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Title  Impact of hospital proportion and volume on primary PCI performance in England and Wales.

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Abstract

Aims: To quantify the determinants of primary PCI performance in England and Wales between 2004 and 2007.

Methods and results: All 8,653 primary PCI cases admitted to acute hospitals in England and Wales as recorded in the Myocardial Ischaemia National Audit Project (MINAP) 2004–7. We studied the impact of the volume of primary PCI cases (hospital volume) on DTB times and the proportion of patients treated with primary PCI (hospital proportion) on 30-day mortality and employed regression analysis to identify reasons for DTB time variations with a multilevel component to express hospital variation. The proportion of patients receiving pPCI increased from 5% in 2004 to 20% in 2007. Median DTB times reduced from 84 minutes in 2004 to 61 minutes in 2007. Median DTB times decreased as the number of pPCI procedures increased. The 30-day all cause mortality rate, 95% CI for hospitals that performed pPCI for less than 25% of STEMI patients was significantly higher than those that performed pPCI for greater than 75% (5.0%, 3.9% to 6.1% versus 2.7%, 2.0% to 3.5%). Time-of-day, year of admission, sex and diabetes significantly influenced DTB times. Hospital variation was evident by a hospital-level DTB time standard deviation of 12 minutes.

Conclusions: There was large variation in DTB times between the best and worst performing hospitals. Although patient-related factors impact upon DTB times, volume and proportion of patients undergoing primary PCI significantly influence
delay and early mortality - hospitals with the highest proportion of primary PCI had the lowest mortality.

**Key words:** Primary PCI; STEMI; door-to-balloon time; mortality; hospital volume; hospital proportion.
Introduction

The benefits of primary PCI diminish if there are delays to revascularisation of the infarct-related artery \(^1-^4\); longer revascularisation times are associated with increased in-hospital mortality \(^5-^7\). Hospital-level influences account for up to a third of the ‘total ischaemic time’ and incorporate many factors, including the availability of a skilled catheterisation laboratory team (specialist centre effect); the number of patients treated (hospital volume effect) and patient–level factors \(^7-^15\).

Earlier studies revealed that lower volume primary PCI centers conferred elevated mortality \(^9,^11,^15,^17\). Recently, however, this has been debated \(^12,^17\) with evidence from the National Registry of Myocardial Infarction to suggest that a greater level of hospital ‘specialisation’ was associated with reduced in-hospital mortality \(^12\). Indeed, integrated systems of care that redirect ST-elevation myocardial infarction (STEMI) patients to higher volume, higher ‘specialisation’ interventional centres (where greater proportions of STEMI cases undergo primary PCI) may offer improved outcomes beyond the length of the hospital admission. Currently such ‘Heart Attack Centers’ do not exist in England and Wales although there is a strategy to provide a national primary PCI service for STEMI, by 2012 \(^18\). This study therefore aimed to quantify the determinants of primary PCI performance for STEMI patients in England and Wales during the period 2004–2007, and to investigate the impact of hospital reperfusion strategies on primary PCI performance.
Methods

Study design

The analyses were based on data from the Myocardial Ischaemia National Audit Project (MINAP) whose national database was established in 1999 to examine the quality of management of acute myocardial infarction in England and Wales and to meet the audit requirements of the National Service Framework for coronary heart disease\(^\text{19}\). MINAP has been long established as a vehicle for evaluating service provision especially regarding call-to-needle (CTN) and door-to-needle (DTN) times for thrombolysis \(^\text{20-22}\). This clinical database collects patient data from all acute hospitals in England and Wales \(^\text{23-25}\).

Data for patients admitted with an acute coronary syndrome (ACS) are collected prospectively at each acute hospital by a secure electronic system, developed by the Central Cardiac Audit Database (CCAD), electronically encrypted and transferred online to a central database \(^\text{26}\). CCAD is part of the National Clinical Audit Support Programme (NCASP) \(^\text{27}\) which is part of the National Health Service (NHS) Information Centre for Health and Social Care \(^\text{28}\). MINAP is overseen by a multi-professional steering group representing the stakeholders and is based at the National Institute for Clinical Outcomes Research (NICOR) at University College London \(^\text{23}\).

Each patient entry offers details of the patient journey, including the method and timing of admission, in-patient investigations, treatment, and date of all cause death
(from linkage to the UK Statistics Authority using a unique NHS number). Data entry is subject to routine on-line error checking. There is a mandatory annual data validation exercise for each hospital 20.

Analogous to the annual national audit of thrombolysis times20, primary PCI performance is evaluated using times to reperfusion. In 2009, the call to balloon (CTB) time was adopted by the NHS Information Centre for Health and Social Care as a new indicator of quality improvement for acute care 29. Our study specifically focuses on hospital performance and therefore analyses are based upon the door to balloon time (DTB), akin to the door-to-needle time for thrombolysis. The DTB time is a hospital-based performance indicator30,31 and is defined as the difference between the time of arrival of the ambulance to the first hospital and the time of first balloon inflation (the accident and emergency time is taken if the patient self presents to hospital).

Cohort description

The MINAP cohort comprised 324,083 independent ACS events admitted to acute hospitals in England and Wales between 1st January 2004 and 31st December 2007. Of these, there were 71,995 patients with an initial diagnosis of STEMI.

Statistical methods

The population was described by unadjusted numbers, percentages with 95% confidence intervals with respect to discrete data, and by medians and interquartile range or mean ±1.96 SD for continuous variables. Pearson’s chi-squared test was used to determine whether there was a significant difference between the expected
frequencies and the observed frequencies in one or more categories. The Mann–Whitney $U$ test was used to assess whether two independent samples arose from the same distribution. The time of admission was divided into ‘day’ and ‘night’ with day defined as 08:00 until 20:00. Temporal data were smoothed using a LOESS algorithm.

To account for variations at the hospital level, a linear mixed-effects regression model was used to model the relationship between DTB times and age, year of admission, time-of-arrival (day or night), diabetic status, hospital proportion of cases, and Index of Multiple Deprivation (IMD) score. The IMD score combines information on income, employment, health deprivation and disability, education skills and training, housing, geographical access to services, and living environment for areas containing a minimum of 1,000 people and 400 households. The primary PCI proportion per hospital was defined as the number of patients with an admission diagnosis of STEMI who underwent primary PCI divided by the global number of cases with an admission diagnosis of STEMI for that hospital. The selection of covariates for the model was based upon those that were clinically and statistically significant. Hospitals with less than 10 primary PCI cases were excluded. Of the STEMI cohort, 5.6% had missing data for 30-day mortality. The DTB times were 85% complete.
Results

There were 8,653 (12%) patients who underwent primary PCI. The mean age for the primary PCI cohort was 62.9 years (95% confidence interval: 62.8 years to 63.1 years), 74.1% were male and 13.9% had diabetes. The mean (95% confidence interval) systolic BP and heart rate on admission was 136.7 mmHg (79.8 mmHg to 193.6 mmHg) and 77.0 bpm (37.4 bpm to 116.6 bpm) respectively. The baseline characteristics for the cohort are presented by year in Table 1.

30-day mortality

The unadjusted all-cause 30-day mortality for primary PCI was 4.1% (95% confidence interval: 3.7% to 4.6%). Primary PCI 30-day mortality rates fell, reaching 3.3% (95% confidence interval: 2.7% to 4.1%) in 2007 from 5.3% (95% confidence interval: 3.6% to 7.0%) in 2004.

Year and time of admission

The total number of treated STEMI cases fell from 19,757 in 2004 to 15,573 in 2007. The rate of introduction of the primary PCI service is presented in Figure 1. In 2005 5% of STEMI cases were treated using primary PCI (n = 915) compared with 9% (n = 1,744) in 2005, 16% (n = 2,853) in 2006, and 20% (n = 3,141) in 2007 (Chi-squared for trend = 2348.59, df = 3, P <0.001). Over the 4 years the total rates of reperfusion for STEMI (thrombolysis and primary PCI) remained constant at approximately 70%. Two thirds of patients who underwent primary PCI (66%) were treated between 08:00 and 20:00.
**Hospital volume and proportion effect**

Figure 2 shows that there was a significant difference in the 30-day all cause mortality rate, 95% CI for those hospitals that performed primary PCI for fewer than 25% of STEMI patients compared to more than 75% (5.0%, 3.9% to 6.1% versus 2.7%, 2.0% to 3.5%). There was no significant relationship between the number of primary PCI cases undertaken (hospital volume) and 30-day all cause mortality. However, higher volume centres had shorter DTB times (Figure 3).

**Reperfusion times**

The median DTB time for males was 8 minutes shorter than for females (Table 2). The median DTB time for patients with diabetes was 71 minutes (interquartile range 66 minutes), whereas for patients without diabetes the median DTB time was 67 minutes (interquartile range 58 minutes).

Figure 4 demonstrates significant diurnal variation in DTB times over 24 hours – with evidence for nocturnal peaks and daytime troughs. The longest DTB times occurred at approximately 08:00, whilst the shorter DTB times occurred between 09:00 and 20:00.

There was a year-on-year decrease in the DTB times (Figure 5). In 2004 the median DTB time was 84 minutes and 56% of patients were reperfused within 90 minutes. By 2007 the median time reduced by 23 minutes to 61 minutes and a further 20% (total 76%) of patients were reperfused within 90 minutes.
Modelling the DTB time

The DTB times by night were 11 minutes longer than those by day (Table 3). Females and those with diabetes had DTB times 3.5 minutes greater than males and patients without diabetes. Each year an improvement in DTB times was observed. Hospitals that performed primary PCI on greater than 75% of STEMIs had DTB times 30 minutes shorter than hospitals which performed PCI on less than 75% of STEMIs: the hospital-proportion effect.

Younger patients had shorter DTB times than older patients. For example, a 40 year patient would, on average have a DTB time 4 minutes shorter than an 80 year old patient. Patients with higher IMD scores (more deprived) are predicted to have longer DTB times than those with lower IMD scores. The hospital effect for DTB times (after accounting for the hospital proportion effect.) was predicted to be 51 minutes between the best and worst performing hospitals. The residual variation in DTB times was greater at the patient-level (SD = 32.7 minutes) than at the hospital-level (SD = 12.1 minutes).
Discussion

This study identifies several important details relating to variations in DTB times and early mortality: namely the time-of-day effect; the hospital effect, the hospital volume effect and the hospital-proportion effect, and are in keeping with findings from other registries 9,10,12,14,16,33-35. In particular, it readily shows that 1) high volume centres have lower DTB times, 2) there is a statistically significant difference in mortality rates between those hospitals that perform primary PCI on over 75% of STEMI patients compared with less that 25% (2.7% versus 5.0% respectively), and that 3) high volume centres do not have lower mortality rates than low volume centres. This study therefore demonstrates that of the analyses, it is the proportion rather than volume of primary PCIs undertaken that is more relevant to improved primary PCI performance at the hospital level 17.

The multilevel analysis splits the variation in DTB times into components associated with the patient and with the hospital. Increasing age, female sex and diabetes are associated with small but statistically significant longer DTB times. In contrast, the individual hospital effects are much larger – they clearly demonstrate that it does matter at which hospital a patient is admitted – there is a statistically and clinically significant delay at some hospitals, the best being almost an hour faster than the slowest. The service in many hospitals in England and Wales, however, is evolving: DTB times and 30-day mortality rates overall have decreased as the service has evolved so that the variation between hospitals may be due solely to the different degrees with which primary PCI has become an established treatment option.
We report a significant year-on-year reduction in the number of STEMI cases and a trend towards reduced annual 30-day mortality rates from primary PCI. The reduction in rates of STEMI is consistent with previously reported registries. Patient characteristics including cardiogenic shock, diabetes, previous myocardial infarction, angina, chronic renal failure and hypertension (see Table 1) did not vary considerably between 2004 and 2007 and are therefore unlikely to explain the reduction in mortality rates. Instead, increased 30-day mortality was associated with hospitals that performed primary PCI on a low proportion of STEMI patients. This study builds on the notion that hospitals with high levels of ‘specialisation’ are associated with lower mortality rates to show that the hospital proportion effect extends beyond the length of the hospital admission to 30 days. It is likely that a statistically significant reduction in mortality was not evident between 2004 and 2007 because there was little change in the proportion of hospitals performing primary PCI on less than 50% of STEMI cases. We speculate that an increase in the numbers of centres performing primary PCI on over 75% of STEMI cases would offer greater reductions in 30-day mortality rates. Indeed, analysis of the National Registry of Myocardial Infarction-4 has revealed that a 36% relative risk reduction in in-hospital mortality was evident for centres performing primary PCI on over 88.5% of STEMI cases compared to those performing it on less than 34.0%.

Those hospitals that perform primary PCI on over 75% of STEMIs are very likely to offer a 24-hour primary PCI service. When a 24-hour primary PCI service is provided, it is apparent that DTB times are longer at night - consistent with the healthcare team being called in for the procedure – at the time of analysis there were no primary PCI centres in England and Wales which had a policy whereby the
primary PCI team and first operator were resident in the hospital. Furthermore, the increase in DTB times between 07:00 and 09:00 is likely to be due to a decision to wait until the primary PCI team was available. With evidence to suggest that delays to reperfusion are associated with higher mortality rates, this might be investigated in more detail at specific hospitals and raises the issue of the decision to thrombolyse should primary PCI only be available after a delay. An alternative model of care would be large volume, high proportion ‘heart attack centres’ with 1) a 24 hour primary PCI service, 2) dedicated primary PCI catheter labs, and 3) a primary PCI team (including the first operator) resident in the hospital.

Whilst there is evidence to suggest that two-thirds of the delay to revascularisation occurs before first medical contact (patient delay), there remains a substantial opportunity for improvement at the hospital level: for example, over the 4 years studied, there was no appreciable decrease in the number of patients with STEMI not reperfused. This is surprising when primary PCI has fewer contra-indications than thrombolysis. We clearly identify hospital characteristics (high volume) which are associated with reduced DTB times and a model of delivery of care (high proportion) associated with reduced early 30-day mortality. Consequently, this research brings to light the necessity for consideration of high throughput "Heart Attack Centres" and provides additional evidence to support the need for strategic networks of care.
Limitations

MINAP does not collect data on all ACS patients in England and Wales and it is possible that patients entered into the MINAP database differ from those not recorded. We noted that the recording of DTB times was 85% complete and the resulting bias due to missing data could potentially be large. Between 2004 and 2007, the emergency management of STEMI in England and Wales differed from that of other countries - the primary PCI rate in other health care systems at a similar period in time was higher. Nonetheless England and Wales compared favorably with data from North America, where in 2004 the median DTB time was reported as 100.4 ± 23 minutes. The modelling of DTB times was limited to 9 key variables and this may have not considered other determinants of DTB times. Hospital performance may have changed recently as this study only considers data to the end of 2007. Finally, this research reveals important associations but cannot prove cause and effect.
Conclusions

Several primary PCI hospital process-related factors have been identified: namely the *time-of-day effect*; the *hospital effect* and the *hospital-proportion effect*. These are central to the development and evaluation of a national primary PCI service. In addition to patient related factors that impact upon DTB times, volume and proportion of patients treated with primary PCI influence delay and early mortality. This paper provides evidence to support the concept of ‘Heart Attack Centres’ where high throughput primary PCI offers improved patient care.

Acknowledgements

All of the authors gratefully acknowledge funding from the British Heart Foundation PG/07/057/23215. CG is funded through the National Institute for Health Research (NIHR). The extract from the MINAP database was provided through the MINAP Academic Group. We acknowledge all the hospitals in England and Wales for their contribution of data to MINAP. There are no competing interests and the authors have nothing to declare.
Table 1. Baseline characteristics for the primary PCI cohort.

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<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of primary PCI cases</strong></td>
<td>915</td>
<td>1744</td>
<td>2853</td>
<td>3141</td>
</tr>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD) age, years</td>
<td>62.2 (12.8)</td>
<td>62.5 (12.8)</td>
<td>63.1 (13.5)</td>
<td>63.2 (12.9)</td>
</tr>
<tr>
<td>Male sex (%)</td>
<td>674 (73.7)</td>
<td>1316 (75.5)</td>
<td>2089 (73.2)</td>
<td>2304 (73.3)</td>
</tr>
<tr>
<td>Median (IQR) IMD score*</td>
<td>25.8 (28.3)</td>
<td>23.5 (25.8)</td>
<td>21.1 (25.1)</td>
<td>20.2 (25.3)</td>
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<tr>
<td><strong>Cardiovascular risk factors</strong></td>
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<td></td>
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<td></td>
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<tr>
<td>Previous myocardial infarction (%)</td>
<td>131 (14.3)</td>
<td>212 (12.2)</td>
<td>354 (12.4)</td>
<td>404 (12.9)</td>
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<tr>
<td>Previous angina (%)</td>
<td>130 (14.2)</td>
<td>249 (14.3)</td>
<td>407 (14.3)</td>
<td>401 (12.8)</td>
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<td>Hypertension (%)</td>
<td>355 (38.8)</td>
<td>683 (39.2)</td>
<td>1153 (40.4)</td>
<td>1154 (36.7)</td>
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<tr>
<td>Diabetes (%)</td>
<td>116 (12.7)</td>
<td>221 (12.7)</td>
<td>371 (13.0)</td>
<td>402 (12.7)</td>
</tr>
<tr>
<td>Current smoker (%)</td>
<td>419 (45.8)</td>
<td>693 (39.7)</td>
<td>1040 (36.4)</td>
<td>1161 (37.0)</td>
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<td>Chronic renal failure (%)</td>
<td>20 (2.2)</td>
<td>25 (1.4)</td>
<td>46 (1.6)</td>
<td>56 (1.8)</td>
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<td><strong>Haemodynamic characteristics</strong></td>
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<tr>
<td>Mean (SD) systolic BP, mmHg</td>
<td>136.2 (28.7)</td>
<td>137.1 (28.4)</td>
<td>137.1 (29.8)</td>
<td>136.2 (29.6)</td>
</tr>
<tr>
<td>Mean (SD) heart rate, bpm</td>
<td>75.7 (21.2)</td>
<td>76.8 (19.7)</td>
<td>77.3 (20.3)</td>
<td>77.2 (20.1)</td>
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<td>Cardiogenic shock (%)</td>
<td>22 (2.4)</td>
<td>37 (2.1)</td>
<td>81 (2.8)</td>
<td>102 (3.2)</td>
</tr>
<tr>
<td><strong>Reperfusion times</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Median (IQR) CTB time, minutes</td>
<td>133 (85)</td>
<td>128 (61)</td>
<td>117 (54)</td>
<td>112 (49)</td>
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<tr>
<td>Median (IQR) DTB time, minutes</td>
<td>84 (60)</td>
<td>77 (66)</td>
<td>65 (61)</td>
<td>61 (63)</td>
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<tr>
<td><strong>Treatments</strong></td>
<td></td>
<td></td>
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<tr>
<td>Aspirin on admission (%)</td>
<td>728 (79.6)</td>
<td>1457 (83.5)</td>
<td>2311 (81.0)</td>
<td>2785 (88.7)</td>
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<td>Aspirin on discharge (%)</td>
<td>736 (80.4)</td>
<td>1248 (71.6)</td>
<td>2238 (78.4)</td>
<td>2679 (85.3)</td>
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<td>Clopidogrel on discharge (%)</td>
<td>81 (8.8)</td>
<td>634 (36.3)</td>
<td>1737 (60.8)</td>
<td>2253 (71.2)</td>
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<tr>
<td>Statin on discharge (%)</td>
<td>731 (79.9)</td>
<td>1262 (72.4)</td>
<td>2219 (77.8)</td>
<td>2674 (85.1)</td>
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<tr>
<td>β blocker on discharge (%)</td>
<td>640 (69.9)</td>
<td>1096 (62.8)</td>
<td>1918 (67.2)</td>
<td>2341 (74.5)</td>
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<td>ACE inhibitor on discharge (%)</td>
<td>682 (74.5)</td>
<td>1176 (67.4)</td>
<td>2045 (71.7)</td>
<td>2489 (79.2)</td>
</tr>
</tbody>
</table>

*Index of Multiple Deprivation, higher scores signify greater deprivation.
CTB: call to balloon; DTB: door to balloon
Figure 1. Primary PCI and thrombolysis rates adjusted for STEMI admission rate.
Figure 2: 30-day mortality rate by proportion of STEMI cases treated by primary PCI.
Figure 3: Median door to balloon time (minutes) by hospital volume and proportion of primary PCI cases.
**Table 2**: Median and interquartile range (IQR) of DTB times by sex and diabetic status.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Median (IQR) DTB time, minutes</th>
<th>Level of significance</th>
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<tbody>
<tr>
<td>Sex</td>
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<tr>
<td>Male</td>
<td>65 (57)</td>
<td>$P&lt;0.001$</td>
</tr>
<tr>
<td>Female</td>
<td>73 (62)</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>71 (66)</td>
<td>$P = 0.03$</td>
</tr>
<tr>
<td>No</td>
<td>67 (58)</td>
<td></td>
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</table>
Figure 4: Diurnal variation in DTB times.
Figure 5: Box-plot of DTB times by year of admission.
Table 3: Modelling of DTB times to show the impact of confounding variables.

<table>
<thead>
<tr>
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<th>Estimate (95% confidence interval), minutes</th>
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<tr>
<td><strong>Fixed effects:</strong></td>
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<tr>
<td>Intercept^</td>
<td>85.2 (79.9 to 90.4)</td>
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<tr>
<td>Arrival at night</td>
<td>11.5 (9.3 to 13.7)</td>
</tr>
<tr>
<td>Year 2005</td>
<td>-6.0 (-9.3 to -2.8)</td>
</tr>
<tr>
<td>Year 2006</td>
<td>-12.0 (-15.1 to -8.9)</td>
</tr>
<tr>
<td>Year 2007</td>
<td>-18.4 (-22.1 to -14.7)</td>
</tr>
<tr>
<td>Female</td>
<td>3.5 (1.1 to 5.8)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>3.9 (1.0 to 6.8)</td>
</tr>
<tr>
<td>Age (by 1 year)</td>
<td>0.1 (0 to 0.2)</td>
</tr>
<tr>
<td>Hospital proportion &gt;75%</td>
<td>-29.9 (-42.2 to -17.7)</td>
</tr>
<tr>
<td>IMD score*</td>
<td>0.1 (0.1 to 0.2)</td>
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<tr>
<td><strong>Random effects:</strong></td>
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<td>Hospital standard deviation</td>
<td>12.1 (9.2 to 16.0)</td>
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<tr>
<td>Patient level standard deviation</td>
<td>32.7 (32.0 to 33.4)</td>
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</table>

^The reference group time is for a 63 year-old male without diabetes admitted in 2004 to a hospital with a primary PCI rate of less than 75% and living in area with an IMD score of 20.

*Index of Multiple Deprivation.
Reference List


32. de Boor C. A practical guide to splines. Springer-Verlag. 1978.


