Q J Med 2010; **103**:929–940
doi:10.1093/qjmed/hcq139 Advance Access Publication 25 August 2010

Original papers

QJM

Patient safety and quality of care continue to improve in NHS North West following early implementation of the European Working Time Directive

J. COLLUM, J. HARROP, M. STOKES and D. KENDALL

From the Junior Doctor Advisory Team, NHS North West Strategic Health Authority, Manchester, M1 3BN, UK

Address correspondence to J. Collum, Junior Doctors Advisory Team, NHS North West Strategic Health Authority, Piccadilly Place, 3rd Floor, Manchester, M1 3BN, UK. email: josephcollum@hotmail.com

Received 15 February 2010 and in revised form 9 July 2010

Summary

Objectives: NHS North West aimed to fully implement the European Working Time Directive (EWTD) 1 year ahead of the August 2009 national deadline. Significant debate has taken place concerning the implications of the EWTD for patient safety. This study aims to directly address this issue by comparing parameters of patient safety in NHS North West to those nationally prior to EWTD implementation, and during 'North West-only' EWTD implementation.

Design: Hospital standardised mortality ratio (HSMR), average length of stay (ALOS) and standardised readmission rate (SRR) in acute trusts across all specialties were calculated retrospectively throughout NHS North West for the three financial years from 2006/2007 to 2008/2009. These figures were compared to national data for the same parameters.

Results: The analysis of HSMR, ALOS and SRR reveal no significant difference in trend across three financial years when NHS North West is compared to England. HSMR and SRR within NHS North West continued to improve at a similar rate to the England average after August 2008. The ALOS analysis shows that NHS North West performed better than the national average for the majority of the study period, with no significant change in this pattern in the period following August 2008. When the HSMRs for NHS North West and England are compared against a fixed benchmark year (2005), the data shows a continuing decrease. The NHS North West figures follow the national trend closely at all times.

Conclusions: The data presented in this study quantitatively demonstrates, for the first time, that implementation of the EWTD in NHS North West in August 2008 had no obvious adverse impact on key outcomes associated with patient safety and quality of care. Continued efforts will be required to address the challenge posed nationally by the restricted working hour's schedule.

Introduction

Since August 2009, doctors in training in the UK have been required by law to work an average of no >48 h/week, calculated over a 26 week reference period. The legislation underpinning this originated from Europe in 1993 and was originally termed the European Working Time Directive (EWTD). This directive was incorporated into UK law in 1998 under the Working Time Regulations

(WTR) and the restriction of doctors' working hours was gradually implemented, allowing an incremental reduction to 48 h by August 2009.

There has been significant debate concerning the implications of the EWTD for patient safety and junior doctor training. Although the initial intention in applying this legislation was to improve patient and doctor safety through reduction in working hours, concerns regarding the threat to quality of training, service provision and continuity of care have been aired with regularity. Alongside this, the implicit concern that patient safety could be adversely affected has received widespread press coverage.[1–4] However, there is no robust evidence to uphold the viewpoint that the adoption of a restricted working hours schedule will impair patient safety, directly or indirectly.

Conversely, there is a body of evidence to support the reduction in doctors working hours with reference to improving patient safety and reducing serious medical error. A number of studies conducted in the USA in recent years provide evidence for increased serious medical error in those working prolonged shifts compared with those undertaking restricted hours.[5,6] Similarly, an incremental increase in adverse patient safety incidents with successive prolonged shifts, especially night-shifts, has been well demonstrated.[7] The Royal College of Physicians Multidisciplinary Working Group published guidance in 2006 which recommended the cessation of traditional full-shift working practises involving blocks of seven 13-h night-shifts, and endorsed a limit of four successive night-shifts that should be minimized in length where possible.[8] A prospective study, recently undertaken in the UK, has demonstrated a marked decrease in medical error rates amongst doctors working in an EWTD compliant rota when directly compared to a group undertaking a traditional 56 h/week working pattern.[9] Moreover, the 2009 postgraduate medical education and training board (PMETB) national survey of trainees provides evidence that trainees operating within the 48-h limit are significantly less likely to report serious error.[10]

The EWTD was not the first move to restrict working hours for junior doctors; the New Deal junior doctor contract, agreed in 1991, stipulated maximum shift lengths, maximum weekly working hours (depending on shift type) and outlined minimum rest requirements.[11] This contract embodied the viewpoint that junior doctors, alongside other workers, were entitled to adequate work/life balance and epitomized the wider perspective that 'tired doctors are not safe doctors'.[12]

The actual implementation of an average 48-h working week represented a significant challenge to the organization and provision of clinical services across the country; in recognition of this, and in order to lead the way in EWTD implementation, NHS North West undertook a project which aimed to implement the EWTD 1 year ahead of the August 2009 deadline.[13]

Although there is now an accumulation of evidence to support the viewpoint that patient safety is improved by restricted working hours amongst doctors, there are no objective UK data examining quantitative parameters of patent safety in an environment where the EWTD limit has been implemented. The unique circumstances existing in the UK from August 2008 allow us to compare the performance of a largely EWTD compliant region (NHS North West) to the rest of England, which had not yet implemented the 48-h limit. These circumstances allow us to test the hypothesis that implementation of the EWTD in the North West has had no adverse impact on several key outcomes associated with patient safety.

This study aims to compare parameters of patient safety in NHS North West to those nationally, prior to EWTD implementation, and after 'North West-only' EWTD implementation. In devising this study, we considered hospital standardised mortality ratio (HSMR), average length of stay (ALOS) and standardised readmission rate (SRR) in acute trusts, across all specialties, to be suitable quantitative indicators of patient safety and quality of care.[14–16]

Methods

Data for this study were collected and analysed by Dr Foster Intelligence. The information is based on the data which is routinely collected from day case and inpatient records throughout the NHS. These data were then extracted for analysis by the Dr Foster Unit at Imperial College London through the secondary users service (SUS). The data were cleaned and anonymized according to established hospital episode statistics (HES) guidelines. HSMR, ALOS and SRR across NHS North West were analysed retrospectively for the three financial years 2006/2007 to 2008/2009 (effectively April 2006 to March 2009). These figures were compared with the national data for the same parameters. No individual patients were identifiable in this study.

The HSMR compares the number of expected deaths with the number of actual deaths in a ratio [(observed deaths/expected deaths) × 100.] The HSMR analysis was performed for acute trusts only, across all specialties. The expected counts are derived using logistic regression and are adjusted for factors to indirectly standardize for

Table 1 National HSMR by month

Financial year	Financial month	Observed	Expected	Relative risk	Low-confidence limit	High-confidence limit
2006	1	14 033	13 481.11	104.09	102.38	105.83
2006	2	16 221	15 947.86	101.71	100.15	103.29
2006	3	15 776	16 110.84	97.92	96.40	99.46
2006	4	16 106	15 296.74	105.29	103.67	106.93
2006	5	15 289	15 344.27	99.64	98.07	101.23
2006	6	14 662	15 208.49	96.41	94.85	97.98
2006	7	15 763	16 023.88	98.37	96.84	99.92
2006	8	16 088	16 790.16	95.82	94.34	97.31
2006	9	17 316	18 300.06	94.62	93.22	96.04
2006	10	19 042	19 619.13	97.06	95.68	98.45
2006	11	17 909	17 622.42	101.63	100.14	103.13
2006	12	17 681	18 007.14	98.19	96.75	99.65
2007	1	16 271	15 629.61	104.10	102.51	105.72
2007	2	15 907	15 988.03	99.49	97.95	101.05
2007	3	14 837	15 172.68	97.79	96.22	99.37
2007	4	14 749	14 863.60	99.23	97.63	100.84
2007	5	14 745	15 129.35	97.46	95.89	99.05
2007	6	14 299	14 104.40	101.38	99.72	103.06
2007	7	15 511	15 980.74	97.06	95.54	98.60
2007	8	15 806	16 462.00	96.02	94.52	97.52
2007	9	17 998	18 069.55	99.60	98.15	101.07
2007	10	19 239	19 501.58	98.65	97.26	100.06
2007	11	16 150	16 694.96	96.74	95.25	98.24
2007	12	16 878	16 563.64	101.90	100.37	103.45
2008	1	16 754	16 220.77	103.29	101.73	104.86
2008	2	15 749	15 588.59	101.03	99.46	102.62
2008	3	14 585	14 562.62	100.15	98.53	101.79
2008	4	14 690	15 177.75	96.79	95.23	98.36
2008	5	14 001	14 212.50	98.51	96.89	100.16
2008	6	14 195	14 619.89	97.09	95.50	98.70
2008	7	15 728	16 236.23	96.87	95.36	98.40
2008	8	16 363	16 082.91	101.74	100.19	103.31
2008	9	21 397	20 933.96	102.21	100.85	103.59
2008	10	21 362	20 843.53	102.49	101.12	103.87
2008	11	15 937	16 655.38	95.69	94.21	97.18
2008	12	16 270	17 480.97	93.07	91.65	94.51

difference in case mix, including: (i) sex, (ii) age group (in 5 year bands up to ≥90), (iii) method of admission (non-elective or elective), (iv) the socio-economic deprivation quintile of the area of residence of the patient (based on the Carstairs Index),[17] (v) primary diagnosis (based on the Clinical Classification System), (vi) co-morbidities (based on Charlson Score),[18] (vii) number of previous admissions, (viii) month of admission (for certain conditions where seasonal variation may be important, e.g. respiratory infection) and (ix) whether a patient is being treated within the specialty of palliative care.

A published methodology for calculation of HSMRs was utilized; however, a detailed description of this methodology is beyond the scope of this article and can be found in our references.[19]

ALOS analysis measures the average duration of all patient episodes in hospital across acute trusts, across specialties, from the day of admission to the day of discharge, divided into elective and non-elective groups.

The SRR analysis takes into account the number of emergency readmissions to acute trusts across specialties within 28 days of discharge, where readmission was not part of the planned treatment. The rate is calculated by dividing the observed readmissions by the expected readmissions. Both are indirectly standardized for the following factors: (i) age on admission (in 5 year bands up to ≥90)

(ii) sex, (iii) admission method (non-elective or elective), (iv) socio-economic deprivation quintile of the area of residence of the patient (based on the Carstairs Index), (v) primary diagnosis (based on the Clinical Classification System), (vi) co-morbidities (based on Charlson Score) and (vii) year of discharge (financial year).

Results

The HSMRs by month for NHS North West and England are included in table form with associated confidence intervals (Tables 1 and 2). When the HSMR analysis for NHS North West is plotted alongside the national trend, a similar pattern for both can be seen throughout the period of analysis.The green markers in Figure 1 show where the HSMR is statistically low in a given month and red markers show where the HSMR is statistically high. When the HSMRs for NHS North West and England are compared against a fixed benchmark year (2005) the data shows a continuing decrease (Figure 2). The NHS North West figures follow the national trend closely at all times.

The ALOS by month for NHS North West and England are included in table form with associated confidence intervals (Tables 3 and 4). When the ALOS for elective and non-elective patients across NHS North West is plotted alongside the national

Table 2 North West SHA HSMR by month

Financial year	Financial month	Observed	Expected	Relative risk	Low-confidence limit	High-confidence limit
2006	1	2174	2013.41	107.98	103.48	112.61
2006	2	2524	2426.19	104.03	100.01	108.17
2006	3	2420	2437.93	99.26	95.35	103.30
2006	4	2447	2312.69	105.81	101.66	110.08
2006	5	2385	2371.77	100.56	96.56	104.68
2006	6	2417	2366.47	102.14	98.10	106.29
2006	7	2462	2432.38	101.22	97.26	105.30
2006	8	2551	2517.56	101.33	97.43	105.34
2006	9	2687	2748.30	97.77	94.11	101.54
2006	10	3011	3022.33	99.63	96.10	103.25
2006	11	2932	2732.56	107.30	103.45	111.25
2006	12	2868	2731.41	105.00	101.19	108.92
2007	1	2566	2382.54	107.70	103.57	111.95
2007	2	2447	2435.41	100.48	96.53	104.54
2007	3	2418	2351.75	102.82	98.76	107.00
2007	4	2357	2329.77	101.17	97.13	105.34
2007	5	2391	2322.09	102.97	98.88	107.18
2007	6	2323	2172.73	106.92	102.61	111.35
2007	7	2459	2469.39	99.58	95.68	103.59
2007	8	2478	2474.66	100.14	96.23	104.16
2007	9	2816	2753.61	102.27	98.52	106.11
2007	10	2952	2878.55	102.55	98.89	106.32
2007	11	2618	2600.77	100.66	96.84	104.59
2007	12	2763	2535.65	108.97	104.94	113.11
2008	1	2616	2451.13	106.73	102.68	110.90
2008	2	2464	2382.25	103.43	99.39	107.60
2008	3	2225	2206.16	100.85	96.71	105.13
2008	4	2373	2345.23	101.18	97.15	105.34
2008	5	2224	2181.87	101.93	97.74	106.26
2008	6	2193	2233.20	98.20	94.13	102.40
2008	7	2375	2451.06	96.90	93.04	100.87
2008	8	2611	2520.76	103.58	99.64	107.63
2008	9	3420	3253.10	105.13	101.64	108.71
2008	10	3257	3090.39	105.39	101.80	109.07
2008	11	2481	2560.75	96.89	93.11	100.77
2008	12	2489	2618.48	95.06	91.36	98.86

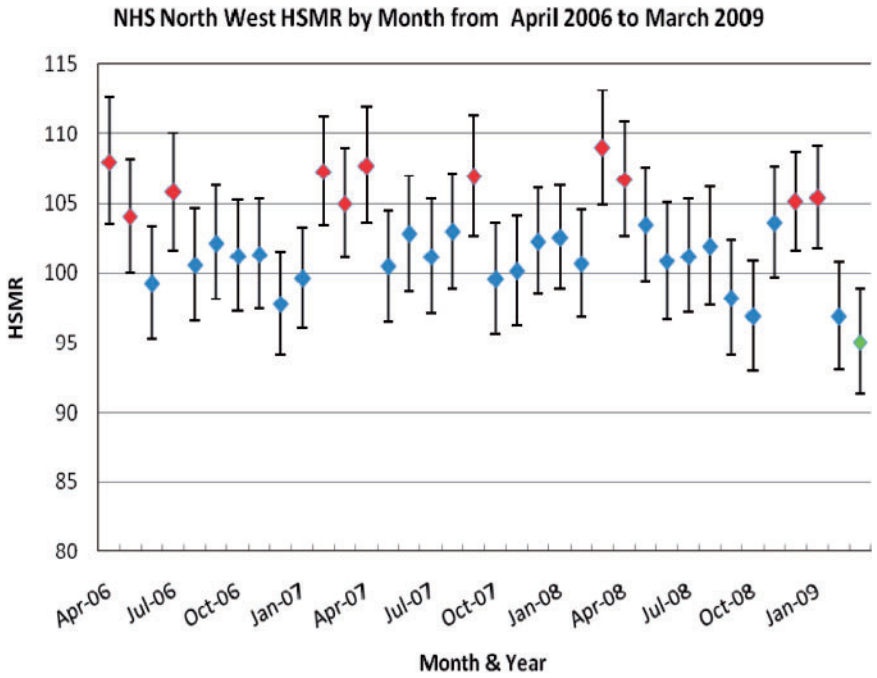

Figure 1. North West SHA HSMR by month from April 2006 to March 2009.

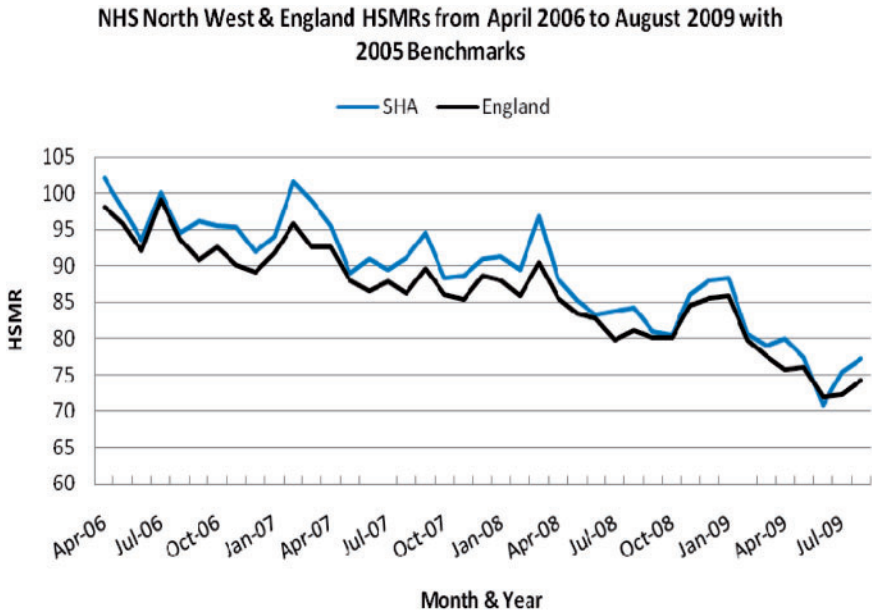

Figure 2. North West SHA & England HSMR by month from April 2006 to March 2009 with 2005 benchmarks.

trend, once again a similar pattern for both can be seen throughout the period of analysis (Figures 3 and 4).

The SRR by month for NHS North West and England are included in table form with associated confidence intervals (Tables 5 and 6). When the SRR for NHS North West is plotted alongside the national trend, once more a similar pattern for both can be seen throughout the period of analysis (Figure 5).

Discussion

For the first time, we present quantitative data which demonstrates that implementation of the EWTD in NHS North West in August 2008 had no adverse impact on key outcomes associated with patient safety and quality of care. HSMR and SRR within the North West continued to improve at a similar rate to the England average after August 2008. The ALOS analysis shows that NHS North West

Table 3 National ALOS by month

Financial year	Financial month	Non-elective spells	Non-elective bed days	Non-elective Length of stay	Elective spells	Elective bed days	Elective length of stay
2006	1	560 155	3 583 923	6.39	140 734	866 833	6.16
2006	2	592 028	3 994 076	6.74	156 534	986 631	6.30
2006	3	581 955	3 786 275	6.50	160 436	952 493	5.94
2006	4	584 265	3 695 384	6.32	158 024	1 035 406	6.55
2006	5	577 935	3 641 041	6.29	154 641	882 057	5.70
2006	6	579 337	3 731 810	6.44	156 131	995 253	6.38
2006	7	586 801	3 646 884	6.21	159 991	983 971	6.15
2006	8	575 032	3 567 735	6.20	164 885	913 653	5.54
2006	9	581 538	3 742 329	6.43	146 765	2 366 563	16.13
2006	10	592 861	3 734 395	6.29	151 422	879 171	5.81
2006	11	540 871	3 433 578	6.34	150 222	867 518	5.78
2006	12	587 685	3 712 307	6.31	174 312	931 691	5.35
2007	1	553 947	3 344 440	6.04	138 287	879 924	6.36
2007	2	585 376	3 476 364	5.94	155 913	891 688	5.72
2007	3	568 208	3 397 584	5.98	155 662	890 068	5.72
2007	4	580 892	3 410 503	5.87	156 801	895 393	5.71
2007	5	575 585	3 335 338	5.79	151 315	876 260	5.79
2007	6	552 812	3 076 003	5.56	149 001	873 906	5.87
2007	7	589 025	3 427 231	5.82	162 997	880 108	5.40
2007	8	571 285	3 341 169	5.85	163 992	894 850	5.46
2007	9	571 093	3 211 611	5.62	136 217	812 565	5.97
2007	10	582 038	3 581 722	6.15	151 025	807 939	5.35
2007	11	552 351	3 329 521	6.03	162 077	850 297	5.25
2007	12	581 393	3 333 778	5.73	149 936	913 187	6.09
2008	1	584 123	3 708 291	6.35	156 591	984 943	6.30
2008	2	598 458	3 393 158	5.67	152 879	887 117	5.80
2008	3	577 853	3 366 717	5.83	150 938	903 224	5.99
2008	4	605 829	3 547 541	5.85	162 843	924 791	5.68
2008	5	578 418	3 181 351	5.50	143 983	824 624	5.73
2008	6	587 079	3 449 686	5.88	153 500	894 024	5.82
2008	7	613 680	3 546 111	5.78	166 553	955 757	5.74
2008	8	584 686	3 337 497	5.71	154 400	873 669	5.66
2008	9	621 547	3 716 861	5.98	137 479	899 885	6.55
2008	10	595 532	3 645 558	6.12	140 080	804 123	5.72
2008	11	554 104	3 323 336	6.00	141 818	815 710	5.75
2008	12	631 338	3 648 723	5.78	160 270	919 499	5.73

performed better than the national average for the majority of the study period, with no significant change in this pattern in the period following August 2008.

When considering the HSMR trends in detail, three seasonal spikes in the death rate during the December to January period in each financial year analysed can be clearly seen; these occur nationally, and the pattern in NHS North West is no different from the national trend. When the NHS North West HSMR across acute trusts amongst elective and non-elective patients was analysed against 2005 benchmarks across the 3-year period, an overall improvement could be seen which matched the rate of overall HSMR improvement for England, and where the North West showed signs of a decline in improvement this is reflected in the national picture. There was no significant variation from the national HSMR trend immediately following EWTD implementation in the North West, or during the whole period of EWTD implementation from August 2008 until March 2009. Moreover, where NHS North West showed signs of a decline in improvement in the HSMR trend, this is reflected in the national picture demonstrating that this decline in improvement cannot be attributed to a localized issue.

The increase in HSMR in the North West in the winter of 2008/2009 should be examined. There is clear evidence to demonstrate that this increase in HSMR was reflected in the national trend, and this can be attributed to the severe winter pressures related to seasonal infection, exacerbation of

Table 4 North West SHA ALOS by month

Financial year	Financial month	Non-elective spells	Non-elective bed days	Non-elective length of stay	Elective spells	Elective bed days	Elective length of stay
2006	1	87 774	567 622	6.47	20 685	109 669	5.30
2006	2	92 023	585 158	6.36	23 376	112 805	4.83
2006	3	89 767	567 218	6.32	24 043	136 044	5.66
2006	4	90 521	537 883	5.94	23 041	126 581	5.49
2006	5	89 401	544 906	6.10	22 599	116 431	5.15
2006	6	89 872	541 369	6.02	23 068	151 777	6.58
2006	7	91 568	535 539	5.85	24 012	121 517	5.06
2006	8	90 001	556 121	6.18	25 029	120 221	4.80
2006	9	91 089	514 335	5.65	21 339	118 453	5.55
2006	10	93 352	565 595	6.06	22 850	101 881	4.46
2006	11	83 742	527 236	6.30	22 388	113 142	5.05
2006	12	90 558	561 964	6.21	25 936	130 449	5.03
2007	1	88 458	517 785	5.85	21 545	116 515	5.41
2007	2	93 483	540 777	5.78	24 072	118 375	4.92
2007	3	90 220	523 084	5.80	24 237	114 878	4.74
2007	4	93 827	523 928	5.58	24 202	120 877	4.99
2007	5	92 812	504 355	5.43	23 455	104 516	4.46
2007	6	89 982	470 781	5.23	22 848	105 349	4.61
2007	7	95 081	529 860	5.57	24 741	116 265	4.70
2007	8	91 414	513 817	5.62	25 191	119 804	4.76
2007	9	92 676	500 942	5.41	20 771	122 160	5.88
2007	10	93 002	552 966	5.95	23 191	98 263	4.24
2007	11	89 292	514 865	5.77	24 857	114 674	4.61
2007	12	93 867	512 556	5.46	22 277	103 858	4.66
2008	1	92 079	546 410	5.93	23 245	117 387	5.05
2008	2	94 081	523 647	5.57	22 803	110 406	4.84
2008	3	90 082	501 180	5.56	22 522	105 430	4.68
2008	4	94 073	520 434	5.53	24 350	102 210	4.20
2008	5	90 485	489 887	5.41	21 246	91 768	4.32
2008	6	92 267	506 968	5.50	22 395	102 585	4.58
2008	7	97 068	532 857	5.49	24 364	113 150	4.64
2008	8	93 119	514 145	5.52	22 295	97 044	4.35
2008	9	97 674	571 888	5.86	19 441	103 441	5.32
2008	10	91 928	547 480	5.96	20 606	90 610	4.27
2008	11	87 712	490 865	5.60	21 053	92 176	4.38
2008	12	99 055	565 954	5.71	23 726	104 921	4.43

chronic disease and hospitalization amongst the growing elderly population.[20]

Although HSMR figures are clearly a headline statistic when considering the impact of EWTD implementation in NHS North West, data concerning ALOS may provide valuable insights when considering the effectiveness of hospital institutions and clinical teams in satisfactorily and efficiently processing patients. Our data reveal a lower ALOS for both elective and non-elective patients at NHS North West in comparison to England throughout the period studied. Where there is a significant increase in the ALOS for England, this is mirrored at NHS North West. There is an uncharacteristic spike in the elective ALOS at the national level in December 2006 but there is also an increase, although much less significant, at NHS North West in the same month. In the period following August 2008, the ALOS for NHS North West continues to follow the national trend, although it remains lower than the national average. Therefore, it is clear that ALOS has not been impacted in any way that can be attributed to EWTD implementation.

Another useful marker to consider alongside the ALOS when assessing the effective provision of care is the SRR. SRR can provide telling data regarding the effectiveness of initial treatments and highlight those instances in which readmission has been required. When the emergency SRR at NHS North West is compared to that of England for the period April 2006 to March 2009, it can be seen that NHS North West plots a similar pattern to that of the

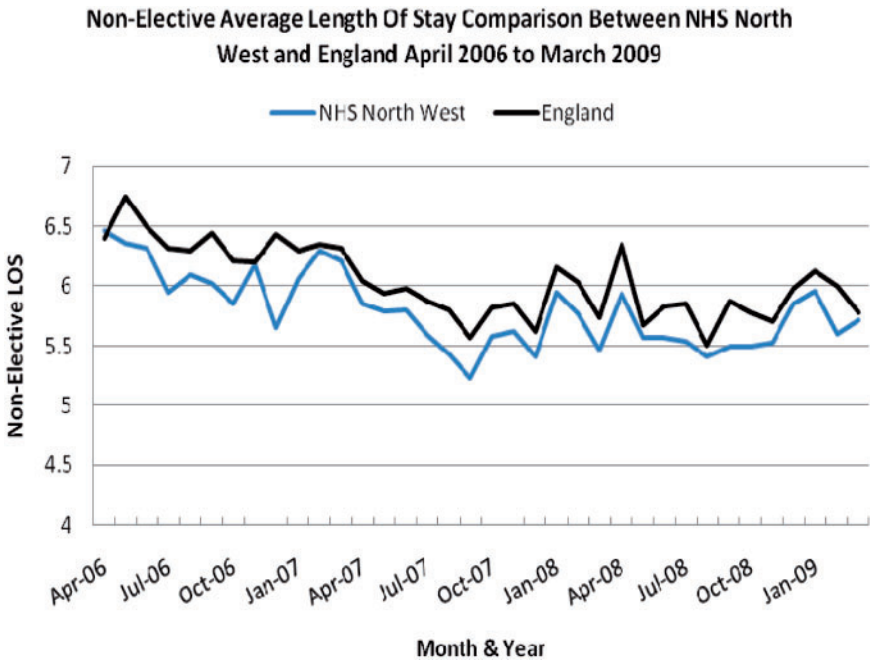

Figure 3. North West SHA & England Non-Elective ALOS by month from April 2006 to March 2009.

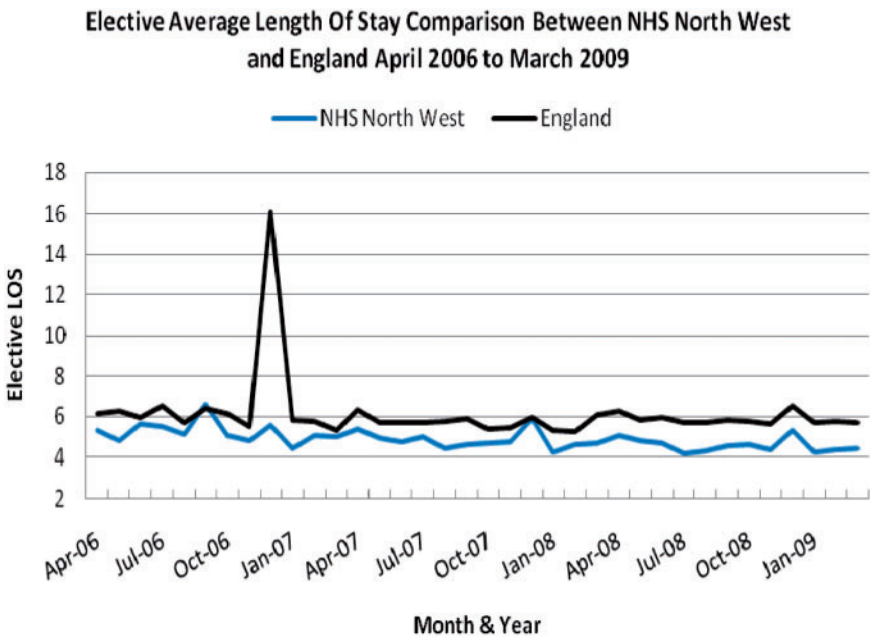

Figure 4. North West SHA & England Elective ALOS by month from April 2006 to March 2009.

national average. A significant divergence occurs in summer 2007, at which time the SRR in NHS North West rises above the national average. The reason for this is unclear. Similarly, there is a drop in SRR in March 2008 across both England and NHS North West. Again the reason for this is unclear and may be due to a data anomaly, but further investigation of this is beyond the scope of our report. However, it can be stated that the introduction of a 48-h week in NHS North West in August 2008 did not lead to any appreciable trend change in SRR or any significant divergence from the national average.

Much of the credibility of this study rests on the robustness of the HSMR as a measure of patient safety. Since the technique was devised by Jarman *et al.*[21] in the UK in the 1990s, HSMRs have been utilized worldwide to focus the discussion of patient safety and quality improvement, to monitor the

Table 5 National SRR by month

Financial year	Financial month	Observed	Expected	Relative risk	Low-confidence limit	High-confidence limit
2006	1	61 778	50 436.30	122.49	121.52	123.46
2006	2	69 239	57 676.69	120.05	119.15	120.94
2006	3	69 512	57 772.29	120.32	119.43	121.22
2006	4	68 292	57 034.15	119.74	118.84	120.64
2006	5	69 390	57 492.49	120.69	119.80	121.60
2006	6	69 258	57 925.42	119.56	118.68	120.46
2006	7	70 851	59 064.74	119.95	119.07	120.84
2006	8	70 930	59 066.35	120.09	119.20	120.97
2006	9	70 354	59 568.54	118.11	117.23	118.98
2006	10	71 602	59 798.56	119.74	118.86	120.62
2006	11	66 482	54 341.69	122.34	121.41	123.27
2006	12	71 075	54 246.35	131.02	130.06	131.99
2007	1	66 259	51 504.84	128.65	127.67	129.63
2007	2	71 337	55 979.51	127.43	126.50	128.37
2007	3	69 016	54 409.31	126.85	125.90	127.80
2007	4	69 220	54 669.00	126.62	125.68	127.56
2007	5	69 665	54 620.95	127.54	126.60	128.49
2007	6	66 477	52 145.72	127.48	126.52	128.46
2007	7	71 847	56 217.44	127.80	126.87	128.74
2007	8	70 196	55 260.18	127.03	126.09	127.97
2007	9	67 946	54 289.95	125.15	124.21	126.10
2007	10	68 555	54 791.32	125.12	124.19	126.06
2007	11	65 051	52 294.03	124.39	123.44	125.35
2007	12	36 592	49 068.08	74.57	73.81	75.34
2008	1	71 841	57 512.20	124.91	124.00	125.83
2008	2	73 254	59 478.17	123.16	122.27	124.06
2008	3	71 054	57 757.49	123.02	122.12	123.93
2008	4	75 171	60 505.15	124.24	123.35	125.13
2008	5	70 552	57 349.53	123.02	122.11	123.93
2008	6	73 810	59 520.53	124.01	123.11	124.91
2008	7	78 443	63 154.74	124.21	123.34	125.08
2008	8	73 663	59 833.17	123.11	122.23	124.01
2008	9	77 125	63 916.94	120.66	119.81	121.52
2008	10	74 663	60 653.37	123.10	122.22	123.98
2008	11	71 691	56 232.84	127.49	126.56	128.43
2008	12	82 032	58 641.91	139.89	138.93	140.85

provision of care over time and to identify opportunities for improvement. It has become an internationally recognized objective measure of quality of care and, in the author's opinion it is simply the best tool we currently have with which to quantify and monitor the difficult and multifactorial variables that comprise patent safety and quality of care.[14] Indeed, the Canadian Institute for Health Information adopted HSMR analysis as recently as 2005 in order to drive their patent safety and improvement agenda.[22] Certainly, the HSMR has its detractors and indeed many researchers do not consider the HSMR to be a suitable measure of, or surrogate marker for, patient safety.[23] The pitfalls of HSMR analysis include the possibility for administrative errors such as miscoding and the possibility of missing data. However, missing data or miscoding would be unlikely to account for the clear and consistent trends that we have demonstrated.

The reliability of this article's claim also depends on the EWTD compliance rate in the North West during the period August 2008 onwards. Robust data exist to demonstrate 94% compliance with a 48-h working week for junior doctors in the North West region of England in August 2008 and this has been published previously.[13] Based on a published methodology, EWTD compliance was calculated using New Deal monitoring data.[24] In addition, NHS North West did not take the approach of increasing junior doctor numbers and rather directed resources towards sustainable solutions. This did not include any significant targeted increase

Table 6 North West SHA SRR by month

Financial year	Financial month	Observed	Expected	Relative risk	Low-confidence limit	High-confidence limit
2006	1	10 039	8306.73	120.85	118.50	123.24
2006	2	11 196	9525.46	117.54	115.37	119.74
2006	3	11 431	9523.16	120.03	117.84	122.25
2006	4	11 157	9444.98	118.13	115.94	120.34
2006	5	11 546	9571.94	120.62	118.43	122.84
2006	6	11 731	9690.57	121.06	118.87	123.27
2006	7	11 875	9963.93	119.18	117.05	121.34
2006	8	11 921	9963.52	119.65	117.51	121.81
2006	9	12 111	10076.81	120.19	118.06	122.35
2006	10	12 245	10141.02	120.75	118.62	122.91
2006	11	11 282	9167.29	123.07	120.81	125.36
2006	12	11 930	9090.89	131.23	128.89	133.61
2007	1	11 473	8833.96	129.87	127.51	132.27
2007	2	12 270	9577.94	128.11	125.85	130.39
2007	3	11 890	9267.42	128.30	126.00	130.63
2007	4	12 263	9370.85	130.86	128.56	133.20
2007	5	12 321	9375.06	131.42	129.11	133.76
2007	6	11 837	8980.58	131.81	129.44	134.20
2007	7	12 474	9643.56	129.35	127.09	131.64
2007	8	12 152	9425.46	128.93	126.65	131.24
2007	9	11 687	9417.38	124.10	121.86	126.37
2007	10	11 942	9308.81	128.29	126.00	130.61
2007	11	11 425	9049.09	126.26	123.95	128.59
2007	12	6465	8458.45	76.43	74.58	78.32
2008	1	12 193	9690.92	125.82	123.60	128.07
2008	2	12 430	9985.39	124.48	122.30	126.69
2008	3	11 878	9654.51	123.03	120.83	125.26
2008	4	12 437	9964.42	124.81	122.63	127.03
2008	5	11 755	9579.12	122.71	120.51	124.95
2008	6	12 411	9928.49	125.00	122.81	127.22
2008	7	13 321	10 550.22	126.26	124.13	128.43
2008	8	12 439	10 105.70	123.09	120.94	125.27
2008	9	12 755	10 547.43	120.93	118.84	123.05
2008	10	12 317	9927.88	124.06	121.88	126.28
2008	11	12 112	9426.93	128.48	126.20	130.79
2008	12	13 654	9712.30	140.58	138.24	142.96

in the number of junior doctors, rather resources were directed towards 'Hospital at Night' schemes, extended practitioner roles and service reconfiguration; this approach was detailed in the article 'Achieving the 48 h week for Junior Doctors in the North West'.[13]

Compliance across England did increase in the period leading up to 1 August 2009, as other trusts across England prepared for the EWTD deadline. Individual Strategic Health Authorities (SHAs), as part of their own quality assurance process, began the collection of compliance data in January 2009.[25] This information was shared with the Department of Health, the Academy of Medical Royal Colleges and the medical professions. NHS North West's own data for January 2009 showed that the North West was advancing at a greater pace than the rest of England. The stated EWTD compliance for England in January 2009 was 72%; this increased to 91% by August 2009. It is therefore clear that, during the period of interest (August 2008–August 2009), the North West had a significantly greater degree of compliance with EWTD than the rest of the country, making our comparison truly valid.

Finally, we recognize that the outcome measures in this article (HSMR, SRR and ALOS) are influenced by a multitude of factors other than the working arrangements of junior doctors and we cannot attribute any changes in these parameters to EWTD

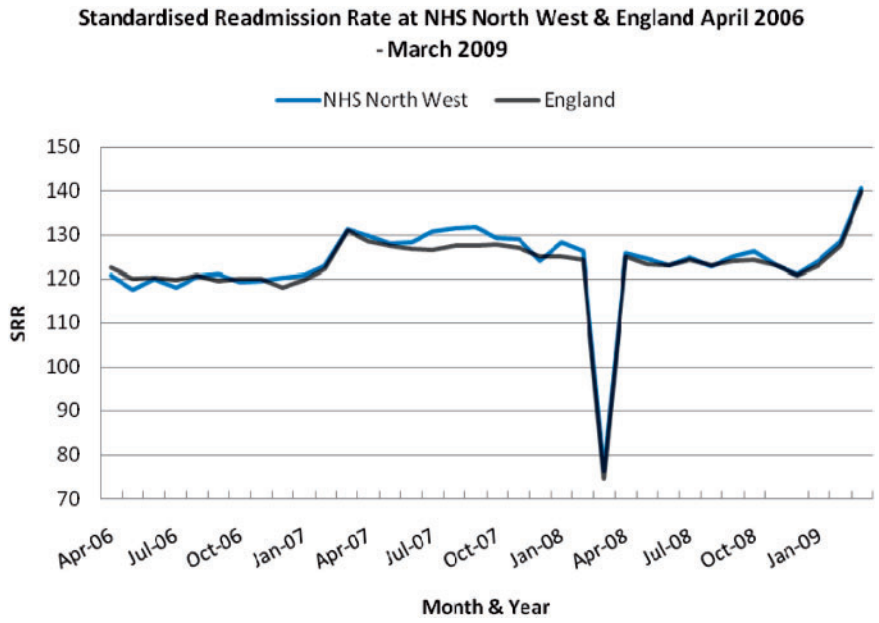

Figure 5. North West SHA & England SRR by month from April 2006 to March 2009.

alone. However, our findings do support the hypothesis that implementation of the EWTD in the North West has had no adverse impact on several key outcomes associated with patient safety.

Conclusions

The implications of these findings are widespread; we can state for the first time that EWTD implementation in the North West region of England has had no obvious adverse effect on parameters of patient safety when considering HSMR, SRR and ALOS across acute trusts among elective and non-elective patients. In fact, there has been continued improvement in these parameters from August 2008, and where trends are at odds with expected results, this is mirrored nationally. No localized variance from national trends could be identified at any stage. The authors do not claim that patient safety improved because of the North West's efforts to fully implement EWTD in August 2008, but simply wish to demonstrate that these activities did not result in any measurable negative impact on our stated outcome measures.

Patient safety is at the heart of the EWTD, and these results provide a firm basis to support a model which sees well-rested, well-supported doctors deployed efficiently and intelligently within a 48-h week. However, continued efforts will be required to address the challenge posed nationally by the restricted working hours schedule; we must endeavour to sustain excellence in postgraduate medical training and prioritize the continual improvement in quality of patient care within the limits of the WTR's 48-h week.

Acknowledgements

J.C. and D.K. developed the original idea for the study. J.C. wrote the first draft of the article and wrote subsequent drafts after feedback from the other three authors. All four authors gave final approval. We thank Dr Foster Intelligence for processing the data. We also thank Paul Barbour and James Thompson for their comments on earlier drafts of this manuscript.

Funding

NHS North West Strategic Health Authority.

Conflict of interest: None declared.

References

1. Campbell D. Doctors' leader warns 48-hour week will endanger patients. *The Guardian*. [http://www.guardian.co.uk/society/2009/apr/11/doctor-working-hours] Accessed 11 April 2009.
2. Letter from John Black to Alan Johnson. [http://www.rcseng.ac.uk/news/docs/Alan%20Johnson%20EWTD%20Reply.pdf] Accessed 8 May 2009.
3. Pounder R. Junior doctors' working hours: can 56 go into 48? *Clin Med* 2008; **8**:126–7.
4. The Royal college of Surgeons. *Background Briefing; Surgery and the European Working Time Directive.*

[http://www.rcseng.ac.uk/news/new-background-briefing--surgery-and-the-european-working-time-directive] Accessed 5 March 2009.

5. Landrigan CP, Rothschild JM, Cronin JW, Kaushal R, Burdick E, Katz JT, Speizer FE, *et al.* Effect of reducing intern's work hours on serious medical errors in intensive care units. *New Engl J Med* 2004; **351**:1838–48.
6. Barger LK, Ayas NT, Cade BE, Cronin JW, Rosner B, *et al.* Impact of extended-duration shifts on medical errors, adverse events, and attentional failures. *PLoS Med* 2006; **3**:e487.
7. Folkard S, Tucker P. Shift work safety and productivity. *Occup Med* 2003; **53**:95–101.
8. Horrocks N, Pounder R. on behalf of the Multi Multidisciplinary Working Group of the Royal College of Physicians. Designing safer rotas for junior doctors in the 48 hr week. *J R Coll Physicians Lond* 2006;1–23.
9. Cappuccio FP, Bakewell A, Taggart FM, Ward G, Ji C, Sullivan JP, *et al.* Implementing a 48 h EWTD-compliant rota for junior doctors in the UK does not compromise patients' safety: assessor-blind pilot comparison. *QJM* 2009; **102**:271–82.
10. Postgraduate Medical Education and Training Board. *National Training Surveys: key findings 2008-2009*, P59. [www.pmetb.org.uk/pmetb] Accessed 14 February 2010.
11. Department of Health, Social Policy and Public Services. *New Deal for Junior Doctors*. [http://www.dhsspsni.gov.uk/scujuniordoc-2] Accessed 14 February 2010.
12. Dr Wendy Reid, Department of Health. *Junior Doctors Across the NHS on Course to Meet New Working Time Target 26th June 2009*. [http://www.dh.gov.uk/en/News/Recentstories/DH_101561] Accessed 14 February 2010.
13. Kendall D, Ahmed-Little Y, Johnston M, Cousins D, Sunderland H, Najim O. EWTD – Achieving the 48 hour week for Junior Doctors in the North West. *Br J Healthc Manage* 2009; **15**:127–31.
14. Wen E, Sandoval C, Zelmer J, Webster G. Understanding and using the hospital standardized mortality ratio in Canada: challenges and opportunities. *Healthc Pap* 2008; **8**:26–36.
15. NHS Institute for Improvement and Innovation. *Quality and Service Improvement Tools-Length of Stay-Reducing Length of Stay* 2008. [www.institute.nhs.uk/quality and service improvement tools/quality and service improvement tools/length of stay.html] Accessed 14 February 2010.
16. Hospital Episode Statistics Online. *Readmission Rates and HES*. [www.hesonline.nhs.uk/Ease/servlet/ContentServer;jsessionid=3xyd0bm811?siteID=1937&categoryID=927] Accessed 14 February 2010.
17. Morgan O, Baker A. Measuring deprivation in England and Wales using 2001 Carstairs scores. *Health Stat Q* 2006; **31**:28–33.
18. Schneeweiss S, Maclure M. Use of comorbidity scores for control of confounding in studies using administrative databases. *Int J Epidemiol* 2000; **29**:891–8.
19. Dr Foster Unit-Imperial College, Dr Foster Intelligence. Aylin P, Bottle A, Jen M, Middleton S. *HSMR Mortality Indicators*. [http://www.nhs.uk/NHSEngland/Hospitalmortalityrates/Documents/090424%20MS(H)%20-%20NHS%20Choices%20HSMR%20Publication%20-%20Presentation%20-%20Annex%20C.pdf] Accessed 14 February 2010.
20. Jordan RE, Hawker JI, Ayres JG, Adab P, Tunnicliffe W, Olowokure B, *et al.* Effect of social factors on winter hospital admission for respiratory disease: a case-control study of older people in the UK. *Br J Gen Pract* 2008; **58**:e1–e9.
21. Jarman B, Gault S, Alves B, Hider S, Dolan S, Cook A, *et al.* Explaining differences in English Hospital death rates using routinely collected data. *Br Med J* 1999; **318**:1515–20.
22. Canadian Institute for Health Information. *HSMR: A New Approach for Measuring Hospital Mortality Trends in Canada*. Ottawa, CIHI, 2007.
23. Penfold RB, Dean S, Flemons W, Moffatt M. Do hospital standardized mortality ratios measure patient safety? HSMRs in the Winnipeg Regional Health Authority. *Healthc Pap* 2008; **8**:8–24.
24. Skills for Health Workforce Projects Team, Doctors Rostering System, DRS Version 3 Rule Book, 2009. [http://www.healthcareworkforce.nhs.uk/working_time_directive/doctors_rostering_system/launch_of_drs_rulebook.html] Accessed 14 February 2010.
25. SHA. *Quality Assurance information*. January 2009 (shared with the Academy of Medical Royal Colleges).