultant Cardiologist

associated with a tariff that determines how much the hospital is paid per admission.

The objective of this study was to use the data from the HEAT-PPCI trial (How Effective are Antithrombotic Therapies in Primary Percutaneous Coronary Intervention) to compare ability of the individual DC and HES methods to determine the incidence of confirmed readmission.[1] A second objective was to compare the ability of HES data to identify the occurrence of trial-specific events declared by adjudication.

Methods

Patients and study design

HEAT-PPCI was a single-centre, randomized controlled trial comparing unfractionated heparin versus bivalirudin in the treatment of patients with suspected ST-elevation myocardial infarction (STEMI). Recruitment took place from 7 February 2012 to 20 November 2013 and 1812 participants were included in the HEAT-PPCI final analysis. Participants were tracked during their index admission for clinical events, by careful review of case notes, and followed up for 28 days following randomization.

The primary objective of follow-up in HEAT-PPCI was to establish vital status and the occurrence of any pre-specified outcome measures. This involved identifying all overnight admissions during the follow-up period and was achieved by direct patient contact (DC) at 4–6 weeks following randomization. The method of contact used was recorded for all patients (Fig. 1). In addition, HES reports were examined for each patient to supplement the information obtained by DC. Suspected readmission events identified by either DC or HES data were then confirmed by review of the medical notes.

Method of assessing the accuracy of DC and HES in identifying readmissions

Patients who had a HES report and responded to direct contact were included in this analysis. The number of readmissions determined by the individual DC and HES methods were then compared to the total number of readmissions confirmed by the medical notes. When evaluating DC, if a readmission was not identified by DC but was identified by HES and subsequently confirmed by medical notes review, this was recorded as a false negative result. When evaluating the HES data, if a readmission was identified in the HES data but not confirmed by medical notes review, this was recorded as a false positive result. If a readmission was not identified by HES but was identified by DC and subsequently confirmed by medical notes review, this was recorded as a false negative result. From these data we could then calculate the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of each method.

Method of assessing the diagnostic accuracy of HES data

The primary efficacy outcome of the HEAT-PPCI trial was the proportion of patients who had at least one major adverse cardiovascular event (MACE) at 28 days. MACE included all-cause mortality, cerebrovascular accident (CVA), reinfarction or additional unplanned target lesion revascularisation. The primary safety outcome was the proportion of patients who had a major bleed by 28 days, classified as types 3–5 according to the Bleeding Academic Research Consortium (BARC).[1] Key clinical information from each patient was reviewed by a blinded physician adjudication panel. This panel would then establish if outcome events had occurred in terms of the specific event definitions declared in the trial protocol.

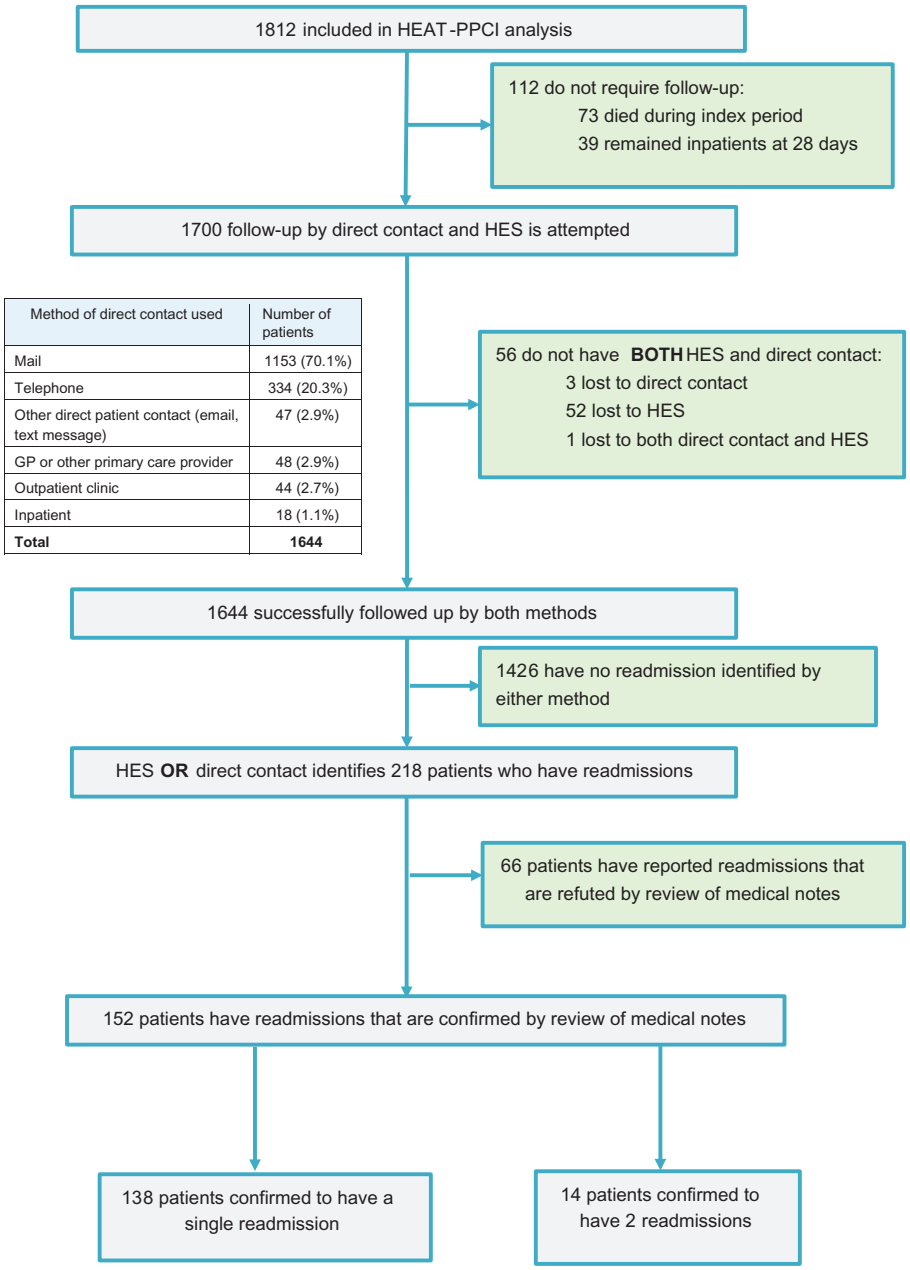
The HES data obtained for the 28 days following randomization was examined to identify ICD-10 codes that indicated the occurrence of any primary efficacy or safety outcome pre-specified in the HEAT-PPCI trial. All patients who were randomized and for whom HES data were obtained were included in this analysis. To identify key clinical events, the relevant ICD-10 codes were used to search the HES database (see Table 1 in online supplemental material). The events identified in the HES data were compared with those declared by physician adjudication. If a diagnosis was identified in HES that was not identified by physician adjudication, this was recorded as a false positive result. If a diagnosis was not identified in HES but was identified by physician adjudication, this was recorded as a false negative result.

Results

Identifying readmissions

The HEAT-PPCI trial included 1812 patients. Following randomization, 73 patients died in hospital before they were discharged from the index event and 39 participants remained inpatients at 28 days. Of the remaining 1700 with the potential to be re-admitted during the 28-day follow-up period, 1644/1700 = 96.7% were successfully followed up by both DC and HES (Fig. 1).

The full results of the analysis of readmissions are presented in Table 1. HES identified 153/166 of confirmed readmissions (Sensitivity: 153/166 = 92.2%; 95% CI: 87.1–95.4%). HES missed 13 confirmed readmissions. All



Method of direct contact used	Number of patients
Mail	1153 (70.1%)
Telephone	334 (20.3%)
Other direct patient contact (email, text message)	47 (2.9%)
GP or other primary care provider	48 (2.9%)
Outpatient clinic	44 (2.7%)
Inpatient	18 (1.1%)
Total	**1644**

Fig. 1 Flow diagram outlining the follow up obtained by direct contact and HES methodology for identifying readmissions. HES = Hospital Episode Statistics.

readmissions identified by HES were confirmed readmissions (specificity: 1492/1492 = 100%; 95% CI: 99.7–100). During the follow-up period, 14 patients experienced 2 confirmed readmissions and 28/28 = 100% of these were identified in HES.

DC identified 144/166 confirmed readmissions (Sensitivity: 144/166 = 86.7%; 95% CI: 80.7–91.1) and missed 22 confirmed readmissions. DC identified 66 suspected readmissions that were not found to be confirmed readmissions (specificity: 95.6%; 95% CI: 94.4–96.5). DC identified 16/28 readmissions in patients found to have 2 confirmed readmissions.

Identifying clinical events

Evaluable HES data were obtained for 1754 patients. Figure 2 describes the reasons why these data were not obtained for other trial subjects. The full results for this analysis are presented in Table 2.

Table 1 The readmissions confirmed by adjudication in the HEAT-PPCI trial are compared to the HES method and the direct contact method of identifying readmissions

	Outcome from physician adjudication		*Sensitivity (CI)*	*Specificity (CI)*	*PPV (CI)*	*NPV (CI)*
	Readmission	No readmission				
HES detects readmission	153	0				
HES does not detect readmission	13	1492	92.2 (87.1–95.4)	100 (99.7–100)	100 (97.6–100)	99.1 (98.5–99.5)
	Readmission	No readmission				
DC detects readmission	144	66				
DC does not detect readmission	22	1426	86.7 (80.7–91.1)	95.6 (94.4–96.5)	68.6 (62.0–74.5)	98.5 (97.7–98.9)

HES = Hospital Episode Statistics; DC = direct contact; CI = 95% confidence interval; PPV = positive predictive value; NPV = negative predictive value.

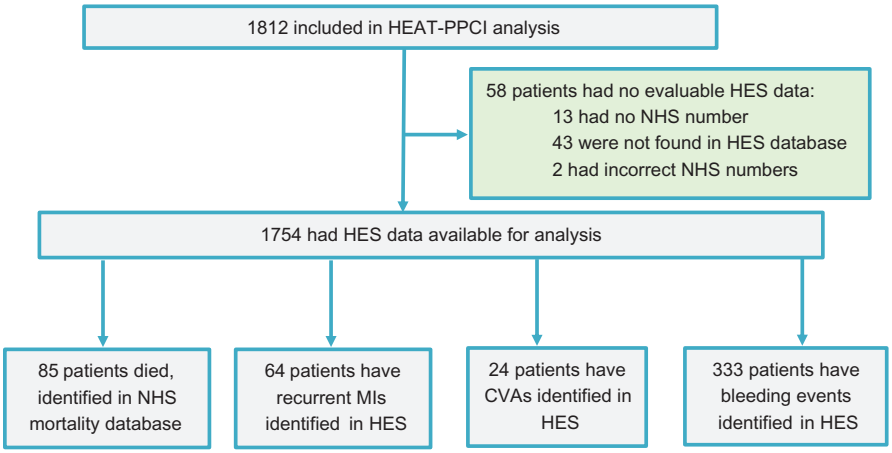


Fig. 2 Flow diagram outlining the number of patients who were identified by HES as having a clinical event in the 28 days following randomization. HES = Hospital Episode Statistics; MI = myocardial infarction; CVA = cerebrovascular accident.

During the index admission, HES correctly identified 1/29 = 3.4% (95% CI: 0.6–17.2) of the recurrent MIs, 16/22 = 72.7% (95% CI: 51.8–86.8) CVAs and 143/222 = 64.6% (95% CI: 57.9–70.4) bleeding events. HES identified 15 recurrent MIs, 1 CVA and 175 bleeding events that were not confirmed by adjudication.

Following discharge, HES identified 2/3 = 66.7% (95% CI: 20.8–93.9) of recurrent MIs, 4/5 = 80.0% (95% CI: 37.6–96.3) CVAs and 15/31 = 48.4% (95% CI: 31.9–65.2) bleeding events. HES incorrectly identified 46 recurrent MIs, 8 CVAs and 7 bleeding events that were not confirmed on adjudication.

Discussion

Main findings of this study

HES and DC are both effective methods of ascertaining readmission in a clinical trial. Our results show that the most comprehensive information was obtained when both methods were used together. Compared to DC, HES demonstrated a trend towards better sensitivity and specificity. An analysis of HES coding does not result in rates for specific events that match those from adjudication, with limitations in both sensitivity and specificity.

What is already known on this topic

A recent study showed that the use of HES data in research has increased from 1 publication in 1996 to a total of 520 publications by 2014.[2] This trend may be due to advantages in using HES over more traditional methods of data collection. For instance, HES captures all events, diagnoses and procedures as perceived by the health service. It records what 'the system says has occurred' during a hospital admission. This information may better reflect the true societal impact, both clinical and fiscal, of the outcomes of trial patients. A study looking at the accuracy of using HES data to calculate inpatient

Table 2 The diagnostic accuracy of the HES data in identifying patients with outcome events during the index admission and in any readmission in the follow-up period is compared to the standard provided by the adjudicated events. By assuming the adjudicated events are accurate, the sensitivity and specificity of each method can be calculated

	Outcome from Physician Adjudication		*Sensitivity (CI)*	*Specificity (CI)*	*PPV (CI)*	*NPV (CI)*
No. of patients with event before discharge	Recurrent MI	No recurrent MI				
HES detects recurrent MI	1	15				
HES does not detect recurrent MI	28	1710	3.4 (0.6–17.2)	99.1 (98.6–99.5)	6.2 (1.1–28.3)	98.3 (97.7–98.9)
	CVA	No CVA				
HES detects CVA	16	1				
HES does not detect CVA	6	1731	72.7 (51.8–86.8)	99.9 (99.7–99.9)	94.1 (73.0–98.9)	99.7 (99.2–99.8)
	Bleed	No bleed				
HES detects bleeding	143	175				
HES does not detect bleeding	79	1357	64.6 (57.9–70.4)	88.6 (86.7–90.0)	44.9 (39.6–50.5)	94.4 (93.2–95.6)
No. of patients with events after discharge						
	Recurrent MI	No recurrent MI				
HES detects recurrent MI	2	46				
HES does not detect recurrent MI	1	1705	66.7 (20.8–93.9)	97.4 (96.5–98.0)	4.2 (1.2–13.9)	99.9 (99.7–100)
	CVA	No CVA				
HES detects CVA	4	8				
HES does not detect CVA	1	1741	80.0 (37.6–96.4)	99.5 (99.1–99.8)	33.3 (13.8–60.9)	99.9 (99.7–100)
	Bleed	No bleeding				
HES detects bleeding	15	7				
HES does not detect bleeding	16	1716	48.4 (32.0–65.2)	99.6 (99.2–99.8)	68.2 (47.3–83.6)	99.1 (98.5–99.4)

HES = Hospital Episode Statistics; DC = direct contact; CI = 95% confidence interval; PPV = positive predictive value; NPV = negative predictive value; CVA = cerebrovascular accident; MI = myocardial infarction.

costs found that data from HES was accurate when compared to data collected from medical notes review.[3] The mean difference in costs between the two methods was £899 with HES calculating 8% lower costs than medical records. HES data could, therefore, be useful in trials aiming to analyse the economic impact of treatments. Traditional trial follow-up pre-specifies the definitions of a clinical event using thresholds for confirming a diagnosis. This selective approach may not accurately reflect the patient experience or cost to the health service. A recent study looked at the non-fatal/non-MACE adverse events in a trial comparing percutaneous coronary intervention (PCI) to coronary artery bypass graft (CABG) in patients with 2 or 3-vessel coronary artery disease.[4] The results showed that CABG was associated with a greater number of non-MACE events despite the original trial publication favouring CABG because of a lower number of MACE adverse events.[5] MACE are commonly used as the primary outcome measures in trials of cardiovascular interventions. Since HES identifies any hospital admission, these data could be used in trials wishing to examine the broader physical and psychological impact of admission.

The accuracy of HES data may vary over time between institutions and is dependent on the quality of the clinical coding performed by each NHS trust. In 2013-14 an audit was performed of the clinical coding at 50 acute trusts assessing the accuracy of the ICD-10 codes allocated to each admission. The average error rate, defined as a change to the codes that would results in a change in the payment received by each trust, was 7%.[6] The lowest percentage error for a given trust was 1.1% and the highest 45.8%, demonstrating considerable variability in the accuracy of clinical coding across trusts. A systematic review performed in 2013 looked at studies of the accuracy of HES data when compared to clinical registries and case notes.[7] Although there is no consensus for an acceptable threshold of diagnostic accuracy, the median accuracy of the HES diagnostic codes was 80.3% when compared to notes review or clinical registry data.[8] This review also found that there has been an improvement in the diagnostic accuracy of HES data over time. A recent study by Wright-Hughes *et al.*,[9] assessing the accuracy of HES data in a trial investigating self-harm in adolescents found that HES identified more than double the

number of hospital attendances that were recorded by researchers. In addition, HES identified only 62% of self-harm diagnoses reported by researchers. This study concluded that HES data are useful in identifying hospital admissions but less accurate in identifying trial-specific clinical diagnoses.

What this study adds

In our study, 153/153 = 100% of the readmissions identified by HES were confirmed by medical notes review. In comparison, 66/210 = 31.4% of readmissions were identified incorrectly by DC. Using HES data remove the need to directly contact any trial patient and is likely to reduce the workload of a trial and subsequently the overall cost. When a patient reports a clinical event or readmission, this is thoroughly investigated by the research team, who must review the medical notes to confirm or refute the claim. If HES data are used, the reduction in workload may allow trial centres to divert resources from follow-up to trial recruitment activity.

This study showed that accuracy of HES in identifying clinical events is limited, in terms of the specific diagnostic thresholds that are the norm in clinical trials. The highly specific trial definitions of clinical outcomes in the HEAT-PPCI trial were not developed to be comparable to the ICD-10 codes used in HES. Therefore, the frequency of clinical events identified in HES is likely to differ when compared to physician adjudicated events. For instance, we were unable to stratify bleeding events into degrees of severity because this is not specified in any ICD-10 code. Therefore, regardless of severity, all bleeds were flagged as events. This demonstrates the limitations related to the number and complexity of diagnoses included in the ICD-10. For researchers planning to use HES in a clinical trial, one solution would be to tailor clinical outcomes to specific ICD-10 diagnoses. This would ensure that the pre-specified outcome measure can be identified in the HES database.

We were unable to perform analyses for the outcomes of unplanned target lesion revascularisation because we could not apply the usual range of trial qualifiers to the outcome of additional revascularisation. For example, the ICD-10 codes do not distinguish between planned and unplanned revascularisation. A possible solution would be to ensure future treatment intentions are recorded on the clinical record form of each patient following the index event. This information could then be used with the HES database to establish if further intervention was planned or unplanned.

HES data only reports admissions that occur in hospitals in England. Of the 14 false negative readmission events, 2 occurred outside this area. This limits the usefulness of HES data in tracking patients who move outside of England, or those who are admitted to hospitals when abroad. One solution would be to limit study inclusion to those with NHS numbers who are resident in England. However, this limits the recruitment and ability to generalize the results of the study and does not solve the issue of patients who are admitted to hospitals abroad or who live on the border of England and another UK home nation or the Republic of Ireland. There is an equivalent of HES data for Wales and Scotland, which also use ICD-10 codes and should be used in addition to the English HES database.

The use of the NHS number as an identifier is useful in trials with lengthy follow-up because the NHS number remains the same even if a patient moves or changes their name or phone number. However, patients without an NHS number will be missed. In this study, 58/1812 = 3.2% of patients did not return any data in the HES database. There were 13/58 = 22.4% patients who did not have an NHS number and an error was found in the NHS number of 2/58 = 3.4%, so the HES database could not identify these patients. This error could be reduced by using a simple check digit code to ensure all NHS numbers are correct at the time of original recruitment. Using more meticulous methods of checking and rechecking the NHS number by the study team would also reduce errors.

Limitations of this study

This study reported very small numbers of clinical events prompting readmission following the index event. For example, only five strokes occurred after the index admission. It is therefore impossible to draw conclusions from such numbers. This study assessed identification of recurrent MI, CVAs and bleeding events. Our assessment of the diagnostic accuracy of HES data is therefore limited to a small number of ICD-10 codes. This limits the generalizability of our results to studies looking at similar outcome measures. More studies should be performed to assess the accuracy of HES data across a wider range of diagnostic codes.

Data from medical notes and physician adjudication were used to confirm the occurrence of a readmission or clinical event. We, therefore, had to assume that the medical notes are accurate and complete. Any errors or omissions in the medical notes would have affected our results.

The adjudication seeks to ensure events are declared to match trial definitions. These may be different from 'normal' clinical definitions and from the definitions used to code diagnoses in HES. Therefore, when using the same clinical

information, there may be differences in the numbers of outcomes reported by each, creating perceived errors in the HES data.

Suspected readmissions identified by DC and HES were subsequently confirmed or refuted by medical notes review. For confirmation to occur, the suspected readmission had to be initially identified by either DC or HES. Therefore, any readmissions missed by both DC and HES would not have been identified in the HEAT-PPCI trial follow-up. To ensure all readmission events were identified, without using DC or HES, the medical notes of every patient in the HEAT-PPCI trial would have to be reviewed which was beyond the resources of this study.

Conclusion

A combination of HES and direct contact provides a comprehensive method of follow-up superior to either method alone. Using HES may reduce the resource burden and cost of follow-up in clinical studies. HES cannot accurately identify outcome measure events to match specific trial definitions tested by independent adjudication. However, the numbers of clinical events in this analysis are too small to draw definite conclusions about the accuracy of HES data when used for this purpose. A HES-based approach may also provide information about the general patient experience and total healthcare costs of a trial. Using HES may support patient recruitment and the completeness of follow-up by reducing the workload for both investigators and patients.

Supplementary data

Supplementary data are available at the *Journal of Public Health* online.

Role of the funding source

The HEAT-PPCI trial was partially funded by unrestricted grants from The Medicines Company and AstraZeneca but these companies were not involved in any aspect of trial design, conduct or reporting.

Conflict of interest

RHS reports grants from The Medicines Company and grants and personal fees from AstraZeneca during the conduct of the study. All other authors declare no competing interests.

Contributors

SRB reviewed the initial HES data, identified the inconsistencies and refined the data, designed and performed the final analysis, and drafted the manuscript. CR acquired and performed initial analysis of the HES download. AS was principle investigator for HEAT-PPCI trial. IK designed the HEAT database. CR, AS, IK, CM and KW were active in clinical conduct and follow-up of patients in the HEAT-PPCI trial. KW acted as the patient representative for trial conduct. RHS was the senior investigator for HEAT-PPCI and suggested the HES analysis concept. CR, AS, IK, CM, KW and RHS reviewed the article.

Ethical approval

The HEAT-PCI trial received full ethical approval and is registered on clinicaltrials.gov (see link below). This substudy used Hospital Episode Statistics data that were obtained as part of the HEAT-PPCI study. No new data were obtained during this study and no patients contacted or affected by the study.

Data sharing statement

Participants gave informed consent for data sharing when recruited into the HEAT-PPCI trial. The presented data are anonymised, and no identifiable data has been included in the article.

HEAT PPCI Trial registration

ClinicalTrials.gov number NCT01519518.

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