

# PROFESSIONAL MATTERS

## Who gets struck off?

**Richard Wakeford** analyses erasures and suspensions from the list of registered medical practitioners by country of primary medical qualification



PAUL BOSTON

### Introduction

Since its establishment in 1858, the General Medical Council (GMC) has been responsible for overseeing the professional conduct of doctors and for disciplining those whose standards are inadequate. Its remit and sanctions have changed over the years, and it is only relatively recently that clinical competence has come within its disciplinary ambit. The GMC publishes overview statistics of its procedures<sup>1</sup> but not, so far as can be established, detailed classifications of who is suspended or erased from the list of registered medical practitioners (LRMP)—those given the current most serious penalties.

The LRMP can, however, be downloaded—for a fee—for analysis. Unfortunately, the database contains only the names of those erased or suspended, without listing the reasons for the penalty.

One study, conducted through laborious perusal of the GMC's minutes and reports in the

**Table 1 | Numbers and percentages of doctors erased or suspended from the list of registered medical practitioners, by major demographic group (list of registered medical practitioners 15 March 2011)**

Specialisation, by UK or non-UK graduate	Primary qualification date			Total
	1995-2005	1985-94	Up to 1984	
<b>UK graduate</b>				
General practitioner	0.061 (9/14 613)	0.173 (23/13 306)	0.448 (73/16 292)	0.237 (105/44 211)
Hospital specialist	0.012 (1/8418)	0.106 (17/16 056)	0.204 (34/16 689)	0.126 (52/41 163)
Trainee/other doctor	0.112 (58/51 767)	1.363 (33/2421)	1.626 (73/4489)	0.279 (164/58 677)
All UK graduates	0.091 (68/74 798)	0.230 (73/31 783)	0.480 (180/37 470)	0.223 (321/144 051)
<b>Non-UK graduate</b>				
General practitioner	0.131 (5/3829)	0.786 (29/3691)	1.748 (94/5377)	0.992 (128/12 897)
Hospital specialist	0.138 (8/5804)	0.214 (23/10 745)	0.563 (45/7988)	0.310 (76/24 537)
Trainee/other doctor	0.206 (60/29 112)	0.769 (75/9751)	1.829 (130/7109)	0.576 (265/45 972)
All non-UK graduates	0.188 (73/38 745)	0.525 (127/24 187)	1.314 (269/20 474)	0.562 (469/83 406)
<b>Total</b>				
General practitioner	0.076 (14/18 442)	0.306 (52/16 997)	0.771 (167/21 669)	0.408 (233/57 108)
Hospital specialist	0.063 (9/14 222)	0.149 (40/26 801)	0.320 (79/24 677)	0.195 (128/65 700)
Trainee/other doctor	0.146 (118/80 879)	0.887 (108/12 172)	1.750 (203/11 598)	0.410 (429/104 649)
All graduates	0.124 (141/113 543)	0.357 (200/55 970)	0.775 (449/57 944)	0.347 (790/227 457)

medical press, classified the sometimes tragic, often salacious, and occasionally scarcely credible reasons for disciplining the 584 doctors erased in the first 133 years of the GMC's existence from 1858 to 1991, before the council's "performance procedures" were instituted.<sup>2</sup> It found, for instance, that the most common reason for the erasure of doctors who qualified in England was adultery with patients and that for doctors who qualified in Ireland the reason was often alcohol related. It also showed that erasure from the register would not necessarily terminate a career: 16 doctors had been erased twice, and two, three times. A contemporaneous book describes the history in sociolegal detail.<sup>3</sup>

The LRMP identifies doctors on the specialist and general practice registers and lists their sex, and the country, date, and medical school of their primary medical qualification. It identifies those who currently work (or who could)—"registered with a licence to practise"—as well as those who are erased or suspended. It is thus possible to examine the prevalence of erasure and suspension by specialty, time since qualification, and source of primary qualification.

**Method**

The LRMP was downloaded on 15 March 2011: it listed a total of 227 457 potentially practising doctors and those who had been erased and suspended. It was imported into IBM Statistical Package for the Social Sciences version 19<sup>4</sup> for cleansing and analysis.

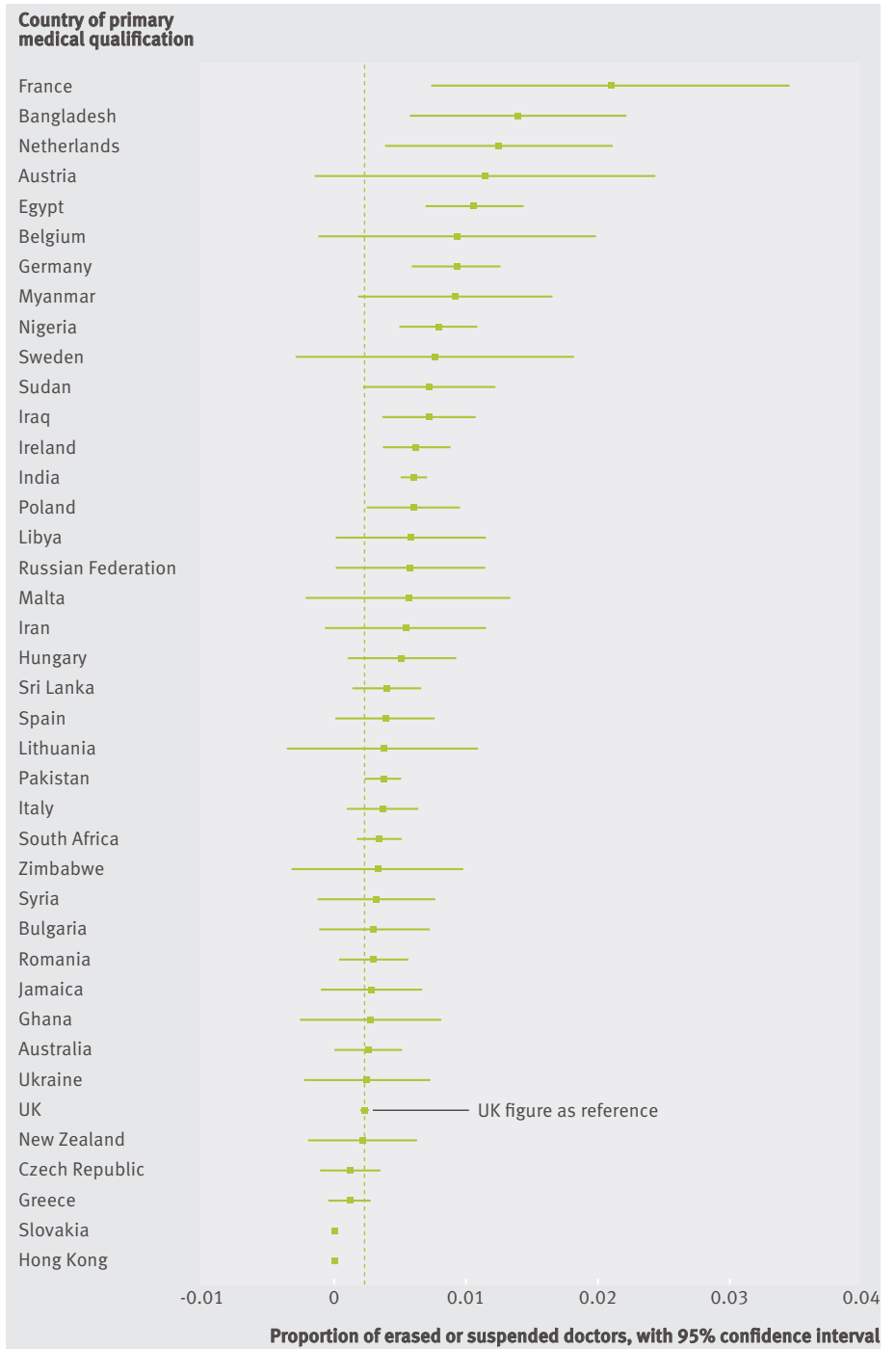
The doctors on the register were classified into general practitioners (those on the GP register); hospital specialists (those on the specialist register); and trainee and other doctors (those on neither register). They were further classified by country of primary medical qualification, by sex, into UK or non-UK qualified and by the time since qualification (into three groups) as a surrogate for age.

The percentages of all the subgroups of doctors who were listed as erased or suspended were then calculated.

**Results**

Overall, 790 doctors (0.35%) on the LRMP were listed as erased or suspended. Of those, 111 (14.05%) were women, representing 0.09% of the women listed, and 679 (85.95%) were men, representing 0.37% of the male doctors ( $\chi^2 = 210.8$ ,  $df=1$ ,  $P<0.001$ ).

Table 1 shows the numbers, denominators, and percentages of GPs, hospital specialists, and trainees or others, suspended or erased, by origin of their medical degree (UK or elsewhere) and by time since graduation. Univariate differences in prevalence within primary qualification date, specialty of practitioner,



Proportion of erased or suspended doctors with country of primary medical qualification. No country's figure is significantly lower than the UK's by  $\chi^2$  test. Slovakia and Hong Kong have no erased or suspended doctors. The statistical package does not produce an error bar in these circumstances

and between UK and non-UK graduates are all highly significant (respectively:  $\chi^2 = 469.6$ ,  $df=2$ ,  $P<0.001$ ;  $\chi^2 = 56.6$ ,  $df=2$ ,  $P<0.001$ ;  $\chi^2 = 119.4$ ,  $df=1$ ,  $P<0.001$ ). Multivariate analysis (stepwise regression) showed that the most important individual demographic variables in predicting current suspension or erasure are time since qualification (longer) and being a non-UK graduate.

Doctors obtained their primary medical

qualifications from 146 foreign countries, five of which provided as few as one doctor—Gabon, Mali, Rwanda, Suriname, and Togo. Forty countries, including the UK, provided 250 or more doctors on the LRMP. Table 2 lists these alphabetically, with the percentage of each country's graduates who are erased or suspended compared with the UK graduates' baseline figure. The data are also shown in the figure in order of relative prevalence of eras-

ure or suspension, showing the proportion of erased and suspended doctors and the 95% confidence interval surrounding this.

Within the group of UK graduates, there were differences between medical schools, but these are generally not significant because of small numbers from each. Overall, the prevalence of erasure or suspension was significantly higher for people with qualifications from the non-university licensing bodies—the Scottish Triple Qualification; the English Conjoint Qualification; and the Licence in Medicine and Surgery of the Society of Apothecaries of London: 277/138 806 university graduates featured (0.199%); whereas 0.886% of the NULB-qualified were erased or suspended, 44/4924 ( $\chi^2 = 101.7$ ,  $df=1$ ,  $P<0.001$ ).

### Discussion

Overall, these results suggest that:

- Proportionately, men are four times as likely to be erased or suspended as women
- Hospital specialists are being erased or suspended at around half the rate of GPs and others
- Doctors in all career groups are much more likely to be erased or suspended later in life
- Non-UK graduates as a group are more than twice as likely to be erased or suspended as those with UK qualifications
- Among those with UK qualifications, those qualified by means of licences from the non-

university licensing bodies are more than four times, likely to be erased or suspended as those with university qualifications

- Some foreign countries' doctors are substantially more likely than UK doctors to be represented in the erased or suspended group: France, Bangladesh, the Netherlands, and Austria head the list, all with five times the UK prevalence
- Doctors from five countries are less likely to be in this group (Czech Republic, Greece, Hong Kong, New Zealand, and Slovakia), but the differences from the UK are not significant.

Some of these findings are unsurprising. Non-UK graduates, for example, have long been perceived as over-represented regarding the disciplinary attentions of the GMC.<sup>3</sup> And licentiates of non-university licensing bodies have also received attention from educationalists and others as regards the robustness of their qualifications.<sup>5,6</sup> But it might surprise some that of the top 20 countries in the figure, half are in the European Union (EU). Authors of a report showing not dissimilar patterns in performance on a postgraduate medical examination speculate that the hurdle of the professional and linguistic assessments board test, not required of EU doctors, might be relevant.<sup>7</sup>

The GMC should be congratulated for developing an induction programme for foreign trained doctors who are starting work in the UK

to help them “gain an early understanding of the ethical and professional standards they will be expected to meet, as well as familiarity with how medicine is practised in the UK.”<sup>8</sup> In the past EU regulations have been interpreted as precluding the placing of requirements, not applied to UK doctors, on doctors coming to work in the UK and other member states. In the light of these data, hopefully the regulations will not be seen as preventing required attendance from all foreign trained doctors on these courses.

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## Paracelsus on the qualifications of a good surgeon

### Regarding his innate temper

A clear conscience,  
 Desire to learn and to gather experience,  
 A gentle heart and a cheerful spirit,  
 Moral manner of life and sobriety in all things,  
 Greater regard for his honour than for money,  
 Greater interest in being useful to his patient than to himself,  
 He must not be married to a bigot,  
 He should not be a runaway monk,  
 He should not practise self-abuse,  
 He must not have a red beard,  
 He must not act without judgment,  
 He must not accept belief without understanding,  
 He must not scorn the workings of chance,  
 He must not boast of knowing anything without experience,  
 He must never boast or praise himself,  
 He must despise no one.

From Paracelsus (1493-1541), Qualifications of a good surgeon. In: *Paracelsus—Selected Writings*, edited with an introduction by Jolande Jacobi, translated by Nobert Guterman. Routledge & Kegan Paul, 1951.

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Wrong un

**Response on bmj.com**

"I wonder if the authors would agree that the paper could have been improved by adding a third group—veterinary surgeons—who by common convention are both more intelligent and stronger than our 'human' colleagues?" Paul D MacFarlane, Kathryn R Owen, Liverpool, UK

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# As strong as an ox and twice as clever?

Which are stronger and more intelligent, orthopaedic surgeons or anaesthetists?

**P Subramanian and colleagues** find out

**Objective** To compare the intelligence and grip strength of orthopaedic surgeons and anaesthetists.

**Design** Multicentre prospective comparative study.

**Setting** Three UK district general hospitals in 2011.

**Participants** 36 male orthopaedic surgeons and 40 male anaesthetists at consultant or specialist registrar grade.

**Main outcome measures** Intelligence test score and dominant hand grip strength.

**Results** Orthopaedic surgeons had a statistically significantly greater mean grip strength (47.25 (SD 6.95) kg) than anaesthetists (43.83 (7.57) kg).

The mean intelligence test score of orthopaedic surgeons was also statistically significantly greater at 105.19 (10.85) compared with 98.38 (14.45) for anaesthetists.

**Conclusions** Male orthopaedic surgeons have greater intelligence and grip strength than their male anaesthetic colleagues, who should find new ways to make fun of their orthopaedic friends.

## Introduction

A humorous anaesthetic colleague recently repeated the following popular saying while an operating table was being repaired with a mallet: "typical orthopaedic surgeon—as strong as an ox but half as bright." Making fun of orthopaedic surgeons is a popular pastime in operating theatres throughout the country. This pursuit has recently spread to the internet; a humorous animation entitled "orthopedia vs anesthesia" had received more than half a million hits at the time of writing.<sup>1</sup> Several comparisons of orthopaedic surgeons to primates have been published, and the medical literature contains suggestions that orthopaedic surgery requires brute force and ignorance.<sup>2-4</sup>

The stereotypical image of the strong but stupid orthopaedic surgeon has not been subject to scientific scrutiny. Previous studies have

shown that the average hand size of orthopaedic surgeons is larger than that of general surgeons.<sup>2-3</sup> However, a search of the worldwide scientific literature found no studies assessing the strength or intelligence of orthopaedic surgeons. In the absence of a cohort of willing oxen as a control group, and given that the phrase is popular with anaesthetists, we designed this study to compare the mean grip strength of the dominant hand and the intelligence test score of orthopaedic surgeons and anaesthetists.

## Methods

We compared the strength and intelligence of orthopaedic surgeons and anaesthetists in three district general hospitals during a two week period in 2011. We included consultant and registrar grades, as these grades indicate commitment to the chosen specialty. We invited all doctors who were present in the hospital during any day of the two week period to participate. We excluded doctors on leave for the whole period and those who chose not to take part. Because of a lack of female orthopaedic surgeons in all three hospitals, we restricted the study to men.

We measured intelligence by using a surrogate for the widely accepted intelligence quotient (IQ). By definition, the median IQ of the general population is 100 and the standard deviation is 15. We used the Mensa Brain Test version 1.1.0 (Barnstorm Entertainment Group) to measure intelligence. This standardised test uses questions taken from official Mensa IQ tests and is endorsed by Mensa (a worldwide organisation for people with an IQ in the top 2%).

We measured strength by using the surrogate of grip strength of the dominant hand. We chose this on grounds of acceptance for participants, portability, and validity. We used a calibrated Jamar hydraulic hand dynamometer (Sammons Preston Rolyan, Chicago, IL, USA).

## Results

Thirty six male orthopaedic surgeons were available to take part. Forty male and six female anaesthetists took part. Sex is a signifi-



CLIVE FEATHERSTONE

Harder than sudoku

**Table 1 | Participants' demographics, intelligence, and grip strength**

Characteristic	Orthopaedic surgeons (n=36)	Anaesthetists (n=40)
Mean (SD) age (years)	42.2 (8.82)	42.5 (8.63)
Grade—consultant:specialist registrar	20:16	21:19
Handedness—right:left	36:0	38:2
Mean (SD) intelligence	105.19 (10.85)	98.38 (14.45)
Mean (SD) grip strength (kg)	47.25 (6.95)	43.83 (7.57)

Data are shown before transformation for ease of interpretation.

cant confounding factor of grip strength.<sup>5</sup> The paucity of female orthopaedic surgeons meant that we could make no meaningful comparison of women, so we excluded these data from analysis, leaving 36 in the orthopaedic group and 40 in the anaesthetist group. Table 1 shows the demographics and measured parameters of each group. Figure 1 shows the results of measured parameters graphically in the form of a scatter plot.

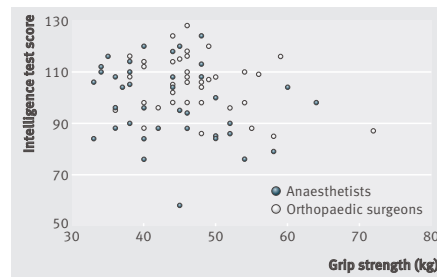
Intelligence did not deviate significantly from a normal distribution ( $P=0.1444$ ). Strength, however, did deviate ( $P=0.0094$ ), and this deviation seemed to be largely driven through skew ( $P=0.007$ ) as opposed to kurtosis ( $P=0.062$ ). We therefore log transformed grip strength data before regression analysis.

We examined the association between specialty and IQ and between specialty and grip strength by using linear regression models with robust sandwich estimation of the variance (allowing for clustering by hospital). These models incorporated various putative predictors available at the time of analysis (specialty, age, handedness, and grade). Specialty showed a significant relation with both intelligence ( $F=18.95$ ,  $df=1,2$ ;  $P=0.0489$ ) and log (grip strength) ( $F=35.02$ ,  $df=1,2$ ;  $P=0.0274$ ). Specifically, orthopaedic surgeons had a higher mean intelligence score (105.19 v 98.38) and a higher mean grip strength (47.25 v 43.83 kg).

## Discussion

This study is the first of its kind to provide evidence for the perpetual banter between orthopaedic surgeons and anaesthetists. We have shown a small but statistically significant difference in both grip strength and intelligence score between the two groups, with higher results for orthopaedic surgeons.

The intelligence scores were lower than anticipated for IQ in the medical profession. This is likely to be a reflection of the way in which intelligence was tested, and the scores derived from the rather difficult Mensa brain test may not be directly comparable to IQ scores. We selected the abbreviated Mensa test carried out by touch screen for speed and convenience. Full formal IQ testing is more time consuming and cumbersome and would have



**Fig 1 | Scatter plot of grip strength against intelligence score, by specialty**

affected doctors' willingness to participate in this study.

The difference in intelligence scores between groups was unexpected. We had predicted that the anaesthetist group might outperform the orthopaedic group, as intellectually challenging activities such as crosswords and Sudoku are popular among anaesthetists. Neither activity has been found to be linked to IQ, however, and the IQ test probably assesses more complex facets of intelligence than those exercised by popular puzzles.<sup>6</sup>

Human muscle strength can be measured in many ways, and the appropriateness of testing particular muscles is debatable. Dominant hand grip strength is just one facet of overall human strength, but it is well validated, reproducible, easy, and convenient to measure.<sup>7</sup> Orthopaedic surgery can be a physical occupation requiring a strong grip on hand operated instruments, so high grip strength is perhaps not surprising. However, many facets of anaesthesia also require a strong grip, such as manipulating a laryngoscope or maintaining a seal with a facemask. If we had assessed other medical specialties, the difference may have been more pronounced.

## Limitations

This work has several limitations. The male preponderance in orthopaedic surgery meant that we were unable to recruit any female orthopaedic surgeons in the three hospitals included in this study, so our findings apply only to men. In the most recent manpower censuses, 94.8% of orthopaedic consultants in the United Kingdom were male compared

with 71.2% of anaesthetists, so our sample is relevant to most of the population.<sup>8 9</sup>

We chose the measures for both strength and intelligence testing as a compromise between validity, cost, and convenience. A full formal IQ test lasting up to two hours per assessment and whole body isokinetic strength testing machines were outside the scope of this study. The three district general hospitals chosen for the study may not be representative of the whole population, and repetition including more centres with a mix of teaching, district general, and private hospitals would be desirable.

Our selection criteria could have introduced bias, as doctors who were on leave for the whole two week period were not sampled and nor were those who declined to participate. People who had insight into their weaknesses may have been under-represented, thereby increasing the mean score in that group. Interestingly, no orthopaedic surgeons and two anaesthetists declined to participate.

## Conclusion

The stereotypical image of male orthopaedic surgeons as strong but stupid is unjustified in comparison with their male anaesthetist counterparts. The comedic repertoire of the average anaesthetist needs to be revised in the light of these data. However, we would recommend caution in making fun of orthopaedic surgeons, as unwary anaesthetists may find themselves on the receiving end of a sharp and quick witted retort from their intellectually sharper friends or may be greeted with a crushing handshake at their next encounter.

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References are in the version on [bmj.com](http://bmj.com).

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bmj.com/podcasts

Listen to the authors debating the relevance of “obs stable”

# “Obs stable” in nursing observations

Gregory Scott and colleagues ask whether this expression is relevant

**Objective** To ascertain whether use of the term “obs stable” with respect to the nursing observations is so liberal as to render it meaningless.

**Design** Retrospective study.

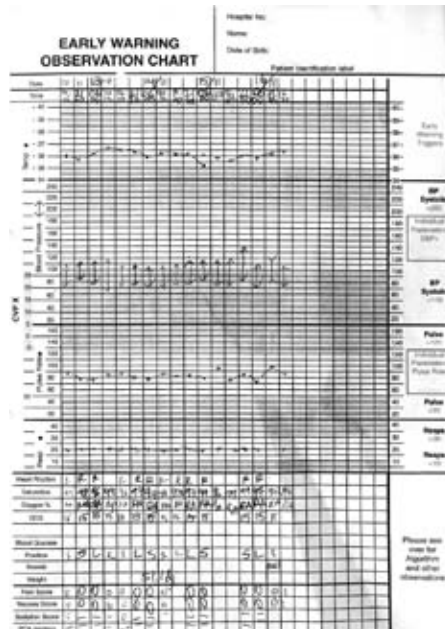
Setting Three teaching hospitals in London, United Kingdom.

**Results** We found at least one entry in 36 (78%) progress notes (95% confidence interval 66% to 90%). Observations in the 24 hours preceding an entry included at least one abnormality for 113 (71%) of 159 cases and at least one persistent abnormality for 31 (19%). The most frequently occurring abnormalities were tachypnoea (respiratory rate  $\geq 20$  breaths/min) and hypotension (systolic blood pressure  $< 100$  mm Hg). An abnormality occurred in the observations immediately preceding an entry in 42% of cases. Mean ranges of observations over 24 hours were within the limits of normal diurnal variation, although we found that some instances of greater than normal variability were described as “stable.”

**Conclusions** The expression “obs stable” does not reliably indicate normal observations or variations in observations within physiological limits. Doctors should avoid using the expression altogether or clarify it with further information.

## Introduction

The expression “obs stable” is written daily in hospital notes. But what does it really mean—a concise shorthand to avoid laborious transcription of essentially normal nursing observations, or a suitably vague term that indicates some sense of wellness and equilibrium, and yet is not as committal as “obs normal” or “obs satisfactory”?



When doctors read medical notes, problems could arise if their interpretation of terms differs from that of the notes' author.<sup>1</sup>

The word “stable” comes from the Latin “stabilis”, meaning steadfast or firm. The *New Oxford Dictionary of English* gives several definitions for the adjective, including “not likely to change or fail” or “firmly established.” The word’s meaning in a medical context receives special mention: “not deteriorating in health after an injury or operation.” But surely a professional definition of “obs stable” needs rigorous physiological characterisation? Certainly, the lack of consensus on the phrase’s meaning has led some senior doctors to prohibit their junior staff from using the expression.

From our experience of ward round discussions on the subject, most criticisms come from the following two, excuse us, stables. Firstly, “stable” might be interpreted as “normal,” suggesting no action is needed. But a patient with persistent tachycardia has “stable” observations; indeed, the diagnosis of death necessitates very “stable” observations. Secondly, “obs stable” implies a lack of rigour, suggesting a cursory glance over the chart rather than a detailed analysis of the nursing observations.

We sought to measure the range of observations which doctors record as “stable,” to ascertain whether their use of the term is so liberal as to render it meaningless.

## Methods

### Design and setting

We did a retrospective review of case notes and nursing observations charts of 46 inpatients who received level one care in adult medical and surgical wards in three teaching hospitals in London, United Kingdom.

### Data collection

We selected the first four to six sets of inpatient progress notes according to bed order from 11 wards across the three sites. We searched these notes for doctors’ entries containing the phrases “obs stable” and “observations stable.” For each entry containing at least one of these phrases, we recorded the nursing observations (that is, temperature, blood pressure, heart rate, respiratory rate, and oxygen saturation) from the bedside chart during the 24 hours preceding each entry, as well as the date and time of the entry, grade of the senior doctor in the title, and grade of the note’s author.

Table 1 | Frequency of abnormalities recorded in the nursing observations preceding entries containing “obs stable” or “observations stable”

Abnormality	Entries (n, %) with abnormality recorded		
	In at least one observation in preceding 24 hours	In every observation in preceding 24 hours	In observations immediately preceding an entry
Hypotension (systolic blood pressure $< 100$ mm Hg)	33 (21)	6 (4)	10 (6)
Tachycardia (heart rate $> 100$ beats/min)	21 (13)	5 (3)	12 (8)
Pyrexia (temperature $\geq 38^\circ\text{C}$ )	4 (3)	0	1 (1)
Tachypnoea (respiratory rate $\geq 20$ breaths/min)	88 (55)	26 (16)	51 (33)
Oxygen desaturation ( $< 95\%$ )	26 (16)	4 (3)	11 (7)
Any abnormality	113 (71)	31 (19)	67 (42)

Data based on 159 entries, after exclusion of 18 entries with missing observation data. Criteria for abnormality (in brackets) are based on hospitals’ early warning systems.<sup>15</sup>

**Table 2 | Ranges of observation values recorded during the 24 hours preceding each entry containing “obs stable” or “observations stable”**

	Range of observation value	
	Maximum	Mean (standard deviation)
Systolic blood pressure (mm Hg)	80	23 (15)
Heart rate (beat/min)	40	13 (8.4)
Temperature (°C)	3.1	0.75 (0.51)
Respiratory rate (breath/min)	12	2.4 (2.3)
Oxygen saturation	10	2.4 (1.9)

Data based on 153 entries with relevant data. Ranges were calculated as difference between maximum and minimum values during the 24 hours preceding each entry in which at least two observations were recorded.

### Analysis

In the nursing observations recorded during the 24 hour period before each entry, we calculated the frequency of abnormalities (defined in table 1) and persistent abnormalities (defined as occurring in every observation), as well as the frequency of abnormalities in the set of observations immediately preceding each entry. We also calculated the range of values (maximum–minimum) if at least two nursing observations were recorded within a 24 hour period.

### Results

We found at least one entry (that is, containing either “obs stable” or “observations stable”) in 36 (78%) of the 46 notes reviewed (95% confidence interval 66% to 90%). We found 178 entries, a mean of 3.9 per patient. Of the 36 notes in which the expression appeared, the first entry was made a median of two days after the date of admission (interquartile range 1–3 days). The mean age of patients described as “stable” was 72 years (standard deviation 14 years).

A mean of 3.9 nursing observations were charted in the 24 hours before each entry (standard deviation 1.4, interquartile range 3–4); we were able to locate these data for the relevant period in 159 of the 178 entries. Observations in the 24 hours preceding an entry included at least one abnormality in 71% of cases and a persistent abnormality in 19% (table 1). The most frequently occurring abnormalities were tachypnoea and hypotension. For 42% of entries, an abnormality was present in the nursing observations immediately preceding an entry, with tachypnoea featuring in a third.

Table 2 summarises the ranges for all observations. Owing to the difficulty in obtaining data for controls matched for age, sex, and pathology, we could not quantitatively compare our group with a reference population. Although the mean ranges of observations were similar to published data for diurnal variation,<sup>4–6</sup> greater than normal variability in our data was also designated as “stable” (for example, a swing of 80 mm Hg in systolic blood pressure).

### Discussion

We have found that doctors of all non-consultant grades frequently used the expression “obs stable” in the inpatient progress notes, and in the notes of almost three quarters of cases after a 24 hour period which included abnormal observations. A persistent abnormality was observed for almost a fifth of cases, and an abnormality was observed immediately before two fifths of entries were made. Tachypnoea and hypotension were the most frequently occurring abnormalities. For a few cases, we found that the range of observations over a 24 hour period that were designated as “stable” exceeded normal values of diurnal variation in healthy individuals. Our combined findings suggest that the expression “obs stable” does not reliably denote normal values or variation in observations within strictly physiological limits.

#### Possible explanations for the use of “obs stable” in nursing observations

##### *Lack of importance given to documentation*

Despite the importance of medical records for good clinical care,<sup>7</sup> doctors’ written entries in case notes have frequently been criticised for their illegibility,<sup>8–9</sup> ambiguity,<sup>3</sup> and misuse of abbreviations.<sup>10–11</sup> On a ward round, clinicians might not have enough time to write observations in full, and the situation of senior clinicians rapidly assessing patients and leaving junior staff with little time to record the notes is not uncommon. The expression “obs stable” could be a convenient alternative to transcribing the observations in full when time is limited.

##### *Notes intended to be less committal*

Medical notes are used increasingly to assess professional competence, and could form the basis of a clinician’s defence if their actions are ever scrutinised.<sup>12</sup> The expression “obs stable” might be regarded as less categorical and therefore preferable to alternatives such as “obs normal” or “obs unremarkable.”

##### *Observation chart design*

The design of nursing observation charts could affect how doctors read them.<sup>13–14</sup> Tachypnoea, a common indicator of poor

health, might have been described as “stable” in our study so frequently because of the relative lack of graphical emphasis given to respiratory rates on the observation charts.

##### *The patient seems well*

Doctors might form the general impression that a patient is well and hence, despite observations showing one or more anomalies, feel justified in describing a patient as “stable” because of clinical correlation.

### Clinical implications

How the injudicious use of “obs stable” affects clinical care is unclear and unstudied. Although ambiguity of the phrase might not result in any serious harm, it could convey a false impression of wellness to another clinician reviewing the progress notes (and subsequently the patient). This misunderstanding might, in turn, unduly influence their impression and reduce the clinical rigour being applied. To avoid the situation, doctors should stop using the phrase altogether and write the observations in full, or qualify it by adding “for the last X hours” or “last abnormal observation was X [observation] at Y [time].”

### Conclusions

The meaning of “obs stable” is ambiguous and does not reliably indicate normality. Our findings should be considered preliminary, but nevertheless we hope to at least provoke discussion. Further studies should establish whether the phrase is associated with the time allocated to documentation during ward rounds.

Scrimping scribes of the ward rounds—and your seniors—take note.

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# When is a “free” registrar not free?

Amrit Lota and colleagues do the sums

## Introduction

The Trojan people were warned by their high priest to “fear the Greeks, even those bearing gifts,” but without hard data he could not prevent them giving in to the temptation of a free gift and suffering calamity.<sup>1</sup> Are UK hospitals relying on apparently free registrars in outpatient clinics heading for the same fate? Patients attending outpatient clinics in NHS hospitals are often seen by higher specialist trainees (registrars) rather than consultants. Registrars are appointed by regional training bodies (deaneries), who allocate them to individual hospitals for specialist training and reimburse the hospitals (NHS trusts) for their salaries. Trusts may therefore view the use of registrars in clinics as saving money.

Numbers of registrars provided by deaneries are set to fall. The first reaction in most hospitals to this prospect is to ask, “How will our clinics cope?” However, rather than struggling to explain to hospitals that registrars are allocated to receive training and not primarily to deliver clinical services, it may be wiser for deaneries to appeal to hospital’s baser instincts: finance.

After an outpatient visit patients are either discharged back to primary care (at which point the hospital receives funding for the completed episode) or offered further follow-up, often with intervening clinical investigations. In addition to the costs of an additional outpatient clinic consultation, the true cost of a follow-up appointment includes innumerable costs of clerical, nursing, and technical staff to arrange and document both that next appointment and any intervening tests. As registrars have less experience than consultants, they may be less likely to reach a diagnosis and complete the treatment episode. We determined the level of deficit in episode completion rates of registrars at which it makes no financial difference to the hospital whether a patient is seen by a registrar or a consultant. We then used data from our cardiology unit to find out whether the nominally “zero cost” registrar is a net financial benefit or burden.

## Methods

### Developing the formula

Let the probability of consultants and registrars concluding the episode by discharging the patient be  $P_C$  and  $P_R$  respectively. The costs of an outpatient appointment to the hospital comprise the consultant salary ( $C$ ), which applies only if the patient sees a consultant, and all other costs associated with a consultation such as clinic nurses, secretaries, medical records, porters, and unreimbursed outpatient test costs, which we will call  $A$ . These apply regardless of whom the patient sees. For the purpose of this analysis, we consider the net salary cost to the hospital of the registrar during clinic to be zero as it is paid by the deanery.

We can now consider the alternatives quantitatively. A convenient base state for comparison is that of a patient seeing a registrar who successfully completes the episode (although any other base state can be used). If a consultation does not complete the episode, then the immediate cost consequence is  $A$ , composed of the administrative elements of a future appointment plus the typical intervening tests. It is not necessary to consider the doctor’s salary of the next consultation because with entry into the consultation room on subsequent consultations, the patient re-enters the analysis again.

Suppose the consultation is done by a registrar. There is a probability  $P_R$  that the patient completes his or her episode (zero incremental cost). There is also a probability  $1-P_R$  that the episode is not completed and therefore the patient consumes further resources  $A$  (before re-entering the analysis). Therefore, as a whole, seeing a registrar has a net financial effect compared with the base state of  $P_R \times 0 + (1-P_R) \times -A$  or  $-A(1-P_R)$ .

The alternative is that the consultation is done by a consultant. In this case there will definitely be a salary cost  $C$  and, with probability  $(1-P_C)$ , the cost of an additional future consultation  $A$ . Having a patient seen by a consultant therefore has a net financial effect compared with the base state of  $-C - A(1-P_C)$ .

### Break-even point

The costs of non-completion between consultant and registrar are balanced when  $-C - A(1-P_C) = -A(1-P_R)$  or, more concisely,  $C/A = P_C - P_R$ . When  $P_C - P_R > C/A$ , having the patient seen by a registrar instead of a consultant is a net drain on hospital resources. All that need be done to complete the case is to calculate actual values for  $C/A$ , and  $P_C - P_R$ .

### Audit of discharge probabilities of consultants and registrars

We conducted an audit of episode completion probabilities for consultants and registrars in several cardiology clinics at our trust during April–June 2010. One observer (ASL) reviewed individual clinic letters to determine the nature of the appointment (new versus follow-up), principal diagnosis, type of doctor (registrar or consultant), and whether the episode was concluded. Proportions are reported as percentages, with 95% confidence intervals calculated by using the binomial theorem. We compared proportions using Fisher’s exact test, two tailed. A  $P$  value  $< 0.05$  was considered significant.

## Results

### Break-even point in UK

From NHS billing rates, a follow-up cardiology consultation including all bundled tests is currently reimbursed at £108 (€126; \$170).<sup>2</sup> We used this as an estimate of  $A$ . If we assume a consultation is about 20 minutes, the average consultant salary cost ( $C$ ) is £13.<sup>3</sup> Thus  $C/A$  is about 0.12.





This means that if a registrar's probability of completing a patient episode is more than 12 absolute percentage points lower than that of a consultant, it is financially damaging to use registrars in clinic, even when their salaries are fully reimbursed.

**Audit of discharge probabilities**

We audited 273 consultations for 273 unique patients in the general cardiology clinic; 149 were new referrals and 124 were follow-up appointments. Table 1 shows the spectrum of diagnoses.

The overall completion probabilities are 69% (95% confidence interval 61% to 77%) for consultants and 26% (19% to 33%) for registrars, a difference of 43 percentage points (32% to 54%,  $P < 0.0001$ ). For new patients, the completion probabilities are 77% (68% to 86%) for consultants and 31% (20% to 42%) for registrars, a difference of 46% (31% to 60%,  $P < 0.0001$ ). For follow-up patients, the completion probabilities are 53% (37% to 69%) and 22% (13% to 31%) respectively, a difference of 31% (12% to 49%,  $P = 0.0014$ ). All these figures (table 2) far exceed C/A, indicating that the net effect of using a nominally free registrar in outpatient clinics is financially adverse.

**Discussion**

The assumption in many NHS hospital trusts that registrars whose salaries are externally reimbursed are always financially favourable for hospital clinics may be incorrect. This assumption is far from true in our cardiology department. Our figures indicate that the extra consultants necessary to replace registrars in clinics could be paid for 3-4 times over with the money saved on administrative costs generated by unnecessary follow-up investigations and appointment administration.

**Implications for trusts**

Trusts worried about the financial damage of losing registrars from clinics will be relieved to learn that the converse may be true. It is wrong to look in isolation at the salary cost of an employee when financially pressed; resource drainage by some employees may be many times greater than their salary. Using our for-

**Table 1 | Principal diagnoses in cardiology outpatient audit**

Diagnosis	No of patients
Ischaemic heart disease	97
Heart failure	70
Valvular dysfunction	40
Arrhythmia	26
Hypertension	10
Congenital heart disease	6
Pregnancy related heart disease	4
Pericardial effusion	1
Diagnosis undetermined*	19

\*Patients with, for example, chest pain, shortness of breath, or palpitations in whom results of key tests were not yet available

mula, trusts can identify situations where it is more cost effective to pay for an additional consultant rather than rely on an apparently free pair of hands.<sup>4</sup>

Hospitals currently think they do not have funds to employ more consultants. Our study shows that additional consultants could be readily funded from the cost savings recouped by not using registrars for outpatient clinics.

**Training perspective**

Registrars are supplied to trusts to receive training, but in times of extreme pressure trusts may think it is rational to treat all employees as tools to deliver service. Educational and clinical supervisors have a professional responsibility to prioritise training, and the knowledge that using registrars in clinics may be more expensive will assist them in protecting registrars from being used by trusts as service providers.<sup>5</sup>

Training is changing.<sup>6</sup> The modern trainee has many fewer years and many fewer hours a year in which to gain the skills necessary to become a consultant.<sup>7</sup> Our results support rearranging timetables to favour training.

Trainees should not be excluded from outpatient clinics because they do need to learn to manage clinic consultations independently once they become consultants. Our analysis shows merely that registrars should not be asked to make decisions beyond their expertise. Paradoxically, trusts would save money by having the clinic registrars sit in with consultants and receiving one to one training, as long as this did not decrease the productivity of the consultant.

**Study limitations**

We have developed a new formula and applied it to a single specialty in a single institution. We do not know if the absolute difference in episode completion rate ( $P_C - P_R$ ) is similarly large in other institutions or other specialties. However, it would have to be about three times smaller for the free gift registrar to be truly free of financial harm to the trust.

This was not an interventional study, and we did not set out to investigate clinical outcomes or patient outcomes and did not assess or incorporate patients' preferences regarding type of physician. Nor can it confirm that there are suitable candidates for new consultant posts in every specialty. However, in cardiology they are plentiful, with trainees nationwide now as numerous as consultants.

New patients had a higher probability of completion than those attending follow-up appointments. Patients already under follow-up tended to continue to need further follow-up regardless of whom they saw. Nevertheless, the probability of completion was still lower for registrars than consultants for these types of appointment and use of a registrar was a net financial harm.

**Conclusion**

The true reason that registrars should not be filling consultant roles in outpatient clinics is that they are supposed to be receiving training instead. However, trainers who want to achieve good training, but face resistance from trusts, can also argue using allegory,<sup>1</sup> algebra, or audit.

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Contributors: RS recognised that trusts erroneously assume a registrar is financially beneficial. DPF (guarantor) developed the three pronged explanation for trusts, ASL derived the formula and conducted the audit, CHM critically reviewed and edited the manuscript.

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**Table 2 | Number of patients seen and episodes completed by consultants and registrars for new referrals and follow-up patients**

	New referrals			Follow-up patients			All consultations		
	Consultant	Registrar	% difference (95% CI, P value)	Consultant	Registrar	% difference (95% CI, P value)	Consultant	Registrar	% difference (95% CI, P value)
No of consultations	81	68		38	86		119	154	
No (%) ending in patient discharge (completed episode)	62 (77)	21 (31)	46 (31 to 60, <0.0001)	20 (53)	19 (22)	31 (12 to 49, 0.0014)	82 (69)	40 (26)	43 (32 to 54, <0.0001)

# Inguinal hernioplasty using mosquito net mesh in low income countries

In Africa, prosthetic repair of inguinal hernias with commercially available mesh is expensive.

**Brian Stephenson and Andrew Kingsnorth** investigated an alternative

In many parts of the world the burden of untreated hernias, particularly inguinal, is high and those who work in advanced health-care systems may believe that little can be done. In addition, many low income countries consider elective surgery to be a low priority. Indeed in parts of Africa many patients develop large inguinoscrotal herniation as a result of delayed presentation, and the need for emergency surgery with its attendant mortality is not uncommon.

Although those who work in developed countries fully appreciate the benefits of alloplastic (synthetic) mesh in the repair of inguinal hernias,<sup>1</sup> this is still not commonly used in poorly resourced communities. Availability and cost of such meshes are generally prohibitive to both surgeons and patients. Although the benefits of Lichtenstein tension-free repairs (earlier return to work and a lower long term recurrence rate)<sup>2</sup> are well appreciated by African surgeons, a traditional sutured repair (Bassini technique) is still common.<sup>3</sup> This can best be described as a low cost approach that has been clearly satisfactory in the past. Can this now be superseded by the

introduction of a widely available and distinctly cheaper mesh to improve the results of repair and quality of life?

## Hernioplasty using mosquito net mesh

Although commercial nylon (polyamide 6-6) has been used for over 60 years as suture material, in some low income countries sterilised nylon fishing line, bought locally, is still used as a cheaper alternative.<sup>4</sup> Given that this has proved a safe option, the next logical step was the use of a net of similar material as a mesh in the repair of inguinal hernias.

The Indian surgeon Tongaonkar must be credited for popularising this novel concept, although he attributes the idea to his coauthor Reddy.<sup>5</sup> A non-insecticide impregnated copolymer (50% polypropylene:50% polyethylene) mesh from mosquito nets was used in 359 repairs in a four centre (including rural settings) audit of various abdominal wall hernias over a six year period. Most of these hernias (278/419, 67%) were inguinal, and overall the repairs were well tolerated. Minor wound sepsis (not requiring mesh excision) was noted in about 5% of patients. Although follow-up was not strict, only one case of recurrence (0.3%) was documented. Indeed, as commercial meshes had also been used in some patients, concerns about early infection were inadvertently addressed as similar rates of sepsis (7%) were noted when prolene or marlex mesh was used.

The wider clinical application of these data was tested in Burkina Faso, west Africa in an ethically approved randomised design carried out by visiting German surgeons.<sup>6</sup> Forty consecutive well matched unselected inguinal hernias were repaired with either a commercial mesh (Ultrapro (polyglactin/polypropylene), Ethicon) or a similar sized sheet of locally bought and sterilised mosquito mesh (100% nylon). The outcome was assessed with an African adaptation of the SF-36 form for quality of life items. All patients significantly improved postoperatively, although no difference was reported between the mesh groups. The cost to the patient was noticeably different, however, at about 25 000-fold.

Clearly the next step was to look at locally obtained mosquito net mesh for its biocompatibility, since a foreign body reaction is generated when any type of mesh is used to augment a hernia repair. Indeed wounds have a different response to mesh than the healing process observed after sutured repairs.<sup>7</sup> This uncertainty is clearly problematic in humans, and animal studies are necessary. Goats in Uganda were subjected to numerous careful analyses at four and 16 weeks after mesh implantation on the posterior sheath of the rectus abdominis muscle.<sup>8</sup> Mosquito net meshes containing 100% nylon were compared with meshes containing 100% polypropylene meshes (Surgipro, Tyco Healthcare), and although both comprised monofilament fibres they varied to some extent for other properties such as weight, pore size, thickness, and tensile strength. No complications occurred. The only difference was a longer and slightly more intense inflammatory response with the mosquito net mesh.

## Operation Hernia

Operation Hernia is an independent UK based charity, established in 2005 when a team of European surgeons got together to establish a link between Deriford Hospital, Plymouth and a government hospital in Takoradi, western Ghana. Operation Hernia primarily acts as a surgical programme to treat hernias and teach hernia surgery in low income countries, particularly those on the African continent ([www.operationhernia.org.uk](http://www.operationhernia.org.uk)). The programme is committed to providing high quality abdominal wall (especially inguinal) surgery at minimal costs to patients who would otherwise not receive treatment.

On our first mission in 2005<sup>9</sup> we used commercially donated mesh to treat 123 patients with inguinal hernias. In 2007, and as a consequence of evolving favourable literature, we introduced sterilised mosquito net mesh to Ghana.<sup>10</sup> This was donated by Scotmas ([www.scotmas.com](http://www.scotmas.com)), a company that manufactures hygiene and environmental care products, and consisted of 100% polyester with reinforcing threads, which was cut and sterilised locally. A total of 106 meshes were used to repair inguinal hernias in 95 patients. At



Fig 1 | Cutting a large sheet of mosquito net mesh to size before sterilisation



Fig 2 | Teaching the principles of tension-free mesh hernioplasty

six months follow-up, seven (7%) patients had minor wound complications but no recurrences. Owing to the surgeon's unfamiliarity with the material, ease of handling improved after two to five cases. The cost of an individual mesh, including sterilisation and packaging, was negligible and estimated at about \$2.00 (£1.26; €1.50). This price is significantly lower than that in the developed world for a similar sized piece of mesh produced commercially (\$40 to ≥\$50).

Although Tongaonkar had been using mosquito net mesh for some time we only heard about it in 2008, as his pioneering contribution was not cited by PubMed or Medline. We obtained some samples of the mesh and found it to be very surgeon friendly. On a mission to the Ivory Coast in late 2010, we cut the donated mesh to size (fig 1) and steam autoclaved it for 25 minutes at 121°C allowing for a predetermined cross sectional shrinkage of about 30%.<sup>11</sup> Over four days we used the mesh to repair the hernias of 54 patients (60% with large inguinoscrotal hernias), mainly under local anaesthesia as day cases. Oral antibiotic prophylaxis was given for five days postoperatively, and at six weeks' follow-up no complications were recorded. The cost of the mesh was low (<€2 for 10×12 cm), including sterilisation and packaging. The mesh handled well, did not fray on cutting, and felt softer than the polyester mosquito net mesh previously used by Operation Hernia since 2009. In all future missions Operation Hernia plans to use the mosquito net mesh because of its handling properties.

Since the inception of Operation Hernia, numerous surgeons, operating in teams, have volunteered their time to teach (fig 2) and treat underprivileged people. Over 50 missions have

taken place since 2005, with more than 4000 people treated, principally in west Africa.

### Discussion

Both clinical and experimental evidence<sup>5 6 8 10</sup> supports the use of indigenous mosquito net meshes to augment the repair of inguinal hernias to achieve results similar to those of developed countries.

The mosquito net mesh has many of the features of modern meshes at a fraction of the cost: they are made of similar monofilament material to those commonly in use with comparable weight, pore size, elasticity, and biocompatibility or reactivity. In the past six years only two patients treated by Operation Hernia have required mesh excision owing to infection, regardless of whether commercially available or mosquito net mesh was used. Nevertheless, the need to be fastidious about sterility cannot be overstated and needs to be stressed before rural surgeons use locally acquired mesh on a regular basis. It would seem that mosquito net meshes are easily sterilised locally, although at different temperatures and for varying times to maintain sterility and mesh integrity.<sup>5 6 8 10 11</sup> In addition a short course of antibiotics as a precaution against potentially unhygienic conditions in the patient's home would be advisable.

Where do we go from here? Operation Hernia is now using donated pre-cut ethylene oxide sterilised (in the United Kingdom) mosquito net

mesh for the repair of inguinal hernias. With more formal audit and stricter follow-up locally we will be able to answer the question of whether such an approach does safely allow mosquito mesh hernioplasty without an increased risk of sepsis<sup>11</sup> and with the lower recurrence rate to which we are all accustomed.

Given that mosquito net meshes are clearly affordable compared with those promoted by commercial companies, hopefully the elective repair of inguinal hernias will be given greater priority in developing countries. Mosquito net mesh technology has been clearly tested and the product should be universally accessible; it certainly seems satisfactory to both surgeons and patients.<sup>12</sup> Nevertheless, before global acceptance is achieved, including that of commercial companies, careful audit and follow-up is required, which could involve many barriers in the African setting.

Finally, is there evidence that these propositions actually improve outcomes by reducing a patient's disability? Political and public health decisions often need to be fostered and then strengthened by firm data. In this respect disability adjusted life years (DALYs) can be used to confirm or refute the economic benefit of such interventions.<sup>13</sup> One DALY represents the loss of one year of equivalent work that someone could accomplish when in full health. In a study of 113 patients undergoing elective mosquito mesh hernioplasty by Operation Hernia, an average of 9.3 DALYs

per patient were averted at a cost of less than \$13 per DALY averted.<sup>14</sup> For comparison, the costs for averting a DALY are \$2 for tetanus immunisation, \$9 for the removal of a cataract, and \$1300 for tibial nailing. Therefore \$13 per DALY averted is surely not a figure that any public health system should ignore, irrespective of the resources being spent

**The mosquito net mesh has many of the features of modern meshes at a fraction of the cost: they are made of similar monofilament material to those commonly in use with comparable weight, pore size, elasticity, and biocompatibility or reactivity**

on other disease burdens such as AIDS and malaria. Mosquito nets are clearly valuable in more ways than one.

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# N of 1, two contemporary arm, randomised controlled clinical trial for bilateral epicondylitis

**Luigia Scudeller and colleagues** conduct a unique trial

**Objective** To investigate the use of a novel study design in analysis of bilateral elbow pain.

**Design** N of 1, two contemporary arm, open label, randomised controlled clinical trial.

**Setting** A clinical epidemiologist at a university hospital in Pavia, Italy.

**Participants** Two elbows with epicondylitis.

**Interventions** Autologous platelet lysate versus “wait and see” strategy.

**Main outcome measures** Visual analogue scale for pain on elbow extension and resisted wrist extension.

**Results** Over six months’ follow-up, the patient experienced bilateral improvement in pain, but higher in the treated arm, with a drop in visual analogue scale for pain from 28 to 4 for right (control) arm (drop of 24 points) and from 67 to 10.5 for left (treated) arm (drop of 56.5 points).

**Conclusions** Platelet lysate might (or might not) work. Competing interests and lack of blinding might be relevant issues in the interpretation of trial results. However, the new study design can be applied to a number of conditions such as bilateral sport or trauma injuries, bilateral otitis, or any condition affecting chiral organs or limbs.

## Introduction

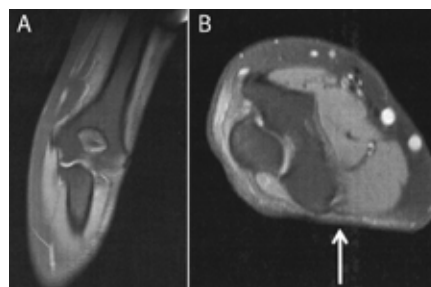
The history of research is replete with examples of researchers experimenting on themselves,<sup>1</sup> but, to our knowledge, this is the first instance where a clinical epidemiologist has drawn up a new study design, performed the trial on herself, and reported the results.

## Patient and methods

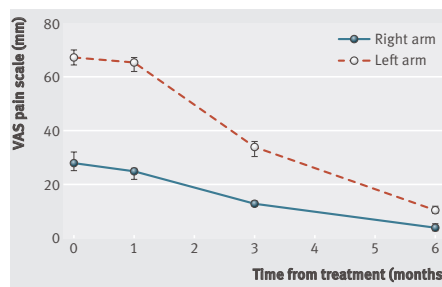
### History

LS, a former infectious disease specialist now a clinical epidemiologist had her third relapse of bilateral epicondylitis in less than two years.<sup>5</sup>

After unsuccessful treatments with topical and systemic non-steroidal anti-inflammatory drugs, arm straps, icing, ultrasound therapy, and laser therapy,<sup>6</sup> these episodes were treated with intra-articular corticosteroid injections with high efficacy in the short term.<sup>7</sup> As a result, severe skin atrophy was present bilaterally at the time the study started.



**Fig 1 |** Magnetic resonance imaging of the patient's left elbow in coronal (A) and transverse (B) views.



**Fig 2 |** Median (interquartile range) measures of elbow pain on visual analogue scale (VAS) for the right (control) and left (treated) arms in the first six months from treatment

Her blood biochemistry, C reactive protein concentration, erythrocyte sedimentation rate, and tests for rheumatoid factor and autoantibodies were normal. Ultrasound examination revealed bilateral active inflammation and minute intra-tendinous calcifications. Magnetic resonance imaging confirmed bilateral thickening of the common extensor tendon, with surrounding soft tissue oedema and focal oedema areas in the bone of the radial head and of the lateral epicondyle of the humerus.

As symptoms reached Nirschl phase VI to VII, she was about to start a course of antidepressant therapy, when she had a surge of professional pride. Conducting a systematic review of the literature, she found many relevant papers on dozens of possible treatments and focused on a promising report of successful treatment with platelet rich plasma<sup>8</sup> (also expected to reverse the deleterious effect of previous steroid injections<sup>9</sup>).

She identified an ongoing clinical trial,<sup>10</sup> wrote to the researchers, and was referred to a published abstract indicating 80% success at one year.

## Study design

She designed an n of 1, two contemporary arm, open label, randomised controlled trial in which the treatment arm would coincide with the treated arm.<sup>11-14</sup> For arm A (in the epidemiological sense), treatment with platelet lysate injections (2.5 ml injection every four weeks for three times) was chosen. Platelet lysate is a solution of bioactive molecules obtained by platelet destruction by freeze-thawing.<sup>15</sup>

The choice of the comparator was a challenge. The researcher, having reviewed the literature, found numerous alternatives: acupuncture, shock wave therapy, topical glyceryl trinitrate, transcutaneous electrical nerve stimulation (TENS), tecartherapy, orthotics, physiotherapy, botulinum injections, complete immobilisation, long term arm straps, and surgery.<sup>6</sup> Ultimately, she selected a “wait and see” strategy for the control arm.

Because of the extremely painful nature of the treatment arm (in the epidemiological sense) (local anaesthetics were not allowed, to avoid dilution of the active drug and to limit the injection volume), blinding and masking was not accepted by the patient. In fact, a placebo effect could not be etymologically anticipated, and injection of any amount of inactive liquid into an inextensible and inflamed tendon is likely to be unacceptable.<sup>16</sup>

Randomisation of arms (in the anatomical sense) was deemed appropriate since no residual and differential effect of previous local treatments was hypothesised. Randomisation was achieved by the flipping of a 1 euro coin. No drugs interfering with platelet functions were allowed, nor systemic support in the form of domestic help.

Since the effects on elbows need to be proved,<sup>17</sup> outcome measures for measures were based on a visual analogue scale for pain on elbow extension and resisted wrist extension (primary), on the patient rated tennis elbow evaluation (PRTEE) scale,<sup>18</sup> and other pain and functional scales, and assessed at baseline and

Baseline and follow-up measures of elbow pain and function in control (right) and treated (left) arms			
	Right arm	Left arm	Difference left–right
Baseline:			
VAS score*	28	67	39
PRTEE scale†	31.5	48.5	17
Mayo score‡	52.5	30	–22.5
Roles-Maudsley score§	4	4	0
1 month follow-up:			
VAS score*	25	65	40
PRTEE scale†	28.5	42.5	14
Mayo score‡	57.5	35	–22.5
Roles-Maudsley score§	3	4	1
3 month follow-up:			
VAS score*	13	34	21
PRTEE scale†	11.5	19.5	8
Mayo score‡	82.5	77.5	–5
Roles-Maudsley score§	1	2	1
6 month follow-up:			
VAS score*	4	10.5	6.5
PRTEE scale†	5	10.5	5.5
Mayo score‡	87.5	80	–7.5
Roles-Maudsley score§	1	2	1
Difference 6 months–baseline:			
VAS score*	–24	–56.5	–32.5
PRTEE scale†	–26.5	–38	–11.5
Mayo score‡	35	50	15
Roles-Maudsley score§	–3	–2	1

\*VAS=visual analogue scale, median value of twice daily measurements over 7 days (n=14).  
†PRTEE=patient rated tennis elbow evaluation scale.<sup>18</sup>  
‡Mayo functional elbow score.<sup>23</sup>  
§Roles-Maudsley score.<sup>24</sup>

at one, three, and six months. All were primary end points to the patient.

## Results

Platelet lysate was injected intratendinously by CP on 19 February, 11 March, and 21 April 2010 under sterile conditions (LS, being an infectious disease specialist, particularly stressed the need for hand washing). At the time of first injection (12 months from last corticosteroid injection), skin atrophy had almost completely resolved.

Baseline and follow-up measures are reported in the table and fig 2. At the one year follow-up, the patient reports having built a piece of furniture by Ikea almost by herself.

## Discussion

The relevance of n of 1 trials in evidence based medicine are increasingly recognised.<sup>25</sup> Criteria for determining whether an n of 1 trial is appropriate are well established,<sup>14 26 27</sup> and, according to these, our trial should not have been conducted in view of having to reply “No” to the question “Will the treatment, if effective, be continued long term?”

However, according to the well known principle “There are more things in heaven and earth than are dreamt of in your clinical epidemiology handbook,”<sup>28</sup> we have created a new study design. In this setting, even with cure as the final objective and without repeated periods

of treatment, “control-ateral” arm (in the anatomical sense) provides the necessary “control” arm (in the epidemiological sense), thanks to a local treatment being available (that is, with no systemic or contralateral effect anticipated), whereas n of 1 trials have otherwise been used only for systemic treatments.

This new study design could be applied to a number of conditions such as bilateral sport or trauma injuries, bilateral otitis media, bilateral conjunctivitis (indeed, any condition involving chiral organs or limbs).

## Study limitations

Many would agree that n of 1 trials do not represent research, but (only) the highest standards of establishing benefits and harms of therapy in an individual.<sup>11 29</sup> On the other hand, as with any single subject research, the generalisability of n of 1 trials is enhanced with within patient (ABA or ABAB designs) replication or between patient replication. This was made explicit by other researchers some years ago—“Death for death, haste still pays haste, and leisure answers leisure; like doth quit like, and measure still for measure.”<sup>30</sup> Hopefully, it will not be possible to replicate the trial in this patient. If other patients with bilateral epicondylitis present, other trials will be conducted (we will be glad to provide the research protocol), and results might be combined.<sup>31</sup>

A considerable source of bias is the fact that the patient is a researcher as well. Single self experiments have been categorised as self indulgence or abuse, and trivial interventions masquerading as research studies as a source of amusement.<sup>19</sup> In the present study, the intervention was by no means trivial, requiring high scientific, clinical, and technical expertise from the investigators, and high motivation from the patient. Besides, experimental units were two (right and left elbows), and the patient-researcher was at the same time self indulgent (right elbow) and self abusing (left elbow). Finally, she was in no way amused by the clinical situation.

In addition, the patient was not blind to the treated arm, and objective measures were not used. However, the patient was carefully instructed to forget which arm was given which treatment, was sent electronic reminders of the scheduled assessments to avoid missing data, and, in case she forgot despite all this,<sup>4</sup> the researcher filled in the questionnaires herself.

## Conclusions

At end of the trial, both arms were almost pain-free, but the drop in pain in the treated arm was greater than in the control arm. This allows several different conclusions to be drawn on efficacy of platelet lysate in chronic refractory epicondylitis:

- 1) It is effective, since drop in pain was steeper in the treated arm
- 2) It is not effective, and improvement was due to the natural course of lateral epicondylitis
- 3) It is effective, and the parallel improvement in the untreated arm could have been mediated by the improvement in the treated arm, by allowing a more equal distribution of workload
- 4) Both arms benefited from participation into a clinical trial<sup>32</sup>
- 5) More studies are needed.

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References are in the version on [bmj.com](http://bmj.com).

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# Christmas picture quiz

For each line, sound out individual images to reveal a medically related word or phrase.



1)



2)



3)



4)



5)

For the answers to this quiz please see 7 January issue

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