Independent review of the orthopaedic knee surgery undertaken by visiting Scandinavian Consultant Orthopaedic Surgeons at the Weston NHS Treatment Centre for comparison with the findings of the British Orthopaedic Association with respect to the same cohort of patients

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Chairman of the Review

May 2011
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Mr Tim Tasker; recently retired Consultant Orthopaedic Surgeon, formerly based at Gloucester Royal Hospital, Gloucestershire

Dr Elise Whitley; Honorary Lecturer in Epidemiology, University of Bristol, Bristol

Dr Jon I Pollock; Reader in Epidemiology, University of the West of England, Bristol

Mr Ian Lowden; Consultant Orthopaedic Surgeon, Great Western Hospitals NHS Foundation Trust, Swindon

Mr Graham Nix, Non-executive Director, North Somerset Primary Care Trust, North Somerset

Dr Will Warin, Chair, Professional Executive Committee, Bristol Primary Care Trust, Bristol

Due to the delays experienced in arranging the Review Panel interviews with the appropriate personnel (23 months) items 2.2 to 2.4 of the Terms of Reference became superseded. As a consequence, the specialist knowledge of Mr Ian Lowden, Mr Graham Nix and Dr Will Warin was not called upon.

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Abbreviations

ACL   Anterior Cruciate Ligament
AOC   Avon Orthopaedic Centre
BASK  British Association for the Surgery of the Knee
BOA   British Orthopaedic Association
BOAR1 1st Reviewer, British Orthopaedic Association
BOAR2 2nd Reviewer, British Orthopaedic Association
C&V   Cardiff and Vale NHS Trust
CI    Confidence Interval
COS-CV1 1st Consultant Orthopaedic Surgeon, Cardiff and Vale NHS Trust
COS-CV2 2nd Consultant Orthopaedic Surgeon, Cardiff and Vale NHS Trust
COS-CV3 3rd Consultant Orthopaedic Surgeon, Cardiff and Vale NHS Trust
DSU   Delivery and Support Unit, Welsh Assembly Government
GMC   General Medical Council
GMP   Good Medical Practice published by the General Medical Council
HCSCH House of Commons Select Committee: Health
HES   Hospital Episode Statistics
ISTC  Independent Sector Treatment Centre
LHB   Local Health Board
OAS   Orthopaedic Associate Specialist
NHS   National Health Services
NJR   National Joint Registry of England and Wales
NPSA  National Patient Safety Agency
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<th>Abbreviation</th>
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<tr>
<td>PCT</td>
<td>Primary Care Trust</td>
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<tr>
<td>RCT–LHB</td>
<td>Rhondda Cynon Taff Local Health Board</td>
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<td>RDSU</td>
<td>The formal letter of response from the Delivery and Support Unit, Welsh Assembly Government sent to the British Orthopaedic Association following receipt of their report</td>
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<td>Review</td>
<td>South West Strategic Health Authority Weston Review</td>
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<tr>
<td>Scanloc</td>
<td>Scandinavian Locums Limited</td>
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<tr>
<td>Scheme</td>
<td>Second Offer Scheme also cited as 2&lt;sup&gt;nd&lt;/sup&gt; Offer Scheme</td>
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<tr>
<td>SCOS</td>
<td>Scandinavian Consultant Orthopaedic Surgeon</td>
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<td>SHO</td>
<td>Senior House Officer</td>
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<td>SM-CV1</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; Senior Manager, Cardiff and Vale NHS Trust</td>
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<tr>
<td>SMR-CV</td>
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<td>THR</td>
<td>Total Hip Replacement</td>
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<td>TKR</td>
<td>Total Knee Replacement</td>
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<td>Tracker</td>
<td>Computerised system for keep ‘track’ of patient as they go through the Second Offer Scheme</td>
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<td>WAG</td>
<td>Welsh Assembly Government</td>
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<td>WAT</td>
<td>Weston Area Health NHS Trust</td>
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<td>WGH</td>
<td>Weston General Hospital</td>
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WHC  Welsh Health Circular
WSM1  Weston Senior Manager 1
WTC  Weston NHS Treatment Centre
1. **Executive summary**

1.1 In June 2006 the *British Orthopaedic Association* (BOA) was invited to undertake a review of the clinical records and X-rays of 14 patients with alleged complications following knee surgery at the *Weston NHS Treatment Centre* (WTC). The review was commissioned by *Rhondda Cynon Taff Local Health Board* (RCT-LHB) at the request of the *Second Offer Commissioning Team* (SOCT) which formed part of the *Delivery and Support Unit* (DSU), *Welsh Assembly Government* (WAG) and in agreement with the *Weston Area Health NHS Trust* (WAT) with whom the contract for the clinical services provided by the WTC had been agreed. It should be noted that the 683 Welsh patients who underwent orthopaedic procedures at WTC had been referred to that healthcare facility from the *Cardiff and Vale NHS Trust* (C&V).

1.2 There appears to be opposition by the BOA and other members of the medical profession to the United Kingdom (UK) Labour Government’s initiative to increase capacity in the National Health Service (NHS) through the introduction of treatment centres and the utilisation of doctors from overseas. Antipathy was also expressed by some BOA members in Wales with regard to the Second Offer Scheme which was designed to increase capacity in NHS Wales. The aversion towards these governmental initiatives appears to have had a deleterious affect on some of the patients who have used such clinical services and also on those who provided them at WTC.

1.3 The 14 knee operations reviewed by the BOA had been performed at the WTC by a visiting team of consultant orthopaedic surgeons under contractual arrangements with the international medical recruitment agency *Scandinavian Locums Limited* (Scanloc). The BOA Review was conducted on 22 August 2006 by two experienced knee surgeons who were past Presidents of the *British Association for Surgery of the Knee* and worked at a distance from both WTC and C&V.

1.4 The Review undertaken by the BOA appeared to reveal that the number of early revisions with respect to Total Knee Replacements (TKR) (a reoperation where the implanted prosthesis is changed or modified) was greater than to be expected within one year, that is, it was alleged that nine cases had been revised out of a total of 147 primary TKR operations in one year. This returned an early TKR revision rate of 6.1% in the first year following the primary operation, which the BOA report stated was six times greater than that to be expected. As a consequence, although the BOA Reviewers had only examined the clinical records and X-rays of the 14 knee patients, they recommended that all patients who had undergone orthopaedic surgery at WTC, regardless of orthopaedic speciality, be reviewed for complications. Therefore, as a precautionary measure, RCT LB requested C&V and Gwent NHS Trust to recall all the patients who had orthopaedic procedures carried out at the WTC.

1.5 As a result of the recall of Welsh patients by the RCT LHB, the WAT in February 2007 requested support from the *South West Strategic Health Authority* with regard to commissioning a further independent review to
identify whether or not poor performance had led to the level of complications reported by the BOA. However the South West Health Authority Weston Review (Review) experienced significant delays (23 months) before it could commence its work in earnest. Since that time there have been other impediments to the work of the Review Panel hence a considerable amount of time has passed since the publication of the BOA report on the 19 January 2007 (although dated 2006). This has led to the items 2.2 to 2.4 in the Terms of Reference for this Review becoming superfluous due to changes in the administrative arrangements at WAT and the closure of WTC.

1.6 The work of this Review Panel has revealed that the statistics cited in the BOA report are incorrect. The time period covered by the BOA Review was the two financial years 1 April 2004 – 31 March 2005 and 1 April 2005 – 31 March 2006 and not one year. There were a total of 224 TKRs undertaken at WTC during that period and not 147. There were seven early TKR revisions conducted over two years and not the nine in one year as stated in the BOA report. Two early TKR revisions were undertaken from 66 primary TKR operations in the financial year April 1 2004 – 31 March 2005 (3%) (95%CI: 0.8% to 10.4%) and five early TKR revisions following 158 primary TKR operations in the financial year 1 April – 31 March 3.2% (95%CI: 1.4% to 7.2%).

1.7 Therefore the early TKR revision rate for all causes over the two year period covered by the BOA report was seven revisions out of 224 primary TKR operations, i.e. 3.1% (95%CI: 1.5% to 6.3%) in one year. However if one of the early TKR revisions contested by the Review Panel’s clinical advisors is eliminated from the figures then the early TKR revision rate would be 2.7% (95% CI: 1.2% - 5.1%). In addition, the maximum 1% TKR expected revision rate cited in the BOA report appears to have been a professional judgement and not based upon any explicit formally recognised national standard. Indeed, such a national standard still does not exist.

1.8 It should also be noted that the clinical advisors to this Review and all the consultant orthopaedic surgeons interviewed, have stated categorically that it is not possible to draw valid conclusions as to the early success or failure of a TKR procedure based solely upon the clinical records and X-rays of patients. This is because before it can be determined whether a TKR operation has been a success or a failure the patient who has undergone the procedure must be consulted. The reason for this is that the recommendation for a patient to have an early revision of a TKR procedure, i.e. less than three years from the primary operation unless there is an infection, is subjective in nature and not objective. Thus the decision reached by a patient and a surgeon as to whether a revision is the most appropriate remedial treatment for any particular patient can vary significantly under what appear to be identical clinical conditions.

1.9 Thus since the BOA Reviewers did not hold consultations with the patients whose clinical records and X-rays they reviewed they were not in a position to recommend that those patients should have early revisions of their knee operations. In fact, the recommendations noted in the BOA report regarding the WTC patients requiring early TKR revisions, were not those of the BOA
Reviewers but those of the patients’ consultant orthopaedic surgeons at C&V who had examined them. This however was not made explicit in the BOA report.

1.10 Furthermore both epidemiological advisors to this Review Panel concur that the quantitative evidence presented in the BOA report, even if it had been correct, is extremely limited and as a consequence difficult to draw any strong conclusions from it. The Review Panel has also identified evidence which suggests that the BOA Reviewers may have been influenced by unconscious cognitive biases when undertaking the review of the WTC Welsh patients.

1.11 Additionally, the BOA has agreed that the revised early TKR revision rates identified by this Review Panel do not support their original recommendations regarding the necessity to review all patients who had orthopaedic surgery at the WTC. Moreover the BOA Reviewers have also stated that they did not undertake a rigorous scientific study and that their review should be considered along the lines of two very experienced consultant orthopaedic knee surgeons looking at the practice processes used at WTC. This however was not made explicit in the BOA report nor did such a process form part of the Terms of Reference for the BOA Review. In addition, a significant number of inadvertent errors and omissions have been identified within the BOA report and as a consequence it is recommended that the BOA consider whether their report should be amended or withdrawn.

1.12 There is also evidence to suggest that the consultant orthopaedic surgeons at C&V involved in reviewing the recalled WTC patients may have unconsciously reduced the threshold at which they would normally recommended early TKR revision surgery due to unconscious cognitive biases. Particularly, as noted above, the decision by a consultant orthopaedic surgeon to recommend that a patient undergo an early TKR revision is highly subjective as is the decision by a patient to consent to such a procedure. In addition there is also evidence to suggest that a patient treated at the WTC was recommended to have a TKR revision by consultant orthopaedic surgeons at C&V when it was not warranted.

1.13 Since the recall of patients by RCT LHB in January 2007 the number of revisions performed on Welsh patients who had TKR operations at WTC has been far greater than would normally be expected. In a study published in the Journal of Bone and Joint Surgery it was reported that at the time of writing the early revision rate in the cohort of TKR knees reviewed by the BOA stood at 15% with a further 14% of patients recommended to have such treatment. Although not part of the original remit for this Review the findings of that study and its methodology were examined at the insistence of some of the consultant orthopaedic surgeons interviewed by the Review Panel. However, during the course of reviewing the study significant inadvertent errors and omissions were found and it is recommended that the Editor of the journal should consider whether the paper should be amended or withdrawn.

1.14 As the BOA report and the paper in the Journal of Bone and Joint Surgery contain serious flaws their findings, it can be argued, are no longer tenable. The only rigorous independent evidence available to the Review Panel is a
study undertaken by Professor Gordon Bannister, Professor of Orthopaedic Surgery at the Avon Orthopaedic Centre, which suggests that the clinical outcomes of the visiting Scandinavian consultant orthopaedic surgeons at the Weston NHS Treatment Centre with regard to early TKR revisions were within the 2% range published by the British Association for Surgery of the Knee and British Orthopaedic Association.

1.15 It should also be noted that the work of this Review Panel was severely hampered by the fact that only five of the 14 patients who were the subject of the BOA Review gave the clinical advisors to this Review permission to review their clinical records and X-rays.

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2. **Background**

2.1 The ‘NHS Plan: a plan for investment, a plan for reform’ published by the Department of Health (DoH) in 2000 was designed to utilise the significant increases in funding to the National Health Service (NHS) that had been planned by the UK Labour Government. The purpose of this extra funding was to ensure that radical improvements could be made in patient access to high quality healthcare services within the UK. By making such an investment in the NHS it was envisaged that:

> ‘Traditional waiting lists for surgery will become a thing of the past. There will be waits of weeks rather than months. The uncertainty of not knowing when your operation will happen will be replaced by the certainty of a booked date. Special one-stop diagnosis and treatment centres will concentrate on performing operations, not coping with emergencies.’

2.2 A change in the structure of the NHS such as that conceived in the NHS Plan had long been desired by many members of the medical profession with Mr Bernard Ribeiro, President of the Royal College of Surgeons of England observing that:

> ‘We from the college and specialist associations have for the last 10, 12, 15 years been talking about separating emergency from elective work. Currently some 64% of consultant general surgeons are on call for emergencies when they are doing elective work. The NHS has to deal with emergencies at the same time as it does its elective work […] if you separate elective from emergency you will get good treatment’.

2.3 Seeking to identify opportunities within the NHS where patient waiting times could be reduced a survey was conducted by the Department of Health in October 2002. The survey revealed that there were a large number of gaps in the capacity of the NHS to meet the patients waiting time targets for 2005 particularly in specialties such as orthopaedics and ophthalmology. As a consequence it was these clinical specialities which became areas of focus for the treatment centre programme.

### NHS and independent sector treatment centres

2.4 The first treatment centre programme was announced in April 2002 and concerned the establishment of publicly owned NHS Treatment Centres. One of the purposes of the NHS Treatment Centres was to ‘... perform a high volume of relatively straightforward elective procedures in a predictable flow.’ Thus, helping to decouple elective from emergency surgery and consequently assist in the reduction of patient waiting times.

2.5 Furthermore in 2002 a group of NHS Chief Executives and clinicians established an organisation specifically to provide support for the development of the NHS Treatment Centres called ‘NHS Elect’. A central objective of NHS Elect, whose members included the Weston NHS Treatment
Centre (WTC), was to optimise patients’ outcomes and their experience of short stay elective care. More information on NHS Elect can be found on their website.⁶

2.6 In addition to the NHS Treatment Centre programme, in December 2002:

‘…a number of independent sector treatment centres (ISTCs) to treat NHS patients for relatively simple, high–volume surgical procedures [was also commissioned]. The first ISTC began operating in 2003’.⁷

2.7 However, beside the shortage of beds another problem facing the NHS in their effort to reduce patient waiting times was a chronic shortage of qualified staff. Thus it was decided that:

‘Where there is other capacity that we can use for the benefit of NHS patients – in the private sector and by bringing in new providers from overseas for example – we will use it’.⁸

2.8 The idea of utilising overseas surgeons to carry out surgical orthopaedic procedures in the UK however proved to be very contentious. For example, Mr Ian Leslie, President of the British Orthopaedic Association (BOA) when giving oral evidence to the House of Commons Select Committee: Health (HCSCH) during their sittings in 2006 on ‘Independent Sector Treatment Centres’ stated that ‘It is this flying teams in and out again which our members totally object to’.⁹ Mr Leslie also raised concerns regarding the quality of orthopaedic surgery performed by overseas doctors in terms of their reoperation rates.¹⁰

2.9 In addition, the notion that ISTCs, using private capital, should also provide additional elective capacity for NHS patients also proved to be controversial. For example, the Chairman of the HCSCH when addressing Mr Leslie about the written evidence that had been submitted by the BOA stated:

‘Your Association was extremely negative in terms of ISTCs…I went on the web [internet] and I found an article presumably written by your predecessor D H A Jones in 2003, which was extremely negative in terms of ISTCs’.¹¹

2.10 Other members of the UK healthcare profession also raised concerns about the clinical standards of overseas doctors suggesting that they might not be as high as those in the UK and hence patient safety might be put at risk.¹² On the other hand there was also support for the views of:

‘Peter West, director of the York Health Economic Consortium [who] said the use of clinical teams raises “potential sensitivities around waiting lists and tensions around private practice”, as well as less self interested concerns about professional standards and care quality. “Nobody really like giving their work to someone else,” said Dr West…’¹³

2.11 While the HCSCH in their report on ‘Independent Sector Treatment Centres’ concluded that:
'There are examples of poor care in ISTCs, as there are in the NHS. However, in the absence of the necessary comparable data from both NHS Treatment Centres and ISTCs, there is not the statistical evidence to suggest that standards are different…

‘Given the difficulty in making comparisons, we are dismayed at the strident and alarmist tone of some criticisms of clinical standards in ISTCs on the basis of anecdotal evidence, highlighted by the BOA’s questionable claim that there are revision rates of 2.3% in ISTCs’.14

2.12 Additionally, it should be noted that the HCSCH also reported that:

‘Traditionally, the NHS paid independent sector providers a premium of 40–100% over reference costs. Following the announcement of the introduction of the ISTC programme, the healthcare sector has seen a downward trend in spot prices. We also heard that the ISTC programme has acted to drive down prices in the wider private healthcare sector. Mr Robin Smith, Chief Executive of Mendip PCT claimed that fees for some operations had fallen by as much as 50% as a result of the existence of ISTCs.

‘ISTCs have had a significant effect on the spot purchase price in the private sector and on charges in the private sector more generally.’15

2.13 Further evidence to support the view that ISTC’s and overseas doctors were not a welcome innovation by some consultant orthopaedic surgeons is to be found in the experience of ‘Netcare’. Netcare is a healthcare organisation which operates a number of ISTCs in the UK and when taking part in the John Studworth BBC Radio 4 programme the Chief Executive stated that:

‘…we have had open hostility. We’ve had some appalling letters written to us and some appalling things said to us. I understand that they are coming from a place of anger and I understand that for many consultants we are threatening their very livelihoods.’16

2.14 Similarly an NHS surgeon who was anonymously interviewed for the same programme was of the opinion that:

‘…part of the medical profession is guilty of holding up progress on waiting lists because of concerns about the impact on their private practice…The majority of consultant surgeons are thoroughly moral, hard working individuals but there is a small group who are exceptionally aggressive, exceptionally ambitious, who are like pigs with their snouts in the trough and it is they who are blocking change’.17

2.15 It was however vigorously denied by Mr David Jones (a member of the BOA and a Council member of The Royal College of Surgeons of England) and others that orthopaedic surgeons were attempting to frustrate the government treatment centre policy in order to protect the financial rewards to be had from private practice.18, 19
2.16 It should be noted however that in a study examining both case-mix and patient outcomes in Independent Sector Treatment Centres as compared to NHS providers, which included hip or knee replacement, Browne et al state:

‘These, the first quantitative data to cast light on the effectiveness of surgery in ISTCs, suggest there is no widespread problem with poor quality care. Indeed, the lower incident of patient-reported complications following treatment in an ISTC is reassuring’.20

2.17 The study was published in April 2008 and the authors note that their findings are to be considered tentative.

2.18 However, regardless of the findings of Brown et al with regard to the quality of ISTCs at interview in April 2009 the first of the two BOA Reviewers interviewed (BOAR1) was of the opinion:

‘…that very poor results are coming out of these treatment centres, and you have to appreciate that the NHS consultants are dealing with all the difficult cases in the first instance, and now they’re being landed with all the failures of the easy cases. So, and it’s happening all around the country I can tell you. A lot of discussion about it at the BASK [British Association for Surgery of the Knee] meeting in Edinburgh two weeks ago, and feelings are running very high actually’.21

Comments

2.19 In an attempt to significantly reduce waiting times for patients within the NHS the UK Labour Government decided to increase capacity in the NHS by introducing a programme of NHS and independent treatment centres staffed, where necessary, by doctors from overseas. The BOA and others from within the medical profession however have publicly expressed antipathy to those innovations even thought they appeared initially to be in favour of them. There is also evidence to suggest that the opposition to treatment centres has led to at least one independent provider of ISTC services becoming the victim of hostile behaviour.

2.20 It has been suggested by some commentators that the antagonism shown towards the use of treatment centres and overseas doctors was less driven by altruism than self-interest. This assertion has been vehemently denied. Nevertheless, there would appear to be no robust evidenced-based quantitative data to suggest that patient outcomes following orthopaedic and other types of surgery performed by surgeons’ from other countries, at treatment centres, is less than satisfactory.

2.21 A recently published quantitative study examining patient outcomes following surgery performed in ISTCs, including hip and knee replacements, suggests that the aversion towards such arrangements expressed by some sections of the medical profession may be unwarranted.
References


21. BOAR1, Transcript - page 51, commencing at Line 31
3. **Weston NHS Treatment Centre**

3.1 During 2002 a newly commissioned day case theatre unit, in part funded by capital from the DoH, became operational at the Weston Area NHS Health Trust (WAT). As there were significantly long waiting times in the Bristol area for orthopaedic procedures it was agreed with the Primary Care and Acute Trusts that the new operating theatre capacity at WAT should be used, as a Weston Senior Manager (WSM1) stated, ‘...in the best interest of Bristol as a whole’.\(^1\) As a result a project was set up inside the WAT and the Weston NHS Treatment Centre (WTC) was established.\(^2\)

3.2 Subsequently a steering committee was set up which included the Clinical Director of the Avon Orthopaedic Centre (AOC), Chief Executive of the North Bristol Trust, a lead person for the Primary Care Trusts (PCT) and senior members of staff at WAT. One of the many issues agreed by this committee was that only those patients whose pre-existing medical condition corresponding to categories 1 and 2 of the American Society of Anesthesiologists physical status classification would be accepted for treatment at the centre, i.e. only patients who did not have complex medical problems would be offered treatment at the WTC.\(^3\)

3.3 The vexing problem of providing sufficient consultant orthopedic surgeons to staff the WTC would be solved by using overseas doctors. To that end WAT followed the Department of Health’s ‘Code of Practice for the healthcare professionals international recruitment of healthcare professions’\(^4\) and also the guidance provided by NHS Employers.\(^5\)

3.4 Thus, having followed the appropriate formal selection procedures the WAT senior management subsequently selected the international medical recruitment agency Scandinavian Locums Ltd (Scanloc) in August 2003 to provide the surgical staff required to staff the WTC. It is important to note that Scanloc is one of a number of organisations listed by NHS Employers who operate according to the code of international recruitment published by the Department of Health and that ‘NHS organisations are strongly recommended to only use agencies on this list’.\(^6\) Hence the recruitment of Scanloc by WAT was compliant with the Department of Health’s policy on such matters.

3.5 It should also be noted with respect to the establishment of the WTC that WSM1 stated:

‘...one of the areas I would dispute in the [BOA] report is the idea that this [the creation of WTC] was happening in isolation of everything else [at WAT]; there were the same nurses in the operating theatre. We did have a unique facility, which had previously been trialled in private practice by our orthopaedic surgeons, which was of a nurse first assistant, and she assisted the Scanloc surgeons pretty much throughout the period...’\(^7\)
3.6 WSM1 also pointed out that:

‘The only thing that was different [between WTC and WAT] was the surgeons. Although I would point out that in fact in 2004, when one of our surgeons was acutely unwell, and in 2005 when one of our surgeons, again, was acutely unwell, a different one, in fact our guys were quite keen to have these chaps [Surgeons recruited by Scanloc] as locums, because by then we were comfortable with their practice. So, in fact, there was a little bit of mixing going on’.

3.7 With regard to the criteria Scanloc applied in recruiting the Scandinavian consultant orthopaedic surgeons to be employed on the WTC project WSM1 stated:

‘…the requirement that the surgeons used, and indeed the anaesthetists, but the surgeons in particular used on this contract: was they must be in existing practice; must have clear results and audit records of their practice historically; must be willing to use and be confident with the prostheses that we were planning to use; and must participate in agreed audit programmes, governance programmes, whatever you wanted to call them, to demonstrate ongoing quality of care. The model of service was pretty clearly defined in the original tender document.’

3.8 Similarly a senior manager from Scanloc (SSM) recalled with respect to the criteria to be used by his company in recruiting surgeons for WTC that:

‘…as far as I remember they wanted orthopaedic surgeons capable of coming over to this country and being placed on the specialist register here, and who had experience of hip or knee prosthesis, and I think the figure was mentioned of 100. A yearly total of 100 hips plus knees, as being not an absolute requirement, but the sort of person we were aiming for. When we produced a surgeon we also produced a list of the operations they had done over the last, I think it was three years’.

3.9 To the question ‘Were the surgeons brought over of the equivalent standard to any consultant over here?’ SSM replied ‘Yes, I would say so.’ To the question:

‘Have any of the [Scandinavian] surgeons working on the Weston contract had similar experiences of their clinical competences being called into question before or since working at Weston?’ SSM replied:

‘We also asked that specifically, and asked for this certificate of good standing, which means they’re not restricted in their practice. We’ve also asked in each case for at least two references, not only did we ask for the written references, but we rang them up and said, “is this the guy, do you know him”’.

SSM also pointed out that all the Scandinavian surgeons recruited to work on
the WTC project were at least 45 years of age and hence were very experienced.\textsuperscript{14}

3.10 Eventually the WTC started operating in October 2003 and patients from the North Bristol NHS Trust started to have elective orthopaedic surgery performed by visiting Scandinavian surgeons.\textsuperscript{15}

**Opposition to the Weston NHS Treatment Centre in Bristol**

3.11 As reported earlier the introduction of treatment centres and use of overseas orthopaedic surgeons met with opposition from the BOA. Similarly the creation of WTC was a cause of specific concern for some consultant orthopaedic surgeons in the Bristol Area. For example, in a BBC news item entitled “Doctor’s ‘visiting surgeons’ warning”, 8 January 2004, it was reported that:

‘A professor of orthopaedic surgery has warned that patients could be put at risk because foreign surgeons are being employed to cut waiting lists.

‘Professor [name of person] is worried that bringing Swedish surgeons over to operate for just a few weeks at a time could mean patients do not receive optimum care.

‘Patients come to Weston-super-Mare’s General Hospital for operations by visiting doctors from overseas to avoid long waits for surgery in Bristol.

‘The scheme has made a positive impact on the area’s waiting times for orthopaedics with more than 100 patients being treated so far....’

‘He [Professor, name of person] says while Swedish doctors have a very good reputation, flying them in for short periods could cause problems when following up any complications.

‘[Professor, name of person] concerns are shared by fellow surgeons in Weston who have written to the British Orthopaedic Association to outline their fears.’\textsuperscript{16}

3.12 However internal clinical audits carried out during the three year period of the North Bristol project at WTC revealed that were no variations in the results of the Scandinavian orthopaedic surgeons from normal local or national practices. A small number of North Bristol patients did experience complications from their knee surgery at the WTC but clinical audits revealed these were similar to ‘…national and local teams’.\textsuperscript{17}

3.13 Moreover, a rigorous independent study led by Professor Gordon Bannister, Professor of Orthopaedic Surgery at the Avon Orthopaedic Centre (AOC) into the North Bristol cohort of WTC patients calculated the revision rate for Total Knee Replacement (TKR) as being 1.9% within two years of their primary operation. The study concluded that while: ‘There were suspicions about the
quality of surgery at both [name of a second treatment centre]...and [WTC]...These were unfounded at [WTC]...48 (Appendix 1)

3.14 Evidence to support the conclusion drawn by Bannister and his colleagues comes from a patient information monograph produced by the British Association for Surgery of the Knee in conjunction with the British Orthopaedic Association, which asserts that ‘Serious complications occur in no more than one or two in every 100 patients’.19 It should be noted however that the monograph does not state the time period, for example, within one or two years in which a serious complication might occur.

3.15 Nevertheless the percentage of serious complication, i.e. TKR revisions, subsequently performed on the North Bristol cohort of WTC patients is within the BOA expected range of 2%. Thus there is no substantive evidence to support the prediction expressed in the BBC article noted earlier that patients’ from the North Bristol Trust could be at risk by having their surgery undertaken at the WTC.

3.16 Indeed, when patients from the Bristol area did have complications following their surgery at WTC the problems they faced seem to have been created by the consultant orthopaedic surgeons in the Bristol area who were reluctant to treat them. For example, in a letter to a colleague a consultant orthopaedic surgeon based at North Bristol Trust stated that:

‘I fear this may by the first of several letters that I believe the issue of re-admitting a patient previously operated on at Weston...will need to be extensively highlighted.

‘Apparently [patient X] was reviewed by his General Practitioner during the daytime hours yesterday and the General Practitioner rang the Orthopaedic SHO [Senior House Officer] on call for an opinion. It was suggested to the General Practitioner that perhaps a referral back to Weston would be appropriate but the General Practitioner was reluctant to do so as this patient lived in the North Bristol region. Subsequently, [patient X] was admitted under my care and has been treated with [name of treatment] overnight. I have reviewed the patient this morning and suggested to him that he has quite a serious problem...

‘Today I am endeavouring to get this patient referred back to the Weston team but I would like to point out to all those concerned that although we agreed to take on any emergency management of patients and perhaps admit them overnight I cannot see any reason why this patient was not referred back to Weston as the referral occurred during daylight hours.

‘It seems that both patients, General Practitioners and the PCT have yet to fully take on board the implications of sending patients down to Weston in terms of continuing post operative management of such complications.’20

3.17 The sense of grievance directed at the WTC portrayed in this letter is also reflected in a statement made by WSM1 that some of the consultant
orthopaedic surgeons at the North Bristol Trust: ‘…were very vigorous in telling us [WTC] how we got it all wrong, and it was never going to work, and it wasn’t fair, and all the rest of it’. While one Scandinavian consultant orthopaedic surgeon (SCOS) who worked at WTC wrote to the Review Panel stating that he and his colleagues had experienced ‘…hostility from orthopaedic consultants in Bristol…’

Comments

3.18 The Weston NHS Treatment centre was established to benefit patients in the Bristol area by reducing waiting times for elective surgical orthopaedic procedures. The recruitment of the surgical staff to work at WTC was rigorous and complied with all the Department of Health criteria for the employment of personnel from overseas. The level of experience required to be employed by Scanloc on the WTC contract by Scandinavian consultant orthopaedic surgeons was extensive and the checking process comprehensive. Thus the only difference to patients attending WTC rather than WAT was that the consultant orthopaedic surgeon who would perform their procedure would be part of a visiting team of Scandinavian surgeon and not directly employed by WAT. It should also be remembered that some of the visiting Scandinavian consultant orthopaedic surgeons did undertake surgery as locums when the WAT surgeons were unavailable through illness.

3.19 Nevertheless, regardless of the potential benefits to patients in the reduction of waiting times there was opposition to the clinical arrangements at WTC by consultant orthopaedic surgeons in the Bristol area and at WAT. While the Scandinavian surgeons have reported they experienced hostility from some of the consultant orthopaedic surgeons who worked in the Bristol area. However internal and external audits at WTC demonstrated that the TKR revision rate for the North Bristol patient were within expected norms.

3.20 The problems experienced by patients when they thought there might be a complication with their TKR operation appears to have come from some of the consultant orthopaedic surgeons in the Bristol area who were reluctant to treat them.

References

1. WSM1, Transcript – page 3, commencing at line 1
2. WSM1, Transcript – page 3, commencing at line 6
3. WSM1, Transcript – page 14, commencing at line 27
5. NHS Employers guidance,
6. NHS Employers, ‘Agencies who adhere to the Code of Practice for NHS employers involved in the international recruitment of healthcare professionals’

7. WSM1, Transcript – page 4, commencing at line 22
8. WSM1, Transcript – page 5, commencing at line 4
9. WSM1, Transcript – page 8, commencing at line 30
10. SSM, Transcript – page 112, commencing at line 4
11. SSM, Transcript – page 113, commencing at line 10
12. Review Panel question, page 113, commencing at line 11
13. SSM, page 113, commencing at line 14
14. SSM, page 114, commencing at line 12
15. BOA briefing dossier supplied by the Delivery and Support Unit, Welsh Assembly Government, paragraph 1.10, p.3
16. BBC News item, ‘Doctor’s ‘visiting surgeons' warning’ at:

17. The content in this part of the briefing dossier produced by the Delivery and Support Unit, Welsh Assembly Government, and sent to the BOA Reviewers was supplied by the Weston NHS Treatment Centre paragraph 2.7, p.4


20. Letter from a North Bristol surgeon to a colleague supplied in confidence. E-mail 04/08/2009
21. WSM1, Transcript – page 27, commencing at line 22

22. SCOS, letter to Review Panel by E-mail 13/08/2009
4. Welsh Assembly Government Second Offer Scheme

4.1 Similar to the introduction of treatment centres in England the ‘Second Offer Scheme’ (Scheme) was part of a package of measures introduced by the Welsh Assembly Government (WAG) to improve health services and reduce waiting times for residents in Wales. The scheme was designed to ensure that those who required elective surgery, except patients needing cardiac surgery and angioplasty where the waiting times were shorter, would be guaranteed to receive treatment within a national maximum standard of 18 months. Thus where there was a risk of a patient waiting for elective surgery longer than the maximum time they would be given the opportunity of receiving treatment from a suitable alternative provider. The scheme was implemented on the 1st April 2004.¹

4.2 A Second Offer Commissioning Team (SOCT) was established to implement the Scheme ‘hosted’ by the Rhondda Cynon Taf Local Health Board (RCT LHB). The purpose of the SOCT was to commission care on behalf of Local Health Boards (LHB) once they had received a referral from them. The SOCT was also intended to be a resource to support LHBs in the operation of the Scheme and ensure that a consistent approach was used across Wales. The reason for this kind of administrative arrangement was because at that time LHBs:

‘…receive a substantial share of the NHS budget for Wales, and as such are involved in planning and allocating health services tailored to their own local population, and then negotiating with hospital trusts, GP practices, dentists and other organisations to provide these services.’²

4.3 It should also be noted that:

‘The 2nd Offer Scheme [was] designed to offer access to treatment for the exceptions rather than the norm.’³

Moreover, the Welsh Health Circular describing the provisions of the scheme states that:

‘Once the pre-existing long waiters have been treated, the objective will be to achieve the targets through effective commissioning and effective delivery, without recourse to the 2nd Offer Scheme other than as a last resort. If the LHB has commissioned sufficient activity to meet demand and deliver targets and if the Trust is managing effectively, it should not be necessary to refer patients to the 2nd Offer Scheme, thereby avoiding the cost of funding the patient’s treatment elsewhere.’⁴

4.4 Thus where the provision of elective surgery could meet the Welsh standard maximum waiting time patients would not be offered a place on the Scheme. Hence, the WAGs intention was clear. Under the Scheme patients should be able to obtain relief from their medical problems as rapidly as reasonably practicable by the prudent use of the resources available to the WAG.
WAGs concern with the husbanding of resources was also echoed in a statement by [name of person] of the British Medical Association Cymru Wales who remarked that:

‘We would prefer it if precious Welsh resources [Wales NHS funding] were invested in Welsh NHS Trusts to build up the capacity to treat patients closer to home.’

However, while building up local capacity to treat patients in Wales was also the WAGs preferred solution waiting times for orthopaedic surgery demanded that action be taken urgently. As a consequence the RCT LHB entered into a contract with WAT for the provision of orthopaedic services at WTC on the 18 October 2004. At this point the WTC North Bristol project had been operating for approximately one year with no problems. Thus it was agreed that all patients’ selected from Cardiff and Vale NHS Trust (C&V) waiting lists to have orthopaedics surgery at WTC would follow the same treatment pathway as those from Bristol. Therefore both Welsh and Bristol patients would have their surgery performed by the same visiting team of Scandinavian surgeons, be on the same ward and have:

‘…, the same ward nurses, ward sister, and all those were involved in their preparation, as well as the delivery of the service. The same audit processes, the same data collection, the same sets of notes’.

Opposition to the Weston NHS Treatment Centre in Wales

As noted above while the British Medical Association Cymru Wales had expressed some reservations regarding the Scheme in relation to the use of Welsh resources outside Wales, there were those amongst the consultant orthopaedic surgeons at C&V who were absolutely opposed to the Scheme. For example, in an article on the BBC web site entitled, ‘Foreign surgeons’ letter row’, it is reported that a consultant orthopaedic hand surgeon employed at C&V had been responsible for an unsigned letter being sent to patients. The BBC stating that:

‘A Welsh health trust has apologised after a letter, apparently from a surgeon, warned patients about the “quality” of foreign surgeons working at an English hospital…

‘Only five of 73 patients later turned up for appointments.

‘The letter, apparently from a senior surgeon at a Cardiff hospital, warned patients not to take up an offer of treatment at a hospital in England.

‘The letter was unsigned but written in the name of consultant orthopaedic and hand surgeon, [name of person].

‘It was received by people who were offered the chance to travel to Somerset for treatment under the Welsh Assembly Government’s Second Offer Scheme, which allows those waiting longer than 18 months to opt for private
treatment or treatment in an English hospital.

‘It told the patients that if they refused the offer to go to England they would be offered a date in Cardiff under [name of person] care.

‘[The letter stated that] “The treatment centre in Weston-super-Mare at which your treatment will take place is run by foreign surgeons whose quality of care and level of specialisation is unknown”.

‘The comments have been described as "unfounded" by the medical director of Cardiff and Vale NHS Trust, [name of person], in a letter he has sent to the patients concerned…’  

4.8 In addition to his work at C&V the consultant orthopaedic hand surgeon named in the article also appears to undertake work in a private capacity. 

4.9 With regard to the allegation cited in the article above when writing to the Review Panel SCOS stated that:

‘…one Swedish consultant specialised in hand surgery was badly treated by a consultant in Cardiff, who questioned him on medical grounds, totally unfair’. 

4.10 SCOS who took part in the BOA Review (Interview 2) also noted in a second letter to the Review Panel that following his interview with the BOA Reviewers that:

‘The two independent reviewers at last said to me, that I/we should not take the criticism personally. They were well aware of the good quality of Scandinavian orthopaedic consultants related to practical work as well as scientifically. But we had to understand the frustration of our Welsh colleagues. They had strived for increased budget to be able to treat the Welsh patients in Welsh hospitals and could not accept that money and patients were sent to other places to have orthopaedic operations performed, i.e. in our case were sent to Weston General Hospital [i.e. WTC].

‘They [BOA Reviewers] stated that the discussions and complaints from the Welsh colleagues were not based on medical reasons but were more of political criticism, directed to the authorities who had made decision on the transferral of money and patients in controversy with the opinion of the Welsh orthopaedic surgeons’. 

4.11 Senior manager in the Second Offer Commissioning team (SM-SOCT1) made a similar point reporting that the Scheme was seen by some in the Welsh medical community as an assault on private practice and that concern had been expressed about local services suffering financially. However, it was also reported that if local orthopaedic services were developed then financial investment would be provided and while the Welsh Assembly Government wanted to ensure that all patients received the care that they needed it was not prepared to pay for them to be treated privately.
4.12 While a senior manager at C&V (SM-CV1) commented that the consultant orthopaedic surgeons at the Trust ‘... were implacably against the second offer scheme’ and also noted that the ‘BOA ‘... were not in favour of ISTCs or the Second Offer Scheme’. SM-SOCT1 also remarked to the Review Panel that the orthopaedic surgeons at C&V did not like the idea that patients who they regarded as theirs should be treated by any other surgeons.\(^\text{14}\)

4.13 Indeed, one consultant orthopaedic consultant at C&V (COS-CV2) stated that:

‘We weren’t against a Second Offer Scheme. We were against patients being forced to leave the area against their will, not being aware of the fact they could have been treated in Cardiff. We were against the way it was set up, that surgeons would be coming in and providing operations without what we regard as standard follow-up, not seeing the same surgeon afterwards.’\(^\text{15}\)

COS-CV2 also noted that:

‘You know, surgeons need ownership of what patients they do. Surgeons coming in for short periods, doing an operation and then disappearing, I don’t think that’s an appropriate way of managing healthcare in this day and age.’\(^\text{16}\)

While another consultant orthopaedic surgeon from C&V COS-CV1 observed that:

‘There was a unanimous view that sending patients’ out of area would result in the problems that did in fact result...’\(^\text{17}\)

4.14 Similarly, the BOA report (Appendix 2) also indicates that at least one consultant orthopaedic surgeon at C&V expected the quality of surgery to be performed at WTC to be less than optimum noting that:

‘One of the surgeons had expressed a desire to be able to see and review all the pre- and post-operative x-rays of the patients who had been treated surgically at Weston, as he was concerned that his unit might be responsible for performing an increased number of early revisions. ‘The Second Offer Commissioning Team hosted by RCT LHB state that a formal request has never been received’.\(^\text{18}\)

4.15 When asked if he knew why the C&V surgeon had thought it necessary to request pre and postoperative X-rays BOAR2 stated that:

‘They were all cross with the whole thing, the whole political thing was they didn’t want their patients sent away, you know, this came out, you know, and we knew this. The problem with the NHS is the politicians speak a lot about quality, and you can’t monitor quality without outcomes, and you can’t have outcomes without spending money, and there is no money for outcomes. The best they can do is a joint registry which is voluntary and inadequate, but it’s better than nothing.’\(^\text{19}\)
While BOAR1 stated in response to a similar question from a member of the Review Panel regarding the request for pre and postoperative X-rays by a C&V consultant orthopaedic surgeon:

‘Well, obviously he had an inkling of the standard of work that was coming through and the problems that were coming through, otherwise why would he have said it?’20

SM-SOCT1 also commented to the Review Panel that the consultant orthopaedic surgeons at C&V appeared to object to the patient transfer review process on a point of principle rather than cooperate and engage with it.21

This view is supported by a COS – CV2 who observed that:

‘…we felt that if surgeons [at WTC] took on this work that they should take on the work and deal with all the complications. We didn’t want to be involved in the clinical care. If they’d felt they were good enough to do the work then they were good enough to treat the complications’.22

A second senior manager at C&V (SM-CV2) also recalled that:

‘…initially the surgeons said we are not going to deal with complaints – I remember one case and the surgeons view was - look they [WTC surgeons] should look at their own - they [WTC surgeons] are the best people to review the patient’.23

Other evidence to support the view that the consultant orthopaedic surgeons at C&V were strongly opposed to the Scheme and WTC can be found in the remarks of COS – CV1 who stated that:

‘Some of my colleagues initially took the view that they were washing their hands of the problem, and refused to see the patient, [who came asking for medical help following their TKR at WTC] and suggested that the Trust arrange for the Second Offer Team to get the patient reviewed in Weston. But I don’t think that there were, I don’t think that position was consistently maintained; essentially I think that eventually even the most intransient surgeon saw the light and felt that, you know, the patients would have to get looked after’.24 (Authors emphasis)

The Review Panel also heard from SM-SOCT1 how some of the patients who had knee operations at WTC returned to C&V as they were in pain but did not wish to travel back to WTC because of the distance. Nevertheless, some of these patients were refused treatment by the consultant orthopaedic surgeons at C&V that were approached.25

While COS – CV2 also noted that:

‘When the patients first started appearing we did suggest that they should be [examined] in Weston by the surgeons that had treated them so they could
remedy the problems. When this didn’t happen it seemed a more humane way forward just simply to treat the patients…”

4.22 As a result of patients being refused treatment at C&V the Review Panel contacted the General Medical Council (GMC) to ascertain whether such a practice was acceptable. The GMC representative in his written response to the Review Panel stated that:

‘Paragraph 11 of GMP (Good Medical Practice) states: “In an emergency, wherever it arises, you must offer assistance, taking account of your own safety, your competence, and the availability of other options for care”. As I explained in our telephone conversation, doctors are not otherwise obliged by our guidance to provide any particular medical service. That is obvious when you consider private doctors, whom we discussed, and indeed retired doctors. I suggested that the contractual obligations of the doctors in question, and the legal obligations of the health boards/trusts by which they were employed was likely to be more relevant to your review’.

4.23 However, in the GMC publication ‘Good Medical Practice’ there is a section entitled, ‘The duties of a doctor registered with the General Medical Council’, among the attributes listed there it is stated a doctor must:

- ‘Make the care of your patient your first concern’
- ‘Work with colleagues in the ways that best serve patients’ interests’
- ‘Support patients in caring for themselves to improve and maintain their health’
- ‘Act without delay if you have good reason to believe that you or a colleague may be putting patients at risk’
- ‘Never discriminate unfairly against patients or colleagues’

4.24 Thus the Review Panel wrote to the GMC once again to ask how it was possible for the consultant orthopaedic surgeons at C&V, who had refused to treat patients, to have been complying with those principles. In a second written communication, reproduced in full so a reader of this report can be fully informed of the GMC’s position on such issues, the Review Panel were informed by the GMC representative that:

‘It may help if I explain our role. The purpose of the General Medical Council is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine. The law gives us four main functions under the Medical Act 1983:

- keeping up-to-date registers of qualified doctors
- fostering good medical practice
- promoting high standards of medical education
- dealing firmly and fairly with doctors whose fitness to practise is in doubt.”
We try to foster good practice primarily through the publication and promotion of good practice guidance, starting with Good Medical Practice.

Because we have a judicial function in considering complaints, we cannot give specific advice about individual cases, as in doing so we may appear to compromise our ability to consider any complaint subsequently made about the same events fairly. You will understand my reluctance to comment on the reported activities of the surgeons you have mentioned.

We are able to give advice about our published guidance; but it is important to set out the boundaries of the GMC’s responsibilities. We have no direct remit in relation to the policy, management and administration of the NHS; nor would we usually become involved in questions concerning the nature of contracts under which doctors provide medical services, either within the NHS or independently. I have repeatedly suggested that the relevant doctors’ duty (or otherwise) to provide care and treatment for patients already being treated at another hospital is a matter primarily for the NHS organisations concerned. If it is established that the surgeons with whom you are concerned were responsible for those patients and declined to provide care and treatment on some improper basis, that may be something about which you should consider making a formal referral, either within the NHS procedures or to our fitness to practise procedures.

The GMC is not a general complaints body and can only act where there is evidence that a doctor may not be fit to practise or where a warning may be required. And we cannot undertake a general investigation into the activities of NHS organisations, which are outside our remit. Information about our fitness to practice procedures can be found on our website at www.gmc-uk.org under ‘concerns about doctors’.

In light of what I have set out, I do not propose to comment on each of the extracts you have selected with regard to the actions of the surgeons with whom you are concerned, except to suggest that it is not clear from what you have sent me that the patients concerned were patients of those surgeons. Please do not take this as an ‘invitation to send me further information about this; you should instead consider whether you wish to refer the issues for investigation within the NHS or through our fitness to practise procedures.

I am sorry that I cannot be of more assistance.29

The Review Panel also contacted the Royal College of Surgeons of England (RCSE), which also encompasses the training of Welsh surgeons, to ask for their opinion with respect to the consultant orthopaedic surgeons at C&V refusing to see patients. The RCSE reply included the following statement:
‘I am sure you will appreciate that, without having full knowledge of the facts surrounding this issue, it would be inappropriate for us to comment upon the points outlined in your email.

The College does offer an invited review service which provides a fair and independent review to ascertain whether there is a cause for concern about the performance of an individual surgeon or surgical team. We would give consideration to such a request if your team felt it appropriate.\(^{30}\)

4.26 Recommendation 3 of this report seeks to addresses the conduct of the consultant orthopaedic surgeons at C&V who refused to treat patients. The recommendation if it were to be accepted, would seek to bring to the attention of C&V senior management the actions of those particular consultant orthopaedic surgeons and to determine whether such behaviour was appropriate in the circumstances.

4.27 Interviewees also recalled illustrations of the anger felt by some of the C&V orthopaedic surgeons to the Scheme. One such example recounted by SM-SOCT1 concerned the disruptive actions of two orthopaedic surgeons on the occasion of a presentation to a group of General Practitioner (GPs) about the Scheme. The surgeons took the unusual step before the presentation of distributing a letter to the GPs setting out their opposition to the Scheme on the basis that; (1) it was an infringement of their clinical freedom; and (2) other surgeons were not up to their standards.\(^{31}\)

4.28 In addition, the Welsh Health Circular setting out the provisions of the Scheme states that:

Patients who select the 2\(^{nd}\) offer referral will be reviewed for clinical suitability by the OP clinician [that is the consultant orthopaedic surgeon at C&V to whom the patient has been allocated]. It is expected that OP clinicians will be in a position to assess fitness for transfer based on patient records / notes, though in some instances it may be necessary to see the patient again or discuss the case with the patient’s GP. It might also be necessary to liaise with the patient’s GP regarding suitability for transfer on social grounds.\(^{32}\)

4.29 Thus the Welsh Health Circular makes it clear that each patient who elects to be transferred to an alternative provider of healthcare services should be reviewed by a clinician to assess their suitability to take part in the Scheme. However, when asked whether the clinical assessments mandated by the Welsh Health Circular were undertaken on the C&V patients who had elected to be treated under the provisions of the Scheme SM-CV2 replied:

‘They weren’t No - and it was made clear as part of the 2\(^{nd}\) offer negotiations with the RCT [Rhondda Cynon Taf LHB] who was hosting it to the SOCT that we didn’t have the capacity for the surgeons here to select the patients to go - so when a patient was offered to go - what we did do is we checked our patient management system and if the patient had major cardiac or renal issues then we would make the decision not to send those patients. But otherwise if a patient agreed to go and they fitted the code of
that was available [clinical service required by patient] at the provider then the patient went. There was no clinical review prior to the patient going.

4.30 When COS - CV1 was asked if he knew why the clinical reviews of patients mandated by the Welsh Health Circular setting out the provisions of the Scheme had not been undertaken he replied:

‘Well, I imagine it wasn’t the case, because it would have been a lot of trouble and a lot of time. My understanding is that the processes were simply that the patients were asked if they were willing to go to Weston, and then when they turned up at Weston, if the Weston surgeons had reservations about the patient’s suitability to be operated on at Weston, either on medical or social grounds, they were then sent back. That was the filter mechanism; I’m not aware of any sort of significant liaison pre-visit, between Weston authorities and the patients’ own GPs.’

4.31 In reply to the same question COS-CV2 replied:

‘We were never asked to…I made it very clear that if there was a political decision made to send patients on my waiting list elsewhere then that was being done at a political level, and had nothing to do with my clinical management of the patient. Therefore, I was not going to select patients for them, to cherry pick, to be sent elsewhere. So it never arose, because we were not interested in doing somebody else’s work for them.’

4.32 However in response to a written question by the Review Panel as to whether senior management at C&V had requested the orthopaedic surgeons to carry out the instructions laid down in the Welsh Health Circular setting out the provisions of the Scheme SM-CV3 stated:

‘The Orthopaedic Surgeons at Cardiff and Vale were asked to personally review fitness for transfer of patients to Weston. They were asked to do so by [name of person] in his role as 2nd Offer Lead. They declined to do so, taking the view that patients had already been assessed and prioritised for treatment. Patients were therefore selected by experienced administrative staff, based on Weston’s range of procedures. [SM-CV3] was aware of this, as was the relevant department in Welsh Assembly Government.’ (Emphasis in the original)

4.33 SM-CV3 was also asked in a written question by the Review Panel if the senior management at C&V were aware that some patients who had TKR operations at WTC and subsequently requested help from the consultant orthopaedic surgeons had been refused treatment by them. SM-CV3 replied as follows:

‘On the second issue, it is the case that some of the Consultant Orthopaedic Surgeons at the Trust were initially unwilling to see patients who had problems relating to surgery at Weston. This was due to a number of factors, including the pressure they were under to reduce local waiting times, their unfamiliarity with prostheses used by the Weston Surgeons, and a belief that it was more appropriate for the original
Surgeon to do any necessary re-work.

‘However, they were persuaded that if patients did want further treatment locally, (some chose to go back to Weston), then they should step in to help, and they subsequently did so (albeit at considerable disruption to the Trust’s waiting-time reduction effort).

‘It is worth adding that I shared many of the concerns expressed by our Surgeons about the contracts drawn up between Welsh Assembly Government and Weston NHS Trust. These included the lack of provision for follow-ups and a weak approach to audit and governance.’

4.34 It should also be noted however that the points made by SM-CV3 in the last paragraph of his letter are not shared by the Delivery and Support Unit. In their letter of response (RDSU) to the BOA report the DSU state in the last paragraph of ‘Review Interview Point 3’ that:

With respect to the [BOA reports] point on clinical governance issues. In both the contract and the protocol for orthopaedic activity (schedule 1 to the contract), there is an explicit requirement for a programme of clinical audit in relation to the delivery of services, to take part in joint audits and to provide comprehensive audit information of the patients treated in the project. This would include an audit of clinical outcomes. Regular audit reports from Weston Trust were submitted to the Second Offer Team and shared with the Medical Director, Clinical Director for Orthopaedics, Directorate Manager for Orthopaedics and the Second Offer Lead within Cardiff and Vale Trust’. (Appendix 3)

4.35 In the context of this Review it is interesting to note that the extract below was published in the British Orthopaedic Association Newsletter ‘BON’ in June 2007:

‘Thankfully we do not have ISTCs (yet) but we do have a scheme called ‘Second Offer’ by which patients who are unwilling to wait for their surgery are offered treatment at English ISTCs. Orthopaedic surgeons in Wales have expressed the same concerns regarding quality of care that colleagues elsewhere in the UK have raised regarding this process, but to no avail – the political imperative has simply been too strong. This may be about to change. An independent audit of clinical outcomes in ‘Second Offer’ patients after knee replacement has demonstrated a 6 percent revision rate at one year, and this has called the whole process into question. It should certainly strengthen the arguments we have been putting forward for improving NHS services rather than paying for the work to be done elsewhere.’

4.36 Hence, it would appear from the article above that the author was of the opinion there was a general view throughout the UK that the quality of orthopaedic surgery in treatment centres was a matter of concern for the BOA and all its members.
The Second Offer Scheme was established by the Welsh Assembly Government in an effort to reduce the patient waiting times for a range of elective surgical procedures within the country. As a consequence the SOCT entered into a contract with WAT so that patients requiring elective orthopaedic surgery could have their procedures performed at the WTC if they wished. At this point WTC had been operating successfully for a year with no reported problems.

However, regardless of the potential benefits to patients due to reduced waiting times reservations were expressed by the British Medical Association Cymru Wales about the use of scarce Welsh NHS resources being used to send patients to England for their surgery. In addition, there were a number of vociferous opponents of the Second Offer scheme amongst the consultant orthopaedic surgeon at the Cardiff and Vale NHS Trust (C&V). One consultant orthopaedic hand surgeon at C&V it would appear going so far as to send letters to patients intimating that they should be cautious about having their surgery undertaken at WTC. It is reported that only five patients out of the 73 patients invited to have their hand surgery undertaken at WTC eventually accepted the offer.

In addition, evidence has been presented that suggests the antipathy directed at the Second Offer Scheme and the visiting Scandinavian consultant orthopaedic surgeons by their counterparts at C&V may have been motivated, at least in part, by self-interest. Indeed, some consultant orthopaedic surgeons at C&V were so incensed by the Second Offer Scheme that when patients treated at WTC came asking for their help they refused to see them. Both the General Medical Council and the Royal College of Surgeons of England reserved their position when asked by the Review Panel if such behaviour was acceptable under the prevailing organisational arrangements at that time.

Evidence has also been presented to suggest that there were consultant orthopaedic surgeons at C&V who believed that sending patients to WTC would result in problems. With at least two consultant orthopaedic surgeon at C&V expecting that some patients would require early revisions as a result of having their orthopaedic procedure performed at WTC. This suggests that there was a prior belief at C&V that patients operated on at WTC were likely to experience clinical complications.

There appears to be some confusion as to whether or not the consultant orthopaedic surgeons at C&V were asked to comply with the directions mandated in the Welsh Assembly Governments Health Circular regarding prospective WTC patients being reviewed by them. What is not in doubt is their failure to carry out those instructions. Patients who elected to have their orthopaedic procedure performed at WTC were not reviewed by C&V consultant orthopaedic surgeons for their suitability for the programme but by administrative personnel who were not medically qualified to undertake such a task. Thus, as will be discussed later in this report, it is likely that C&V patients who fitted the medical criteria but required complex surgery were sent
to WTC and accepted by visiting Scandinavian consultant orthopaedic surgeons qualified to carry out such surgery. That a situation could exist where the directions of the Welsh Health Circular, with respect to the evaluation of patients who wish to take up the Second Offer Scheme are not complied with, suggests there may be a lacuna in the arrangements made by WAG for accountability with respect to the Second Offer Scheme.

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5. Chronology of the BOA review

Background

5.1 On the 3rd April 2006 a letter was received at WTC from a senior manager with the Second Offer Commissioning Team (SM – SOCT2) stating:

‘2nd Offer Scheme – Governance issues

‘Over the last 12 months we have received a relatively small number of complaints from Consultant colleagues [at C&V] regarding the management of their patients referred to Weston under the Second Offer scheme…

‘I would appreciate a joint meeting be convened as soon as possible, particularly in light of the fact we have recently received formal complaints from two patients through their local MP regarding the treatment they received at Weston’.1

5.2 WSM1 at interview stated that: ‘…we had no indication at the beginning of 2006 of any dissatisfaction or any complaints’.2 This was even though WTC had a formal complaints system in place to address concerns that Bristol or Welsh patients might have had regarding their treatment.3 WSM1 noting that:

‘…we gave them [Welsh patients] a calling card, that was their first port of call, it was their choice, could be us. So they’d ring the ward, or ring into the service, and then get put on an outpatient list. So, you know, they were given that opportunity’.4

5.3 When asked if the Welsh patients had in fact used the complaints system at WTC, as was intended by the arrangements specified in the contract between WAT and RCT, LHB, WSM1 replied:

‘That probably was not happening…either they weren’t coming back or we weren’t being copied in, for patients coming from Wales. Obviously, because of the distance involved between ourselves and Wales…then some of those patients didn’t want to come back to Weston for follow up after six weeks, although some of them indeed did, and the satisfaction survey would suggest that they all felt that they were well treated with, no differently from the AOC (North Bristol) patients’.5

5.4 One of the reasons that WTC was not aware that there were Welsh patients who had concerns regarding their knee operations was because as COS CV2 stated:

‘Certainly the patients that I saw for review, I didn’t take it as my role to inform Weston of the complications, I told our direct manager; my priority was treating the patients in front of me’.6
5.5 This failure by the consultant orthopaedic surgeons at C&V to communicate with WTC will be discussed later during a critique of the BOA report in 'Section 6: a critique of the British Orthopaedic Association report', subsection, ‘…background and context’.

BOA review context

5.6 It was reported by SM-SOCT1 that the trigger for the SOCT to seek a review of the clinical services provided by WTC was the profile raised by one or two of the C&V orthopaedic surgeons who grew very vocal about what they perceived as poor clinical practice at WTC.

5.7 As a result of the concerns expressed by those particular consultant orthopaedic surgeons at C&V to the SOCT, on 2nd June 2006 the Access 2009 Project Board, Welsh Assembly Government on the recommendation of the Second Offer Scheme Governance Group, decided not to send patients:

‘…to Weston who required knee replacement surgery and ACL (Anterior Cruciate Ligament) procedures pending the outcome of the Independent Review.’

5.8 Sometime during June 2006 an Orthopaedic Associate Specialist (OAS, non-consultant) at C&V carried out a radiological audit on approximately 20 X-rays of Welsh patients who had knee operations at WTC. He noted that it had taken sometime for WTC to produce the X-rays but was not aware of any reason for the delay. He then went on to say that in his opinion some of the implants were grossly out of alignment. However he could not remember the specifics of how the radiological review he conducted had come to be instigated. He did however recall presenting his results to colleagues in the Trauma and Orthopaedics Department at C&V. It should be noted however, as will be discussed later, that radiological evaluations are mainly subjective in nature and therefore open to involuntary Reviewer bias.

5.9 The results of the audit undertaken by the OAS were then sent to senior management at C&V for their information. It has not proved possible for the Review Panel to ascertain what role this radiological audit played in the BOA review, if any, and is included here only for the sake of completeness since it is briefly referred to in the BOA report.

5.10 It should however be noted with regard to the X-rays taken at WTC, that one of the Scandinavian orthopaedic consultants, ‘Interviewee 2’ (SCOS), observed that: ‘…the quality of the post-operative x-rays was poor i.e. they were badly centred’. Additionally, both clinical advisors to this Review agreed that if the WTC X-rays were not taken in a standard fashion as recommended by the American Knee Society then this leads to difficulties in applying measurement to the X-rays. It should also be noted that the X-rays at WTC were not taken in the standard manner as prescribed by the American Knee Society.
5.11 Also in June 2006 the Delivery and Support Unit, Welsh Assembly Government wrote to the BOA stating:

'We have had a few complications in the knee surgery undertaken at Weston and it has been agreed to commission an independent review. I believe you have kindly agreed to consider undertaking this review if it fits in with your work commitments. I have attached the draft terms of reference which I would welcome your views on.'

5.12 Later the Minutes of a meeting held by the C&V Board, Thursday 6 July 2006 recorded that:

'The Weston Treatment Centre – the second offer team had decided to undertake an objective audit of orthopaedic knee cases and not to rely on anecdotal evidence. It was noted that there were no plans to undertake an overall audit of the second offer scheme provision.' (Author emphasis)

5.13 Subsequently the following Terms of Reference for the BOA Review were agreed:

1. 'To review the notes, x-rays and other supporting information of the patients who have undergone knee surgery at Weston under the second offer scheme and who have complained or their GPs or surgeons have complained;

2. 'To review the notes, x-rays and any other supporting information on a sample of patients who have had knee surgery at the Weston under second offer scheme and in whose regard there have been no complaints;

3. 'To comment on the type of operation, appropriateness of technique and outcome.'

5.14 Before the BOA Review could be undertaken however permission had to be sought by C&V from the 14 patients whose treatment had apparently caused concern and also from those patients who had not complained. To that end a letter was drafted for the DSU by Bro Morgannwg NHS Trust solicitors (Appendix 4 and 4a). However the letter produced while fulfilling legal requirements does not appear to comply with medical ethics best practice according to the National Research Ethics Service. The reason for this is because the letter to the 14 patients whose treatment at WTC was alleged to have given cause for concern does not explicitly state it is for that reason their consent is being requested, i.e. the letter does not explicitly state that there was a concern over the orthopaedic surgery performed on them at WTC. Thus, the patients were not fully informed of the reason for which their consent had been requested.

5.15 To conduct the Review the BOA asked two experienced knee surgeons who were past Presidents of the British Association for Surgery of the Knee and also worked at a distance from both WTC and C&V. It should be noted however that neither of the BOA Reviewers had received any formal training on how a review of the kind required by the DSU should be conducted.
order to assist the BOA Reviewers in their task a dossier was produced by the DSU (some of the content was provided by WTC) and supplied to each BOA Reviewer by the DSU prior to their review.18 The briefing pack contained background information on a range of issues including:

- a copy of the Contract signed by RCT LHD and WAT for the year 2005-2006;
- an overview of the Scheme;
- an overview of WTC and the work which had been undertaken on behalf of the Scheme;
- the results of clinical audits carried out at WTC on both North Bristol and Welsh patients and which do not appear to show any significant differences in the high levels of patient satisfaction;
- a brief biography of each Scandinavian consultant orthopaedic surgeon's clinical experience;
- a document on the management of complaints at WTC which states they were ‘no greater than national or local figures’;
- a computer patient ‘Tracker’ sheet which provided key details on each of the 14 patients to be reviewed including the date of their primary operations, a case summary and where revision surgery had taken place or been recommended;
- the notes of two meetings between WTC and the SOCT concerning the reported complications;
- a document containing the dates, times and telephone numbers when six members of the visiting team of Scandinavian orthopaedic surgeons at WTC, who were not attending the BOA Review, could be contracted by telephone.

The information provided within the dossier supplied by the DSU is comprehensive, concise and very thorough.

**BOA review day**

5.16 On the day of the BOA Review (22 August 2006) the whole process, including travelling from C&V to WTC, was scheduled by the Delivery and Support Unit, Welsh Assembly Government to be completed in nine hours. While the time to be spent undertaking interviews, reviewing patients’ notes and X-rays was seven hours. BOAR1 noting that:

“We did the review of the x-rays and the interviews in a day. We wrote 11 drafts and took six months over writing it up. So, to say we did it in a day is not strictly true, we did the groundwork in a day.”19
5.17 When the author of this report noted to BOAR1 that the, BOA Reviewers, could not have had ‘…very long to look at each particular patient‘, BOAR1 replied:

*It takes about two seconds, actually, to see that a knee has not been done right, less than that probably. I mean, how long does it take you to look at that x-ray, you know?*

5.18 However, contrary to the view of BOAR1 the clinical advisors to this Review are of the opinion that it would take significantly longer than two seconds to examine any patients’ orthopaedic knee X-ray when seeking to establish an accurate diagnosis.

**BOA draft reports**

5.19 As noted by BOAR1 the BOA Reviewers created a number of drafts of their report. When asked about the draft reports by the Review Panel a senior manager at the BOA stated that:

‘…I have examined the four versions [of the BOA Report] in my system, and can confirm as follows:

*The first version contained a Background introduction, a Report on meetings with individuals, the Review, a Summary, Recommendations and References. It was felt inappropriate to retain mention of individuals within the submitted report. The report was therefore anonymised…*

*On your point of possible confusion between ISTC and NHS Treatment Centre, I accept there remained a mention of ISTC in [BOA Report section] 5.3; this was an inadvertent error and you will note that there is clear recognition elsewhere in the report that Weston is an NHS Treatment Centre.*

*In summary, apart from the changes made between draft 1 and subsequent versions to maintain anonymity, no substantive changes were made to the report drafted by [named individuals].*

*‘Amendments were made almost entirely for stylistic and presentational purposes‘.*

**Submission of BOA final report**

5.20 On 19 January 2007 the following E-mail was sent to the DSU by a senior manager at the BOA:

*‘We have consulted all involved on our side in this exercise following your comments and I now attach the final report. A formal hard copy is in the mail‘.*

5.21 A few minutes later the following E-mail was sent from the DSU to WSM1 stating:
‘Please find attached a copy of the final report from the British Orthopaedic Association. As discussed with [name of person] yesterday, the Communications Officer at Rhondda Cynon Taf is [name of person and telephone number] to work on a joint media statement’.24

5.22 The BOA report will be discussed later in ‘Section 6: a critique of the British Orthopaedic Association report’.

**Action by the Delivery and Support Unit Welsh Assembly Government**

5.23 Following the receipt of the BOA report on the 19 January 2007 a communication handling plan was developed by the *Department of Health and Social Services, Welsh Assembly Government* with respect to informing all interested party of its contents. As part of that process the BOA was contacted by the DSU to establish who owned the copyright of the report and whether or not all the Welsh patients who had orthopaedic procedures at WTC should be recalled. On the 25 January 2007 a member of the DSU administration staff sent the e-mail below to a senior manager at the DSU:

‘Just to update you on some feedback from [name of person] in the BOA.

1. In terms of the scope of the recall he has discussed with the reviewers and they conclude that this should be all orthopaedic procedures, not just knees, and is therefore consistent with our planned implementation.

2. He has confirmed that copyright of the report does rest with the BOA but the commissioners of the report are welcome to circulate as they deem appropriate…’25

5.24 On the 26 January 2007 the communication handling plan that had been developed by the *Department of Health and Social Services, Welsh Assembly Government* was E-mailed to *Weston Area Health NHS Trust* for their information.

5.25 In addition letters were posted from C&V to reach all the Welsh patients who had been treated at WTC prior to the public announcement of the BOA reports findings. In total five different types of letter were developed at C&V and sent to patients depending upon the surgical procedure that had performed at WTC or if they had been directly involved with the BOA Review. In cases where the patient had knee surgery they were informed that:

‘In view of concerns raised about the standard of treatment at Weston General Hospital, the British Orthopaedic Association was asked to review the results of knee surgery performed there. The review highlighted that more patients have experienced complications after knee surgery than would normally be expected.

‘What this means for you.'
The British Orthopaedic Association has recommended that all Welsh patients who have had knee surgery at Weston General Hospital under the Second Offer scheme should have a review in Wales. This review is a precaution. We will contact you in the next few weeks to arrange an appointment. During this appointment you will have the opportunity to discuss any concerns you have with a member of the Orthopaedic Department in Cardiff…'

5.26 It should be noted that in each letter the name of the NHS organisation where the patient received their medical treatment is inaccurate. The Welsh patients who availed themselves of the Second Offer Scheme were treated at the Weston NHS Treatment Centre and not at the incorrectly attributed Weston General Hospital (WAT). The distinction is important because although both organisations used the same medical and surgical facilities the consultant orthopaedic surgeons employed by WGH were different from those who worked for WTC.

Media coverage

5.27 A media briefing regarding the findings and recommendations of the BOA report took place at The Angel Hotel, Castle Street, Cardiff, 31 January 2007. The meeting was chaired by the Chief Executive of RCT LHB. The Director of NHS Wales’ Delivery and Support Unit, Welsh Assembly Government and the Deputy Chief Medical Officer for Wales were present and took questions from the media. The findings of the BOA report were published through a range of media outlets once the briefing was concluded.

5.28 When asked if the BOA Reviewers were aware from the beginning that their report would be published BOAR1 replied:

‘I honestly can’t remember, but all I can say is that I have been involved in similar issues before in surveys, and it’s always been confidential’.

5.29 Upon being asked the same question as BOAR1 regarding whether or not he had been informed by anyone that the report would be published BOAR2 stated, ‘No, not to my knowledge’. However when asked, ‘was the BOA Reviewers permission sought before the report was published?’ BOAR1 stated that:

‘…it was made clear to us that it was a BOA report and we were only acting as agents of the BOA, we were covered by indemnity. So I’m very happy with all the conclusions that I’ve drawn, and there’s nothing there I’m unhappy about being released actually, in the public domain’.

5.30 Whereas when asked if his permission had been sought by anyone to publish the report BOAR2 replied, ‘No, I didn’t know it was published.’

5.31 At interview BOAR1 was asked if the BOA report had been written so the ‘lay’ public would understand its contents BOAR1 replied:
No. I mean it’s very difficult, no, I mean it was written with medical practice in mind; I don’t think we had anybody in mind, we just reported our conclusions really’.34

5.32 When asked the same question as BOAR1 with regard to the BOA report and its intended readership. BOAR2 replied: No, we didn’t write it with that in mind.35 A little later BOAR2 noted that: ‘As I said before, this report wasn’t mean to be published, it wasn’t meant to be for a lay read’36

5.33 It should be noted however that in the documentary record of a telephone conversation between a member of the DSU and a senior manager at the BOA with respect to the BOA report, dated 25 January 2007 and noted earlier, it is stated that:

‘1. In terms of the scope of the recall, he [senior manager at BOA] has discussed with the reviewers and they conclude that this should be all orthopaedic procedures, not just knees, and is therefore consistent with our planned implementation.

‘2. He confirmed the copyright of the report does rest with the BOA but the commissioners [RCT LHB] of the report are welcome to circulate as they deem appropriate’37

5.34 Thus whilst the BOA did not formally publish their report they did give permission for RCT LHB to distribute it which they did by way of a technical briefing to the media as noted above. In addition, a summary of the circumstances surrounding the recall of patients was also posted on the Welsh Assembly Government web site38 and also on that of the Health of Wales Information Service.39 Both web pages contain information on how to obtain a copy of the BOA report and telephone number of a patient helpline.

Welsh Ministerial announcement

5.35 On the 1 February 2007 Dr Brian Gibbons, Minister for Health and Social Services, Welsh Assembly Government made the following statement regarding the BOA Report and the recommendations that had been made:

‘It gives me no pleasure to comment on this issue either. The second-offer scheme was set up in April 2004 to ensure that Welsh patients who might have had to wait over the maximum waiting time would receive their treatment in a timely manner. Patients could be referred to a NHS hospital in Wales or England or to an independent hospital. Since this scheme started, nearly 23,000 procedures have been carried out through it, with over 8,500 procedures provided by an alternative provider, such as a hospital in the independent sector or another NHS hospital.

‘Through regular checks of patients at Cardiff and Vale NHS Trust, regrettably, a problem has come to light with regard to a small number of patients who were sent, through the scheme, to Weston Area Health NHS Trust for surgical procedures on the knee. This led to an independent review being carried out by the British Orthopaedic Association on behalf
of Rhondda Cynon Taff Local Health Board and Weston Area Health NHS Trust. Pending the outcome of this review, all new knee surgery referrals to Weston were suspended.

The report has recommended that all patients who were sent to Weston for knee surgery under the second-offer scheme should have their x-rays reviewed. As a precaution, the second-offer team has also decided that all patients who went to Weston for orthopaedic surgery of any sort should have their x-rays reviewed. While the only concerns to date relate to knee surgery, all patients who have had joint surgery at Weston will therefore be offered a radiological review. Approximately 384 patients have been referred for knee surgery, 157 for hip surgery, and a further 152 for other orthopaedic procedures.40

5.36 It should be noted that no reference is made in the statement to the employer of the consultant orthopaedic surgeons who carried out the surgery, i.e. WTC. It is however incorrectly stated that the patients were referred for treatment at the Weston Area Health NHS Trust which in fact acted as the ‘host’ for WTC. It is also stated incorrectly that the Weston Area Health NHS Trust was one of the commissioners of the BOA Review - it was not. Furthermore it is also noted erroneously that ‘Through regular checks of patients at Cardiff and Vale NHS Trust…’ No regular checks on patients who had treatment at WTC were ever carried out at Cardiff and Vale NHS Trust. Indeed, evidence has been presented in this report that at least one of the consultant orthopaedic surgeons at the Trust turned patients away when they asked for medical help because they had elected to be treated at WTC.

BOA patient recall

5.37 Significant numbers of the patients who received a recall letter from C&V offering them an appointment to discuss any concerns they might have about the orthopaedic procedure that had been performed at WTC accepted the offer. The subsequent review of the patients who had TKRs at WTC by consultant orthopaedic surgeons at C&V has led to a revision rate in that cohort of patients which is “…significantly worse than previously published figures,2,3 with a very high revision rate at only three years.41 The circumstances surrounding these findings will be discussed later in ‘Section 7’.

Comments

5.38 It came as a complete surprise to the Scandinavian consultant orthopaedic surgeons and the senior managers at WTC that it was alleged Welsh patients had complained about the outcome of their knee surgery. Particularly as there was a formal complaints system in place for them to use. Thus it would appear that some of the Welsh patients, although informed of what action to take in the event of a complication with their knee operation, decided for personal reasons not to follow that advice. Instead, the patients approached the consultant orthopaedic surgeons at C&V for assistance who also did not inform WTC about their concerns. However, due to these complaints being
volubly brought to the attention of SOCT by the consultant orthopaedic surgeons at C&V it was eventually decided to suspend the orthopaedic services being undertaken at WTC.

5.39 Rather than rely solely upon anecdotal evidence with regard to the alleged problems with knee surgery at WTC Rhondda Cynon Taff Local Health Board decided to commission an independent review. The BOA was approached to undertake the review and subsequently Terms of Reference were agreed by all the parties involved. However the letter sent from C&V to the patients concerned asking for their permission to allow the BOA Reviewers to examine their clinical records and X-rays while legal, does not appear to have complied with best practice in medical ethics.

5.40 Although the Consultant Orthopaedic Surgeons who were approached to undertake the BOA Review were very experienced in surgery of the knee they had received no formal training in how to undertake a review of that nature. Furthermore, they only had nine hours in which to review all the patients’ clinical records and X-rays and to take witnesses statements at two separate locations. The BOA Reviewers appear to have been working at a pace which was not conducive to the production of a comprehensive and accurate account of the circumstances they had been invited to review.

5.41 The draft report was rewritten on a number of occasions and reviewed by senior members of the BOA and the Delivery Support Unit, Welsh Assembly Government of which SOCT was part. The final BOA report, produced following a review of the clinical records and X-rays of the 14 patients who had undergone surgery at the knee at WTC recommended, without any further evidence, that all patients who had orthopaedic surgery at WTC should be recalled.

5.42 Inadvertently, all the letters sent from C&V to the patients who had undergone orthopaedic surgery at the Weston NHS Treatment Centre (WTC) incorrectly cite the Weston General Hospital (WAT) as being the organisation at which they had their surgery. Although the WTC used the same facilities as the surgeons at WAT the distinction is important as the consultant orthopaedic surgeons who worked for the two organisations were totally different.

5.43 A significant media handling exercise was conducted by the WAG although the BOA Reviewers appear to have been confused as to whether it was always the intention to place the BOA report in the public domain. Nevertheless, the subsequent media coverage appears to have been significant and thus the reputational repercussions with regard to WTC, the visiting teams of Scandinavian consultant orthopaedic surgeons, Scandinavian recruitment agency Scanloc and WAT are likely to have been substantial.

5.44 The recall of patients to C&V has led to a significant number of those Welsh patients who underwent TKRs at WTC having revisions.
References

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3. WSM1, Transcript – page 10, commencing at line 4

4. WSM1, Transcript – page 24, commencing at line 30

5. WSM1, Transcript – page 10, commencing at line 28

6. COS CV2, Transcript – page 25, commencing at line 26

7. SM-SOCT1, transcribed from interview tape recording

8. BOA briefing dossier produced by the Delivery and Support Unit, Welsh Assembly Government, paragraph 5, p.4

9. OAS, telephone interview 4 August 2009

10. Interviewee 2 (SCOS), British Orthopaedic Association, Independent Review of Knee Surgery carried out under the Second Offer Scheme in the NHS Treatment Centre, Weston, Delivery and Supply Unit, Welsh Assembly Government, dated 18 January 2006 (although 2007), paragraph 4, p.6

11. Radiological superintendent, Weston Area NHS Health Trust

12. DSU request to BOA, copy to Review Panel by E-mail 01/08/2009


15. National Research Ethics Service representative during a telephone interview following the C&V consent letter being sent to them for comment


17. Senior Manager, British Orthopaedic Association

18. BOA briefing dossier produced by the Delivery and Support Unit, Welsh Assembly Government, copy sent to Review Panel by surface mail
19. BOAR1, Transcript – page 45, commencing at line 30
20. Professor Toft, Transcript – page 46, commencing at line 25
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23. WSM1 in E-mail to Review Panel, 25 November 2008
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26. SM-CV2, E-mail to Review Panel, 27/09/2009
27. For example, see Telegraph.co.uk at:
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29. BOAR1, Transcript – page 44, commencing at line 30
30. BOAR2, Transcript – page 77, commencing at line 9
31. Professor Toft, Transcript – page 45, commencing at line 3
32. BOAR1, Transcript – page 45, commencing at line 4
33. BOAR2, Transcript – page 77, commencing at line 11
34. BOAR1, Transcript – page 45, commencing at line 10
35. BOAR2, Transcript – page 77, commencing at line 16
36. BOAR2, Transcript – page 92, commencing at line 7
37. DSU in E-mail to Review Panel 03/08/2009
38. WAG website announcement at:
39. Health of Wales Information announcement at:
40. Welsh Ministerial announcement at:
6. **Chronology South West Strategic Health Authority Weston Review**

6.1 Once the findings of the BOA Review had been published questions were raised by a variety of people with regard to the quality of surgery performed by the visiting Scandinavian consultant orthopaedic surgeons at the WTC. As a result the **Weston Area Health NHS Trust** who had hosted the WTC:

‘... was approached by a number of interested parties including patients, Trusts and their legal representatives. [As a consequence WAT]...asked for support from the South West Strategic Health Authority with regard to a further independent review that would seek to identify whether or not poor performance had led to the adverse outcomes that have been experienced’.

6.2 Thus having undertaken an examination of the circumstances surrounding the BOA Review a decision was taken by the **South West Strategic Health Authority** to hold an independent arms length review (Review). Subsequently, the author of this report was commissioned by Dr Michael Durkin, Medical Director, South West Strategic Health Authority to act as the Chairman of a Review Panel with the following remit:

1. **PURPOSE**

1.1 To undertake an independent review of orthopaedic knee surgery carried out on behalf of Weston Area Health NHS Trust by SCANLOC, operating from the Weston Treatment Centre. The purpose of the review is to assess the clinical work carried out by the SCANLOC doctors and determine if the clinical outcomes are comparable with national comparators, the local NHS services provided by the Weston Area Health Trust orthopaedic teams and Avon Orthopaedic Centre at North Bristol Healthcare NHS Trust. The review will also assess the procurement and commissioning processes undertaken by Weston Area Health NHS Trust and the Commissioners to identify good practice and areas of learning for future schemes.

2. **THE TASKS**

2.1 To compare the clinical outcomes of the work undertaken by SCANLOC, against random sampling of the audit of outcomes at Weston area NHS Trust; national outcomes data; and with outcomes data from the Avon Orthopaedic Centre. These findings will then be compared with those of the British Orthopaedic Association report produced in January 2007 though dated January 2006. The work will include examination of the 14 patients that were reviewed by the British Orthopaedic Association for their report.

2.2 To consider the processes and procedures together with the governance arrangements in the setting up and managing of the
contract with SCANLOC; in particular the performance monitoring arrangements for clinical governance, including clinical audit.

2.3 To consider the processes and procedures for referrals of patients from North Bristol NHS Trust and patients from Wales to Weston Area Health NHS Trust and the processes and procedures at the Weston Treatment Centre, following receipt of these referrals.

2.4 To assess the quality of the patient experience including the mechanisms for offering choice.

2.5 To produce a report that identifies actions to be taken in relation to lessons learned'.

6.3 It should be noted however that due to delays (discussed below) it took 23 months from the time the Review was commissioned before the majority of the interviews could be held with the required personnel. As a consequence items 2.2 to 2.4 inclusive of the Terms of Reference for this Review are no longer applicable. This is because the Weston NHS Treatment Centre no longer exists and a great deal of organisational and administrative change has taken place in all the organisations involved during that period.

Methodology

6.4 One of the conditions specified for undertaking this review was that the methodology employed would be rigorous. To that end the methodology adopted in this review broadly conforms to that devised by the National Patient Safety Agency (NPSA).

6.5 Thus, as recommended by the NPSA and others the report draws upon a number of sources of information including, verbal statements of the witnesses interviewed, confidential internal reports, confidential medical records, epidemiological studies, publicly available documents, expert opinion and a limited amount of research carried out by the author of this report.

6.6 Interviews were conducted using a modified version of the 'Cognitive Interview' technique. During the interviews that were held both free recall and semi-structured questionnaires were employed by members of the Review Panel. The mapping of data has been undertaken using a chronological approach. An explanatory synthesis of the data was undertaken by drawing upon the knowledge base of the Review Panel and where appropriate, others qualified to offer the information sought.

6.7 It should be noted that this Review Panel attempted to follow the sequence of events discussed in the BOA report as closely as possible.

6.8 While many of the other techniques discussed in the NPSA ‘Root Cause Analysis Toolkit’ could have been utilised to carry out this review it is the opinion of the author that the time required to use them would have been disproportionate to their exploratory value. That is, they appeared to have
little probative merit and therefore were unlikely to have produced any additional insights other than those which have been achieved.

Reliability of interview evidence

6.9 It should be noted that the events which are the subject of this Review took place over two years before the Review Panel was able to interview those involved with the BOA Report. Thus, when questioned some of the healthcare professionals associated with the WTC orthopaedic project and the BOA Review provided evidence based upon indistinct memories.

Cognitive biases

6.10 A cognitive bias is an influence that can affect the judgement of human beings without the person or group of people affected being aware that such a psychological mechanism has operated, i.e. it can occur unconsciously.\(^{10}\) The Review Panel however were explicitly cognizant of the NPSA caveat regarding such biases and that:

‘Care should be taken to avoid the following:

‘Hindsight bias is when actions that should have been taken in the time leading up to an incident seem obvious because all the facts become clear ‘after the event’. This leads to judgement and assumptions around the staff closest to the incident.

‘Outcome bias is when the outcome of the incident influences the way it is analysed, for example when an incident leads to a death it is considered very differently from an incident that leads to no harm, even when the type of incident is exactly the same. When people are judged one way when the outcome is poor and another way when the outcome is good, accountability becomes inconsistent and unfair.’\(^{11,12}\)

6.11 The relevance of taking cognitive biases into account particularly, where it is thought poor clinical practice might be involved, is clearly spelt out by Crosby who argues that, ‘Bias is pervasive in the analysis of medical occurrences and may result in findings against caregivers which are unfair’.\(^{13}\) While Hugh and Tracy note:

‘Doctors have long been aware of the pitfalls of the “retrospectoscope”, but it is not generally known that considerable scientist evidence indicates that hindsight bias is inevitable when a reviewer is aware of an outcome. Hindsight bias ensures that some reasonably acting defendants will be unfairly subjected to adverse litigation’\(^{14}\)

6.12 Additionally, through the explicit use of a critical approach to the collection and analysis of the data the Review Panel also sought to minimize the potential negative affects of number of other cognitive biases. The first of these is ‘Confirmation Bias’ which can cause healthcare and ‘lay’ professionals to unconsciously engage in:
'Selective seeking out or filtering of information that seems to confirm favored diagnosis (but in fact may be redundant) and ignoring data that are inconsistence with the diagnosis and suggestive of other diagnosis'.  

Dawson and Arkes, observing that:

‘…physicians and non-physicians alike tend to seek only evidence that can be used to confirm hypotheses… [This] confirmatory bias not only causes one to seek predominantly confirmatory evidence but influences data interpretation as well’.  

While Pines has argued that ‘Confirmation bias is a pitfall in emergency care and may lead to inaccurate diagnosis and inappropriate treatment care plans’.  

6.13 The Institute for Safe Medication Practices based in the United States of America has also warned healthcare professionals that:

‘Confirmation bias refers to a type of selective thinking whereby one selects out what is familiar to them or what they expect to see, rather than what is actually there. Many errors often occur when practitioners, due to familiarity of certain products, see the one they think it is rather than what it is. It is human nature for people to associate items by certain characteristics. It is very important for the health care community to recognize the role that confirmation bias may play in medication errors and to work together to address associated problems’.  

6.14 With Merry et al making the observation that errors in the administration of anaesthetics are frequently made because ‘…people see what they expect to see’. While Klein observes that:

‘Confirmatory bias has been shown to affect peer-reviewers’ assessments of manuscripts. Mahoney sent fictitious manuscripts with identical methods but different results to reviewers. Reviewers gave significantly better ratings to the methods section when the results supported their pre-existing beliefs.  

‘Once again, doctors are not immune to confirmatory bias. In taking medical histories, doctors often ask questions that solicit information confirming early judgments. Even worse, they may stop asking questions because they reach an early conclusion, thus failing to unearth key data. More generally, the interpretation of information obtained towards the end of a medical work-up might be biased by earlier judgments’.  

6.15 Another cognitive bias that the Review Panel also sought to minimise was that of the ‘Availability Heuristic’ which is a:

‘Tendency [for a healthcare professionals] to accept a diagnosis because of ease in recalling past similar cases rather than on the basis of prevalence or probability’.
With respect to the availability heuristic Sweeney has observed that:

‘Doctors are neither passive recipients of, nor simple conduits for, clinical evidence. We conduct an “inner consultation” with evidence, analysing it in both a logical and intuitive way. In so doing, we are exposed to what Tvensky and Kahneman call the “availability heuristic”—a fancy way of saying that we are more likely to recall events which are more easily recalled—and the “chagrin factor,” whereby doctors tend to avoid actions that cause them hassle. Patients conduct similar internal conversations, adding the experience of a consultation to their previous intellectual and emotional understanding of illness’.22

While Klein informs us that:

‘In one study [doctors were asked] to judge the probability that medical inpatients had bacteraemia. The probability was judged to be significantly higher when doctors had recent experience of caring for patients with bacteraemia’.23

It is perhaps interesting to note that in 1992 Robertson wrote:

Anyone who has attempted to do research knows that the rosy estimates of the numbers of available patients will always end up to be many less in reality. There is a simple psychological reason for this. It is called the “availability heuristic.”

‘The availability heuristic means that if something springs readily to mind, you will tend to think that it actually occurs more frequently in reality. So, a currently fashionable medical interest will be overestimated in its frequency by clinicians simply because it happens to be on their minds at the time’.24

Thomas and Kershaw however suggest that to help reduce potential cognitive bias errors:

‘Clinicians need to routinely ask what else could explain the patient’s signs and symptoms? Is there any disconfirming evidence that would have indicated that the initial diagnosis of [X] was wrong?...Clinicians would also need to become aware of their own thinking process (or metacognition) so as to be the model reflective practitioner who can gauge their own clinical reasoning, minimize errors, and enhance patient outcomes’.25

In a similar vein Berlin suggests that:

‘...bias, affects all human judgement, and it probably can never be eliminated from litigation and judicial proceedings. Acknowledging its existence, and recognising its influence on expert witnesses and jurors alike, might mitigate its pejorative effect.’26

There are numerous other papers and books that discuss cognitive biases and readers of this report who are interested in the topic with respect to
healthcare should be aware that there is a growing body of literature on the subject. The *BMJ* and the journal *Quality and Safety in Health Care* web sites both carry papers on the topic.

**Operational concerns**

6.21 As this Review concerned two countries within the UK, it was decided that one consultant orthopaedic surgeon advisor should come from Wales and the other from England. Thus attempting to ensure a national bias was not inadvertently introduced into the work of the Review.

6.22 Additionally, a number of English patients whose knee procedures had been undertaken by different consultant orthopaedic surgeons at WAT and who had not reported any problems following their operations were selected at random to form a ‘control group’. After which the two anonymised groups of clinical records and X-rays to be reviewed, i.e. Welsh and English patients were then arbitrarily assigned to each of the Reviews clinical advisors. The objective was to ensure that the clinical advisors to this Review should not examine the records of the Welsh patients consecutively as had occurred at the time of the BOA Review. Thus reducing the opportunity for the psychological biases discussed above to produce a significant affect on their clinical decision making abilities.

6.23 Moreover, since it was possible that this Review might produce findings contrary to those of the BOA each healthcare professional approached to be a member of the Panel was informed that the report might be challenged by some or all of the parties with an interest in the first review. However, the specific details of what this review concerned were not revealed to anyone until they had formally accepted the invitation to be a member of the Review Panel.

**Difficulty in recruiting consultant orthopaedic surgeons**

6.24 The first issue to be addressed when establishing this Review Panel was to recruit suitably qualified and experienced consultant orthopaedic surgeons and other appropriate healthcare professionals to become members. However, while finding the most appropriate individuals to fulfil the remit for the non-surgical aspects of the review proved challenging finding two practicing consultant orthopaedic surgeons was impossible.

6.25 Several eminent consultant orthopaedic surgeons currently practicing surgery at the knee from different parts of the UK were approach to become members of the Review Panel. All of whom declined to join after being briefed, as noted above. It was therefore interesting to note item ‘g’ of paragraph 14 in the GMC document ‘*Good Medical Practice*’ which states that doctors must ‘…contribute to confidential inquiries and adverse event recognition and reporting, to help reduce risk to patients.’

6.26 Thus since so many distinguished consultant orthopaedic surgeons had declined to join the Review Panel the situation was brought to the attention of the *General Medical Council* (GMC). Their representative replied as follows:
‘With regard to the duty [of a doctor] to contribute to confidential inquiries and adverse event recognition and reporting, to help reduce risk to patients, I can confirm the view I expressed in our telephone conversation of 11 September [2009], i.e. that this does not extend to any general duty to join a review panel or any other commitment of a similar nature. The duty to contribute to confidential inquiries, etc. is usually satisfied by providing information. Doctors are not compelled by our guidance to undertake onerous duties beyond their contractual work obligations, except in the context of emergencies…’  

6.27 On the other hand however, it might be that the refusals may have been driven by the same reason given to the Review Panel by one renowned practicing consultant orthopaedic surgeon who stated:

‘I have twenty to twenty-five years of service left in the National Health Service and I do not wish to compromise my career by joining your Review Panel.’

6.28 Subsequently, two very experienced and recently retired consultant orthopaedic surgeons agreed to join the Review Panel. It was therefore not until the 9 August 2007 that the final membership of the Review Panel was provisionally agreed. Administrative clearance was received from South West Strategic Health Authority on the 4 September 2007 and the next stage of the review commenced.

**Delays in obtaining clinical records of patients involved in BOA review**

6.29 Although the WAT had readily agreed to RCT-LHB commissioning the BOA Review they were completely unaware which patients’ had been involved. Thus the next task was to contact the SOCT and request the list of patients’ names involved in the BOA Review and copies of their clinical records and X-ray’s. On the 18 September 2007 the E-mail reproduced below was received from a member of the SOCT stating that

‘…the Second Offer team has been briefed about the Independent Review at Weston and has highlighted a significant issue that will need to be addressed. When the BOA undertook their review last year, we were legally obliged to get the permission of each of the 14 patients in order to access their notes and x-rays. The patients did consent, but only for the BOA review and no other, and consequently we would not be legally able to release this information without further consent.

‘Therefore, we would require evidence of patient consent in every case and would request that Weston [WAT] writes to the 14 patients to obtain consent for their notes and x-rays to be disclosed for the purposes of this review. This consent would also need to include the provision for Cardiff and Vale NHS Trust to release the clinical information pertaining to these patients since the last review was undertaken.'
‘Attached is a copy of the letter and consent form which was drawn up by our legal team, for your information. As the letter relates to the BOA review, it would require some updating regarding context; however the consent form itself is fairly standard.’

6.30 However, as noted earlier, the letter asking for the consent of the 14 patients whose treatment had caused concern by Cardiff and Vale NHS Trust while legal was not in line with medical ethics. Thus the letter to patients from this Review Panel was modified to take into account such issues and a copy can be found at Appendix 5, 5a and b.

6.31 Subsequently, letters were sent out asking 13 of the 14 Welsh patients involved in the BOA Review to consent to take part in this Review. One patient was now deceased. In total only five of the 13 patients agreed to take part in this Review and their clinical records and X-rays were made available by SOCT on the 12 December 2007. The anonymised patient reference numbers of the patients who consented to take part in this Review as cited in the BOA Report are; CV 0224; CV 0308; 0457; 0458 and CV 0785.

**Delays in obtaining patients X-rays**

6.32 Unfortunately a member of staff at WAT who was assisting the Review had to take emergency leave of absence and inadvertently this situation was not relayed to the Review Panel. Consequently, several weeks went by before the X-rays of the five patients who had agreed to take part in this Review were inspected. However, when the X-rays were eventually checked they were found to be digital X-ray images and not the X-ray film type which had been expected. This was relayed back to C&V and another attempt was made by them to locate what were thought to be the Welsh patients correct X-ray films.

6.33 After a great deal of effort had been expended trying to find the original X-rays without success and this Review almost terminated as a result, it was discovered that the assumption regarding the use of the original WTC X-rays in the BOA Review was erroneous. Once this was discovered anonymised X-rays films of the five patients’ knees were then produced by C&V from the digital images that they had. The clinical advisors to this Review subsequently met on the 25 September 2008 to review the clinical records and X-rays of the five Welsh patients who had agree to take part in this Review. The findings of the clinical advisors to the Review will be discussed later in this report.

**South West SHA Weston interview day**

6.34 Owing to a number of delays, due in part, to incompatible work schedules the interview day of the *South West Strategic Health Authority Weston Review* eventually took place at Taunton on the 21 April 2009. The members of the Review Panel present were Mr Lake, Dr Pollock and the author of this report. Unfortunately Mr Tasker was indisposed on the day but had developed a number of questions to be put to the interviewees in his absence by the author of this report.
6.35 The interviews started at 10:00hrs each one lasting approximately one hour. Two consultant orthopaedic surgeons from C&V, both of whom also have private practices, kindly attended the Review Panel. One of the two C&V consultants was COS-CV2 who had previously been interviewed for the BOA Review. This Review Panel also interviewed a senior manager from WAT who had been intimately involved with the WTC project, the two consultant orthopaedic surgeons who had conducted the BOA Review and a senior manager from the international medical recruitment company Scanloc. The final interview was concluded at approximately 5pm.

6.36 One of the Scandinavian consultant orthopaedic surgeons, who had worked at WTC and interviewed by the BOA Reviewers, had previously been contacted by telephone by the author of this report. Subsequently, this particular consultant orthopaedic surgeon (SCOS) submitted evidence to the Review Panel by E-mail and by surface mail. Some of the evidence provided by SCOS has already been presented.

6.37 A Stenographer was also present to take a contemporaneous record of all the proceedings. A tape recorder was used by the Stenographer throughout the interviews to ensure, in so far as was practicable, that all comments were accurately captured. A type written transcript of the proceedings was subsequently produced and a copy provided for each member of the Review Panel.

6.38 Additionally, each member of the Review Panel had a semi-structured questionnaire prepared for each interviewee to ensure that questions would not be missed and where appropriate the answers of interviewees could be compared. This is because if differences in perspectives are revealed to have taken place they can often help to explain why misunderstandings have arisen.

Comments

6.39 Because of the delay in holding the Review interview day some of the Terms of Reference for this Review became irrelevant. The reason for the delays to the review process was in the first instance due to not being able to secure the services of two highly experienced currently practising consultant orthopaedic surgeons to be members of this Review Panel. There is however evidence to suggest, at least for some, that they were afraid their career might be harmed if this Reviews findings were to refute those of the BOA report. As will be discussed later, the findings of this Review Panel do in fact differ significantly from those reported by the BOA.

References

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28. General Medical Council representative, E-mail 14/09/2009

29. Personal communication to Professor Toft

30. DSU communication to Review Panel, E-mail 18 September 2007
7. A critique of the British Orthopaedic Association report

7.1 BOA report: Introduction

The introduction to the BOA report starts with the assertion:

‘In June 2006 Rhondda Cynon Taff Local Health Board (RCT LHB) and Weston Area Health NHS Trust (Weston Trust) invited the British Orthopaedic Association (BOA) to undertake a review of patients with reported complications following knee surgery performed at the Weston NHS Treatment Centre, under the Second Offer Scheme’.\(^1\)

7.2 This statement as noted earlier is inaccurate. It was at the request of the Director of the Delivery and Support Unit, Welsh Assembly Government that the Rhondda Cynon Taff Local Health Board commissioned the BOA to undertake their review. The Weston Area Health NHS Trust (WAT) did readily agree to take part in the BOA Review but played no part in the commissioning of the work or the drafting of the report. That is other than making a number of comments on the BOA draft report before it was finalised. A senior manager at the BOA noting to the Review Panel that:

‘I confirm that our sole formal contact throughout [the review] was the DSU in Cardiff. The BOA took the view that ownership of the report lay with the DSU and has never formally published the report’.\(^2\)

In this section of the BOA report it is also stated that:

‘The British Orthopaedic Association (BOA) asked two experienced knee surgeons, who practise at a distance from Weston and Cardiff and who have both been Presidents of the British Association for Surgery of the Knee, to conduct the review’.\(^3\)

7.3 However, the report does not disclose that besides their NHS work BOAR1 and BOAR2 both have their own ‘…private practice’.\(^4,5\) Which, given the circumstances surrounding the surgical and organisational arrangements at WTC could be interpreted as a ‘conflict of interest’ and thus a potential source of unconscious cognitive bias.

7.4 Another concern regarding potential involuntary cognitive bias with respect to the evaluation of evidence by the BOA Reviewers is that BOAR1 stated at interview:

‘The system is totally flawed, period. [That is the one which was in place at WTC] That’s our main thrust, and this is what we should focus on. The statistics of it aside, it is the process that is so flawed. If someone flew me to Linköping and said, “do half a dozen knee replacements and then fly home again two days later”; it’s just not on, you know, you can’t practice orthopaedic surgery like that, it’s just not on, I’m sorry.'
‘We’ve known it for years, early failure of total hip replacements, this is the Exeter report, patients who were shipped up to London, very high failure rate of hip replacements, 2005; we’ve known this for years.’

7.5 Thus, indicating that BOAR1 held an opinion prior to undertaking the BOA Review that the outsourcing of orthopaedic surgery will lead to higher than expected early complication rates and the failure of prosthesis.

7.6 The results summarily described by BOAR1 in relation to the Exeter Total Hip Replacement (THR) initiative can be found in a paper published in 2005, *Annals of the Royal College of Surgeons of England.* It should be noted however, that the total number of patients who took part in the original Exeter programme could not be established by the Researchers who wrote the paper. Although they did manage to identify 27 primary hip replacements in 24 patients which were suitable for radiological and clinical review. The Total Hip Replacements (THR) were performed on patients at the outsourced hospitals during the period 1990 – 1993. The paper states that of the THRs carried out at the subcontracted hospitals 12 (44%) required revision surgery with a mean time to failure of 6.5 years (range 3 months to 10 years). The paper also notes that:

‘Primary total hip replacement surgery carried out at the local orthopaedic centre during the same time period has a published revision rate for septic and aseptic loosening of 4.9% with no sciatic nerve palsies in 325 cases’.

7.7 However, the two cohorts of patients are not necessarily comparable. For example, a number of different types of prostheses were implanted in the patients who had their THR at the outsourced hospitals. Whereas in the study undertaken in the local orthopaedic centre every patient had the same *Exeter Universal* stem (Stryker Howmedica Osteonics) implanted when the THR was performed. It should therefore be noted that the 6th annual report from *National Joint Registry of England and Wales*, published in 2009, warns that:

‘The results of this multivariable analysis indicate that even after adjustment for other factors, prosthesis type is an important determinant of revision in men and women’.

7.8 Additionally, the patient ‘case-mix’, i.e. patients with different grades of joint destruction or differences in age, general health and activity may have also been significantly different.

7.9 Although though the identified sample size of the outsourced surgery consisted of only 24 patients and the case-mix may have been significantly different between the two cohorts of patients the authors of the paper came to the conclusion that their findings:

‘… further highlights the imperative of having a local, nominated accountable surgeon by whom the patient can be reviewed urgently in the event of such complications, and by whom regular follow-up needs to be arranged.'
The issue of delegating complex surgery to practitioners who are not accountable for their results or complications is currently a subject of intense discussion. The debate has, however, been stifled by the lack of evidence for or against this practice, and joint replacement overseas on British patients is currently being encouraged. We believe that our paper is the first evidence that major surgery carried out at a distant site may have an inferior outcome, and possibly be of disastrous human and financial cost to the community. In the light of this evidence we would like to urge the UK Government to address waiting list problems by investing in the local infrastructure. Expanding those facilities where properly audited and fully accountable surgeons operate must be the way forward.  

7.10 It is interesting to note that the BOA Reviewers, as will be discussed later, also came to similar conclusions regarding the provision of local orthopaedic services based upon an even smaller sample of patients than in the Exeter study, i.e. the 14 patients who were enrolled in the BOA Review.

7.11 Another potential source of cognitive bias that could have affected the BOA Reviewers is that as BOAR2 noted, ‘...we were told there were a lot more cases in the pipeline, and we were only asked to look at these 12 or 14’. Thus the BOA Reviewers were given an expectation that the cases in their review were potentially the ‘tip of the iceberg’. This information however is not included in the BOA report.

7.12 COS-CV2 also made the same point as BOAR1 regarding the outsourcing of orthopaedic surgery stating that:

'It struck me from experience that whenever these schemes have been run before the complication rate has always been higher than the local service. I recall as a trainee in the West Midlands, we sent hips and knees down to London, to British surgeons, good name surgeons, and their complication rate was much higher than the local service, simply because they’d done the operation as a fee for service, and had no follow up. Dislocation of the hips, the DVT rate, the infection – it was all higher than locally, and that was 15 years ago. There is nothing new here in Weston'.

7.13 Thus it would appear that within the community of consultant orthopaedic surgeons and in particular those involved with the BOA Review, there appears to have been an expectation by some that when orthopaedic surgery is subcontracted away from an area that it will be poorly performed and patients will experience higher complication rates.

7.14 It is also stated in this section of the BOA report that:

'The trigger for the review was an increasing number of clinical concerns being reported by the Consultant Orthopaedic Surgeons at Cardiff and Vale NHS Trust, who were the referring organisation under the Second Offer Scheme'.

58
However, SM-SOCT1 informed the Review Panel that they could not recall the SOCT receiving a constant stream of complaints sufficient to have alerted an objective third party to there being an issue with the orthopaedic surgery at WTC. The view expressed to the Review Panel was that it was more to do with the C&V orthopaedic surgeons raising issues about one or two patients which had led to them having to do revisions and that those surgeons then extrapolated from those patients to a view that all patients treated at WTC had received a poor service there.

This statement paints a somewhat different picture than the one advanced in the BOA report.

It is also noted in this section of the BOA report that:

‘The main areas of focus were to interview key members of the two Trusts and undertake a review of the clinical case notes of the 14 patients with reported complications, together with a control group.’

However the BOA report does not state that the time period to be covered by their Review are the financial years 1 April 2004 – 31 March 2005 and 1 April 2005 – 31 March 2006, i.e. a two year period and not a one year period. Nor is there any indication that BOAR1 considers the BOA Review to be, ‘…a look at a practice process by two very experienced knee surgeons’. Which would appear to be a significantly different objective to the ones set out in the Terms of Reference provided by the DSU and noted above.

BOA report: background and context

In the first instance the BOA report provides little information in this section on the operational methodology used in the Review. For example, it does not highlight the fact, as noted earlier, that the whole of the BOA Review data was collected in one day.

The BOA report also states that:

‘Concerns were raised by the Cardiff surgeons with respect to both individual patients and the overall process. In summary these were: ‘Patients not doing well clinically, namely continued pain and stiffness, with many still on crutches 6 months after surgery’.

However, it was suggested to the Review Panel by SM-SOCT1 that some of the consultant orthopaedic surgeons at C&V were in fact searching for problems with the orthopaedic surgery that had been undertaken at WTC. When SOCT requested data on the complication rates for the C&V orthopaedic surgeons, however, no such data was available.

Moreover there is no discussion in the BOA report as to what concerns the C&V consultant orthopaedic surgeons had in relation the patients. For example, there is no mention of the degree of pain and stiffness experienced by patients, the range of movement that each of the patients had or how many
patients’ were on crutches. Although, it is noted in the section of the BOA report that summarily covers ‘The Clinical case Note Review’ that, two of the patients (CV 0191 and CV 0308) were using crutches. There is however no mention of the other 12 patients requiring such assistance.

7.22 The BOA report also notes there was a ‘Lack of continuity of care’. There is however no discussion as to what this phrase means and consequently ‘lay’ readers are likely to be at a loss as what the expression is meant to convey. For while it is recognised that the BOA Reviewers have stated they did not write their report for lay reader the BOA did give permission for it to be released into the public domain. The BOA report therefore, it can be argued, should have been rewritten so the ‘public’ could understand its contents.

7.23 When asked about the BOA assertion that there had been a deficiency in the continuity of patient care provided at WTC WSM1 replied:

‘Well, I think if you read the BOA report, what they are describing is that it’s not the same surgeon that saw the patient. It’s not that Weston didn’t provide continuity of care; it’s that there was a possibility that when [the patient] came back for the six week visit, or the one year visit, the surgeon that [they] saw was not the man, because it invariably was a man, who put the knee joint in.’

WSM1 also noted that:

‘What is their definition of that? I made a comment about that [Lack of continuity of care] originally with them, because, of course, sometimes [a patient might] come back to a standard orthopaedic outpatients and see the registrar, who might be a new registrar.’

7.24 In a similar vein SM-SOCT1 stated with regard to continuity of treatment that surgical operations are usually undertaken in acute hospitals while the patients’ aftercare is provided in the community. Hence, it was not a question of an absence of aftercare but of operations being carried out at WTC and the aftercare being undertaken at or arranged by C&V. It was also reported that this was yet another example of the orthopaedic surgeons at C&V being against the idea that patients who they regarded as theirs not being treated by them.

7.25 Similarly both clinical advisors to this Review noted that an Orthopaedic Surgical Registrar (a non-consultant) will often see a patient that has been operated on by the Consultant in charge of the case for the follow-up appointment. Not least of all because a Registrar is training to be a Consultant and needs practice in undertaking clinical consultations with patients.

7.26 BOAR1 however, as noted earlier, was of the opinion that:

‘…knee replacement surgery is complex demanding surgery, and you can’t just fly in, do an operation in unfamiliar surroundings, with unfamiliar
equipment, with unfamiliar backup staff, and hope to get good results. The system is totally flawed, period. That’s our main thrust, and this is what we should focus on. The statistics of it aside, it is the process that is so flawed.\textsuperscript{25}

7.27 In contrast BOAR1 later stated that:

‘I go out to Cairo, and work in the international medical centre out there, and I make absolutely certain that I’ve got the reps and all the equipment, and I take quite a lot of it out myself actually. It’s very stressful, even doing a mundane operation. I mean, Egyptians are great, but there is a language barrier and you’re working in a strange environment, but, yes, I take a whole load of stuff in my suitcase’.\textsuperscript{26}

7.28 Thus it would appear that when the process used at WTC, i.e. there is a disjuncture between the orthopaedic surgery and the post operative care of patients applies to BOAR1 it does not appear to pose the same kind of problems for patients in Egypt as it did at WTC. Notwithstanding, the fact that BOAR1 stated categorically that it was inappropriate for consultant orthopaedic surgeons to fly to other countries and undertake surgery in short term posts.\textsuperscript{27}

7.29 Another issue raised in this section of the BOA report was that there was: ‘No communication between Weston NHS Treatment Centre and Cardiff surgeons’.\textsuperscript{28}

7.30 However, SM-SOCT1 reported that both the Medical Director and visiting orthopaedic surgeons at WTC had on more than one occasion invited the C&V orthopaedic surgeons to visit them and review the facilities at WTC. It was also stated that the C&V orthopaedic surgeons did not accept these invitations. In addition, it was also made clear that the orthopaedic surgeons at WTC had felt a sense of frustration that the C&V orthopaedic surgeons appeared to reject the idea that Welsh patients could be treated elsewhere.\textsuperscript{29}

7.31 Similarly in ‘Section 3’ of the RDSU letter it is stated that:

‘At the very start of the scheme, Weston Trust was keen to engage with the Cardiff clinicians and on numerous occasions, Weston Trust requested to meet with the orthopaedic surgeons in Cardiff and Vale NHS Trust.

‘All contract review meetings have been attended by general managers from Cardiff and Vale NHS Trust. The Clinical Director for Orthopaedics did attend an initial meeting, but despite frequent requests, no further clinical representation was put forward’. (Appendix 3)

7.32 Additionally SCOS stated in his letter to the Review Panel (reproduced in full later) that:

‘We also suggested contacts between referring orthopaedic departments [C&V] and [WTC]. Also in this case nothing happened’.\textsuperscript{30}
7.33 However, COS – CV1 when asked as to whether or not he was aware of the attempts by the surgeons at WTC to establish formal communications with C&V stated that, ‘I’m not aware of any direct contacts being attempted and certainly none that were rebuffed’.\(^{31}\) While COS – CV2 when asked if attempts to set up communications by WTC with the surgeons at C&V had been rebuffed replied: ‘Absolutely not’.\(^{32}\) Similarly, the BOA Reviewers also said that they were not aware of any attempts by WTC to set up communications which had been rejected by the consultant orthopaedics surgeons at C&V. BOAR1 stating that:

‘No, but in practical terms the surgeons in the hospital have got enough of their own work to do, without taking on aftercare, which is a huge part of the process, of other patients. They’re fully occupied looking after the patients they’ve operated on’\(^{33}\).

7.34 While BOAR2 replied, ‘I don’t know; I wasn’t aware of that’.\(^{34}\)

7.35 The BOA report also notes that there had been ‘Problems with obtaining postoperative x-rays from Weston’\(^{35}\). However, once again there is no explanation given as to what the problems were and what, if any, attempts there had been by the surgeons at C&V to resolve that issue.

7.36 The last issue raised in this section of the BOA report was that:

‘A radiological audit was carried out by an Orthopaedic Associate Specialist in Cardiff and Vale Trust in June 2005 and this showed some technical problems.’\(^{36}\)

7.37 There is no discussion regarding this audit in the BOA report or what the technical problems were. However summary details of this audit were briefly touched upon earlier in this report in Section 4, ‘BOA review context’.

**BOA report: terms of reference**

7.38 This section of the BOA report starts by stating that the Review had ‘…been commissioned by RCT LHB and Weston Trust…’\(^{37}\) as noted above, in the critique of the ‘Introduction’ section of the BOA report this statement is incorrect.

7.39 The BOA Reviewers *Terms of Reference* states among a number of issues that they are to report on: ‘…the type of operation performed, the appropriateness of the surgical technique and patient outcomes’.\(^{38}\) The BOA report however does not discuss any of those issues and there is no explanation as to why that is the case. This would appear to be a serious omission as a discussion on those matters could have provided evidence to support the BOA recommendations to recall all the Welsh patients treated at WTC.

7.40 Furthermore, as noted above, a recommendation should never be made as to whether a primary knee operation should be revised without a clinical examination and a consultation with the patient. However, that crucial
element of the clinical diagnosis methodology did not form part of the BOA Terms of Reference.

7.41 The Terms of Reference for this Review on the other hand did allow for such a clinical examination and consultation with the patients by the clinical advisors to this review if it were thought to be necessary. This Review’s Terms of Reference, as noted above, stating that: ‘The work will include examination of the 14 patients that were reviewed by the British Orthopaedic Association for their report’. However, as noted earlier, while five patients did kindly agree to have a clinical consultation if required and also gave permission for their medical records to be reviewed, the other nine patients either did not respond to the letters sent on behalf of this Review Panel or explicitly decided not to take part in this Review.

BOA report: Weston NHS Treatment Centre (Weston Trust)

7.42 In this section of the BOA report it is noted that:

‘Both Welsh and English residents are treated by this unified service using the same clinical team and through the same clinical processes. Data are collected in separate groups for Welsh and English residents for all monitoring purposes’. 39

7.43 As there was audit data available regarding the treatment of both Welsh and English patients at WTC a comparison of the early complication rates of both groups could have proved helpful to the BOA Reviewers. Particularly, as noted above, the clinical team and the processes used on both cohorts of patient were similar. However when Mr Lake asked BOAR2:

‘….were you aware that in addition to this South Wales initiative that was going on, there was also an identical initiative going on with Bristol? So Bristol patients and South Wales patients were going through the same process and having the same treatment by the same surgeons, in the same hospital here?’ 40

7.44 BOAR2 replied: ‘I didn’t know’. 41 Similarly, BOAR1 did not appear to be aware of that data when it was brought to his attention. 42 Which is surprising since, as cited above, the BOA report makes explicit reference to the collection of data on both the Welsh and English patients treated at WTC.

7.45 It is therefore interesting to note that in the dossier of information supplied by the DSU to the BOA Reviewers, discussed earlier, that under the heading ‘Weston Area Health NHS Trust’ those same two sentences are used. 43

BOA report: the Review

7.46 It is noted in the first part of this section of the BOA report that the information presented ‘…was obtained by interviews with relevant personnel’. 44 The BOA report does not however explicitly state what the roles were of those who the BOA Reviewers interviewed in all cases. Thus it is not possible for a reader to know the status or appropriateness of the person providing the information
in all cases. For example, although this Review Panel is aware from the information provided in the BOA briefing dossier that COS-CV2 and SM-CV1 were interviewed by the BOA Reviewers it has proved impossible to discern which of the two interviewees provided any particular aspect of the evidence regarding the situation at C&V.

7.47 It is also noted in this section of the BOA Report that:

‘It was stated that the funding of the post-operative care of these patients and all its possible ramifications was not fully explored beforehand and that this had led to misunderstandings and tensions’.

7.48 However, at paragraph four ‘Review Interview point 3’ of the RDSU letter sent following the submission of the BOA final report it is stated:

‘Regarding the point on the funding of post operative care, these requirements were clearly stated in the contract and as such, this statement is inaccurate. Patients are not limited to a definitive number of follow up appointments and the Trust is responsible for providing physiotherapy support. Additional funding was provided to the Trust to support additional physiotherapy sessions in the community’. (Appendix 3)

7.49 The BOA report also states that:

‘It was felt that the contract should have included Clinical Governance issues, namely that a transparent audit component should have been integral to the process.’

7.50 On the other hand at paragraph five, ‘Review Interview point 3’ the RDSU letter states categorically that:

‘With respect to the point on clinical governance issues. In both the contract and the protocol for orthopaedic activity (schedule 1 to the contract), there is an explicit requirement for a programme of clinical audit in relation to the delivery of services, to take part in joint audits and to provide comprehensive audit information of the patients treated in the project. This would include an audit of clinical outcomes. Regular audit reports from Weston Trust were submitted to the Second Offer Team and shared with the Medical Director, Clinical Director for Orthopaedics, Directorate Manager for Orthopaedics and the Second Offer Lead within Cardiff and Vale Trust’. (Appendix 3)

7.51 Additionally, in this section of the BOA report, when the Reviewers discuss the issue raised at interview it is impossible for a reader to identify whether or not the information presented in the report accurately reflects the meaning intended by the interviewee’s utterances. For example, the only direct quote used in the BOA report is in ‘Interview 2’ where it is stated that:

*He [the Scandinavian surgeon] sensed that, as the number of surgeons coming to Weston increased; this had created difficulties with both culture and communication and resulted in the patients having “less good care”*. (Author emphasis)
The phrase ‘less good care’ can be interpreted in a number of ways and precisely what ‘Interviewee 2’ (SCOS) intended the BOA Reviewers to understand by his use of that expression is not explored in the report. Thus the author of this report contacted SCOS in Sweden by telephone and asked if he would be so kind as to contextualise his statement. The complete text of the letter SCOS sent to this Review Panel in response to that question is reproduced in full below.

‘Statement’ 26 Nov 2008

‘In the Independent Review of Knee Surgery [BOA Review] I was interviewed by the two prominent consultants in orthopaedic surgery who were engaged to investigate the waiting list project at Weston General Hospital [WTC]. The interview took about 1½ hours and my opinion about the report is, that it is not very extensive in relation to what was said during the meeting. Also one very important statement is reported in a misleading way.

The project started with 8 Swedish orthopaedic surgeons who came from three geographically close hospitals. All these consultants knew each other extremely well and through many years of close working relations all had the same orthopaedic culture and the same way to evaluate and treat orthopaedic conditions. During this first period of the project the consultants professionally acted as one person. There were no problems due to discontinuity. Even if one consultant met the patient in the preoperative clinic, another operated on the patient and a third consultant performed the follow up visit it was as if one consultant had performed the whole treatment. When the consultants went back to Sweden after their working periods the obligatory handover reports were given either directly after return, most often at the hospital but not very seldom at Copenhagen airport, where the arriving consultants met the departing colleagues.

As time passed the project expanded and a larger number of orthopaedic consultants were engaged in the work at Weston General Hospital [WTC]. As I have understood from Scanloc the increase in the number of consultants was mainly due to the short length of forward planning available to them. Consultants in Scandinavia have to plan their working weeks for many months ahead but [WTC] customers only had very short term planning as regards the number of patients they would send in any particular week. [WTC] could therefore only renew its contract with Scanloc for shorter and shorter periods. Towards the end of the project this was only a few months at a time. The short forward planning meant that many of the original team were already booked in at home and more consultants from other parts of Scandinavia were needed to fill the shortfall.

This made it more difficult to communicate between the involved orthopaedic surgeons, i.e. the continuity in reporting patients became more difficult and not always all orthopaedic surgeons had the same
opinion about how to perform the work. This was no different to the
differences in opinions you may find in UK consultants about how to treat
individual patients!!

'On page 6 in the report it is written under "Interview 2" that due to the
increased number of involved consultants "the patients were having ""less
good care"". This is not what was meant by me in the interview. The
professional orthopaedic treatment given did not change, the consultants
were very experienced in the treatment of orthopaedic patients. What
became "less good" was not the orthopaedic treatments given but the
continuity of the treatment.

'During the whole project the involved orthopaedic surgeons tried to
improve the processes. We acted to improve continuity, to change knee
implants, to introduce computer based systems to handover patients to
coming consultants, to be informed about the extension of the contract
with Scanloc etc, etc. It was totally impossible to introduce any
improvements in the handling of patients. Instead of a more extensive and
durable data registration system, information was transferred from leaving
to arriving consultants on hand written pieces of paper. We also suggested
contacts between referring orthopaedic departments [C&V] and Weston
General Hospital [WTC]. Also in this case nothing happened.

'All these problems I discussed with the independent consultants
evaluating the project. Not much of it is reported and the most negative
statement about "less good care" is wrongly cited. 'Swedish Orthopaedic
Consultant'

7.53 As can be observed from the above letter SCOS considers that the interview
section of the BOA report which discusses his remarks is incomplete and
inaccurate. Moreover SCOS states categorically that in his opinion the quality
of the surgical and medical care provided by him and his colleagues did not
change. This inadvertent discrepancy in the reporting of SCOS utterances
raises the question of how much reliability is to be placed on the accuracy of
the information reported from the other interviews discussed in the BOA
report.

7.54 There are also a number of other issues broached in the interviews with the
two Scandinavian consultant orthopaedic surgeons which appear to require
additional information if the reader is to grasp the significance of their
evidence. For example, the BOA report notes in 'Interview 1':

'He performs at most five operating sessions per week of which 2 are day
case sessions and three are for major cases. The lists for major "cases are
usually on Monday, Friday and Saturday (sometimes a double list). The
current workload is very variable.'

7.55 There is however no discussion as to how many patients’ were operated on at
each of the five sessions, how long the sessions lasted, nor what the case-
mix or the level of difficulty involved on these occasions. Nor is there any
explanation as to whether the other Scandinavian surgeons on the team had the same schedule. In addition, no explanation is provided as to what the phrases ‘(sometime a double list)’ or ‘The current workload is very variable.’ actually mean.

7.56 In this section the BOA report also notes that:

‘The SHO [Senior House Officer – a junior doctor] they had been promised did not materialise and, though the surgeons performed twice-daily ward rounds themselves, they did not decide on when to discharge the patients. This was a decision taken for them and they were not sure by whom’.

7.57 However, the BOA report does not say why the promised Senior House Officer was not provided or whether the visiting Scandinavian consultant orthopaedic surgeons made any efforts to have WTC keep their promise. There is also no explanation as to why the Scandinavian surgeons did not discharge their own patients. Or who it was who took that decision at WTC to discharge a patients and why they were organised in such a way.

7.58 It is also stated in the BOA report that ‘Interview 2’ (SCOS):

‘…commented that the quality of the post-operative x-rays was poor i.e. they were badly centred. He said that he did not see the post-operative x-rays of those patients he had operated upon on Friday and Saturday.’

7.59 The BOA report however does not explain what the term ‘…badly centred’ means or the effect that such a problem would present to a consultant orthopaedic surgeon examining a patients X-ray. The author of this report however has been given to understand by the clinical advisors to this Review that if the X-ray of a patient’s knee is ‘badly centred’ then accurate measurements with regard to that patient’s knee implant would be very difficult if not impossible to achieve.

Interviewee 2 (SCOS) also is reported as stating that:

‘He had noticed that the patients had not often received any physiotherapy by the time they attended for their six-week outpatient visit.’

7.60 Once again there is no discussion by the BOA Reviewers as to the nature of the interviewee’s observation, i.e. the part that physiotherapy might play with respect to a patient’s desired outcome from knee surgery. This is a little perplexing given that following an international study on ‘Physiotherapy following elective orthopaedic procedures’ Kleijn et al state that they:

‘…conclude that physiotherapy management is of major importance in any invasive or orthopaedic procedure, regardless of which joints are involved. Both pre and postoperative physiotherapy, as part of comprehensive care is needed to achieve optimal functional outcome…’
7.61 In a similar vein Laskin and Beksac have observed that ‘...postoperatively, problems with physical therapy likewise can cause limitation of both extension and flexion [i.e. bending of the knee]’\textsuperscript{56} While a study undertaken for the United States Institute for Medical Technology Innovation on the outcomes of patients who have had Total Knee Replacements concluded, ‘...exercise programs to address loss of strength in quadriceps muscle are critical.’\textsuperscript{57}

The BOA Reviewers also report that ‘Interview 2’ (SCOS) stated that:

‘When he saw a patient in outpatients for a pre-operative assessment (all patients had been scheduled for either arthroscopy, total knee replacement (TKR) or anterior cruciate ligament (ACL) reconstruction) and he wanted to change the procedure to a unicompartmental arthroplasty or osteotomy as he felt this might be more appropriate he was not allowed to have this option and found this frustrating.’\textsuperscript{58}

7.62 There is however no discussion as to what any of the procedures entail or why a change to ‘...a unicompartmental arthroplasty or osteotomy’ would be more appropriate than the operation for which a patient had been scheduled. Similarly there is no discussion as to why the Scandinavian surgeon could not change the scheduled operation to one which he judged more appropriate.

7.63 However, the RDSU letter with respect to that issues states at ‘Review Interview point 5’ that:

‘Regarding the comment made by the Swedish surgeon about not having the option to “change the operative procedure”, we would record that this is categorically not a restriction of the contract. An authorisation process is in place, and where there is a clinical requirement for an alternative procedure to be undertaken, this has never been refused. The Second Offer Team has never been made aware of any difficulties experienced by the surgeons in feeling obligated to perform certain procedures. We are concerned that the report does not make any comment about the individual surgeon’s professional accountability when this alleged issue arose, nor does the report refer this back to Weston Trust to explore the internal procedures for dealing with an issue where clinical practice was perceived to have been restricted’. (Appendix 3)

BOA report: the clinical case note review

7.64 With respect to this section of the BOA report it is important to bear in mind that both clinical advisors to this Review and all four consultant orthopaedic surgeons interviewed agreed, that the decision to recommend that a patient have their Total Knee Replacement operation revised early cannot be based solely upon medical records and X-rays. This is because the decision to recommend an early TKR (less than three years after the primary operation) other than for an infection is essentially subjective in nature. For example, Dorey, Grigoris and Anstutz state in an Editorial for \textit{The Journal of Bone and Joint Surgery} that:
‘Most clinical and radiographic evaluations...are very subjective and therefore prone to observer bias. Whenever possible, radiographs should be evaluated by independent observers and clinical scores should be based on quality-of-life questionnaires answered by the patient...rather then upon scoring systems applied by the surgeon’.59

7.65 Thus, where an early revision is being contemplated the patient concerned must always be consulted before such an action can be recommended.60, 61, 62, 63, 64, 65

7.66 Similarly BOAR2 stated with respect to the BOA Review that the Welsh patients:

‘...were listed for revision having been seen in the clinic listed by a consultant...orthopaedics, as a branch of medicine, isn’t an exact science, and although we were asked to comment and judge, if you like, in a way, independently on this, when someone is on the list for revision surgery, they are on the list for revision surgery. If we as orthopaedic surgeons have to judge whether that was an appropriate decision, we would have to see the patient and ask questions, and do an examination. To be presented with, these are the patients for revision, what do you think, and it says, ‘patient has pain’, a subjective analysis; you look at an x-ray it doesn’t tell you whether a patient should necessary have a revision, and this is the inexactness of orthopaedics’.66

7.67 Thus just because an X-ray appears to show a technical problem with TKR prosthesis does not mean that the patient requires an early revision BOAR1 stating that:

‘You get patients’ whose x-rays don’t look great, and they’ve got a fantastic result, and you see patients’ whose x-rays look perfect, and they’re not happy, they’ve got pain’.67

Similarly COS-CV2 stated that:

‘I can open my computer and show you x-rays of people with awful looking x-rays, but reasonable function. So the indication for surgery is very much painful joint or dysfunctional joint’.68

While Mr Lake was of the opinion:

‘In my view, to rely on these X-rays as a method of assessment for the necessity of a revision would be tantamount to negligent behaviour’.69

The case note review section of the BOA report commences with the statement that:

‘We reviewed the notes and x-rays of 14 patients whose treatment had caused concern: 9 TKRs, 3 ACL reconstructions and 2 arthroscopies’.70
However, what is not stated is that the X-rays of the 9 TKRs were taken using short X-ray films. As will be discussed later in ‘Section 7’ this leads to errors being made in the measurement of bone cuts, implant angles and the interpretation of whether a TKR procedure is satisfactory.

Crucially it is not stated in the BOA report that the details recording the clinical condition of each patient’s knee is a summary drawn from the clinical observations of the consultant orthopaedic surgeon at C&V who examined them prior to the BOA Review. This includes the statement that an early revision was required. Thus the details reported in this section of the BOA report are not those based upon a completely independent assessment of the clinical records and X-rays of the patients by the BOA Reviewers. For example, when asked about the recommendations that had been made in the BOA report regarding patients requiring revisions BOAR1 replied that:

“One stage revision required” [reading from the BOA report] yes, that wasn’t our well, maybe we didn’t make that clear. Required isn’t the BOA advisors require, it’s that Cardiff surgeons required. It means that the patient was requiring a revision, was on the [C&V] waiting list’.71

While BOAR2 remarked that:

‘...if you look at a fellow consultant’s notes and it says, “patient in pain, stiffness, range of movement X, requires revision”, and you say, do my comments agree with his, fine, and you just write down, you know, that, which is my summary of the notes and x-rays, this is what we did. I can understand that you reading it as a layperson might think that was my opinion rather than my summary of the notes and x-rays’.72

BOAR2 also made the crucial point, but not stated within the BOA report, that:

‘...we were asked to look at the cases, but the decision had already been made, that’s the point I’m making. You could not unpick a decision based on the evidence that we were presented with’.73 (Author emphasis)

Thus the BOA report is unintentionally misleading for it does not explicitly highlight these very important and pertinent issues to a reader.

It should also be noted that the BOA report does not discuss the patient case-mix which is an important factor with respect to potential TKR revision rates that might be expected in a cohort of patients. For example, Weng and FitzGerald note that, ‘Patients with poorer preoperative function tend to have poorer outcome, regardless of baseline pain or function’.74 Similarly, the Medical Technology Assessment Working Group also came to the conclusion that:

‘...functional improvement is strongly correlated to the degree of impairment before surgery and TKA does not, in the vast majority of cases, return the patient to full functionality’.75
While Wylde et al note that:

‘…there is increasing evidence, based on research using patient-based outcome measures, that a significant proportion of patients experience chronic knee pain, functional disability, a poor quality of life and dissatisfaction after TKR. Although some poor outcomes after TKR are due to surgical technique and implant factors, much of the pain and disability after surgery is medically unexplained. A range of possible patient factors could contribute to a poor outcome after TKR’.76

7.71 In a similar vein Woolhead et al conclude from their study on patient outcomes following a TKR that:

‘Individuals reported their outcome from TKR as good despite the continued experience of pain and immobility. Although TKR has been shown to be a highly effective procedure using quantitative methods, they may need to be qualified by these qualitative findings’.77

7.72 Thus having a TKR, it would appear, is no guarantee that a patient will be free from a range of distressing symptoms after the operation has been performed even following text book surgery. This is because there seems to be a range of confounding variables which are not yet fully understood.

7.73 In addition, the BOA report does not explicitly draw attention to the fact that two of the patients in the list of ‘TKR Cases’ (CV 0201 and CV 0396) plus one patient in the list of ‘ACL cases’ (CV 0482) had not been diagnosed as requiring early revisions but had been put on the C&V list as ‘wait and see’, i.e. wait and see if eventually the patient does require an early revision.78 However it is now known that CV 0201 asked to be removed from the C&V list of early revisions and that CV 0396 did have their knee revised. It is not known whether or not CV 0482 had an early revision as that patient did not give permission for their clinical records to be examined by the clinical advisors to this Review.

7.74 This Review Panel has also identified that two of the five patients who gave permission for their clinical records to be examined had accidents prior to attending C&V to report that their knee was causing problems. These were CV 0308 and CV 0457 who both suffered minor twisting injuries.79 With regard to patient CV 0785 the BOA report stated ‘Said to have a plica resected but still has bucket handle tear of medial meniscus. Re-arthroscopy required’. However, the computerised DSU system (known as ‘Tracker’) which keeps track of patients as they enter, progress through and depart the Second Offer Scheme following discharge from hospital states in a summary of this patient’s case states that: ‘MRI shows a bucket handle tear meniscus which consultant thought would have been present at the time of surgery’.80 Thus there would appear to be a change in emphasis between what is
recorded on the DSU Tracker system, which both BOAR1 and BOAR 2 had a copy of, and the patient summary in the BOA report.

7.75 It should also be noted that this Review Panel requested that all the visual evidence, i.e. X-rays and arthroscopic pictures (or appropriate copies) that had been evaluated by the BOA Reviewers when undertaking their review be made available to the clinical advisors of this Review. With respect to patient CV 0785 the consultant orthopaedic clinical advisors to this Review stated that the arthroscopic pictures were not good enough to enable them to give an opinion as to whether the bucket handle tear would have been present at the time of surgery. Mr Tasker noting that:

‘...there is a distinct possibility that the patient may have had an event damaging the meniscus subsequent to the arthroscopy performed at Weston’.81

While Mr Lake observed with respect to patient CV 0785:

_I am not in full agreement with the BOA report, simply because, it cannot be clear that the patient did not tear the meniscus after the surgery at Weston_.82

With regard to the statement in the BOA report that ‘CV 0224 Deep infection requiring 2-stage revision. Not recognised at Weston’.83 Mr Tasker made the following observation:

_‘In my experience a deep infection in a total knee replacement requires removal of both the femoral and the tibial components and all the cement. Usually a period of months is left between the removal of the prostheses and the revision procedure being undertaken. This allows time for the antibiotics to eradicate the infection from the bone. X-rays taken in 2006 show that the tibial component has been removed and the femoral component left in place, a subsequent X-ray shows the tibial component has been replaced suggesting that only a partial revision was undertaken. There is nothing in the notes or in the subsequent management of the patient to confirm that this patient ever had a deep infection or that they were mismanaged by Weston. There is therefore some doubt as to what exactly occurred with this patient and I therefore do not agree with the BOA report’.84

7.76 Evidence, if any were needed, to support the view of Mr Tasker comes from Gonzalez and Mekhail who state that ‘If infection is suspected, aspiration is mandatory to attempt to confirm the diagnosis and identify an organism’.85 However such a procedure does not appear to have been undertaken with respect to patient CV 0224.
Likewise, Mr Lake with respect to patient CV 0224 came to the conclusion that; 'I do not endorse the view expressed in the [BOA] report on this case'.

The BOA report also states that: ‘CV 0457 Femoral and tibial screws far too anterior. Graft failed. Revision required’. However, Mr Lake commented that:

‘Post operative X-ray indicates anterior placement of the femoral screw. Also, subsequently, the graft ruptured and the patient required revision surgery, though the post operative film from this indicates that the femoral screw has been changed, but the impression given is that the same screw track was used which remains too anterior. In my view, the tibial placement is satisfactory in both surgeries. I do not entirely agree with the BOA report, and suggest the tibial screw is not “far too anterior”, though the femoral screw is not well placed. The revision, subsequently, suggests that the Cardiff surgeon had still left the femoral screw too anterior’.

The BOA report also notes that the BOA Reviewers:

‘…also reviewed the x-rays of 14 control TKR patients selected by the Delivery and Support Unit of the Second Offer Scheme…’

However, that statement appears to be inaccurate. The ‘control’ cases were in fact selected by healthcare professionals at the Weston NHS Treatment Centre.

The BOA report also observes with respect to the ‘control group’ of patients that ‘Of the 14 cases 6 had technical faults and 8 were acceptable’. BOAR2 observing that ‘The second 14 we didn’t see the notes, we just saw the x-rays, because they said there was no concerns’. Thus the BOA ‘control group’ consisted of Welsh patients who had not actually complained of any problems at the time of the BOA Review even though six were assessed as having technical faults. Thereby demonstrating the inconsistent nature of the relationship between X-rays which appear to show technical faults with TKR implants and the fact the patients concerned do not necessarily complain about their outcomes.

As noted earlier, the ‘control cases’ for this present Review were patients who had been randomly selected, operated on by consultant orthopaedic surgeons not connected with the Second Offer Scheme and who had no reported problems. However, even in this group two of the five patients were deemed to have had technical faults by the clinical advisors to this Review. This is roughly the same ratio of technical faults to satisfactory outcomes as in the BOA Reviewers control cases. This again highlights that technical faults perceived on a knee X-ray do not necessarily translate into a problem for a patient.
7.82 This section of the BOA report starts with the statement that:

“There is a much higher incidence of early complications than expected with the TKRs. Nine cases out of 147 6.1% required revision within a year...."  

7.83 However, although the BOA Reviewers report numerical findings with regard to the alleged number of early TKR revisions required neither Reviewer possessed any academic or professional expertise in the field of medical statistics or epidemiology. Hence, they had no formal knowledge to draw upon with regard to the significance of the numerical results which they reported.

7.84 Moreover, it should be noted, particularly in light of the recall of patients which subsequently took place based upon the statistics cited in the BOA report that at interview BOAR1 stated:

“...I am not claiming any statistical or epidemiological credibility to our review; our review was looking at a process, this is what I would like to focus on really, and we made some recommendations based on a suspicion, but it wasn’t a statistically significant or an epidemiologically valid calculation, in no way would I claim that, and that wasn’t the purpose. The purpose was to flag up a possible problem'.

While BOAR2 remarked that:

“...when I do statistics I always talk to a statistician, because I know that I don’t know enough about statistics and populations, and norms and means and errors, and all the things, and that’s not the world I live in, but I know enough to know. But this wasn’t meant to be an accurate statistical analysis, if it was we’d have got the numbers right, and checked it and had an independent statistical analysis. I mean, that’s what we do when we write papers'.

7.85 BOAR1 also stated that the BOA report: ‘...wasn’t a scientific paper in any shape or form'. Similarly BOAR2 also noted that 'It’s certainly not a scientific study as such'.

7.86 Additionally when asked how they had obtained the baseline figure of 147 cases for their report BOAR1 replied, ‘I don’t know'. While BOAR2 said:

'I would imagine it’s because we were told that number when we went down there. The process when we went down there was that I wrote down in long hand everything people said to us at interview, and we used my notes to compile the report, so there would be no possible argument about the things, very much as you are doing now'.

74
7.87 Subsequently staff at both the DSU and those concerned with the BOA Review at C&V categorically denied providing the BOA Reviewers with any numerical data.\textsuperscript{104} However, further enquires as to where the BOA report baseline data of 147 TKR cases came from resulted in the Review Panel receiving a copy of the letter sent by the DSU following their receipt of the BOA report (as noted earlier, RDSU). Where upon it was discovered that both the DSU and BOA were aware shortly after the publication of the BOA Report that:

‘The baseline figure of 147 that has been used to calculate the [WTC, TKR] incident rate is incorrect. Using the actual baseline for 2004/05 of 65 cases does return a revision rate within one year of 6.1%; for 2005/06 the baseline is 156 cases, returning a revision rate of 3.2%. The average revision rate across the two year period is 4% based on combined TKR activity of 221. We consider that the conclusions you draw remain correct, in that this incidence rate of early complications is higher than would be expected in the first year, and therefore the implementation of your recommended actions is proceeding’. (Appendix 3, section 5.1)

7.88 When asked what actions the BOA had taken on receiving the DSU letter and in particular to the information regarding the apparently incorrect early TKR revision rate cited in their report a BOA representative replied:

‘The letter was forwarded to then-President [name of person] and reviewers [names of BOA Reviewers] for information. The particular section in question, Section 5.1, was phrased in such a way that no response was required and we merely noted that the DSU was to proceed with implementation of the recommendations’.\textsuperscript{105}

7.89 Therefore the recall of patients back to C&V was no longer on the basis of the BOA Reviewers finding of a ‘six-fold increase in the expected revision rate’.\textsuperscript{106} But upon the one third smaller (4%) early TKR revision rate calculated by the DSU. Nevertheless, neither the BOA nor their Reviewers raised any objections to the recall of the WTC patients proceeding on the smaller DSU revised number of early TKR revisions.

7.90 Similarly to the BOA this Review Panel also asked a senior manager from SOCT (SM-SOCT3) why the recall of WTC patients had been implemented given that SOCT were aware that the size of early revision rate cited in the BOA report was incorrect. SM-SOCT3 replied as follows:

‘The BOA advised that an upper limit of 1% revision rate within one year would be the expected national norm. Based on the view of the profession and the revised calculation which remained in excess of 1%, the decision to act on the recommendations of the report is regarded as appropriate’.\textsuperscript{107}

7.91 Thus the recall of all Welsh patients that had been treated at WTC appears to have been implemented on the basis that the early TKR revision rate calculated by the DSU, although a third smaller than that reported by the BOA, was in excess of an asserted 1% expected national norm. However, as will be discussed later, there does not appear to be any recognised national
robust evidence-based 1% maximum norm for expected TKR early revision rates.

Joint SOCT and WAT audit

7.92 Following additional enquiries by SOCT and WAT the evidence demonstrates that the RDSU letter in response to the BOA report also contained inadvertent errors regarding the number of expected early TKR revisions regarding the Welsh patients treated at WTC. The extra enquiries consisted of a SM-SOCT3 taking a list of the Welsh patients recorded on the Schemes Tracker computer system as having had TKR procedures, including early revisions, during the periods April 1 2004 – 31 March 2005 and 1 April 2005 – 31 March 2006. This list of TKR procedures was then checked against a list of Welsh patients recorded on the WAT computer database as having had TKR procedures, including revisions, during that same time period to produce an agreed (SOCT and WAT) definitive list of all TKR primary procedures and subsequent early revisions.

7.93 The check of the SOCT and WAT lists of TKR procedures and early TKR revisions revealed that there had been seven TKR procedures undertaken at WTC that were listed for early revision at C&V and not the nine quoted in the BOA report or the RDSU letter. Moreover those seven TKR early revisions had taken place over a two year and not the one year period as stated in the BOA report. In addition, the seven TKR early revisions consisted of two TKR procedures that allegedly required early revision out of a series of 66 TKR primary operations which had taken place in the financial year 1 April 2004 – 31 March 2005. While the other five TKR early revisions that was allegedly required were from a cohort 158 TKR primary operations that had taken place in the financial year 1st April 2005 – 31st March 2006. Thus a total of 224 primary TKR operations had taken place during the period covered by the BOA review and not the 147 as stated in the BOA report or the 221 stated in the RDSU letter.108

7.94 Thus the early TKR revision rate for the financial year 1st April 2004 – 31 March 2005 was 2/66 = 3.0% (95% CI: 0.8% to 10.4%). While the early TKR revision rate for the financial year 1st April 2005 – 31st March 2006 was 5/158 = 3.2% (95% CI: 1.4% to 7.2%) This returns an average early TKR revision rate over one year of 7/224 = 3.1% (95%CI: 1.5% to 6.3%).109 Therefore depending on how one looks at these statistics either the incorrect BOA revision rate of 6.1% is virtually 100% greater than the percentage of early revisions it was alleged were required in one year. Or the actual percentage of early TKR revisions it was alleged were required is approximately 50% of the BOA figure. With respect to the statistic quoted in the RDSU letter that the number of alleged early TKR revisions was 4% this is approximately 25% larger than has proved to be the case. Thus in either case the distribution of the correct number of the allegedly required early revisions is different and smaller than the figures quoted in the BOA report or the RDSU letter.
7.95 Put another way the use of 95% confidence interval (CI) for the proportion of 7/224 is 1.5% to 6.3%. What this means is that the true probable value (that is likely to occur 95 times out of a hundred that similar early TKR revision estimate is made) lies somewhere between 1.5% and 6.3%. The numbers of revisions is small and that is why the range is large. We can say with 95% confidence (95% is a standard measure used by statisticians) that the true rate could reasonably be as low as 1.5% or reasonably as high as 6.3% in the total population of TKR performed. We do not, consequently, have much confidence that the true rate is actually lower than 1.5% or higher than 6.3%.

7.96 It should be recalled at this point that the independent study carried out by Bannister et al on the North Bristol patients operated on at WTC by the Scandinavian consultant orthopaedic surgeons returned an early TKR revision rate of 1.9% which reflects more closely the findings of this study than that of the BOA or the DSU. Moreover if patient CV 0224, whose revision is contested by the clinical advisors to this Review, is excluded from the figures the revision rate for the two years which the BOA Review covered would be 6/224 = 2.7% (95% CI: 1.2% – 5.7%). However, as will be discussed later in this report, the early TKR revision rate of the Welsh cohort of patients treated at WTC following the DSU recall is far greater than any of the statistical estimates given above.

**Trent Arthroplasty Study**

7.97 The BOA report also states that:

> ‘Figures from the Trent Arthroplasty Study show a 95.5% survival at 10 years and, for the first year, the Weston figures represent a six-fold increase in the expected revision rate’.

But when asked whether or not there was an explicit robust evidence-based national or international standard with respect to a maximum 1% acceptable revision rate for TKRs on which they had based their evaluation BOAR1 replied:

> ‘The NJR wasn’t really underway then, I mean, that’s what we use now, but I think [name of a person] and I have quoted references at the end; one from the North Hampshire Joint Registry, and one from Trent. The Trent was the first established National Joint Registry, yes, so we did quote that’.

7.98 However it can be observed that there is no citation in the ‘Reference’ section of the BOA Report with respect to a *Trent Arthroplasty Study*. This Review Panel did however contacted the *Trent (and Wales) Regional Arthroplasty Audit Group* (Trent Group) in an attempt to locate the paper to which the BOA Reviewers referred. However the paper kindly sent to the Review Panel by the Trent Group does not contain any reference to a one year maximum acceptable level TKR revision rate.

7.99 It is also asserted in the BOA report that there are data from the *North Hampshire Joint Registry* which agrees with the *Trent Arthroplasty Study* however that data is not cited in the BOA report and consequently a reader is
left unaware of the exact nature of the proposed correlation. It is important to note however, that the statistics generated from the Trent Arthroplasty Study or North Hampshire Joint Registry with regard to orthopaedic procedures were and are not recognised as robust evidence-based national standards. Indeed, the issues surrounding the creation of national standards for orthopaedic procedures are complex and will be briefly discussed in the next section.

BOAR1 also stated with respect to the statistics quoted in the BOA Report that:

‘There were nine cases requiring revision, but, again, I mean, we only made recommendations that these patients needed to be looked at more closely. So I honestly don’t think that the figures that are in here are of particular significance’.115

The driver for the BOA’s recommendation to recall the 683 patients treated at WTC however were the statistics produced by the BOA Reviewers. Thus it is important to note again at this point that both epidemiological advisors to this Review are in agreement. Even if quantitative evidence cited in the BOA Report to the Delivery and Support Unit, Welsh Assembly Government was correct it was ‘…extremely limited and it is difficult to draw any strong conclusions from it’.116

National Joint Registry and National Institute of Clinical Excellence

7.100 Since the recall of the Welsh patients who had been treated at WTC appeared to have been based, at least in part, upon the 1% statistic cited by the BOA an attempt was made to clarify the position with respect to a recognised acceptable maximum national TKR revision rate standard. The Review Panel therefore contacted the National Joint Registry (NJR) of England and Wales and the National Institute for Clinical Excellence (NICE). The Review Panel asked NICE if they offered definitive evidence-based guidance as to an acceptable rate of TKR revisions. A NICE representative responded as follows:

‘I can confirm that it’s outside of the remit of the NICE interventional procedures programme to provide definitive evidence-based TKR revision rate guidance’.117

7.101 The NJR was also approached by the Review Panel with the same request as that to NICE. The NJR replied as follows:

‘NICE have produced guidelines for hip joint replacement surgery (10% revision rate at 10 years) but have not produced similar guidelines for knee replacement surgery. It is expected that they would be responsible for providing a national benchmark and would consult with professional bodies, such as the British Orthopaedic Association, in order to do so. Data held by the NJR may be used in drawing up any proposed benchmarks.’
The current status of data within the NJR suggests that 1 and 3 year revision rates for knee replacement surgery are as follows:

- 0.7% (95% CI: 0.6%-0.7%) at one year
- 2.5% (95% CI: 2.4%-2.6%) at three years
- 3.7% (95% CI: 3.5%-3.9%) at five years

However the NJR data set is incomplete. This may have an effect on the ability to produce an accurate benchmark particularly for comparing outcomes between hospitals.

It is essential that reporting of data to the NJR is made mandatory to avoid this in the future.\(^{118}\)

One of the reasons for the NJR data set being incomplete is that while ‘All NHS trusts and NHS foundation trusts are expected to submit details of all hip and knee joint replacement operations to the NJR\(^{119}\) the fact of the matter is ‘Compliance varies widely, with some orthopaedic units failing to submit any records’.\(^{120}\)

In addition the:

- NJR requires patient consent to obtain patient details. Only those procedures submitted with patient details (specifically NHS number) can be used for revision rate analysis. Procedures with no NHS number are 'lost' to follow-up and are not included in revision rate calculations.\(^{121}\)

The importance of having a patients' NHS numbers is so that they can be followed longitudinally, i.e. so that the same patient can be re-located and, hence, revisions confirmed.

Therefore since some healthcare organisations appear to be less diligent than others in the submission of orthopaedic data and patients do not always give their permission for their details to be shared with the NJR their data set is incomplete. The difficulty with the NJR data set not having 100% of the data on knee procedures in England and Wales is that the statistical analysis of TKR revision rates they undertake may be inaccurate. This is because of 'selection bias'; defined as:

- The introduction of error due to systematic differences in the characteristics between those selected and those not selected for a given study. In sampling bias, error is the result of failure to ensure that all members of the reference population have a known chance of selection in the sample.\(^{122}\)

Hence it is possible that there are significant differences between the reporting of primary TKR and revision operations to the NJR. Therefore the revision rate calculated by the NJR may not reflect the actual number of revision operations that are performed. For example, Table 1 below gives the
number of primary TKR operations reported to the NJR from 2004 - 2008 and Table 2 those with NHS numbers for the same time period.

<table>
<thead>
<tr>
<th>Operation Year</th>
<th>Primary Knee England</th>
<th>Primary Knee Wales</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>45,000</td>
<td>1,467</td>
</tr>
<tr>
<td>2005</td>
<td>57,826</td>
<td>2,638</td>
</tr>
<tr>
<td>2006</td>
<td>58,579</td>
<td>3,449</td>
</tr>
<tr>
<td>2007</td>
<td>68,510</td>
<td>4,055</td>
</tr>
<tr>
<td>2008</td>
<td>69,002</td>
<td>4,706</td>
</tr>
</tbody>
</table>

Table 1  
**Source:** National Joint Registry – May 2009

<table>
<thead>
<tr>
<th>Operation Year</th>
<th>Primary Knee England with NHS Number</th>
<th>Primary Knee Wales with NHS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>26,201</td>
<td>1,143</td>
</tr>
<tr>
<td>2005</td>
<td>38,789</td>
<td>2,237</td>
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<tr>
<td>2006</td>
<td>45,799</td>
<td>3,023</td>
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<tr>
<td>2007</td>
<td>61,238</td>
<td>3,878</td>
</tr>
<tr>
<td>2008</td>
<td>64,737</td>
<td>4,564</td>
</tr>
</tbody>
</table>

Table 2  
**Source:** National Joint Registry – May 2009

7.106 As noted above, the total number of primary knee procedures undertaken in England and Wales may in fact be significantly greater than the total number of knee procedures reported to the NJR. Secondly, the number of primary knee procedures reported to the NJR with NHS numbers, while steadily rising, is still less than the total number reported in Table 1. Hence there can be no certainty as to the accuracy of the TKR revision rates that have been calculated.

7.107 It can also be observed comparing Tables 1 and 2 that in the financial years covered by the BOA report 2004 - 2006, the number of primary knee procedures reported to the NJR with NHS numbers was significantly less than the total number of primary knee procedures reported to them. Thus drawing upon the NJR data knowing what the actual early TKR revision rates for England and Wales were during that period is problematic. Indeed, it still is - the NJR report for 2009 stating that:

‘Initial results from this [NJR] analysis indicate that the revision rates continue to be underestimated by at least 15%’.  

7.108 In addition, it must also be noted that following a comparison of TKR knee and hip revision rates recorded in the orthopaedic registries of other countries the NJR reported in 2008 that:

‘A comparison of revision rates observed in the NJR with those reported in other national registries showed that the rates reported in the NJR were
generally lower than those reported elsewhere. Table 4.13 summarises results of a number of national registries that have published quantitative figures on revision rates in patients who had a hip replacement since 2000. The revision rates observed in Norway and Australia are higher than observed in the NJR, whereas those observed in New Zealand are very similar.

The interpretation of these differences is not straightforward and a number of explanations have to be considered. First, the completeness of the identification of revisions might be higher in Norway and Australia than in England and New Zealand. Second, the definitions of what constitutes a revision may differ between the registries. For example, the NJR explicitly excludes re-operations other than revisions. Third, data validation procedures in some registries that check the completeness of the reporting of revisions may lead to selective inclusion of patients who had a revision which in turn would overestimate the revision rate. These possible explanations as well as others need to be explored in more detail before any conclusions about the quality of orthopaedic services can be calculated.124

7.109 Thus based upon the guidance provided by the NJR it would appear that there is no national standard evidence-based maximum expected early TKR revision rate that can be applied to England and Wales or internationally.

7.110 However in an Editorial for the Journal of Bone and Joint Surgery Cannon asserts that a study undertaken by Sibanda et al125 into ‘Revision Rates after Primary Hip and Knee Replacement in England between 2003 - 2006’ has set ‘... a national standard’ with regard to revision rates.126

7.111 In their study Sibanda and his colleague linked the NJR records of NHS patients treated in England and Hospital Episode Statistics (HES) between 2003 and 2006. Revision for any reason of a THR or TKR was identified through patient readmissions to hospital that are recorded in the Hospital Episode Statistics. However, the authors note that there are methodological limitations to their study such as ‘The identification of revisions of primary hip and knee replacement within the HES database may have been incomplete’.127

7.112 Furthermore, it is also noted in the paper that of the 327,557 primary knee or hip replacements the group identified only 167,076 (51%) that could be linked between the two databases. Hence the revision rates calculated are based upon approximately half of the total population identified. Thus, as argued earlier, under such conditions there could be a significant ‘selection bias’ effect. Moreover, the HES website has a section entitled ‘When (not) to use HES data’ and one of the headings in that section is ‘Re-admissions’128. From the ‘Re-admissions’ heading a reader is redirected to a HES webpage entitled ‘Readmission rates and HES’129 and under the heading ‘Using readmission rates and making comparisons’ on that web page, it is stated that:

‘In HES, when considering readmission rates, we usually only take into
consideration emergency readmissions (elective readmissions were always an intentional part of the treatment).\textsuperscript{130}

7.113 Since the revision of primary TKR and THR operations are elective then readmission data held by the NJR on revisions is clearly problematic. Indeed, under the heading ‘Can I get readmission figure from the HES?’ on the same web page it is also stated that:

‘Readmission rates aren’t routinely calculated in HES. This is mainly because it is not possible to say with absolute certainty that we have identified all potential readmissions, and that those that we have identified clinically relate to the original admission’.\textsuperscript{131}

7.114 Thus, given the authors caveat regarding methodological limitations of their study; the HES’s warning about the use of readmission data and that only 50\% of the population identified could be used in calculating the revision rates, it can be argued, that the findings are not sufficiently robust to be accepted as a national standard. Notwithstanding that a surgeon’s decision to recommend that a patient should undergo an early revision of their orthopaedic procedure and a patient’s decision to accept or reject that advice is fundamentally based upon subjective criteria.

Complexity of surgery

7.115 It is also stated in the ‘Summary of Findings’ section of the BOA Report that:

‘It should be emphasised that these are in general not complex cases from either the orthopaedic or medical point of view’.\textsuperscript{132}

7.116 However, when asked a question about the complexity of surgery performed at WTC WSM1 stated:

‘The intention was not to have complex cases, but inevitably when an administrator is pulling patients off a list they have no idea really on the complexity of the patient. So several things happened, both for the Welsh patients and the AOC [Avon Orthopaedic Centre] patients; is that some patients when they arrived in the pre-operative clinic, because I arranged it with the orthopaedic surgeons on their advice that all the patients would be seen in a pre-op clinic, and then a decision would be made: was the surgery appropriate, was the patient suitable for the project, and if both of those were right and the anaesthetist was happy, then the patient would be listed for their surgery at Weston’.\textsuperscript{133}

7.117 As noted above, the BOA report does not discuss why or how the Reviewers came to the conclusion that the surgery performed at WTC by the visiting Scandinavian surgeons was not complex. Rather they cite a reference to a paper that discusses the affect on the ‘…case mix within the trauma and orthopaedic department at Southampton General Hospital, after the establishment of a local ISTC…’\textsuperscript{134} However regardless of whether or not the case-mix at Southampton General Hospital changed after the establishing of
an ISTC that paper cannot be treated as evidence that some of the surgery undertaken at WTC was not complex.

7.118 Additionally, the BOA Reviewers’ *mindset* seems to have been that WTC was an ISTC when it was not. Evidence to support this assertion comes from the BOA report where the Reviewers state with reference to WTC that ‘Surgeons visiting an ISTC should only…’135 Additionally, when asked at interview about whether or not patients requiring complex TKR surgery would have been sent to WTC BOAR1 replied that:

’No they wouldn’t have been sent to an ISTC, that’s part of the contract, they only take the easy stuff. I have cases bounce back at me almost on a weekly basis that have been sent off, our ISTC…’136

7.119 Furthermore BOAR1 appeared to associate WTC as being comparable with ISTC throughout the interview. BOAR1 used the term on a dozen occasions and when the question ’...you mentioned ISTC?’ was put to BOAR1 he replied, ‘This is an ISTC isn’t it.’137 It was then pointed out that WTC was in fact an NHS treatment centre not an ISTC.

7.120 With respect to the complexity of the surgery performed at WTC contrary to the view stated in the BOA report Mr Lake was of the opinion that:

’At least 2 of the 4 patients I reviewed in fact had significant deformities of the knee which would have been technically demanding and require considerable experience to manage. Furthermore, it could be argued equally that patients who have accepted a second offer are the more severe patients, because they are in greater distress and are willing to travel to get help for their problems. Whereas the patient that remains on the considerable Cardiff waiting list took the easier option because they were less troubled. Thus, I do not believe it has been substantiated that Weston were dealing with less severe cases on the basis of the patients that the BOA Team reviewed. The innuendo here is that Weston had easier cases, yet still managed to foul it up. That innuendo should not enter a report of this seriousness, for there is no evidence to make the suggestion.

What has been well shown is that in countries whose waiting lists are significantly shorter that the UK, e.g., the USA and Australia patients achieve significantly better results because their knees do not deteriorate functionally as badly, and deformity is significantly reduced. This means that long waiters in the Wales, and Cardiff certainly had long waiting lists compared with other parts of the principality, may well contain much more deformity and functional debility than areas where waiting lists are under better control, as in England compared to Wales. None of these factors are drawn in the reports critique’.138

**Competence of Scandinavian consultant orthopaedic surgeons**

7.121 In paragraph 5.2 of the BOA report, ‘Summary of Findings’, the BOA Reviewers note that:
Two out of 9 ACLs [Anterior Cruciate Ligament] failed and there was 1 bucket handle meniscal problem undiagnosed. Clearly this failure rate does not reach statistical significance owing to the small total number of cases but two out of nine failures still causes concern and prompts questions about clinical competence.  

7.122 However, as noted earlier, the BOA report states quite clearly that the BOA Reviewers reviewed the notes and X-rays of 14 patients. The 14 patients comprised of 9 patients who had undergone TKRs, 3 patients who had ACLs and 2 patients who had Arthroscopy. Therefore it is logically impossible for the BOA Reviewers to have reviewed nine sets of notes and X-rays on patients who had ACLs. That is unless they had the notes and X-rays of 20 patients to review - which they did not. Thus an error has been made at some point during the BOA Reviewers analysis of the data and as a consequence, they have inadvertently drawn an erroneous and completely unfounded conclusion.

7.123 It should be noted however that the logical inconsistency noted above in relation to the ACL analysis was not recognised until after the Review day had been completed. Thus at interview BOAR1 was asked about the comments made in paragraph 5.1 regarding clinical competence to which he replied with reference to the recommendations made in the BOA Report that, ‘…none of [the recommendations] have actually said that the surgery is definitely substandard.’ BOAR1 also noted that:

‘…we haven’t got enough statistical or epidemiological evidence to directly criticise the individual Swedish surgeons. I think they’re part of a process, it may be that they’re incompetent, one has to be suspicious of that, because of the poor results, but I personally don’t feel, and that’s the point you were making, I don’t have the evidence to say that…’

In a similar vein BOAR2 stated that:

'We interviewed the surgeons, we looked at their CVs, the surgeons were good guys, they’d got all the qualifications, they were working, they’d done all these procedures, one or two hadn’t. So you’ve got good surgeons, working with prostheses they know about, why are the patients getting complications, and are these complications real?'

7.124 It should also be noted that the BOA report does not state that the surgical skills of the visiting Scandinavian consultant orthopaedic surgeons who performed surgery of the knee at WTC was less than satisfactory and no recommendations are made in that regard. Indeed, the RDSU letter makes the same observation:

Section 6

'The report earlier states that there are no doubts regarding the experience or skills of the two surgeons interviewed (comment on section 5.4 above
refers) and the recommendations that follow in section 6 of the report, relate only to processes in the care pathway.

'We note that the reviewers found technical faults and a much higher incidence of early complications with the knee TKRs than would be expected, and that of the control cases 6 were found to have technical faults. In this respect, and with the magnitude of technical faults found, we would have expected a recommendation to relate directly to the concerns about clinical competence'. (Appendix 3)

Nevertheless, as noted above, the BOA report does not discuss the clinical competence of the visiting Scandinavian surgeons at WTC or make any comment regarding the proficiency with which the surgery under review was undertaken.

Recommendations that Welsh TKR patients required early revisions

7.125 On the other hand with respect to the judgement of the consultant orthopaedic surgeons at C&V who had recommended the Welsh patients have revisions BOAR2 commented that:

'It did concern me, to some extent, that some of the cases down here were based on subjective rather than objective data…' 144

A short while later BOAR2 also stated:

'We had to assume that these surgeons [at Cardiff and Vale NHS Trust] were doing their stuff properly and that the very, very big decision, it’s a really big operation revision knee surgery, to put someone on the list for it, you really need to be sure you’re going to improve the quality of life'. 145

7.126 It should also be noted however that the clinical advisors to this Review Panel are of the opinion that it is much more difficult for a consultant orthopaedic surgeon not to recommend an early revision for a patient having problems with a TKR if that surgeon did not perform the surgery. The reason for this is when a surgeon has undertaken a procedure to insert a TKR prosthesis she or he is well acquainted with the internal architecture of the knee of the patient concerned, their pre-operative condition and whether any problems were encountered during the operation. Hence being aware of such information makes it easier for a surgeon to recommend a range of alternative treatments to try to solve the patient’s problem before turning to an early revision.

7.127 The consultant orthopaedic surgeon and the patient will also have built up a rapport allowing the surgeon to assess the likelihood or not of the revision being successful (the surgeon knowing that the success rate for revision surgery falls short of the primary procedure). Lemaire observing within the speciality of orthopaedic surgery that:

'It is best only to treat patients with whom a confident relationship appears possible, as we know that they will usually fail to understand completely all
the issues and will rapidly forget most of the information provided.\textsuperscript{146}

7.128 Additionally, where a consultant orthopaedic surgeon has undertaken the primary TKR operation she or he would also have access to the physiotherapist who had treated the patient following their original TKR procedure. Information on how closely the patient followed their physiotherapy regime giving a further indicator as to the potential outcome of the original surgery.

7.129 On the other hand when a consultant orthopaedic surgeon is reviewing a patient who is distressed and on whom she or he has not performed the primary TKR surgery they are at a significant disadvantage. They are not familiar with the patient pre-operative condition, the internal construction of the patient knee and not aware of any problems that might have arisen during the patient’s primary TKR operation. As a result when a surgeon perceives what she or he believes to be technical faults on a patients X-ray then their normal threshold for recommending an early revision may well be lowered. Tentative evidence to support such a position can be found in the evidence from Mr Tasker who states that:

‘I am unaware of any paper that has been published advocating early revision of a total knee replacement for mal-positioning of the components alone. By early revision… I mean within the first 3 years following the primary total knee replacement provided that no infection is or is suspected of being present within the knee joint. In many of the papers mal-positioning of the components is cited as a cause for increased wear and failure usually represented as loosening of the components after a number of years. It is also cited as a cause of poor movement and function of the knee post-operatively. However the ideal time to get the position correct is at the first operation and revision surgery is often not completely successful. It is therefore imperative that in assessing a patient who is having problems after a total knee replacement all the facts are available. These include the preoperative state of the patient, particularly their preoperative pain levels and function, an examination of the patient and current x-rays. With all these factors accounted for the decision of the surgeon will still be subjective and therefore vary from surgeon to surgeon.’\textsuperscript{147} (Emphasis in original)

While BOAR2 when discussing revision surgery of a TKR stated:

‘The operation itself has an increased complication rate, and you can make someone worse by operating, and as surgeons talking about revision surgery, that’s really important. \textbf{Normally, often, you don’t make a decision on one outpatient consultation}.’\textsuperscript{148} (Author emphasis)

Evidence to support this view can be found in a study by Toms et al where it is stated that:

‘The management of patients with a painful total knee replacement requires careful assessment and a stepwise approach in order to diagnose
the underlying pathology accurately'.  

Similarly, Mandalia et al state that the:

‘Evaluation of patients with painful total knee replacement requires a thorough clinical examination and relevant investigations in order to reach a diagnosis.’

7.130 Likewise, the clinical advisors to this Review stated that before recommending a patient should have their TKR revised early they would try other forms of treatment to improve a patient’s condition, such as, manipulation of the knee under anaesthesia or additional physiotherapy. However, following just one outpatient consultation at Cardiff and Vale NHS Trust each of the five patients who gave their permission to have their clinical records and X-rays reviewed by the clinical advisors to this Review was recommended to have their knee operation revised. COS-CV2 at interview stating with respect to the patients the reviewed, ‘…at [the] first presentation of these patients they needed revision’.  

BOAR1 noted however that it is possible:

‘…if you get the patient physio [physiotherapy] or more frequent physio, and liaise with the physiotherapist and maybe get them back in and do a manipulation, you can actually get a good result from a technically less-satisfactory x-ray.’

7.131 It should also be noted however that when recommending a patient to have an early revision of their knee operation that BOAR1 observed that:

‘No one is going to force a patient to have a revision, you know, you can lean on them, but you can’t force them. I mean, I would lean on a patient by a variable amount depending on what I felt the risk benefit ratio was’.

**BOA report: recommendations**

7.132 In paragraph 6.1 of the BOA report it is recommended that:

‘Post-operative x-rays must be available for viewing by the operating surgeon before the patient (or the surgeon) leaves the hospital.’ (Emphasis in original)

However, there is evidence to suggest that this assertion can be challenged. In a study by Jibri et al on ‘Quality assessment of early versus late post-operative radiographs in joint replacement surgery’ the research group came to the conclusion that:

‘…this study has demonstrated that there is a significant difference in the quality of postoperative radiographs in favour of late films. We recommend obtaining the first image following primary uncomplicated knee replacements in the first follow up visit [at six weeks]. Early
postoperative radiographs in the pre-discharge period need to be requested only when they are clinically indicated.155

7.133 The recommendation made at 6.4 of the BOA report states that:

‘Surgeons from the original hospital should be informed of any problems (Emphasis in original)

‘There were no apparent channels of communication between the Scanloc surgeons and the Cardiff surgeons in case and when patients had problems. These had to be picked up on an ad hoc basis which meant delay and a possible poorer clinical outcome’.156

However, as pointed out earlier by WSM1, SM-SOCT1, the letter from SCOS to the Review Panel and the RDSU letter to the BOA the reason there were no channels of communication between the two sets of surgeons was because the consultant orthopaedic surgeons at C&V apparently refused to have any such contact with the Scandinavian surgeons at the WTC.

7.134 Recommendation 6.5 is in two parts and states that:

‘Patient Review

1. The radiographs of all patients who have undergone joint replacement at the Weston NHS Treatment Centre be reviewed and those found to be suboptimal should be recalled for a clinical and further radiological check.

2. All patients treated at Weston NHS Treatment Centre should be written to and offered a clinical review if they had any ongoing concerns about the outcome of their surgical treatment’.157

7.135 However, the BOA Reviewers only consulted the X-rays and clinical notes of 14 patients who had knee operations. Thus the BOA Reviewers had no evidence whatsoever regarding the success or failure of any other orthopaedic procedure carried out at WTC. Indeed, there does not appear to have been any notable number of complaints from the Welsh patients who had been operated on at WTC regarding other procedures, for example, hip replacements at the time of the BOA Review.158

7.136 Additionally, when the BOA were informed of the errors that had been made in their report with respect to the statistics concerning the Welsh patients TKR revisions and were asked if they would have made the same recommendation given the revised figure they stated, ‘No, we would not have made those recommendations’.159

7.137 Moreover, other than the BOA recommendations made with respect to recalling and reviewing patients the majority of recommendations seek to make the patient pathway in place at WTC as close to a local normative NHS process as possible. For example, there are no recommendations with regard
to changes that could be made to surgical procedures that were performed or how patient outcomes might be improved.

**BOA report: conclusions**

7.138 The conclusion drawn in the first paragraph of ‘Section 7’ of the BOA Report is that:

‘The issues outlined above illustrate the importance of an adequately funded and well-organised high quality **local** orthopaedic service for major reconstructive surgery. The outsourcing of major orthopaedic surgery uncouples the operation itself from the overall care pathway, increases the likelihood of problems and complications and thus potentially gives a poorer result for the patient…’

(Emphasis in the original)

7.139 There is however no chain of evidence presented within the BOA report to support such a conclusion. The evidential links between outsourcing orthopaedic surgery and the Welsh patients’ complications is not made. Moreover the BOA Reviewers did not consult with the patients thus they cannot say unequivocally that the patients actually required revisions. The BOA Reviewers simply agreed with the recommendations drawn by their professional colleagues at C&V based upon a table top review of the 14 patients.

7.140 In addition, the BOA report does not offer any independently verified statistics regarding the early TKR revision rates of the consultant orthopaedic surgeons at C&V to support such a claim, i.e. the TKR early revision rate would have been significantly smaller with that particular cohort of patients than they allege was the case at WTC. Indeed, when this Review Panel requested early TKR revision data with respect to the consultant orthopaedic surgeons at C&V during the period covered buy the BOA Review, i.e. 2004 – 2006 SM-CV1 replied that ‘I am afraid that we cannot provide the information that you require.’

7.141 It is interesting to note that when asked by Mr Lake if he thought the WTC outsourcing model of surgical care could be improved or should never be used BOAR1 replied:

‘If there was money available, then they should have built another ward, another operating theatre, and taken on three more orthopaedic surgeons in Cardiff. Of course, it’s a Tony Blair / Alan Millburn doctrine that you have to pluralise services, and it’s a political decision, and it’s flawed medically; that’s basically it. If there was money available to buy services from SCANLOC, then they should have appointed two or three more orthopaedic surgeons, built another ward and another operating theatre in Cardiff…This has been the problem all around really, that the NHS has been relatively starved of funds over the years, and suddenly they throw money at these foreign companies to come in, in the name of competition, but it doesn’t work. So, no, I don’t think’.

In reply to the same question BOAR2 noted:
'It could be improved, by all means, but it is very much a second or third class model, very much so. Patients do best if they are treated locally, if the services are of sufficient quality. They are then in an environment they know they can be visited by their families, if something goes wrong they don’t have to travel very far, and they know the people they are dealing with. I think the package of care, if it can be delivered locally, should be supported and funded. The funding issues, and all the political stuff that’s happened, I mean, has been to the detriment of patient care, unfortunately. It might have looked good on paper, and it might have been a good business model, but it hasn’t operated in the patient’s best interests…

'We spent a long time in this country agonising over the quality of medical and nursing training, and the safeguards professionally that the colleges have done; the inspections and the tests, as you know. To release your patients to a different part of the country, to unknown surgeons, of unknown standards and quality, and then you have to pick up the pieces, is a real slap in the face for most surgeons who have grown up in this culture of double and triple checking on their quality and their qualifications. I think that these models being foisted on hospitals and surgeons have engendered immense resentment, because it hasn’t been a level playing field, the patients have been cherry picked for being the easy ones, and any complications, and the difficult patients, have been picked up by the local hospitals. The whole NHS fraternity has called foul and hasn’t been listened to. That’s it in a nutshell, and if you want good quality care, you have to set up models locally, which has been done, over years; and it’s a complex business, the delivery of health is complex, and all the components need to be in place, and they need to be nurtured, and they need to be supported. The local people usually know how to do it, but it’s not a system that; it will support local things in theory but not in ‘practice, and that’s unfortunately my experience of the health service. As I said earlier, we have managed to get round it where I work, you know, we do not have this problem, and we’ve got our own joint registry, and we’ve got a stupidly low complication rate and revision rate, and that because we’ve been supported by our managers, and, you know, I would urge local doctors and managers to get together and support each other. If a manager goes above what is coming down from the Department they don’t progress very far, and that’s the reality unfortunately.'

7.142 In the second paragraph of ‘Section 7’ of the BOA report it is stated that ‘It has recently been recognised from another centre that “major reconstructive orthopaedic surgery does not travel well”’. It should be noted the numerical reference cited at the end of the sentence in support of the assertion refers to a paper discussing early hip failures - not knees. The advice received by the Review Panel is that the two surgical procedures are not equivalent and therefore the citation is misleading.
As noted earlier, the Trent Arthroplasty Study referred to in section 5.1 of the BOA report is not cited in the references. It is this particular paper however which is apparently cited in the text of the BOA report as providing the legitimacy for the statement ‘….for the first year, the Weston figures represent a six-fold increase in the expected revision rate’. However, given the earlier discussion regarding selection bias and voluntary nature of reporting to all orthopaedic registries in England and Wales the level of evidence it would have provided for the BOA assertion is questionable.

The report produced by the BOA is written more in the style of the former rather than the latter example. Thus, there is very little detailed evidence presented to a reader of the BOA report to show how the Reviewers arrived at their recommendations and conclusion. Hence the balance of evidence, logic and objectivity of the Reviewers deliberations cannot be independently tested by a reader following the lines of evidence that drew the Reviewers to their findings.

BOA report: references

7.143 As noted earlier, the Trent Arthroplasty Study referred to in section 5.1 of the BOA report is not cited in the references. It is this particular paper however which is apparently cited in the text of the BOA report as providing the legitimacy for the statement ‘….for the first year, the Weston figures represent a six-fold increase in the expected revision rate’. However, given the earlier discussion regarding selection bias and voluntary nature of reporting to all orthopaedic registries in England and Wales the level of evidence it would have provided for the BOA assertion is questionable.

Presentation of BOA report evidence

7.144 There are many different ways of presenting the evidence from a Review such as that conducted by the BOA. For example, authors may use a management style overview, where a summary of the evidence is presented or through an analytical style report, where the raw data such as the evidence gained through interviews, quotes from relevant documentation, diagrams or photographic images are discussed as appropriate.

7.145 The report produced by the BOA is written more in the style of the former rather than the latter example. Thus, there is very little detailed evidence presented to a reader of the BOA report to show how the Reviewers arrived at their recommendations and conclusion. Hence the balance of evidence, logic and objectivity of the Reviewers deliberations cannot be independently tested by a reader following the lines of evidence that drew the Reviewers to their findings.

7.146 However, when asked about the production of the draft BOA report by this Review Panel BOAR2 replied:

‘It went backwards and forwards to the Second Offer Team, the BOA said ‘you can’t put people’s names in it, you can’t tell them where you got this information from, you have to summarise it as if it’s just come out of the ether’. I said, I wasn’t happy with it, I was told to do it’.

7.147 Thus the style in which the BOA report is written was not that preferred by the Reviewers but by others.

7.148 It is perhaps interesting in this context to note that Lord Justice Clarke in his final report on the Thames River Inquiry (January 2000) concluded that a Public Inquiry should be held with respect to the collision between the river pleasure boat Marchioness and the aggregate dredger Bowbelle, 20 August 1989, even though a report into the accident had already been published by the Marine Accident Investigation Branch in 1990. Lord Justice Clarke’s reason for allowing the Public Inquiry which had previously been denied by Government Ministers on many previous occasions was because:

‘…the reader of the Inspectors’ Report…except in general terms… cannot identify the evidence upon which it is based. He does not even know what
evidence the MAIB had available to it. He is not therefore in a position to submit the report to critical scrutiny.'\(^{170}\)

7.149 The MAIB report of the investigation into the collision had in fact been written in a style similar to that of the BOA report and thus the evidence could not be tested by a reader of the report. It is therefore important to note that when asked if they, the BOA Reviewers, had written their report with ‘lay’ readers in mind. BOAR1 stated that ‘No. I mean it’s very difficult, no it was written with medical practice in mind; I don’t think we had anybody in mind, we just reported our conclusions really.’\(^{171}\) While BOAR2 replied, ‘… it wasn’t meant to be for a lay read’.\(^{172}\)

7.150 Yet the DSU who commissioned the BOA Report are an organisation comprised of ‘lay’ people in the context of orthopaedic surgery. In addition when BOAR1 was asked, ‘If [he] had been writing that for the journal, for the BOA journal, you would have done it in a different way?\(^{173}\) replied, ‘Gosh, yes. It wasn’t a scientific paper in any shape or form’.\(^{174}\) Similarly when BOAR2 was asked:

‘…if you had been told that this [BOA Report was to be published]…you wouldn’t have done it in the way that you have done it?’\(^{175}\)

BOAR2 replied:

‘No. I mean, that sounds as if I’m admitting sloppiness, but given the terms of reference, and we were told that we’d got a day, we did this’.\(^{176}\)

Comments

7.151 The BOA Review was undertaken by two Consultant Orthopaedic Surgeons very experienced in surgery at the knee but who had not received any formal training on how to undertake Reviews such as that required by the DSU. The BOA Reviewers also appear to have had an aversion to the surgical organisational arrangements at the WTC prior to the Review taking place. Additionally, both surgeons have private practices which, given the situation at WTC, was a potential ‘conflict of interest’. Furthermore, they were informed in confidence by someone during the course of the BOA Review that there were far more patients being recommended to have their operations revised than the ones which they were reviewing. Taken together this would suggest that unconscious cognitive biases, in particular ‘confirmation bias’ may have affected their evaluation of the evidence presented to them.\(^{177}\) The BOA Report however shows no awareness of cognitive bias.

7.152 Numerous important inadvertent factual errors, omissions and misinterpretations are to be found in the BOA report and these may have been caused by the timetable to complete the collection of data. There is also evidence to suggest that the BOA Reviewers did not fulfil the Terms of Reference agreed with the Delivery and Support Unit, Welsh Assembly Government and that they were concerned to examine the processes in place
at WTC which were not part of their *Terms of Reference*. This also suggests unconscious cognitive biases may have been at work.

7.153 The evidence also suggests that the consultant orthopaedic surgeons at Cardiff and Vale NHS Trust (C&V) were predisposed to believe that the outsourcing of knee surgery from the Trust to the visiting Scandinavian consultant orthopaedic surgeons at WTC would result in early complications. This suggests that unconscious cognitive biases, in particular *confirmation bias*, may have affected the threshold at which point they would normally recommend a revision to a patient. Particularly, as the revisions were recommended on the patient’s first visit to C&V.

7.154 There is also evidence to suggest that the communication between the Scandinavian consultant orthopaedic surgeons became more difficult as the project progressed. However, there is no evidence that patient care suffered.

7.155 The recommendation for a patient to have an early revision (within the first three years) should not be made on their X-ray and clinical records alone. The patient must always be consulted first. This is because there is an inconsistent relationship between the technical faults perceived on an X-ray and the patient’s satisfaction with their knee operation. Therefore given the BOA Reviewers did not consult any of the patients involved in their Review this clinical methodological limitation should have been made explicit in the BOA report. Thus it should also have been made explicit within the BOA report that the recommendations for patients to have early revisions, as cited in the BOA Review, were those of the consultant orthopaedic surgeons at C&V and not those of the BOA Reviewers.

7.156 The evidence suggests that a recommendation by a consultant orthopaedic surgeon for a patient to have their knee operation revised early, i.e. less than three years from the primary operation other than for an infection, is subjective in nature. Similarly, the decision by a patient to accept or reject a recommendation to have an early revision is also subjective. Thus, if two patients have X-rays that show the same technical faults with their implant one might decide to have an early revision and the other may not. While the consultant orthopaedic surgeons whose patients they are may or may not recommend an early revision based upon those same X-rays. Hence the fact that one consultant orthopaedic surgeon recommends that a patient should have a revision does not mean that all consultant orthopaedic surgeons would take the same view. Similarly not all patients would take the same decision about accepting or rejecting a recommendation to have a revision given what appears to be comparable physical circumstances.

7.157 Therefore if the visiting Scandinavian consultant orthopaedic surgeons, who undertook the original surgery at WTC, had reviewed the patients who were the subject of the BOA Review, whether they would have made the same recommendations for early revisions, as the consultant orthopaedic surgeons at C&V, must be considered to be problematic.
7.158 The clinical advisors on this Review Panel did not agree with the findings of the BOA Reviewers in three of the five cases they were allowed to Review. In addition, the evidence also suggests that some of the surgery undertaken by the visiting Scandinavian consultant orthopaedic surgeons was far more complex than that stated in the BOA report. It was also revealed that the X-rays of the patients in the BOA Review who had or were recommended to have early TKR revision procedures were taken using a short film which is known to lead to errors of measurement and interpretation.

7.159 The epidemiological advisors to this Review stated that a strong conclusion could not be drawn on the basis of the quantitative evidence available to the BOA Reviewers. The BOA Reviewers not realising how epidemiologically weak their quantitative evidence was recommended the recall of all Welsh orthopaedic patients treated at Weston. Enquiries made by this Review Panel however have revealed that the quantitative results published in the BOA report with respect to the early revision rate at WTC were substantially incorrect. The evidence suggests that the early revision rate at WTC over the two years the BOA report covers is 3.1% or even lower. If this had been recognised at the time the BOA would not have recommended the recall of all the Welsh Patients treated at WTC.

7.160 The BOA report also implies and the DSU were advised, that there was a national maximum expected early revision rate for TKR procedures of 1%. However, enquiries by this Review Panel have failed to find any recognised evidence-based national or international standard published with respect to the maximum expected early revision rates for TKR procedures. Although the BOA do state in the advice they now publish for those considering whether or not to have a TKR that they expect the complication rate to be no more than 2%. Although, given the subjectivity which surrounds such decisions, it would seem questionable whether early TKR revisions should be used, as in this case, as an objective endpoint comparator.

7.161 The reporting of primary and revisionary TKR and THR to the National Joint Registry for England and Wales is voluntary. This leads to the underreporting of those orthopaedic procedures and in particularly revisions.

7.162 There is no conclusion drawn or recommendation presented in the BOA report to suggest that the surgical competence of the visiting Scandinavian consultant orthopaedic surgeons at WTC was anything less than acceptable. Indeed, there is evidence to suggest that the consultant orthopaedic consultants at C&V may have been affected by unconscious cognitive biases which lowered their threshold to recommend revisions immediately rather than try other alternative therapies.

7.163 The BOA report does not provide any evidential links to support the recommendations that have been made. Indeed, there is literature regarding the provision of post operative X-rays which contradicts the first recommendation made. In another case the recommendation regarding poor communications was flatly refuted by the written and oral evidence from the Scandinavian Orthopaedic Surgeons at which it was aimed. In addition, the
majority of the recommendations in the BOA report simply seek to make the patient pathway at WTC normative.

7.164 The recommendations to recall all the Welsh patients treated at WTC, regardless of the type of orthopaedic procedure performed, was made by the BOA Reviewers solely on the evidence provided by the consultant orthopaedic knee surgeons at C&V. There was no evidence at that time to suggest that patients who had been treated in other orthopaedic specialities had complications which required their recall.

7.165 The BOA report is written in such a way that a reader cannot follow the evidence and hence the Reviewers lines of argument through to their conclusion and recommendations. Therefore the report is opaque to a reader. Thus, if this Review had not taken place the errors, omission and misinterpretations that have been identified would have remained unchallenged.

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5. BOAR2, Transcript – page 103, commencing at line 24

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13. BOAR2, Transcript – page 83, commencing at line 5

14. COS-CV2, Transcript – page 24, commencing at line 10


16. SM-SOCT1, transcribed from interview tape recording


18 BOAR1, Transcript – page 49, commencing at line 19


20. SM-SOCT1, transcribed from interview tape recording


22. WSM1, Transcript – page 16, commencing at line 29

23. WSM1, Transcript – page 17, commencing at line 10
24. SM-SOCT1, transcribed from interview tape recording

25. BOAR1, Transcript – page 52, commencing at line 23

26. BOAR1, Transcript – page 71, commencing at line 3

27. BOAR1, this report Section 6, ‘BOA report: introduction’, paragraph 5


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32. COS – CV2, Transcript – page 27, commencing at line 1

33. BOAR1, Transcript – page 59, commencing at line 25

34. BOAR2, Transcript – page 96, commencing at line 31


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41. BOAR2, Transcript – page 104, commencing at line 22

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61. Lake. D. N. W. Review of surgery at the Treatment Centre Weston Super Mare, June 2009, p.4 (Review Clinical Advisors report)

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66. BOAR2, Transcript – page 75 commences at line 23
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68. COS-CV2, Transcript – page 33, commences at line 14
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86 Lake, D. A review of elective surgery undertaken at the Treatment Centre at Weston-super-Mare, p.6 (Review Clinical Advisors report)


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98. BOAR1, Transcript – page 67, commences at line 10

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107. SM-SOCT3, E-mail 08/06/2009

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110. Dr. J. Pollock, Review Epidemiologist - telephone communication


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8.1 As noted earlier, following the publication of the BOA report all the Welsh patients who had undergone orthopaedic procedures at WTC were recalled to C&V by the DSU. Of the patients who were recalled a significant number were recommended to have their TKRs revised by the consultant orthopaedic surgeons at C&V who reviewed them. Subsequently a clinical study of these patients was undertaken at C&V and the results published in *The Journal of Bone and Joint Surgery*. BOAR1 stated this was ‘…the world’s premier peer reviewed orthopaedic journal…’ While the online magazine ‘Medical News Today’ also states that ‘The Journal of Bone and Joint Surgery - British Volume is a world leading orthopaedics journal with an Impact Factor of 1.868’. The journal therefore has considerable global influence in the theory and practice of orthopaedic surgery. Thus although the findings of the paper (see Appendix 6) were not part of the original Terms of Reference for this Review they were considered to be very important and so the circumstances surrounding the paper have also been subjected to Review.

8.2 Indeed, BOAR1 was very insistent that the findings of the paper written by three of the orthopaedic surgical staff at C&V be included in this Review because he was of the opinion that the findings ‘…really updates and rubber stamps what we’ve said basically’. This view has already been contested as the incorrect early TKR revision rate published in the BOA report was significantly higher than it should have been. Thus, the paper cannot support the quantitative findings of the BOA report as they were incorrect.

Notwithstanding the decision to recommend a revision is subjective and therefore the visiting Scandinavian consultant orthopaedic surgeons who undertook the original operations may have come to a completely different view as to what remedial treatment was required.

8.3 Similarly to BOAR1 COS-CV2 was also adamant that the findings of the paper should be discussed in this report. However, the evidence discussed below casts grave doubts as to the robustness of the papers findings.

8.4 A number of errors have been identified in this paper the first of which is made at the end of the following sentence:

‘In June 2006, Rhondda Cynon Taff Local Health Board, in agreement with Weston Area Health NHS Trust, invited the British Orthopaedic Association to carry out an independent review of the surgery performed at the Weston NHS Treatment Centre because the complication rate following surgery was higher than expected (Fig. 1).’

Fig.1 however does not provide any evidence to demonstrate that following early TKR surgery there was a higher than expected complication rate. Fig.1
in fact comprises of the two X-ray images, reproduced below, showing three knees. It should be noted that although the patient whose knee is shown in Fig. 1a was recommended by a consultant orthopaedic surgeon at C&V, to have their TKR revised the Review Panel was informed at interview by a consultant orthopaedic surgeon at C&V (COS-CV3) that ‘... the patient did not want the revision’. Thus, as previously observed whether or not a patient should have a revision when recommended by a consultant orthopaedic surgeon is a moot point. Particularly since several studies have suggested that ‘The concerns and priorities of patients and surgeons may differ…’ The patient whose knee X-ray is shown in Fig. 1a being a prime example.

8.5 In the section entitled ‘Patients and Methods’ it is stated that:

‘Between April 2004 and January 2006, 258 Kinemax TKRs were inserted for osteoarthritis in the Weston-Super-Mare NHS Treatment Centre’.

8.6 As noted earlier in order to ensure that this Review reported the correct number of TKRs performed on the Welsh patients treated at WTC an audit was undertaken by WSM1 and SM-SOCT3. The time periods covered by the TKR audit were the two financial years 1 April 2004 to 31 March 2006. The audit revealed that 224 TKR procedures had been performed at WTC during that time. Thus the 258 procedures quoted by the authors of the paper during the time period cited are incorrect.

8.7 Although not stated in the paper the implication is that the 258 TKRs are the total population of primary TKRs undertaken at WTC on Welsh patients. However, a check of the primary TKR data undertaken by an administrator at C&V, at the request of the Review Panel, has revealed that the total number of TKR procedures carried out at WTC was 262 and these were not completed until the end of October 2006. This is nine months later than the end date of January 2006 quoted in the paper and an additional four procedures.
8.8 It is also stated in the ‘Patients and Methods’ section of the paper that:

‘All 224 patients were contacted by telephone or letter, and offered clinical and radiological review, which was performed by one of the Cardiff and Vale NHS Trust consultant knee surgeons’.

8.9 However between 1 April 2004 and 31 March 2006 the WSM1 and SM-SOCT3 audit also showed that within that period 215 patients had been treated and not the 224 cited in the paper. In addition the text above is ambiguous as to whether it was one or more of the C&V consultant knee surgeons who performed the clinical and radiological reviews of the recall patients. However, at interview a consultant orthopaedic surgeon connected with the production of the paper COS-CV3 stated that the recalled patients:

‘…were revised in a lot of different ways they didn’t all just come down to me - I did a significant portion of them – I’m not sure that I did most of them COS-CV2 probably did quite a few too. There wasn’t just him all the surgeons have done some of them’.

8.10 Hence it would appear that a number of the consultant orthopaedic surgeons at C&V were involved with reviewing the TKR patients recalled as a result of the BOA recommendations. It was also confirmed at interview that the population of patients on which the paper was based were those who had been recalled by the DSU and not because they had previously complained of a problem to their General Practitioner. SM-CV2 stating that:

‘…the way patients came through initially - before the BOA Review - was that patient were presenting with problems - which was what started the questioning – then from [COS-CV3s] point of view we recalled every hip and knee replacement and offered them an appointment in a clinic with a with a knee or hip surgeon’.

8.11 Thus prior to the DSU recall it would appear that all these patients were satisfied with the outcome of their orthopaedic surgery.

It is also stated in the ‘Patients and Methods’ section of the paper that:

‘The radiographs of the patients were reviewed using the IMPAX (AGFA) image software (Agfa Health Care UK Ltd, Brentford, United Kingdom) and the positions of the components were assessed according to the Knee Society Scoring System described by Ewald. Angles were measured using IMPAX digital templating software (Medi CAD, Altfraunhofen, Germany). Data concerning revision, recommendation for revision and follow-up were taken from the patients’ notes’.

8.12 However, at interview a senior member of the Radiography Department at C&V (SMR–CV) informed members of the Review Panel that the X-rays of the patients recalled to have their TKRs reviewed were not taken to the rigorous
standard set out in a paper by Ewald. SMR-CV noted that he was not familiar with the contents of the paper by Ewald and that ‘We were not advised that [Ewald] was the way we should be proceeding...we did a lot of these patients’.

8.13 As a consequence through the failure to use the Ewald standard when taking X-rays it would appear that the criteria required by the Agfa HealthCare to ensure accuracy when using their product to measure TKR angles has not been met. The ‘Agfa Orthopaedic Tools User Manual’ states:

‘Before you even start importing images into the Agfa Orthopaedic Tools it is important you realize to which requirements the x-ray images should comply. To obtain the best results when planning prosthesis you should only use images that meet the following requirements:

‘The images must have been produced in accordance with orthopaedic and radiographic criteria as mentioned in all reference literature (e.g. Bernau, Einstelltechnik in der Orthopädie)’.

8.14 The ‘Agfa Orthopaedic Tools User Manual’ also states that:

‘Agfa Orthopaedic Tools provides two different methods of determining the axes and angles, and of correcting any deformities. Both methods require a long leg image in a standing position’.

Additionally, the Agfa HealthCare representative who was interviewed by telephone also wrote to the Review Panel and stated that:

‘...you will need a full leg image and not just a small portion around the knee to obtain a complete set of measurement data with good accuracy’.

8.15 When asked by a Review Panel member if ‘long films’ such as those as required by the Agfa Orthopaedic Tools Manual to ensure the accuracy of the measurements was used when taking X-rays of the recalled patients TKRs. SMR-CV replied ‘Not in my recollection no...there wasn't a request from the Cardiff surgeons for long films’. Following this answer a member of the Review Panel asked the following question:

‘If they [the consultant orthopaedic surgeons at C&V] didn’t make a request for the Ewald standard and they did not make a request for the X-ray to be taken standing and they didn’t request long film it would not be done’. To which SMR-CV replied ‘No’.

8.16 At interview COS-CV3 agreed that the X-rays of the recalled TKR patients ‘...were not on long leg film’.

8.17 COS-CV3 was then asked if he was ‘...aware of the error that is built in to a short film that is then used to extrapolate to produce Ewald figures?’ To which COS-CV3 replied:

‘I would accept that - but the over sizing of the femoral component and
8.18 However one of the clinical advisors to the Review then pointed out that:

‘...it is possible for people to make errors of judgement on an X-ray when they have not been taken very well...’

8.19 Thus, it would appear that the methodological rigour implied by the standards cited in the paper with respect to the radiological review of the patients recalled back to C&V were not adhered to. Therefore the findings cited in the paper with respect to the evaluation of X-rays and the measurements associated with misalignment of patients TKRs and bone cuts may contain significant errors. Moreover because the rigorous scientific methodology described in the paper was not undertaken in practice the study and its findings, it can be argued, are seriously flawed.

8.20 In the ‘Results’ section of the paper it is stated that ‘A total of 258 knees, 115 knees in 101 men and 143 knees in 20 women, had the Kinemax knee implanted.’ However, as noted earlier, a check of the Weston NHS Treatment Centre TKR data has revealed that there were 262 knees which had the Kinemax knee implant and not 258.

8.21 Furthermore, while it is readily appreciated that 20 women cannot have 143 knees and that such an error is probably typographical it does raise the issue of how meticulous the authors of this paper have been in its production, likewise the papers peer reviewers and the journals editors. This is because if the number of women should in fact read 120 then the number of men and women patients comes to a total 221 and not the 224 cited earlier in this paper. Why this difference arises is not explained in the paper and no erratum (error introduced during the publication process) or a corrigendum (author error) has been issued by the Journal of Bone and Joint Surgery to explain why the numbers of patients differ.

8.22 Additionally, in this section of the paper it is noted that 52 knees, for a variety of reasons, could not be followed up in the study leaving 206 knees to be reviewed. However, although the 52 knees could not be followed up by the authors of the paper the primary TKR operations which were performed cannot be ‘excluded’ from the study as they are part of the population of patients being reviewed. The authors of the paper however have done exactly that when calculating a number of important statistics including early TKR revision rates. For example, the paper states:

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‘In 76 knees (37%) the result was unsatisfactory. Ongoing pain, for which no cause was found, was present in 14 patients (15 knees) and one patient (one knee) had developed a complex regional pain syndrome. Re-operation had been undertaken in 29 patients (30 knees, 15%) and a further 29 patients (29 knees, 14%) had been recommended to have a revision, but had either declined further surgery at present or were on the waiting list (Fig. 2)’.
8.23 All the percentages provided in the text quoted above have been calculated by the authors of the paper using only the 206 patients who agreed to take part in the review. Thus all the percentages cited by the authors in the paper that use a patient population of 206 are inflated since the total number of procedures completed was 262. Indeed, using this logic if enough patients had refused to be reviewed, theoretically, the revision rate could have been 100%.

8.24 However when these errors were brought to the attention of COS-CV3 he stated:

*I really don’t see why you are questioning it [the paper] the revision rate is what it is…The main issue of this [paper] is the revision rate and that the patients were having problems – that doesn’t require [an] in-detail statistical analysis to know that the numbers of patients that would have been revised and altered was too high…*

"The number that were done and revised are out of proportion to what they should have been and that is the main thrust of the paper. **The rest of it is all semantics and positioning.** The main thrust of it all is the fact there is too many revisions and the patients didn’t do well – didn’t do as well as expected."  

(Authors emphasis)

8.25 In the section of the paper entitled ‘Survival analysis’ the authors refer to some of the numerical results to be found in ‘Table II. Life table showing cumulative survival data and 95% confidence interval for overall revision for any cause and aseptic revision, ‘where it is stated that:

‘The overall cumulative survival rate with re-operation of any kind as the endpoint was 79.2% at three years (95% confidence interval (CI) 69.2 to 86.8)’.

8.26 However, an epidemiological advisor to this Review has calculated the survival rate as being 80.4% and not the 79.2% stated by the authors. The difference between the two calculations is not large but assuming the Review Panels epidemiological advisors calculation is correct this is another error. Moreover, as already pointed out the number of TKR procedures carried out was 262 and not the 258 noted in Table II. Once again the difference between the two numbers is not large but it does mean that all the calculations in the table are incorrect as they are all based upon an inaccurate population. In addition, the number in the column ‘Lost to follow-up’ in Table II is 49. This is however the number of patients that were lost to follow-up thus since the table is supposed to relate only to knees then this is yet another error in this paper.

8.27 In the ‘Discussion’ section of this paper the authors state that:

'The Weston-Super-Mare NHS Treatment Centre was an entirely separate facility from the NHS hospital and was staffed by Swedish locums, flown in
to perform the operations’.  

8.28 This statement is incorrect in all respects. In the first instance the Weston-Super-Mare NHS Treatment Centre was, as noted earlier, an integral part of WAT. The only physical difference between the two entities was that visiting Scandinavian consultant orthopaedic surgeons carried out the orthopaedic procedures on patients at WTC, as opposed to the consultant orthopaedic surgeons permanently employed by WAT. Secondly, the WTC was not ‘…staffed by Swedish locums…’ but by locum consultant orthopaedic surgeons from different Scandinavian countries.

8.29 It is also noted in this section of the paper that:

‘Varus angulation of the tibial component of greater than 3° is generally accepted as an error in alignment for the normal mechanical function of the knee. Many of the arthroplasties performed in Weston-Super-Mare were outside this range’.

8.30 The authors do not however provide any evidence from the orthopaedic literature to support their assertion with regard to what is normally considered to be an ‘…error of alignment…’ They also assert that ‘many’ of the operation performed at WTC were outside this normal range. Given the authors had the data available to calculate how many cases were outside the stated range it would have been helpful to known exactly how many. In a similar vein the authors write that:

‘There remains a large number of patients disappointed by the outcome of their TKR; many of those who initially refused the offer of revision are now reconsidering their decision. There are also a large number of patients with asymptomatic TKRs with malpositioned or incorrectly-sized components that might still fail’.

8.31 Once again the authors do not state how large the number is of patients who are dissatisfied with their operation or how large the number is of asymptomatic patients who have TKRs that could fail. Similarly, there is no mention of how many patients refused to have their TKRs revised or why they took such a position. It might also have been of value for a reader of the paper to have known how many patients were reconsidering having a revision and perhaps more importantly why. Failure by the authors to address such issues, it can be argued, once again reflects a lack of rigour in preparing this paper.

Welsh recall patients TKR revision rate

8.32 It is clear form this paper that far more early TKR revisions have been performed by the consultant orthopaedic surgeons at C&V than would normally be expected. The authors of the paper reporting that early TKR revisions were performed on 30 knees out of a total population, according to their analysis, of 258 which returns a rate of approximately 12% (15% is cited in the text of the paper). While using the population derived from the audit undertaken by the C&V administrator of 262 TKRs the revision rate is 11%.
8.33 There is however a conundrum to be solved. In the first instance it was claimed by BOAR1 and COS-CV2 that the findings in this paper supported the assertion in the BOA report that there was a ‘six-fold increase in the expected revision rate’. However, this BOA finding with regard to the early TKR revision rate at WTC has been shown to be incorrect. Additionally, the BOA in their patient information monograph state that the expected complication rate (revision rate) for TKRs is 2% thus the alleged revision rate at WTC, given the revised figures of 3.1%, while greater than it is alleged might be expected is significantly less than ‘...the six-fold increase’ asserted in the BOA report. Moreover, because of the small numbers involved the apparent observed TKR revision rate of 3.1% would not be statistically inconsistent with a true underlying rate somewhere between 1.5% and 6.3%, these values representing the 95% confidence limits.

8.34 Hence the observed revision rate was not statistically distinct from a true rate as low as 1.5% (which is less than the BOA figure of 2%), or as high as 6.3% (which would be three times as high). It was of course calculated as being 3.1% which is approximately three in 100 hundred patients as opposed to two in one hundred patients. Thus the numerical evidence in terms of whether or not to sanction the recall of 683 patients is far weaker than that originally presented to SOCT. Particularly, if as noted earlier, the patient whose early TKR revision operation has been contested by the clinical advisors to this review is excluded from the figures as this would return a revision rate over the two years of 2.7% (95% confidence limits 1.2% to 5.7%).

Findings of the Bannister et al study

8.35 Another part of the conundrum to be resolved is that created by the meticulous study undertaken by Professor Bannister on the North Bristol cohort of patients operated on at WTC. In the paper produced by Bannister et al they report that 368 Total Hip Arthroplasties (replacements) (THR) and 365 Total Knee Arthroplasties replacements) (TKR) were carried out at WTC. The study defined an early complication as being one that occurred within two years of the primary TKR operation. The early revision rate for THR at WTC was 1.4% and for TKR 1.9%.

8.36 Thus the early TKR revision rate attributed to the visiting team of Scandinavian consultant orthopaedic surgeons is within expected 2% limit and significantly lower than that of the Welsh patients. It should also be remembered that the Welsh patients’ revision rate is based on a full service-led recall whereas the North Bristol patients were requiring revisions according to normal self-referral practices.

8.37 Moreover, the visiting Scandinavia surgeons performed 103 additional TKR procedures on the North Bristol patients than on the Welsh. What makes the differences in early TKR revision rates even more puzzling is that the study by Bannister et al of the North Bristol patient at WTC commenced on the 1 April 2004 and continued until 30 September 2005 (18 months). The TKR operations on Welsh patients started in October 2004 and continued until June 2006 (21 months) when the programme was suspended. Thus for approximately 12 months or over 50% of the time it would appear that the
same visiting teams of Scandinavian consultant orthopaedic surgeons were operating in parallel on Welsh and English patients. Hence, only having a high number of early TKR revisions in the Welsh cohort of patients is not to be expected all other things being equal.

8.38 It should be noted however that although the Bannister et al study was presented at the BOA Annual Congress in September 2007 it had not been accepted for publication at the time of the interview with COS-CV3. COS-CV3 noting this when the significantly different findings of the two studies were brought to his attention that:

‘…the point to make here is that other paper [Bannister et al] hasn’t been through peer review which would suggest that there is some problems within it – otherwise it would have been accepted’.

8.39 However, the assertion made by COS-CV3 is not the only reason why the Bannister et al study might not have been accepted for publication at that time. It might also be argued, as raised in the press by Lord Lawson of Blaby, that when a paper is submitted for peer review and contains evidence which is contrary to a preferred expert view its publication can be delayed. Evidence to support such a view is provided by Stern and Simes who note following their study investigating delays in the publication of clinical research projects concluded, ‘This study confirms the evidence of publication bias found in other studies and identifies delay in publication as an additional important factor’.

In a similar vein Charlton notes with regard to peer review that:

‘…despite its considerable convenience, peer review has significant limitations related to its reliance on opinion. One major limitation of peer review has proved to be its inability to deal with conflicts of interest, especially in a “big science” context when prestigious scientists may have similar biases, and conflicts of interest are widely shared among peer reviewers.’

8.40 The interview with COS-CV3, it should be noted, took place on 5 November 2009 and that the Bannister et al study was subsequently published in the double blind peer reviewed journal *Annals of the Royal College of Surgeons of England*, Vol. 92, 16 June 2010 [Electronic publication ahead of print].

**Patient expectations**

8.41 Following a study undertaken by Medical Technological Assessment Working Group at Duke University Centre for Demographic Studies on the ‘Effects of Advanced Medical Technologies – Musculoskeletal Diseases’ the study group came to the conclusion that ‘…functional improvement [of a patients knee] is strongly correlated to the degree of impairment before surgery and TKA [TKR surgery] does not, in the vast majority of cases, return the patient to full functionally’. Support for this contention comes from Nobel et al who also:

‘…found that a TKA [TKR] does not restore normal knee function, independent of the effects of age and gender. Although this procedure restores a patient’s ability to do many routine activities, a substantial deficit
remains in meeting the challenges of many functional tasks that are important to the patient, especially tasks involving kneeling or squatting."  

Additionally, the United States of America National Institutes of Health Consensus committee following a comprehensive study came to the conclusion that ‘…about 85 percent of patients are satisfied with the results of [TKR] surgery’. Which implies that 15% of TKR patients are not satisfied with their outcome following surgery. This in fact agrees with the remarks made at the ‘Great Debate’ meeting held on the ‘Early Intervention in the Hip and Knee' where it was observed that:

‘…several studies have shown that between 10 and 15 percent of patients who have a total knee replacements are dissatisfied or very dissatisfied with the results of surgery’.

Similarly, Bennett et al in their study looking at a 10 year outcome of TKR patients observed that:

‘Eighty-two percent of patients had been satisfied with the result of their knee replacement. Twenty one percent of patients felt that [their knee] was not as good as they had been led to believe before surgery’.

Likewise, Nobel et al reported that in their study on the satisfaction of patients who had undergone TKR that the percentage of patients who were dissatisfied with their knee replacements was 14%. The study group also found evidence:

‘…that patient satisfaction with the outcome of TKA [TKR] depends on the extent to which that outcome meets the patient’s expectations, no matter how reasonable or unreasonable they may be…Patient satisfaction was strongly associated with fulfilment of patients’ expectations that their activity level, after recovery, would be at least as they expected before surgery. Conversely, patients who were less active than they expected were highly likely to be dissatisfied with the procedure…Clearly, the more patients’ expectations are based on outcomes not directly connected to joint function, the less likely joint replacement will meet those expectations, and thus, the less likely a patients might regard their outcome as being satisfactory.’

The study group subsequently concluded that:

‘…the surgeon must guide patients in helping them formulate reasonable expectations for the outcome of each available treatment. This suggests that real improvements in patient satisfaction after TKA [TKR] will be realized once we address patients’ preoperative concept of a satisfactory outcome as much as the functional performance of the knee prosthesis itself.’

In addition, it should also be noted, that in a cross cultural study of patients from the United States, United Kingdom and Australia with respect to their expectation on outcomes following TKR surgery it was concluded that:
‘Patients from different countries have different expectations regarding total knee arthroplasty [TKR], which are not fully explained by difference in socio-demographic factors, clinical characteristics, and pain and functional status’.52

8.47 All of which may help, at least in part, to explain the view noted earlier that the concerns of patients may significantly differ from those of their surgeon.

Objectivity of recall review

8.48 In the methodological section of this Review a number of cognitive biases were discussed to inform readers of some of the psychological mechanisms that can unconsciously affect an individual’s judgement when undertaking a Review. This Review Panel through the use of an explicit critical approach to the collection and evaluation of the data for this Review have attempted to reduce the affect of such biases to as low as reasonably practicable.

8.49 It is of interest to note that a recent Review Panel established by the Royal College of Anaesthetists also explicitly attempted to reduce the chances of its members being affected by cognitive biases.53 The Chairman of the Review Panel noted that while they had no formal methods for excluding biases his view mirrored that of Berlin who, as noted earlier, rightly concluded that:

‘Acknowledging its existence and recognising its influence on expert witness and jurors alike, might mitigate its pejorative effect’.54

8.50 Similarly Eli has reasoned that ‘To reduce schematic thinking [seeking a category in which to place a symptom] and to avoid confirmation bias, one must acknowledge their existence’.55

8.51 While Kaptchuk has concluded that:

‘…a view that science is totally objective is mythical, and ignores the human element of medical inquiry. Awareness of subjectivity will make assessment of evidence more honest, rational and reasonable’.56

8.52 On the other hand neither the BOA Reviewers nor the consultant orthopaedic surgeons at C&V appear to have made any attempt to reduce the potential affects of cogitative biases. Interestingly, when asked about the potential for cognitive bias to be at work in relation to the patients recalled to C&V COS-CV2 stated:

‘I think you can always throw the label of bias against us in Cardiff, but I think the way COS-CV3 review was done minimises that risk’.57

8.53 However, as COS-CV3 observed at interview:

A lot of the people who are in this paper had already been revised before I had even been contacted.56
Thus COS-CV3 was not the only consultant orthopaedic surgeon reviewing and performing revision surgery on the patients who had been to WTC for their TKR. Furthermore, when asked by a Review Panel member ‘Were there any attempts to get somebody in from somewhere else to prevent cognitive biases operating?’ COS-CV3 replied:

‘That wouldn’t be standard practice like I said it’s not practical to get everybody reviewed twice - We treated them the same as we treat every NHS patient - I don’t see there is any particular need to have somebody else look at them’. I wasn’t here when the second offer scheme was started I was appointed afterwards – that holds no bias with me at all – I have no direct experience of it at all – the patient were treated as I saw the situation at the time’.

However, as COS-CV3 pointed out, by the time he and his colleagues were in the process of reviewing the patients that had been recalled to C&V ‘…a lot had already phoned in’. Thus, not only were the consultant orthopaedic surgeons at C&V, including COS-CV3, aware of the BOA Reviews findings, i.e. ‘…the Weston figures represent a six-fold increase in the expected revision rate’. But they were also conscious that many of the patients recalled to C&V had telephoned the Trust to say they were having problems with their TKRs. Notwithstanding, all the consultant orthopaedic surgeons at C&V who the Review Panel interviewed, are members of the BOA and with the potential ‘conflict of interest’ of having private practices in the Cardiff area. Therefore given the publicly expressed antipathy of the members of the BOA towards treatment centres, the a priori questioning of the surgical skills of visiting teams of overseas orthopaedic surgeons by some of the surgeons at C&V; the open hostility of C&V consultant orthopaedic surgeons to the Second Offer Scheme; the knowledge that two past Presidents of the British Association for Surgery of the Knee had explicitly stated that there were far more early TKR revisions than to be expected and that patients had telephoned C&V stating they were having problems with their TKRs, it can be argued, that the likelihood of a range of cognitive biases, particularly those of ‘confirmation, hindsight and outcome bias’ unconsciously affecting their judgment, including COS-CV3 was high. COS-CV1 having observed that:

‘…to remove all bias you’d have to have presented the patients to the surgeons as if they’d been in a double blind study, which was never done; it wasn’t practical. So I accept the fact that if a patient came along with knee problems, perhaps a poor x-ray, and the operation had been done in Weston, there was an inherent, I mean, one would have to accept that’.

Furthermore there is also evidence to suggest that approximately 15% of patients are never satisfied with their TKR for a variety of subjective reasons. Thus when notified by C&V that the BOA Review had raised concerns about the standard of treatment at WTC patients in this group, as well as others, would have come forward to complain about their TKRs. As noted above the recommendation to revise a patient’s TKR early is not based upon objective clinical indicators as with a broken leg. For example, the fact that a patient
has had problems following a primary TKR and the X-ray shows that the implant is perfectly aligned does not indicate that a revision is out of the question. On the other hand just because a patient’s X-ray shows that technical faults appear to be present with their TKR implant does not mean that a revision should be performed. This is because each consultant orthopaedic surgeon has their own subjective criteria for each individual patient against which a recommendation to revise will be made.

8.57 In the case of the recalled patients none of the consultant orthopaedic surgeon at C&V carrying out the reviews had performed the original TKR operation. Thus they had no way of visualising what the actual architecture of the knees of the recalled patients’ they were reviewing except by the X-rays that had been taken. However, these X-rays as noted above, were not taken using the rigorous methodology prescribed by Ewald nor were the strict criteria for undertaking measurements on those X-rays with the Agfa IMPAX software complied with. Therefore the degree to which the TKR implants in the Welsh patients varied from the ‘normal’ may not have been as severe as perceived by the consultant orthopaedic surgeons at C&V.

8.58 It is interesting to note that COS-CV3 stated that:

‘…even in those people who weren’t revised - there were still a significant number of people who were having a lot of problems- who may have benefitted from revision but decided for whatever reason it wasn’t for them.’

8.59 It would appear therefore that COS-CV3 had recommended a number of patients to have their TKRs revised and they had refused. Hence, providing evidence there were patients who COS-CV3 judged their TKR implant should be revised early but the patients’ perception of their needs was different. Thus, supporting the view noted earlier, that the subjective assessments made by patients with regard to their requirements can significantly differ from the subjective decision made by a surgeon.

8.60 Other evidence to demonstrate that unconscious cognitive biases may have been at work among the community of consultant orthopaedic surgeons at C&V who reviewed the recalled patients can be found in a report prepared by Mr Lake for the Review Panel. Mr Lake stating that:

‘You will be aware [Review Panel] that I am already aware of one case where a patient became aware of the alleged inadequacies on an X-ray from another Cardiff surgeon and the patient interpretation was that an error had occurred and he sought legal advice. I happen to be the surgeon to whom the instructing Solicitor referred the case for assessment. When I saw this patient, he had no symptoms at all at the knee and indeed quite normal function. This view was reinforced when he returned to Cardiff to a knee revision surgeon. He was advised not to have further surgery and in my view there was simply no case to answer in terms of negligence, even if alignment was not perfect.'
The impression left by the patient was that the Cardiff Surgeon developed a prejudice against the Weston Treatment Centre to a point where patients became aware of Weston’s inadequacies. If this was reflected in any other cases, it is likely to result in a significant increase in the apparent complication rate. This of course begs a series of questions about the actual complication rate that occurred. In other words, was the attitude of the Cardiff Surgeon such that it actually increased the complication rate by instilling in patients minds that the Weston system was inferior and there were deficiencies on X-rays etc.65

8.61 As argued earlier, where unconscious cogitative biases are operating this is precisely the type of situation that can be envisaged. It should also be noted that it was at the patient’s first encounter with the C&V surgeon when he was informed an error had taken place. Moreover no attempt was made to recommend any other form of remedial treatment other than for the patient concerned to undergo an early TKR revision.

8.62 Finally, the paper does not draw any conclusions regarding the nature of the primary TKR operations performed at WTC or to the surgical skills of the surgeons who undertook the original TKR surgery at WTC.

Comments

8.63 The findings of this paper do not support the early TKR revision rates published in the BOA report. This is because the BOA findings were inaccurate and overstated the number and distribution of the early TKR revisions that had been performed on the Welsh patients treated at WTC. In addition, evidence has been presented which suggests that the consultant orthopaedic surgeons at C&V could, for the WTC patients, have unconsciously reduced their normal threshold for recommending patients to have a revision due to unconscious cognitive biases.66 It was also noted by BOAR1 earlier that he might pressure a patient into having a revision if he thought the risk benefit equation was large enough. Therefore given COS-CV3 appears to have been convinced that some of the patients who refused early TKR revision needed them the same may have been true on some occasions with respect to the Welsh WTC patients reviewed at C&V. That such a situation could have arisen is tentatively supported by the experience of the patient who had a TKR at WTC and was recommended to have a revision at C&V even though he did not need one.

8.64 One of the X-ray images reproduced in the paper is of a patient’s knee with a TKR implant (Fig 1a). It was recommended that the patient should have it revised. However, that particular patient refused as did many other patients who were given similar recommendations by the consultant orthopaedic surgeons at C&V. Thus there is empirical evidence to suggest that the concerns and priorities of the consultant orthopaedic surgeons at C&V appear to differ from some of their patients.

8.65 As with the BOA report there are numerous important inadvertent errors and omissions within the paper. For example, the wrong number of Welsh patients was cited as being treated in the time specified and population of
patients used for calculating the TKR revision rates in the text of the paper was incorrect. Most importantly however the rigorous methodology cited in the paper as being used for the taking of X-rays, measurements of TKR implants and bone cut angels was not followed in practice. Therefore this paper and its findings appear to have grave scientific flaws. As a consequence, it can be argued, that the paper should no longer be accepted as valid by the orthopaedic community to which it is addressed. It is therefore to be recommended that the Editors of The Journal of Bone and Joint Surgery should consider whether to amend or withdraw this paper.

8.66 Of prime concern to the Review Panel is the fact that the recommendations for patients who had a TKR performed at WTC to have early revisions was informed by the X-rays and measurements made when the methodology cited in the paper was not being adhered to. This in turn suggests it might be possible that some of the recommendations for the Welsh patients who had their TKR performed at WTC to have early revisions are not as robust as previously thought. Particularly as the Bannister et al study which does appear to have engaged in the meticulous auditing of the North Bristol cohort of patients returned an early TKR revision rate for the visiting teams of Scandinavian consultant orthopaedic surgeons that was within expected norms. The Bannister et al study covering the same visiting teams of Scandinavian consultant orthopaedic surgeons as operated on the Welsh cohort of patients for over 50% of the time. It would seem unlikely therefore that the visiting Scandinavian consultant orthopaedic surgeons could operate on the Bristol cohort of patients with a low early revision rate and on the Welsh patients with an abnormally high early revision rate at the same time.

8.67 Furthermore there is evidence from difference countries to suggest that approximately 15% of patients who have TKR operations are dissatisfied or very dissatisfied with the outcome of their surgery. Thus in the case of the primary TKRs undertaken at WTC where a formal recall was issued to all patients it is reasonable to expect that there would be many in that group who were not content with their surgery. Therefore when this group of patients are officially informed that there are concerns about their treatment at the WTC and that there have been more complications than expected it is likely they will attribute their perceived poor outcome, no matter how unreasonable, to their surgery.

8.68 Consequently the act of officially recalling the WTC patients, rather than waiting for patients to come forward when they perceive they had a problem, may have inadvertently created the conditions to heighten the dissatisfaction of all such patients. This in turn may have led to patients making far more vigorous complaints regarding their TKR surgery than they would have under normal circumstances and as a consequence significantly increased the pressure on the consultant orthopaedic surgeons at C&V to take surgical action to improve their condition.

It should also be noted that the paper is silent as to the cause or causes of the high early TKR revision rate of the Welsh patients treated at WTC.
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22. Global Solution Manager Clinical Applications, Agfa HealthCare, kindly sent a copy of the relevant sections of ‘*Agfa Orthopaedic Tools User Manual*’, p.77, - E-mail 28/10/2009

23. Global Solution Manager Clinical Applications, Agfa HealthCare, E-mail 28/10/2009

24. SMR-CV, transcribed from interview tape recording

25. Professor Toft, transcribed from interview tape recording

26. SMR-CV, transcribed from interview tape recording

27. COS-CV3, transcribed from interview tape recording

28. Mr Tasker, transcribed from interview tape recording

29. COS-CV3, transcribed from interview tape recording

30. Mr Tasker, transcribed from interview tape recording


32. Kempshall, P. J., Metcalf, A. and M. C. Forster, ‘Review of Kinemax knee arthroplasty performed at the NHS Treatment Centre, Weston-Super-Mare’, *Journal

33. COS-CV3, transcribed from interview tape recording


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41. Lord Lawson of Blaby, ‘Copenhagen will fail – and quite right too’, The Times, 23 November 2009


http://www.hedweb.com/bqcharlton/conflicts.html - accessed 03/01/2010


http://www.hipkneeclinic.co.uk/article.asp?article=111

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http://www.ebjjs.org/cgi/content/abstract/88/6/1201?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&author1=lingard&full text=expectations&andorexactfulltext=and&searchid=1&FIRSTINDEX=0&sortspec=relevance&resource=HWCIT


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http://www.jdentaled.org/cgi/content/abstract/60/10/831

57. COS-CV2, Transcript – page 25, commences at line 15
58. COS-CV3, transcribed from interview tape recording
59. Mr Tasker, transcribed from interview tape recording
60. COS-CV3, transcribed from interview tape recording
61. COS-CV3, transcribed from interview tape recording
63. COS-CV1, Transcript – page 5, commences at line 33
64. COS-CV3, transcribed from interview tape recording
65. Lake, D, Review of surgery at the Treatment Centre Weston-super-mare, June 2009, p.5, (Review Clinical Advisors report)
9. Conclusions and recommendations

9.1 The conclusions that I have drawn as Chairman from the evidence presented to this Review Panel, with regard to the BOA Review and the paper entitled ‘Review of Kinemax knee arthroplasty performed at the NHS Treatment Centre, Weston-Super-Mare’, *J Bone Joint Surg [Br]* 2009; 91-B: 229-33, are noted below in plain text, while recommendations are shown in *bold italic*.

**Independent and NHS Treatment Centres**

9.2 The means selected by the UK Labour Government to reduce patient waiting times continues to meet with relentless opposition even though there appears to be no robust scientific evidence to support such a position. However, until the concerns expressed by those affected by the initiative are addressed the resentment towards the scheme seems unlikely to abate.

**Recommendation 1**

*The UK Coalition Government and the Welsh Assembly Government should, in consultation with the relevant professional bodies, seek to address the concerns expressed by the healthcare professions regarding the employment of visiting surgical staff from overseas and the use of independent and NHS Treatment centres.*

**Welsh Assembly Government Second Offer Scheme**

The strength of the opposition by some of the consultant orthopaedic surgeons at *Cardiff and Vale NHS Trust* to the *Welsh Assembly Government Second Offer Scheme* and the initiative to refer their patients to the WTC is incalculable. In part, this antipathy to the Scheme, appears to have led to the instructions, mandated in the *Welsh Health Circular (WHC (2004) 015)* regarding the selection of suitable patients, not being complied with at *Cardiff and Vale NHS Trust*.

**Recommendation 2**

*If the Second Offer scheme is utilised in the future, Local Health Boards should ensure full compliance with all facets of the Welsh Health Circular mandating the provisions of the scheme.*

A small number of consultant orthopaedic surgeons at *Cardiff and Vale NHS Trust* refused to see Welsh patients who had undergone knee operations at the *Weston NHS Treatment Centre* and were concerned about the outcome of their operation.
Recommendation 3

Evidence that some Consultant Orthopaedic Surgeons at the Cardiff and Vale NHS Trust refused to see patients who had previously undergone knee surgery at the Weston NHS Treatment Centre and were concerned about the outcome of their operation is made known to Cardiff and Vale University Health Board for their consideration and action.

Recommendation 4

The senior management at Cardiff and Vale NHS Trust should develop a Trust wide policy to ensure that patients are never refused treatment solely because they have previously had medical or surgical treatment at an independent sector or NHS treatment centre.

Chronology of the BOA review

A number of the Welsh patients who had concerns regarding the knee procedures which had been performed at the Weston NHS Treatment Centre did not use the arrangements that were in place but contacted the consultant orthopaedic surgeons at the Cardiff and Vale NHS Trust. However the consultant orthopaedic surgeons at the C&V did not consider it their duty to inform the Weston NHS Treatment Centre about the problems the patients were allegedly experiencing. Hence, it came as a surprise to the senior management at the Weston NHS Treatment Centre that some of the Welsh patients were not satisfied with the results of their knee surgery.

Recommendation 5

The Cardiff and Vale NHS Trust should develop a policy that ensures when a patient complains about the medical treatment they have received at another healthcare facility that the organisation concerned is promptly informed.

The letters sent to Welsh patients from the Cardiff and Vale NHS Trust asking for permission to allow their clinical records and X-rays to be examined as part of the British Orthopaedic Association review did not explicitly state the full rationale of why permission was being sought. Thus the patients who had been treated at the Weston NHS Treatment Centre reached their decision to withhold or give permission for their clinical records and X-rays to be examined without being fully informed. This would appear not to be best ethical medical practice.

Recommendation 6

The Cardiff and Vale NHS Trust should develop a policy to ensure that when it is necessary to seek the permission of a patient or patients, so that their clinical records and X-rays can be reviewed by someone other than the healthcare professionals responsible for their care, then all the reasons for wanting a review will be specified in the communication to the patient or patients concerned.
The British Orthopaedic Association’s Reviewers had not received any formal training on how to undertake an investigative review of the type required by the Delivery and Support Unit, Welsh Assembly Government.

Recommendation 7

The British Orthopaedic Association should develop or identify a training course for members who undertake investigative reviews on their behalf.

The British Orthopaedic Association report recommended there should be a review of all the Welsh patents that had undergone orthopaedic procedures at the Weston NHS Treatment Centre. This was even though the only complaints from that cohort of patients were a relatively small number who had reported problems with their knee operations. As a precaution the Delivery and Support Unit, Welsh Assembly Government accepted the recommendation.

Recommendation 8

The British Orthopaedic Association and the Delivery and Support Unit, Welsh Assembly Government should consider the criteria to be applied for the mass recall of a cohort of patients who have undergone different surgical orthopaedic procedures when there is limited evidence to suggest that a problem exists with any of the other procedures that have been undertaken.

Chronology South West Strategic Health Authority Weston Review

The substantial delays experienced by this Review Panel have led to items 2.2 to 2.4 of the Terms of Reference not being addressed due to the significant changes which occurred in organisational arrangements at Weston Area NHS Health Trust during that period and the closing of the Weston NHS Treatment Centre.

One of the substantial time delays incurred during this Review was due to the continual refusal of experienced practicing consultant orthopaedic surgeons within the United Kingdom to join the Review Panel.

Recommendation 9

The Department of Health should consider establishing a register of doctors, across the medical profession, who possess the necessary expertise and are prepared to sit as Review Panel members.

A critique of the British Orthopaedic Association report

The British Orthopaedic Association Reviewers had not received any formal training on how to undertake an investigative review of the type required by the Delivery and Support Unit, Welsh Assembly Government.
Recommendation 10

As set out in recommendation 7, the British Orthopaedic Association should develop or identify a training course for members who undertake investigative reviews on their behalf.

The BOA Reviewers evaluation of the evidence presented to them during the course of their Review may have been unconsciously affected by a range of cognitive biases.

Recommendation 11

The British Orthopaedic Association should, when they accept a commission to undertake a Review, ensure that their Reviewers are explicitly warned about the range of unconscious cognitive biases that could affect their evaluation of the evidence presented to them.

The BOA did not explain in their report why item 3 of the Terms of Reference, i.e. ‘To comment on the type of operation, appropriateness of technique and outcome,’ that had been agreed with the Delivery and Supply Unit, Welsh Assembly Government was not addressed.

Recommendation 12

The British Orthopaedic Association should publicly state the reason or reasons why item 3 of the Terms of Reference of the BOA Review was not discussed in their report.

There is evidence to suggest that the consultant orthopaedic surgeons at Cardiff and Vale NHS Trust who treated the Welsh patients that were the subject of the BOA Review may have been unconsciously influenced by a range of cognitive biases. These biases in conjunction with other factors such as the non-standardisation of X-rays may have involuntarily lowered the threshold at which they would normally recommend a patient to have an early revision of their knee operation.

Recommendation 13

It should be brought to the attention of the consultant orthopaedic surgeons at Cardiff and Vale NHS Trust that unconscious cognitive biases may have affected their evaluation of patients treated at the Weston NHS Treatment Centre.

The British Orthopaedic Association report is inadvertently misleading in that it does not explicitly state that a recommendation for a patient to have an early revision of their knee operation is subjective in nature and that another consultant orthopaedic surgeon given the same situation may not make the same recommendation. Nor does the British Orthopaedic Association report make it clear that the recommendations that some Weston NHS Treatment Centre patients should have early revisions of their knee operations were not those of the BOA Reviewers but those of the consultant orthopaedic surgeons at Cardiff and Vale NHS Trust.
The British Orthopaedic Association Reviewers did not consult or examine the patients who were the subject of their Review. Therefore they were not in a position to confirm the recommendations made by the consultant orthopaedic surgeons at Cardiff and Vale NHS Trust that the patients treated at Weston NHS Treatment Centre should have early revisions of their knee operations. However these important features of the British Orthopaedic Association Review process was not made explicit within the British Orthopaedic Association report.

Recommendation 14

The British Orthopaedic Association should ensure that all relevant information, including methodological constraints, is included in all the reports they produce or are produced on their behalf.

The British Orthopaedic Association report contains a significant number of inadvertent serious factual errors and omissions and therefore appears to be seriously flawed.

Recommendation 15

The South West Strategic Health Authority should make this report available to the British Orthopaedic Association so that they can consider the evidence that has been presented and consider whether their report should be amended or withdrawn.

The reporting of primary Total Knee and Hip Replacements and the revisions of such surgery to the National Joint Registry of England and Wales is voluntary and leads to significant under reporting. As a consequence the healthcare statistics produced by this crucial national body are not as robust as they might be.

Recommendation 16

The UK Coalition Government and the Welsh Assembly Government should make the reporting of all primary Total Knee and Hip Replacements in England and Wales mandatory. A range of penalties should be available for the National Joint Registry to use in cases of non-compliance.

Recommendation 17

The UK Coalition Government and the Welsh Assembly Government should make the reporting of all Total Knee and Hip revisions in England and Wales mandatory unless the speciality of orthopaedic surgery, as set out in recommendation 24, determines otherwise. A range of penalties should be available for the National Joint Registry to use in cases of non-compliance.

Data regarding the number of primary Total Knee and Hip replacements and subsequent revisions rates for individual orthopaedic surgeons does not appear to be readily available for comparison by the public in England and Wales.
Recommendation 18

The UK Coalition Government and the Welsh Assembly Government should mandate that the number of primary Total Knee and Hip Replacements performed and the revision rates for all consultant orthopaedic surgeons operating in England and Wales should be published annually by the National Joint Registry of England and Wales.

Clinical outcomes of the visiting Scandinavian consultant surgeons

The only rigorous independent audit evidence available to the Review Panel (the study undertaken by Professor Gordon Bannister, Professor of Orthopaedic Surgery at the Avon Orthopaedic Centre) suggests that the clinical outcomes of the visiting Scandinavian consultant orthopaedic surgeons at the Weston Treatment Centre were within the 2% range published by the British Association for Surgery of the Knee and British Orthopaedic Association. In addition, the inadvertent errors and omissions within the British Orthopaedic Review entitled: Independent Review of Knee Surgery carried out under the Second Offer Scheme in the NHS Treatment Centre Weston, appear to be so significant that this Review has recommended the report be amended or withdrawn.

Recommendation 19

Scanloc should be invited by the South West Strategic Health Authority to contact the Scandinavian consultant orthopaedic surgeons who were recruited to work at the Weston NHS Treatment Centre and inform them of the findings of this Review.


The rigorous methodological standards cited in the paper, that were intended to ensure accuracy with regard to the measurements of patients Total Knee Replacement implants and bone cuts, were not followed in practice. It is therefore possible that there were unperceived errors in the data. Furthermore, there is evidence to suggest that some of the consultant orthopaedic surgeons at Cardiff and Vale NHS Trust and their patients, may have been affected by unconscious cognitive biases. As a result the recommendations that patients treated at Weston NHS Treatment Centre and who complained about their procedure should have their TKR revised early may not have been as robust as first thought. In addition, the paper has numerous inadvertent factual errors and omissions. As a consequence the paper appears to be seriously flawed.

Recommendation 20

The South West Strategic Health Authority should make this report available to the Editor of the Journal of Bone and Joint Surgery so that the evidence
presented can be considered and a decision taken as to whether the paper, ‘Review of Kinemax knee arthroplasty performed at the NHS Treatment Centre, Weston-Super-Mare’. J Bone Joint Surg [Br] 2009; 91-B: 229-33 should be amended or withdrawn.

Recommendation 21

As a precaution if there are any patients still waiting to have an early revision of their Total Knee Replacement, from the cohort of Welsh patients treated at the Weston NHS Treatment Centre, such operations should be postponed until they can be reviewed independently by two eminent consultant orthopaedic surgeons from outside the UK. This is so practicing members of the BOA will not have to endure the unenviable task of having to critique their fellow members’ clinical judgement. The review should include the implementation of a rigorous methodology such as that described on page 230 of the paper J Bone Joint Surg [Br] 2009; 91-B: 229-33 with respect to the measurement of TKR implants angles and bone cuts.

Clinical outcomes of the visiting Scandinavian consultant surgeons

The paper ‘Review of Kinemax knee arthroplasty performed at the NHS Treatment Centre, Weston-Super-Mare’. J Bone Joint Surg [Br] 2009; 91-B: 229-33 is silent on the surgical competence of the visiting Scandinavian consultant orthopaedic surgeons. The only rigorous independent evidence available to the Review Panel (the study undertaken by Professor Gordon Bannister, Professor of Orthopaedic Surgery at the Avon Orthopaedic Centre) suggests that the clinical outcomes of the visiting Scandinavian consultant orthopaedic surgeons at the Weston NHS Treatment Centre with regard to early TKR revisions were within the 2% range published by the British Association for Surgery of the Knee and British Orthopaedic Association. Additionally, due to the nature of the potential cognitive biases that may have been operating during the study, the significant inadvertent errors and omissions that appear to have been made it has been recommended that the paper should be amended or withdrawn.

Recommendation 22

As set out in recommendation 20, Scanloc should be invited to contact the Scandinavian consultant orthopaedic surgeons they recruited to work at WTC and inform them of the findings of this Review with respect to the publication of the article entitled: ‘Review of Kinemax knee arthroplasty performed at the NHS Treatment Centre, Weston-Super-Mare’. J Bone Joint Surg [Br] 2009; 91-B: 229-33.

Recommendations for early revisions of Total Knee Replacement procedures, i.e. less than three years from the primary operation unless there is an infection, are subjective in nature and not objective. Thus the decision reached by a patient and a surgeon as to whether a revision of such a procedure is the most appropriate remedial treatment for any particular patient can vary significantly under what appear to be identical clinical circumstances.
Recommendation 23

The World Health Organisation Collaborating Centre for Evidence-Based Health Care in Musculoskeletal Disorders, in collaboration with the appropriate national organisations, should be formally requested to determine whether the number of early revisions of Total Knee Replacement operations, except for infection, should continue to be used as a single endpoint for the purposes of comparing patient outcomes.
Appendix 1

Early Complications of Total Hip and Knee Replacement: A comparison of outcomes in a regional orthopaedic hospital and two Independent Sector Treatment Centres

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Abstract

We compared the early complication rates of total hip (THA) and total knee (TKA) arthroplasty carried out at a regional orthopaedic hospital (AOC) and two Independent Sector Treatment Centres (ISTCs) (WGH and CNH). After THA, reoperation rates were higher at CNH (9%) than AOC (0.6%) or WGH (1.4%).

After TKA, reoperation rates at CNH were higher than AOC (1%) and WGH (1.9%). After THA, dislocation rates at CNH (6%) were higher than AOC and WGH (1.8%).

Readmission from CNH (13%) was higher than AOC (1.2%) and WGH (0.6%). Major wound problems at CNH (20%) were higher than WGH (3.8%) and AOC (0.4%).

After TKA, major wound problems were higher at CNH (19%) compared to WGH (1.9%) and AOC (1.1%). Readmission rates from CNH (13%) were higher than AOC (1.1%) and WGH (1%). AOC and WGH audited their outcomes. CNH did not.

Results and audit from ISTCs are variable and patients should be warned of this before undergoing treatment at them.

Introduction

Joint replacement in the United Kingdom has traditionally been performed either at National Health Service (NHS) facilities or by NHS consultant orthopaedic surgeons at private hospitals. One of the strategies adopted by the Department of Health to improve access to joint replacement was Independent Sector Treatment Centres (ISTCs)1.

The intention was that these should provide additional capacity and therefore not engage staff currently employed in NHS hospitals1. Thus, surgeons were therefore recruited from overseas, often for very short periods2. The service provided differed from NHS hospitals in that ISTCs did not provide long term care for patients with complications in the event of which patients generally attended their local NHS hospital2.

There was anecdotal evidence that complication rates in the ISTCs serving our area were higher than those in local NHS hospitals so we compared the early complications of total hip and knee replacements at our orthopaedic hospital (AOC) with those of two ISTCs in adjacent towns to which patients originally scheduled for surgery at AOC had been sent.
Materials and Methods

We recorded the early complications described at the Mayo Clinic\(^3\) (Table 1) and defined early complication as being within 2 years of primary arthroplasty\(^3, 4\). Surgery at AOC was carried out by NHS consultants and their trainees and at the ISTCs by surgeons from overseas.

At one ISTC (WGH), Swedish surgeons visited for 1-2 weeks in rotation and practised in the private wing of a NHS District General Hospital. Surgeons with different areas of expertise were flown across depending on the type of surgery required.

At the other ISTC (CNH), surgeons operated in one of a national chain of private hospitals. Much of the surgery was carried out by a German surgeon on a long term contract who performed a wide range of general orthopedic procedures. At WGH, the prostheses were all cemented and surgeons implanted the Exeter Universal stem (Stryker, Newbury, Berkshire), the Elite all-polyethylene cup (De Puy) and the Kinemax Plus TKA (Stryker, Newbury, Berkshire) as these were the most widely used prostheses at AOC. At CNH, surgeons implanted the uncemented Corail-Duraloc ceramic on ceramic THA and the cemented PFC knee (De Puy, Leeds, UK) although other cemented devices were used.

Data were collected on an outcome form in outpatient clinics at the AOC and WGH. The returns on these forms were approximately 40% and data collection was completed by the authors by telephone. All outcome data from CNH were collected by telephone and all reoperations except three performed at CNH were validated by reference to AOC records. This review was confined to the outcome of primary THA and TKA to standardize material although a range of other orthopaedic procedures were performed at the ISTCs.

The ISTCs declined to treat a proportion of patients likely to remain in hospital for more than 5 days because of comorbidity or complexity.

Statistical Analysis

Data were analysed by \(\chi^2\) test. The variables assessed were reoperation and complications not requiring reoperation. Some patients had more than one complication and these were considered as individual events. Thus the sum of the complications exceeded that of the patients affected by them.

Results

Between 31.10.2003 and 31.3.2005 (17 months), 880 primary THAs and 874 TKAs were performed at AOC. Between 1.4.2004 and 30.9.2005 (17 months), 368 THAs and 365 TKAs were performed at WGH and from 1.4.2003 to 31.3.2005, 67 THAs and 86 THAs were performed at CNH. The retrieval from
AOC was 94%, WGH 95% and CNH 100%. The study periods overlap but do not correspond because the comparison was commenced as we became aware of unforeseen admissions of patients with complications from ISTCs to our base hospitals.

Reoperation

After THA, reoperation rates at AOC were 0.6%, WGH 1.4% and CNH 9%. Reoperation rates at CNH were significantly higher than AOC ($\chi^2 38 p=0.000$) and WGH ($\chi^2 13.2 p=<0.001$).

After TKA, reoperation rates at AOC were 1%, WGH 1.9% and CNH 8%.

Reoperation rates at CNH were significantly higher than AOC ($\chi^2 55 p=0.000$) and WGH ($\chi^2 97.6 p=0.000$). There was no significant difference in reoperation rates between AOC and WGH after either after TKA or THA or the two combined. After TKA, patients at WGH (4.3%) experienced significantly fewer complications than AOC (7.9%) ($\chi^2 5 p=0.05$) and CNH (29%) ($\chi^2 27.33 p=0.000$).

Other Complications

WGH (14.6%) reported a significantly lower rate of complications not requiring surgery than AOC (23%) ($\chi^2 11.7 p=0.001$) or CNH (29%) ($\chi^2 4.8 p>0.05$). There was no difference between AOC and CNH. Rates of dislocation were significantly higher at CNH (6%) than AOC and WGH (mean 1.8%) ($\chi^2 5.23 p=>0.05$). Readmission rates at CNH (13%) not followed by reoperation at the same admission were ten times higher than AOC (1.2%) and twenty times greater than WGH (0.6%) ($\chi^2 62 p=0.000$). Major wound infections at CNH (20%) were forty five times higher than AOC (0.4%) and five times greater than WGH (3.8%) ($\chi^2 76 p=0.000$).

After THA, there were nineteen reoperations of which a little over one third (seven) were for dislocation and a quarter (five) for deep infection. After THA, six of the seventeen reoperations were for deep infection and four of these followed surgery at CNH.

After TKA, major wound infection at CNH (19%) was seventeen times greater than AOC (1.1%) and nine times greater than WGH (1.9%). Readmission rates at CNH (13%) were twelve times higher than AOC (1.1%) and thirteen times more than WGH (1%) ($\chi^2 108 (p=0.000$).

Case Selection

The ISTCs performed the procedure for which patients had been treated at base hospital in 67% of cases sent to WGH and 71% at CNH. Reasons for rejection at WGH were comorbidity in 4.2% and complexity of surgery in 1%. 10% of patients
who had initially agreed to undergo surgery at WGH subsequently decided to have their operation at AOC. At CNH, 23.2% were rejected on medical or surgical grounds and 5.6% elected for surgery at AOC.

**Discussion**

This study contrasts highly variable performances of two ISTCs which excluded patients with greater comorbidity and complexity but had higher reoperation rates than AOC. Indeed, as approximately one third of the activity over this period was carried out by ISTCs, AOC was likely to have faced a more challenging case mix than before their introduction. In Sweden more difficult cases are sent to University hospitals where early reoperations are 76% higher than the national mean on which basis AOC should have had the highest early reoperation rate of the three hospitals.

The reoperation rate of AOC and WGH was similar to other comparable studies in Europe. The reoperation rate for THA within one year in five English regions was 2.9%, in the Trent Hip Arthroplasty Survey 2.3% and in Sweden 1.4%. At AOC and WGH, the reoperation rate for TKA was higher than the mean 0.7% cited by the Scottish Arthroplasty Project after one year but less than the 2% reported by the Swedish Knee Arthroplasty Survey. However, reoperation rates after THA at CNH were between 3 and 4 times higher than other English surveys and 6 times greater than those reported in the Swedish Hip Arthroplasty Register and after TKA 4 times higher than the Swedish Knee Arthroplasty Survey and 11 times greater than the Scottish Arthroplasty project.

After THA, WGH had a lower rate of complications requiring reoperation than both AOC and CNH. Their case mix was probably similar to CNH. Dislocation rates after THA at AOC and WGH were similar to the 1.9% reported in the Scottish Arthroplasty Project 2005 but lower than the 5% report in the Trent Arthroplasty Study and the 3% in 5 English regions. Infection rates at AOC and WGH after were comparable to the 1% reported in the Scottish Arthroplasty Project and the 1.4% reported by the Trent Arthroplasty. By contrast CNH had significantly higher complication rate after TKR than either of the other hospitals in this reviewed or the contemporary published literature.

Variations in outcomes amongst centres and surgeons after joint replacement have been reported for over 25 years. Reoperation after the Charnley THA in the early 1970s varied between 0% in Iowa and Oxford and 4.3% at the Mayo Clinic.

Variations were even greater with the McKee-Farrar when Langenskiold in Helsinki reported reoperation rates of 0% compared with 14% in Vancouver. The Vancouver experience was associated with low volumes of surgery performed by a large number of practitioners.
The volume of cases carried out at CNH comprised some six THAs or TKAs per month compared with 103 at AOC and 61 at WGH yet the actual number of reoperations was the same. Small volume surgery has been associated with higher relative risks of revision in uncemented THA in Norway\(^{14}\) and infection \(^{15,16}\) and mortality \(^{15,17,18}\) after THA in North America. The relative risk of infection in North America however ranged between 1.2\(^{16}\) and 4\(^{15}\) which was a much smaller differential than amongst the hospitals in this study.

Data acquisition for this study involved many hundreds of hours of telephone calls by the authors indicating that data collection at all these units was inefficient. AOC and WGH used both surgeons in outpatient clinics and NHS audit personnel. Surgeons failed to complete the audit forms in 60% of cases. This probably related to their being hidden in volumes of paper notes and their concentrating on patients’ problems rather than data collection. WGH initially audited the hospital record of their patients’ admissions for the first five postoperative days and follow-up records of those who attended for follow-up. Inpatient records however were generally for the initial five postoperative days and most of their infections and dislocations presented to patients’ local hospitals where they were subsequently followed. Thus WGH underestimated their dislocation rate by a factor of 10 and combined infection rate by a factor of 25 on their initial review. Such audit as was carried out by CNH was not made available and this is common to private sector activity. The Scottish Arthroplasty Project 2005\(^5\) was unable to capture any records NHS patients treated in the private sector. In the Swedish Arthroplasty Register 2005\(^4\) no reoperations within 2 years were reported in 3 of the 71 University, Central or Rural hospitals (4%) and four of the eight (50%) private ones.

This study has identified an outlying performance by one ISTC. Outliers are recorded in Scotland but whereas the Scottish Arthroplasty Project\(^7\) identifies these and seeks to assist the hospitals and surgeons concerned, this can only occur if providers report their outcomes promptly and honestly. There were suspicions about the quality of surgery at both WGH and CNH. These were unfounded at WGH but earlier action at CNH might well have enabled their problems to be rectified before patients were exposed to the major complications that occurred.

The aim of this study has been to compare the short term complications after THR and TKR performance at one NHS hospital and two ISTCs. Longer term follow up of a small number of patients sent from Exeter to four London hospitals revealed revision rate after ten years of 44% in the London hospitals compared with 4.9% at Exeter\(^{19}\). There will need to be further review of our patients to establish the relative revision burden of this exercise on the patients of our city and the resources of AOC. The revision burden on AOC by the activity at CNH has already included six septic and four aseptic revisions which have cost AOC the equivalent of 30 primary hip and knee replacements.
Apart from improving access to care, one of objectives of the ISTCs was to increase patient choice\textsuperscript{20}. Private providers do not make their complication rates available so patients sent to such units cannot make an informed choice\textsuperscript{20}. The outcome of NHS patients treated in the private sector should either be subjected to a robust and transparent review made available in the public domain or it should be made quite clear to patients who are approached to be sent to ISTCs that the outcome of these units is not generally known and there has been a 15 fold difference in early and a nine fold in long-term reoperation rates in the only two competent studies currently available.
Reference List


Table 1: Serious wound problems included major infection or discharging haematomas. Miscellaneous included urinary tract infections and arthroplasties with unexplained pain.

Death
Pulmonary Embolism
Deep Vein Thrombosis
Major Cardiopulmonary
Major Neurological
Serious wound problem
Minor wound infection
Dislocation
Miscellaneous
Readmission
Reoperation
Appendix 1

Table 2: Early complications of hip and knee replacement. The numbers of arthroplasties performed are recorded in crude figures and the retrieval and complications are percentages of arthroplasties performed.

<table>
<thead>
<tr>
<th></th>
<th>THA</th>
<th>TKA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AOC</td>
<td>WGH</td>
</tr>
<tr>
<td>Period</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number</td>
<td>880</td>
<td>368</td>
</tr>
<tr>
<td>Retrieval</td>
<td>94%</td>
<td>92%</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>6.8</td>
<td>0.8</td>
</tr>
<tr>
<td>Death</td>
<td>1.9</td>
<td>0.6</td>
</tr>
<tr>
<td>PE</td>
<td>0.8</td>
<td>0.5</td>
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<tr>
<td>DVT</td>
<td>1.7</td>
<td>2.6</td>
</tr>
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<td>Cardiac</td>
<td>0.9</td>
<td>0.3</td>
</tr>
<tr>
<td>Neurological</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Major wound problem</td>
<td>0.4</td>
<td>3.8</td>
</tr>
<tr>
<td>Minor wound problem</td>
<td>4.8</td>
<td>3.8</td>
</tr>
<tr>
<td>Dislocation</td>
<td>2.1</td>
<td>1.5</td>
</tr>
<tr>
<td>Readmission</td>
<td>1.2</td>
<td>0.6</td>
</tr>
<tr>
<td>Reoperation</td>
<td>0.6</td>
<td>1.4</td>
</tr>
</tbody>
</table>
## Table 3: Complications requiring surgery

<table>
<thead>
<tr>
<th>Patient</th>
<th>Reason for Reoperation: THR</th>
<th>Reasons for Reoperation: TKA</th>
</tr>
</thead>
<tbody>
<tr>
<td>AOC</td>
<td>Anterior instability secondary to complete abductor detachment</td>
<td>Instability</td>
</tr>
<tr>
<td>NR</td>
<td>Recurrent dislocation</td>
<td>Instability &amp; malposition of tibial component</td>
</tr>
<tr>
<td>MM</td>
<td>Deep prosthetic infection</td>
<td>Deep infection: debridement</td>
</tr>
<tr>
<td>BJ</td>
<td>Open reduction dislocation</td>
<td>Washout</td>
</tr>
<tr>
<td>PC</td>
<td>Deep prosthetic infection</td>
<td>Deep infection: debridement</td>
</tr>
<tr>
<td>CV</td>
<td>Deep prosthetic infection</td>
<td>Washout</td>
</tr>
<tr>
<td>WGH</td>
<td>Deep infection secondary to haematoma</td>
<td>Aspiration</td>
</tr>
<tr>
<td>TD</td>
<td>Loose cemented acetabular component</td>
<td>Supracondylar fracture following notch</td>
</tr>
<tr>
<td>TB</td>
<td>Chronic dislocation</td>
<td>Persistent pain</td>
</tr>
<tr>
<td>WL</td>
<td>Loose cemented acetabular component</td>
<td>Loose tibial component</td>
</tr>
<tr>
<td>PN</td>
<td>Recurrent dislocation</td>
<td>Wound dehiscence</td>
</tr>
<tr>
<td>JS</td>
<td>Recurrent dislocation</td>
<td>Patellar pain: not resurfaced</td>
</tr>
<tr>
<td>IF</td>
<td>Loose stem &amp; recurrent dislocation</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td>PJ</td>
<td>Septic loose coall stem</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td>EC</td>
<td>Malunion of greter trochanter</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td>AN</td>
<td>Loose acetabular component</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td>JM</td>
<td>Recurrent dislocation: revision at CNH</td>
<td>Malaligned components</td>
</tr>
<tr>
<td>AD</td>
<td>Failure of abductor repair &amp; haematoma: repaired at CNH</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td>BD</td>
<td>Deep prosthetic infection: radical excision</td>
<td>Overstuffed knee</td>
</tr>
<tr>
<td>CB</td>
<td>Major wound infection: reoperation at CNH</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td></td>
<td>WGH (7 in total)</td>
<td>CNH (7 in total)</td>
</tr>
<tr>
<td></td>
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<td>PH</td>
</tr>
<tr>
<td>GP</td>
<td>Instability</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td>CR</td>
<td>Instability &amp; malposition of tibial component</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td>DS</td>
<td>Deep infection: debridement</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td>DF</td>
<td>Washout</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td>JB</td>
<td>Aspiration</td>
<td>Malaligned components</td>
</tr>
<tr>
<td>PL</td>
<td>Supracondylar fracture following notch</td>
<td>Overstuffed knee</td>
</tr>
<tr>
<td>HB</td>
<td>Persistent pain</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td>MC</td>
<td>Loose tibial component</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td>EC</td>
<td>Wound dehiscence</td>
<td>Malaligned components</td>
</tr>
<tr>
<td>MD</td>
<td>Patellar pain: not resurfaced</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td>WS</td>
<td>Deep infection: two stage revision</td>
<td>Deep infection: two stage revision</td>
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<tr>
<td>AI</td>
<td>Deep infection: two stage revision</td>
<td>Deep infection: two stage revision</td>
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<tr>
<td>JR</td>
<td>Deep infection: two stage revision</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td>BS</td>
<td>Deep infection: two stage revision</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td>RM</td>
<td>Malaligned components</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td>BM</td>
<td>Overstuffed knee</td>
<td>Deep infection: two stage revision</td>
</tr>
<tr>
<td>PH</td>
<td>Deep infection: two stage revision</td>
<td>Deep infection: two stage revision</td>
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</table>
Independent Review of Knee Surgery carried out under the Second Offer Scheme in the NHS Treatment Centre, Weston

British Orthopaedic Association
18 January 2006
1. **Introduction**

In June 2006 Rhondda Cynon Taff Local Health Board (RCT LHB) and Weston Area Health NHS Trust (Weston Trust) invited the British Orthopaedic Association (BOA) to undertake a review of patients with reported complications following knee surgery performed at the Weston NHS Treatment Centre, under the Second Offer Scheme. The trigger for the review was an increasing number of clinical concerns being reported by the Consultant Orthopaedic Surgeons at Cardiff and Vale NHS Trust, who were the referring organisation under the Second Offer Scheme. The British Orthopaedic Association (BOA) asked two experienced knee surgeons, who practise at a distance from Weston and Cardiff and who have both been Presidents of the British Association for Surgery of the Knee, to conduct the review. The main areas of focus were to interview key members of the two Trusts and undertake a review of the clinical case notes of the 14 patients with reported complications, together with a control group.

The review was conducted on 22 August 2006 and the report is appended herewith.

2. **Background and Context**

The Second Offer Scheme was introduced in April 2004 to support the achievement of the waiting time target for 2004/05 that no patient should wait more than 18 months for inpatient or day case treatment.

A policy decision was taken in June 2004 to reduce waiting times to a maximum of 12 months by March 2007, unless the patient had declined an offer of treatment elsewhere or had accepted an offer and was awaiting treatment. The national target for 2005/06 was to sustain a maximum wait of 12 months for inpatient and day case treatments, reducing to 8 months by March 2007.

Providers used by Cardiff to achieve their targets have been the BUPA Hospitals in Cardiff and Worcester and the NHS Treatment Centre in Weston (Weston Trust). Commissioned by Cardiff at Weston in 2004/2005 were 96 knee procedures (32 day cases and 64 inpatients), in 2005/2006 there were 309 (134 and 175 respectively).

Concerns were raised by the Cardiff surgeons with respect to both individual patients and the overall process. In summary these were:

- Patients not doing well clinically, namely continued pain and stiffness, with many still on crutches 6 months after surgery
- Lack of continuity of care.
- No communication between Weston NHS Treatment Centre and Cardiff surgeons.
- Problems with obtaining postoperative x-rays from Weston.

A radiological audit was carried out by an Orthopaedic Associate Specialist in Cardiff and Vale Trust in June 2005 and this showed some technical problems.
Appendix 2

Terms of Reference

The review has been commissioned by RCT LHB and Weston Trust of patients who have undergone knee surgery at Weston Trust, on the type of operation performed, the appropriateness of the surgical technique and patient outcomes. The terms of reference for the review were agreed between the commissioners of the review, the British Orthopaedic Association and the two nominated surgeons undertaking the review. They are as follows:

- To review the notes, x-rays and other supporting information of the patients who have undergone knee surgery at Weston under the second offer scheme and who have complained or their GPs or surgeons have complained;
- To review the notes, x-rays and any other supporting information on a sample of patients who have had knee surgery at the Weston under second offer scheme and in whose regard there have been no complaints;
- To comment on the type of operation, appropriateness of technique and outcome.

Weston NHS Treatment Centre (Weston Trust)

Weston Treatment Centre is part of NHS Elect. NHS Elect is a coalition of NHS hospitals with active day case and treatment centre functions. The initial partners were Central Middlesex, Ravenscourt Park, Kidderminster, Weston Area Health Trust and Portsmouth. Several other Trusts have joined the group in recent years. Weston was one of the founding partners in this Department of Health-supported project.

During 2004/5 orthopaedic work was undertaken for the Welsh Assembly Government, through the Second Offer Scheme, as an integral part of NHS Elect. Weston Trust use visiting teams of Swedish surgeons, through contractual arrangements with SCANLOC, an agency dealing with Scandinavian medical staff. Both Welsh and English residents are treated by this unified service using the same clinical team and through the same clinical processes. Data are collected in separate groups for Welsh and English residents for all monitoring purposes.

3. The Review

The BOA team was met and escorted by representatives from the Delivery and Support Unit but had no formal interviews with them.

The following information was obtained by interviews with relevant personnel:

- When the patients were first informed that it was recommended that they “go away” for their surgery (2004/2005), 600 of those contacted for referral away from Cardiff turned down the offer.

- One of the surgeons had expressed a desire to be able to see and review all the pre- and post-operative x-rays of the patients who had been treated surgically at Weston, as he was concerned that his unit might be responsible for performing an increased number of early revisions. The Second Offer Commissioning Team hosted by RCT LHB state that a formal request has never been received.
• It was stated that no local orthopaedic surgeon was involved in the scheme but subsequent recognition indicated that their input might have helped avoid future problems. It was stated that the funding of the post-operative care of these patients and all its possible ramifications was not fully explored beforehand and that this had led to misunderstandings and tensions.

• It was felt that the contract should have included Clinical Governance issues, namely that a transparent audit component should have been integral to the process.

• The Weston NHS Trust strongly espoused an ethos of the initial strategy:
  * A consistent team of experienced surgeons.
  * One standard prosthesis (as was used by the Weston NHS surgeons).
  * The same audit process as the Weston surgeons, with a specific form six weeks post-operatively to be completed in outpatients.
  * The surgeons would not be paid for on call for their patients but instead would have time off.
  * The same operating theatres and nurses would be used as the Weston surgeons and, instead of junior doctors, they would have a nurse first assistant in theatres.
  * There would be two visiting surgeons at any one time carrying out day case lists, outpatient clinics and operating lists for major cases.
  * The patients would be looked after by an on-call surgical SHO.
  * That only certain procedures would be part of the project work and surgeons were expected to return patients to their base hospital if the surgeons were unable to offer the appropriate procedure (eg unicompartmental replacement) or the patient was not medically fit for a procedure without direct access to their previous medical team (eg renal or cardiac complications already under another physician’s care).

  * That there was careful training of consultants on the Kinemax system when they commenced on the project and by ensuring that the nurse first assistant was at almost all lists there was a high level of support available to ensure familiarity was rapidly gained.

It had been requested that there be an objective assessment of the patients and suggestions as to how the system be improved.

• Interviews were conducted with two of the surgeons from Sweden.

  Interview 1: His CV and the interview confirmed him as a well-qualified and experienced surgeon. Due to his work timetable in Sweden he has three months off each year as he has time off for doing his on call commitments and these are not paid extra. He comes to Weston approximately every six weeks and his
Appendix 2

weekly routine is to perform three evening clinics at which he sees on average 10 patients with a mixture of new and follow-ups.

He performs at most five operating sessions per week of which 2 are day case sessions and three are for major cases. The lists for major cases are usually on Monday, Friday and Saturday (sometimes a double list). The current workload is very variable.

He feels that the handover process is robust, with the leaving team telephoning the incoming team and discussing the patients in detail. The patients on the Friday and Saturday operating lists are not x-rayed until Monday and so, as the surgeons always leave on Sunday, they never see the post-operative x-rays of those patients, though they are seen by the next team.

He felt that the surgeon who performed the pre-operative clinic assessment and listed the patient for surgery should be the one who carries out the procedure.

Although they operated in the same theatre complex as the Weston surgeons there was no involvement with the orthopaedic surgeons or their unit; however, he would have liked there to have been an ongoing professional relationship.

Interview 2: The surgeon’s CV and the interview confirmed that he was a well qualified and experienced surgeon. He was one of the first surgeons to be recruited to the scheme. Initially there were two pairs of neighbouring surgeons (in Sweden) who communicated well and knew the way each other worked. He sensed that, as the number of surgeons coming to Weston increased, this had created difficulties with both culture and communication and resulted in the patients having “less good care”. He attends Weston every four weeks and has the same timetable as Interviewee 1 (see above).

The SHO they had been promised did not materialise and, though the surgeons performed twice-daily ward rounds themselves, they did not decide on when to discharge the patients. This was a decision taken for them and they were not sure by whom.

He expressed a preference for seeing his own (operated upon) patients at follow-up but the system did not allow for this unless his visit was exactly six weeks post-operatively.

He commented that the quality of the post-operative x-rays was poor ie they were badly centred. He said that he did not see the post-operative x-rays of those patients he had operated upon on Friday and Saturday.

He had noticed that the patients had not often received any physiotherapy by the time they attended for their six-week outpatient visit.

When he saw a patient in outpatients for a pre-operative assessment (all patients had been scheduled for either arthroscopy, total knee replacement (TKR) or anterior cruciate ligament (ACL) reconstruction) and he wanted to change the procedure to a unicompartmental arthroplasty or osteotomy as he felt this might be more appropriate he was not allowed to have this option and found this frustrating.
4 The Clinical Case Note Review

We reviewed the notes and x-rays of 14 patients whose treatment had caused concern: 9 TKRs, 3 ACL reconstructions and 2 arthroscopies. We also reviewed the x-rays of 14 control TKR patients selected by the Delivery and Support Unit of the Second Offer Scheme. A protractor was used to confirm measurements where necessary.

TKR Cases

- CV 0112 Instability due to flexion/extension gap mismatch. 1-stage revision required.
- CV 0191 Overstuffing of patellofemoral joint (too tight) with patella infera causing pain and loss of extension. Still on crutches at 6 months. 1-stage revision required.
- CV 0201 Femur cut in 5° valgus. Tibia in 10° varus. Lateral tibial cortex penetrated.
- CV 0224 Deep infection requiring 2-stage revision. Not recognised at Weston.
- CV 0308 Femur flexed 20° and patellofemoral joint overstuffed. Tibia in 10° varus. Unable to fully extend and needing crutches. 1-stage revision required.
- CV 0458 Oversized tibia in 10° varus. Operation performed without x-rays being available. Awaiting 1-stage revision.
- CV 0496 Patellofemoral symptoms due to overstuffing. On waiting list for 1-stage revision.

ACL Cases

- CV 0457 Femoral and tibial screws far too anterior. Graft failed. Revision required.
- CV 0482 Bucket handle tear lateral meniscus not dealt with.
- CV 0711 Ruptured graft possibly by femoral screw. Requires revision.

Arthroscopy Cases

- CV 0785 Said to have a plica resected but still has bucket handle tear of medial meniscus. Re-arthroscopy required.
- CV 0818 Symptoms not changed. Re-arthroscopy required.
Appendix 2

Control Cases

Of the 14 cases 6 had technical faults and 8 were acceptable.

5. **Summary Of Findings**

5.1 There is a much higher incidence of early complications than expected with the TKRs. Nine cases out of 147 6.1% required revision within a year. It should be emphasised that these are in general not complex cases from either the orthopaedic or medical point of view. Figures from the Trent Arthroplasty Study show a 95.5% survival at 10 years and, for the first year, the Weston figures represent a six-fold increase in the expected revision rate. These are all cases, not just the easy ones and the surgery was carried out in 1990 - 1992 when techniques were inevitably less sophisticated than they are now. Since no long-term follow-up is built into the contract we may never know the long-term complication rate. The TAS figures are in agreement with another database of 2,500 patients.

5.2 Two out of 9 ACLs failed and there was 1 bucket handle meniscal problem undiagnosed. Clearly this failure rate does not reach statistical significance owing to the small total number of cases but two out of nine failures still causes concern and prompts questions about clinical competence.

5.3 There do not appear to be any problems related to the vast majority of the arthroscopies although the comment was made that it was difficult to plan treatment on the basis of an invasive investigation which is open to interpretation and that has been carried out by a different surgeon. A bucket handle tear was missed. One of the surgeons does not appear to do arthroscopic procedures routinely according to his CV yet proceeded with them when he found them on his list. Surgeons visiting an ISTC should only proceed with operations that they are performing regularly in their own hospitals.

5.4 Having interviewed the two Swedish surgeons we have no doubts regarding their particular experience or skill. We do however have a number of concerns regarding the process.

5.5 The Kinemax TKR implant has been used for all procedures. There seems to have been no surgical input into this decision from either the Cardiff or Scanloc surgeons. The operating surgeon may not be familiar with it and the Cardiff surgeon who may have to revise it may not be familiar with it. One implant will not be appropriate for all patients needing a TKR as anatomy and deformity can be very variable. It has been reported that in osteoarthritis of the knee up to one third of patients may be suitable for a medial unicompartmental replacement and a small proportion may be suitable for a patellofemoral arthroplasty. Younger patients may benefit from an osteotomy in preference to a TKR. If the patients were placed on the Cardiff waiting list by anyone other than a consultant (SpR, Fellow, Associate Specialist etc) then the above factors might not have been evaluated optimally and an alteration to the procedure would need to be made at the pre-assessment stage.

5.6 There is discontinuity of care at all stages of the treatment process.
5.7 Ideally the same team should be responsible for the decision-making regarding treatment, the treatment itself and the follow-up. There are usually (but not always) three different surgeons for the three different phases of the surgical process.

5.8 If the surgery is carried out on a Friday or Saturday (at least two-thirds of operating), the post-operative x-rays are not seen by operating surgeon. This is not good practice. There were difficulties in managing patients’ post-operative problems due to geographical and communication factors and even if Weston were willing to treat post-operative complications it seemed very difficult to see a patient on a regular basis as is often necessary with post-operative TKR problems.

6. Recommendations

Due to the findings of this report, it is recommended that:

6.1 **Post-operative x-rays must be available for viewing by the operating surgeon before the patient (or the surgeon) leaves the hospital**

This is standard practice in all UK hospitals and enables immediate feedback to occur. Usually surgeons are their own sternest critic but need this vital piece of information particularly when using a “new” prosthesis.

6.2 **There should be close communication between the surgical team and the rehabilitation services so that concerns can be identified at any early stage and addressed**

This would pick up those patients who had not attended for treatment (physiotherapy) or who had made poor progress and may be candidates for a manipulation under anaesthetic (MUA), as leaving this too late may prejudice the outcome.

6.3 **Ideally one surgeon should oversee the 3 surgical phases of pre-assessment, surgery and follow-up**

One function of a pre-assessment clinic is to re-evaluate the clinical condition and indications for surgery. If the operation (TKR) was not thought to be the best choice for the patient then the only option for the Scanloc surgeons was to send the patients away or to list the patient for an operation with which they did not agree. Their preferred option of a change of operation was not possible under the terms of the contract. It is not within our remit to comment on the nature of the contract but the absence of clinical freedom given to the surgeon indicates a lack of understanding by the contract negotiators of the usual clinical process in the UK.

Although it is best clinical practice for the operating surgeon to review the patient post-operatively we do not consider this to be an absolute recommendation or indeed a failing at Weston but would request that some flexibility be built into future contracts so that this could be achieved as had been requested by the Scanloc surgeons.

6.4 **Surgeons from the original hospital should be informed of any problems**
There were no apparent channels of communication between the Scanloc surgeons and the Cardiff surgeons in case and when patients had problems. These had to be picked up on an ad hoc basis which meant delay and a possible poorer clinical outcome.

6.5 Patient Review

1. The radiographs of all patients who have undergone joint replacement at the Weston NHS Treatment Centre be reviewed and those found to be suboptimal should be recalled for a clinical and further radiological check.

2. All patients treated at Weston NHS Treatment Centre should be written to and offered a clinical review if they had any ongoing concerns about the outcome of their surgical treatment.

7. Conclusion

The issues outlined above illustrate the importance of an adequately funded and well-organised high quality local orthopaedic service for major reconstructive surgery. The outsourcing of major orthopaedic surgery uncouples the operation itself from the overall care pathway, increases the likelihood of problems and complications and thus potentially gives a poorer result for the patient. Revision TKR is very distressing for the patient, has an increased complication rate and is much more expensive when compared to primary TKR.

It has recently been recognised from another centre that “major reconstructive orthopaedic surgery does not travel well” 3. It is hoped that the Cardiff and Vale Orthopaedic Centre development will provide the solution to this problem so that these mistakes will not be repeated in Cardiff and so that other centres which have to employ similar contracts will be informed of this experience.

British Orthopaedic Association
for Rhondda Cynon Taff Local Health Board and Weston Area Health NHS Trust

19 January 2007

References


INDEPENDENT REVIEW OF KNEE SURGERY

We are writing with our joint response to the final report which we received on 19 January 2006. We are grateful to the British Orthopaedic Association for conducting the review and for the independent clinical assessment of patient outcomes.

Our comments cover issues of context, factual accuracy, areas of ambiguity, and some typographical errors. These are detailed below.

Section 1: Introduction

We feel that the introduction to the report portrays a reactive response to the increasing number of incidents being notified. The identification of clinical incidents that triggered the review were picked up through the comprehensive incident reporting system established by the Second Offer Scheme at its inception. This enabled a proactive rather than reactive response to the concerns received by Consultant staff within Cardiff and Vale NHS Trust, but this does not come through in the report.

Section 2: Background and Context

The context provided about the Second Offer Scheme (paragraph 2 & 3 refers) is disjointed and provides a very restricted perspective. An additional paragraph would have linked the two, by describing the measures that were taken to achieve the target reduction in waiting times. Effectively, NHS Trusts either increased their internal capacity through local initiatives, or used Second Offer Scheme capacity through arrangements with alternative providers to increase the number of patients treated in order to achieve the targets. However, use of alternative providers is only to reduce the backlog and not as a sustainable solution. The policy in Wales is to develop local NHS sustainable solutions.

As such, utilising the capacity available in Weston is a temporary solution to remove backlog from Welsh waiting lists as we reduce waiting times targets. Sustainable solutions to achieve a balance between demand for services and the capacity available are being continuously developed, so that services are locally provided and access improved.

We have previously highlighted that the list of providers used by Cardiff as stated in paragraph 3 should also reference the Nuffield Group, including Hereford, Birmingham, Cheltenham and Bristol, and also the BUPA hospital in Bristol.
The procedures undertaken in Weston were commissioned by the Second Offer Scheme, and not Cardiff as stated.

**Section 3: The Review**

This section lacks context about how the review was conducted i.e. the main focus of the review was to interview key members of the two Trusts and undertake a clinical case note review of the 14 patients with reported complications and a control group of patients.

The escort arrangements on the day of the review are irrelevant to the review itself. These arrangements were put in place to ensure that the reviewers did not have to be concerned with travel arrangements, and locating venues for example. It could be perceived as significant to readers of the report that these individuals were not interviewed, and in our view reference to them should have been removed as we have previously indicated.

Prior to the on-site review, the reviewers were notified of the surgeons that would be available on the day of the review. Due to the summer period, one Consultant within Cardiff and two Swedish Consultants were available for interview on the day. Other Consultants, who were involved in the care of the patients concerned, were available for telephone conference call in the period leading into the review and post review, but there is no reference to telephone interviews taking place with these individuals.

Whilst we acknowledge that section 3 of the report represents a summary account of interviews with individuals, the fact that these statements have not been substantiated by the authors should be stated. There are a number of factual inaccuracies and irrelevant remarks within the comments provided by interviewees, as follows:

**Review Interview point 1**

- There is no evidence that the phraseology cited by the interviewee “it was recommended that they [the patient] go away for their surgery” was that conveyed to patients. This would represent a poor standard of communication and should have been substantiated by the reviewers if the quote was felt to be relevant to the review findings.
- The number of patients quoted to have declined the offer has neither been validated, nor is relevant to the review. If it was to remain in, it should be qualified by the total number of patients.
- There is a typographical error – “pf” instead of “of”.

**Review Interview point 3**

- With respect to the comment that “no local orthopaedic surgeon was involved in the scheme”, this is unsubstantiated. Whilst we appreciate that the report reflects the content of information gained through interviews with individuals, we would wish to record that many attempts made by the Second Offer Team to develop formal interfaces between the two respective Trusts, namely:
  - At the very start of the scheme, Weston Trust was keen to engage with the Cardiff clinicians and on numerous occasions, Weston Trust requested to meet with the orthopaedic surgeons in Cardiff and Vale NHS Trust.
• All contract review meetings have been attended by general managers from Cardiff and Vale NHS Trust. The Clinical Director for Orthopaedics did attend an initial meeting, but despite frequent requests, no further clinical representation was put forward.

Regarding the point on the funding of post operative care, these requirements were clearly stated in the contract and as such, this statement is inaccurate. Patients are not limited to a definitive number of follow up appointments and the Trust is responsible for providing physiotherapy support. Additional funding was provided to the Trust to support additional physiotherapy sessions in the community.

With respect to the point on clinical governance issues. In both the contract and the protocol for orthopaedic activity (schedule 1 to the contract), there is an explicit requirement for a programme of clinical audit in relation to the delivery of services, to take part in joint audits and to provide comprehensive audit information of the patients treated in the project. This would include an audit of clinical outcomes. Regular audit reports from Weston Trust were submitted to the Second Offer Team and shared with the Medical Director, Clinical Director for Orthopaedics, Directorate Manager for Orthopaedics and the Second Offer Lead within Cardiff and Vale Trust.

Review Interview point 5 (ii)

Regarding the comment made by the Swedish surgeon about not having the option to “change the operative procedure”, we would record that this is categorically not a restriction of the contract. An authorisation process is in place, and where there is a clinical requirement for an alternative procedure to be undertaken, this has never been refused. The Second Offer Team has never been made aware of any difficulties experienced by the surgeons in feeling obligated to perform certain procedures. We are concerned that the report does not make any comment about the individual surgeon’s professional accountability when this alleged issue arose, nor does the report refer this back to Weston Trust to explore the internal procedures for dealing with an issue where clinical practice was perceived to have been restricted.

Section 5.1

The baseline figure of 147 that has been used to calculate the incident rate is incorrect. Using the actual baseline for 2004/05 of 65 cases does return a revision rate within one year of 6.1%; for 2005/06 the baseline is 156 cases, returning a revision rate of 3.2%. The average revision rate across the two year period is 4% based on combined TKR activity of 221. We consider that the conclusions you draw remain correct, in that this incidence rate of early complications is higher than would be expected in the first year, and therefore the implementation of your recommended actions is proceeding.

Section 5.3

There is a typographical error – “requird” instead of “required”.

Section 5.3

The report refers to the Weston Treatment Centre as an ISTC. This is inaccurate as it is in fact part of NHS Elect.
Section 5.4

The report states that there are no doubts regarding the skill or experience of the two Swedish surgeons. However, section 5.2 clearly indicates that the failure of two ACL procedures and an undiagnosed meniscal problem “causes concern and prompts questions about clinical competence”. There is no reference to any recommendation in this regard.

Section 6

The report earlier states that there are no doubts regarding the experience or skills of the two surgeons interviewed (comment on section 5.4 above refers) and the recommendations that follow in section 6 of the report, relate only to processes in the care pathway.

We note that the reviewers found technical faults and a much higher incidence of early complications with the knee TKRs than would be expected, and that of the control cases 6 were found to have technical faults. In this respect, and with the magnitude of technical faults found, we would have expected a recommendation to relate directly to the concerns about clinical competence.

At several points in the report, reference is made to perceived constraints upon surgeons in their clinical practice. The report does not address the key issue of whether / how they exercised their own professional accountability when these clinical process issues arose, nor are there any recommendations in this regard.

We assume that our formal response would be attached to the final report.

Yours sincerely

RCT LOCAL HEALTH BOARD DELIVERY AND SUPPORT UNIT
I am the [Role of the person sending letter] at Cardiff and Vale NHS Trust. Over the past two years Cardiff and Vale Trust has given patients the option of receiving treatment at Weston Treatment Centre at Weston-Super-Mare under the ‘second offer’ scheme. Under this Scheme patients are offered referral to other hospitals with shorter waiting times so they can receive their treatment more quickly. I understand that you were recently referred for knee surgery to Weston Treatment Centre at Weston-Super-Mare under the ‘second offer’ scheme.

We are always looking for ways of improving our services to patients and to this end a clinical review of the treatment provided to patients under the ‘second offer’ scheme at the Weston Treatment Centre has been commissioned. To enable us to complete this, two consultant orthopaedic surgeons have been asked to assess a number of medical records, including yours, held at Weston and Cardiff and Vale during August.

The purpose of this letter is to seek your consent to the disclosure of these records to the appointed surgeons. I can assure you that your records will be anonymised before they are disclosed to the surgeons so your identity would at no stage be revealed to them or to anyone else unconnected with your treatment.

I attach a standard consent form for your completion and return to me in the event that you are happy for your records to be disclosed to our expert reviewers on an anonymised basis. However, if you have any queries that need to be addressed before you sign the attached consent, could you please contact [Name of contact person and telephone number] as soon as possible to discuss them.

The address to send the consent form to is
[Name of contact person]
Etc

I look forward to hearing from you shortly and thank you in anticipation of your co-operation.
[Name]

of [address],

date of birth [   ]:-

1. I hereby agree to my medical records (including all xrays, scans and electronically held information) relating to the orthopaedic treatment I received at Weston Treatment Centre, Weston-Super-Mare and Cardiff & Vale NHS Trust being disclosed to the appointed orthopaedic surgeons commissioned to review the treatment provided to patients.

2. I understand that my records will be anonymised before they are disclosed in accordance with paragraph 1 above.

Signed ...........

Dated ...........
Appendix 5a

Please print

Full Name:  …………………………………………

Address:  ……………………………………………

………………………………………………………

………………………………………………………

………………………………………………………

………………………………………………………

Date of birth:  ………………………………………

I agree to all clinical records, including X-rays, scans and electronically held information, relating to orthopaedic treatment held at Weston Area Health Trust and Cardiff and Vale NHS Trust being disclosed to the review panel appointed by the South West Strategic Health Authority in England and led by Professor Brian Toft.

Signed:  ………………………………………

Date:  ………………………………………
Appendix 5b

Full Name: ..................................................

Address: ..................................................

..................................................

..................................................

..................................................

Date of birth: ...........................................

I further agree to attend Weston Area Health Trust for a physical examination by an independent Consultant Orthopaedic Surgeon if requested to do so.

Signed: .................................

Date: .................................
As part of the government’s initiative to reduce waiting times for major joint surgery in Wales, the Cardiff and Vale NHS Trust sent 224 patients (258 knees) to the NHS Treatment Centre in Weston-Super-Mare for total knee replacement. The Kinemax total knee replacement system was used in all cases. The cumulative survival rate at three years was 79.2% (95% confidence interval (CI) 69.2 to 86.8) using re-operation for any cause as an endpoint and 85.3% (95% CI 75.9 to 91.8) using aseptic revision as an endpoint. This is significantly worse than that recorded in the published literature. These poor results have resulted in a significant impact on our service.

In Wales in 2004 the waiting time for total knee replacement (TKR) was approaching 36 months. In order to reduce this, the Welsh Assembly Government introduced the ‘Second Offer Scheme’ in April 2004, whereby no patient was to wait more than 18 months for in-patient surgical care, reducing to 12 months in March 2007. In order to be treated within this time patients had to travel for their surgery, with provision shared between the BUPA Hospital Cardiff and the NHS Treatment Centre at Weston-Super-Mare. The Orthopaedic Department at the Weston-Super-Mare General Hospital is separate from the Weston Area Health NHS Treatment Centre. This paper relates only to the work carried out at this latter centre. The two organisations should not be confused.

In June 2006, Rhondda Cynon Taff Local Health Board, in agreement with Weston Area Health NHS Trust, invited the British Orthopaedic Association to carry out an independent review of the surgery performed at the Weston NHS Treatment Centre because the complication rate following surgery was higher than expected (Fig. 1). Their report concluded by making the following recommendations:

1. The post-operative radiographs must be available for viewing by the operating surgeon before the patient or the surgeon leave the hospital.
2. There should be close communication between the surgical team and the rehabilitation services so that concerns can be identified and addressed at an early stage.
3. Ideally, one surgeon should oversee the three phases of pre-assessment, operation and follow-up.
4. Surgeons from the original hospital should be informed of problems that might arise.
5. The radiographs of all patients who have undergone joint replacement at the Weston NHS Treatment Centre should be reviewed, and for those found to be suboptimal the patient should be recalled for a further clinical and radiological check.
6. All patients treated at the Weston NHS Treatment Centre should be contacted and offered a clinical review if they have concerns about the outcome of their surgical treatment.

As a result of this report, this paper was written to compare the results of the surgery performed at the NHS Treatment Centre to those already published by other centres. The Kinemax total knee system (Stryker, Howmedica, Rutherford, New Jersey) has proved to be of robust design and has a reported survival at ten years varying between 96% and 97%.2,3

Patients and Methods

Between April 2004 and January 2006, 258 Kinemax TKRs were inserted for osteoarthritis in the Weston-Super-Mare NHS Treatment Centre by a variety of surgeons from Sweden supplied by Scanloc Medical Recruitment (Scanloc, Battle, United Kingdom). All 224 patients were contacted by telephone or letter, and offered clinical and radiological review, which was performed by one of the Cardiff and Vale NHS Trust consul-
tant knee surgeons. The radiographs of the patients were reviewed using the IMPAX (AGFA) image software (Agfa Health Care UK Ltd, Brentford, United Kingdom) and the positions of the components were assessed according to the Knee Society Scoring System described by Ewald.\(^4\) Angles were measured using IMPAX digital templating software (Medi CAD, Alttraunhofen, Germany). Data concerning revision, recommendation for revision and follow-up were taken from the patients’ notes.

The radiographs were evaluated for varus malalignment, the degree of posterior slope of the tibial component, valgus malalignment and flexion of the femoral component, oversizing of the components resulting in reduced range of movement, or ‘overstuffing’ of the patellofemoral joint and overlapping of the tibial tray. The cement-component interface was also evaluated for radiolucent lines and signs of loosening of the components.

For the survival analysis a ‘life-table’ method was used as described by Armitage and Berry.\(^5\) This allows the analysis of data from patients with differing durations of follow-up, and also enables joints to enter or be withdrawn from the study at any time. The annual failure rate is calculated, and survival rate is cumulated for each successive year. A variety of endpoints were used, including revision for any cause, aseptic revision and cumulative survival. The 95% confidence intervals were calculated using the Rothman equation.\(^6,7\)

**Results**

A total of 258 knees, 115 knees in 101 men and 143 knees in 20 women, had the Kinemax knee implanted. Their mean age was 68 years (36 to 85). Of the 49 patients (52 knees), who were not reviewed, 26 (28 knees) did not ask for an appointment, 20 (21 knees) did not respond or did not attend their appointment, and three (three knees) had died of unrelated causes. There were 206 knees (80%) left in the study (116 in 98 women and 90 in 77 men); of these, 144 were unilateral single joint arthroplasties and 31 were bilateral (28 staged, three simultaneous). The mean follow-up was for two years (2 to 3). A total of 130 knees (63%) had obtained a satisfactory result, with the patient experiencing no or minimal pain and a range of movement of at least 0° to 90° in a stable knee.

In 76 knees (37%) the result was unsatisfactory. Ongoing pain, for which no cause was found, was present in 14 patients (15 knees) and one patient (one knee) had developed a complex regional pain syndrome. Re-operation had been undertaken in 29 patients (30 knees, 15%) and a further 29 patients (29 knees, 14%) had been recommended to have a revision, but had either declined further surgery at present or were on the waiting list (Fig. 2).

**Alignment of the implants.** The mean angle of the tibial component was 3.1° of varus (SD 2.4) for the whole group. Of the 206 knees accepting an error of 3° of valgus to 3° of varus as a reasonable margin of accuracy for the horizontal tibial cut, 73 (35%) were found to lie beyond 3° of varus (Fig. 3). There were 80 knees (39%) with more than 8° of valgus of the femoral component (mean 8.20°, SD 2.35). The femoral components were oversized in 75 knees (36%) and the tibial component too large in 80 (39%). Both components were oversized in 37 knees (18%).

**Re-operation/revision.** Revision operations were carried out in ten knees in ten men and 20 knees in 19 women with mean ages of 70 years (50 to 81) and 67 years (46 to 83) respectively. Revision was required for infection in three patients, two in the first year and another at 24 months. There were eight revisions for malalignment, six for aseptic loosening, one for arthrofibrosis and four for oversized
components. In a further eight patients the patella was resurfaced as a secondary procedure (Table I).

**Survival analysis.** The overall cumulative survival rate with re-operation of any kind as the endpoint was 79.2% at three years (95% confidence interval (CI) 69.2 to 86.8). If aseptic revision was used as the endpoint, including revision for malalignment, oversizing, instability or aseptic loosening, but not including infection or secondary patellar resurfacing, the cumulative survival rate was 85.3% (95% CI 75.9 to 91.8) at three years. The cumulative survival rate in patients who have been recommended revision but have either declined or were awaiting surgery was 75.9% (80.3%, 95% CI 69.5 to 85.3) at three years (Table II, Fig. 4).

**Fig. 2**
Flow diagram showing patients in the study.

**Fig. 3**
Histogram showing the distribution of varus angulation of the tibial resection in the cohort.
In the drive to reduce waiting times it is essential that all patients receive a high quality of treatment in existing NHS hospitals or new facilities. The Weston-Super-Mare NHS Treatment Centre was an entirely separate facility from the NHS hospital and was staffed by Swedish locums, flown in to perform the operations.

The Kinemax implant has been used widely with good results. Back et al\textsuperscript{2} reported a series of 422 Kinemax TKRs with a cumulative survival of 99.05\% at three years, 99\% at five years and 96.5\% at nine years. Similarly, an American study by Wright et al\textsuperscript{3} followed 523 knees for ten years; the overall survival with the risk of re-operation for any cause is as endpoint was 96.1\%, and with the risk of aseptic revision as the endpoint was 97.2\%.

Table I. Reason for revision

<table>
<thead>
<tr>
<th>Reason for revision</th>
<th>Number of knees</th>
<th>Mean number of months to failure (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Septic Infection</td>
<td>3</td>
<td>15.3 (9 to 24)</td>
</tr>
</tbody>
</table>

Aseptic

<table>
<thead>
<tr>
<th>Reason</th>
<th>Number of knees</th>
<th>Mean number of months to failure (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loosening of the tibial component</td>
<td>3</td>
<td>26.7 (14 to 34)</td>
</tr>
<tr>
<td>Loosening of the femoral component</td>
<td>1</td>
<td>29</td>
</tr>
<tr>
<td>Loosening of both components</td>
<td>2</td>
<td>23.5 (11 to 25)</td>
</tr>
<tr>
<td>Malalignment</td>
<td>8</td>
<td>19.5 (11 to 28)</td>
</tr>
<tr>
<td>Oversize</td>
<td>4</td>
<td>17.8 (13 to 20)</td>
</tr>
<tr>
<td>Arthrofibrosis</td>
<td>1</td>
<td>19</td>
</tr>
<tr>
<td>Secondary patellar resurfacing</td>
<td>8</td>
<td>17.8 (11 to 26)</td>
</tr>
</tbody>
</table>

Table II. Life table showing cumulative survival data and 95\% confidence interval for overall revision for any cause and aseptic revision

<table>
<thead>
<tr>
<th>Years since operation</th>
<th>Number at risk</th>
<th>Failure</th>
<th>Deaths</th>
<th>Withdrawn</th>
<th>Lost to follow-up</th>
<th>Number at risk</th>
<th>Annual failure rate (%)</th>
<th>Annual success rate (%)</th>
<th>Cumulative survival rate (%)</th>
<th>95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Re-operation any cause</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 to 1</td>
<td>258</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>49</td>
<td>231</td>
<td>1.7</td>
<td>98.3</td>
<td>98.3</td>
<td>96.6 to 99.4</td>
</tr>
<tr>
<td>1 to 2</td>
<td>204</td>
<td>17</td>
<td>0</td>
<td>43</td>
<td>0</td>
<td>174</td>
<td>9.8</td>
<td>90.2</td>
<td>88.5</td>
<td>82.8 to 92.6</td>
</tr>
<tr>
<td>2 to 3</td>
<td>144</td>
<td>8</td>
<td>2</td>
<td>105</td>
<td>0</td>
<td>86</td>
<td>9.3</td>
<td>90.7</td>
<td>79.2</td>
<td>69.2 to 86.8</td>
</tr>
<tr>
<td>3 to 4</td>
<td>29</td>
<td>0</td>
<td>1</td>
<td>28</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Aseptic revision      |                |         |        |           |                   |                |                         |                          |                           |                          |
| 0 to 1                | 258            | 1       | 1      | 1         | 49                | 232            | 0.4                     | 99.6                     | 99.6                      | 97.2 to 100.0             |
| 1 to 2                | 206            | 11      | 0      | 51        | 0                 | 175            | 6.2                     | 93.8                     | 93.4                      | 88.5 to 96.5              |
| 2 to 3                | 144            | 7       | 2      | 107       | 0                 | 86             | 8.1                     | 91.9                     | 85.3                      | 75.9 to 91.8              |
| 3 to 4                | 28             | 0       | 1      | 27        | 0                 | 0              |                          |                          |                           |                          |

Discussion

In the drive to reduce waiting times it is essential that all patients receive a high quality of treatment in existing NHS hospitals or new facilities. The Weston-Super-Mare NHS
mechanical function of the knee. Many of the arthroplasties performed in Weston-Super-Mare were outside this range. The results of the Cardiff patients treated at the Weston-Super-Mare Treatment Centre are significantly worse than previously published figures, with a very high revision rate at only three years. This rate continued to rise. There remains a large number of patients disappointed by the outcome of their TKR; many of those who initially refused the offer of revision are now reconsidering their decision. There are also a large number of patients with asymptomatic TKRs with malpositioned or incorrectly-sized components that might still fail. These poor results have resulted in a significant economic impact on our service.

The authors would like to thank the Administrator, Louise College, Cardiff and Vale NHS Trust for their assistance in collection of the data.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References

1. No authors listed. BOA. Independent Review of Knee Surgery carried out under the Second Offer Scheme in the NHS Treatment Centre, Weston. BOA Jan 2006.