National Joint Registry
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NATIONAL JOINT REGISTRY STEERING COMMITTEE (NJRSC)

MINUTES

Meeting: NJR Steering Committee **Date:** Wednesday 7 November 2007

Location: MLS Venue, 130 Shaftsbury Avenue, London W1D 5EU

Present:

Bill Darling	BD	Chair
Mick Borroff	MB	Orthopaedic Device Industry Member
Patricia Cassidy	PC	Independent Healthcare Sector Member
Andrew Crosbie	AC	Medicines & Healthcare Products Regulatory Agency (MHRA)
Patricia Durkin	PD	Patients Representative Member
Prof. Paul Gregg	PG	Vice Chair, Orthopaedic Surgeon Member
Peter Howard	PH	Chair, Regional Clinical Coordinators
Alex Macgregor	AM	Public Health and Epidemiology Member
Christine Miles	CM	Welsh Assembly Government
Carolyn Naisby	CN	Practitioner with Special Interest in Orthopaedics Member
Martyn Porter	MP	Orthopaedic Surgeon Member
Andrew Smallwood	AS	NHS Supply Chain
Keith Tucker	KT	Orthopaedic Surgeon Member
Andrew Woodhead	AW	NHS Management Member
Anne Macleod	AMc	Department of Health
Elaine Young	EY	Department of Health
Richard Armstrong	RA	Northgate Information Solutions, Programme Director
Charlotte Humphry	CH	Northgate Information Solutions, Programme Manager
Kathryn Lehner	KL	Northgate Information Solutions, Service Manager
Ian Mulcahy	IM	Northgate Information Solutions Technical Support Assistant
Claire Newell	CNe	Northgate Information Solutions, Data Quality Manager
Kirsty Smith	KS	Northgate Information Solutions, Programme Support Manager
Mike Swanson	MS	Northgate Information Solutions, Principal Consultant

In Attendance: For NJR Manuscript Submission – Lancet and British Medical Journal (BMJ) (Item 6.2), Independent Sector Treatment Centre (ISTC) Audit (Item 14) and Outliers (Item 16) only:

Jan van der Meulen	JvdM	Royal College of Surgeons, Clinical Effectiveness Unit

Apologies: Mary Cowern, Martin Pickford

REF	ITEM	ACTION
	AGENDA: PART 1	
1	**Welcome and Apologies for Absence** The meeting commenced at 10.30am. The Chair welcomed all present. Apologies were received and noted. The Chair extended his thanks to everyone, including the Vice Chair and his team, for the successful production of the NJR 4th Annual Report, and launch at the BOA conference.	
2	**Minutes of the Previous Meeting** The minutes of the meeting held on Tuesday 24 July 2007, were approved as an accurate record.	
3	**Matters Arising (not appearing elsewhere on the agenda)** **3.1 Timperley letter (prev. min ref 3b)** Confirmed by EY, that a reply had been sent to Mr Timperley. **3.2 NJRSC Member Resignation (prev. min ref 5.2)** EY reported that the Appointments Commission were handling the replacement for Anthony Lowther, Manufacturing/Supply Industry NJRSC member. An advert had been placed with a closing date of 30 November 2007, and interviews were planned for early New Year, with the Chair as a member of the panel. **3.3 Supplier Information – Brand Usage (prev. min ref 6.4)** Reported by EY that this matter would be referred to the DH legal department, prior to any decision being confirmed about whether Suppliers could receive this information. The NJRSC would be notified of the outcome, and rationale. **Agreed: That the NJRSC would be notified of the decision regarding this matter. Action Ref Nov 07 (3.3)** **3.4 Hip Owners Manual and Patient Information (prev. min ref 8)** AMc proposed that a special interest group be set up to consider the Hip Owners Manual and potential links to the 'Information for Choice' agenda. This was accepted by the NJRSC. **Agreed:** **a. That nominations for the special interest group should be made to Anne Macleod via anne.macleod@dh.gsi.gov.uk. Action Ref Nov 07 (3.4a)** **b. That the DH contact Colin Esler, Vice Chair, RCC Network for his input. Action Ref Nov 07 (3.4b)** **3.5 Bulk Upload (prev. min ref 10)** The Chair invited any declarations of interest prior to discussing this item. Noted that	**DH** **NJRSC** **AMc**

	no declarations of interest were received. The inability within third party total orthopaedic management systems to read component barcodes was reported, with results in some records going into the edit stack, and then requiring manual input for upload. Noted by MS that the current bulk upload was clumsy and did require upgrade, but not under pressure from one particular supplier. The NJRC could develop a solution, but would require the NJRSC to prioritise this, as cost versus benefit may not be comparable. It was felt that if data could be uploaded to the NJR via a single source, e.g. the total orthopaedic management system, it may lead to heightened levels of data entry. MP stressed the importance of ensuring that data collection became embedded into the processes of an orthopaedic department. **Agreed: That the NJRC would produce a business case, with timescales, costs, and implications, for the January meeting of the NJRSC. Action Ref Nov 07 (3.5)** **3.6 Consent (prev. min ref 18.2)** An amended form of text was presented to the NJRSC for approval. It was confirmed that this had been approved by DH lawyers and PIAG. **Agreed:** **a. To improve local acceptance of the consent wording, the Chair would write to CEO's advising them that the approved consent text was available if they wished to utilise it; Action Ref Nov 07 (3.6a)** **b. That Patricia Cassidy would undertake similar action in respect of the private sector; Action Ref Nov 07 (3.6b); and** **c. That the DH explore inclusion of the text within the general consent forms printed for use by the NHS. Action Ref Nov 07 (3.6c)**	**NJRC** **BD** **PC** **DH/EY**
4	**Minutes of the Regional Clinical Coordinators Meeting held on 11 September 2007** Peter Howard was introduced as the appointed Chair of the RCC Network. Draft minutes of the Regional Clinical Coordinators meeting, held on the 11 September 2007, were received and noted for information. The following points were reported; **4.1. Smith & Nephew product recall** It was noted that the affected Smith & Nephew product lot numbers, had been obtained from the MHRA and fed in to the NJR. This had enabled a unique NJR reference number to be generated, which could be notified to individual units and the MHRA, to assist with investigations into where the components had been used. This had demonstrated the value of the NJR. It was agreed that the process for dealing with potential 'outlier' implants would be discussed further during the afternoon agenda dedicated to 'Outliers'. **4.2. Data Entry** The RCC's requested that the NJRC produce a paper on the issues surrounding	

	data entry to the NJR, for submission to the January 2008 NJRSC meeting. **Action Ref Nov 07 (4.2)** **4.3. RCC Vacancy, SE Wales** CM agreed to liaise with PH regarding the RCC vacancy for SE Wales. **Action Ref Nov 07 (4.3)**	**NJRC** **CM**
5	**Procurement of the National Clinical Audit and Patients Outcome Programme (NCAPOP)** EY reported on the DH procurement of the NCAPOP which would include the NJR. The new contract would commence from the 1 April 2008, following the appointment of a provider by the end of the year. The contract currently held by Northgate to manage the NJRC would remain in place, but would be managed by the new provider rather than the DH. PG queried possible duplication between PROMS and the National Clinical Audit, but it was confirmed that these were different issues.	
6	**NJR Annual Report** **6.1 Launch of the NJR 4th Annual Report** It was noted that the report had been presented at the BOA Congress in Manchester on the 26 September, by PG, KT, MP and Jan van der Meulen, Royal College of Surgeons. The NJRSC commended the production and launch of a successful Annual Report. **6.2 NJR Manuscript Submission – Lancet and British Medical Journal (BMJ)** As the manuscript on the NJR had been rejected by both the Lancet and BMJ, the Chair requested that the reasons for rejection be reviewed, to increase the chance that future submissions would be accepted. **6.3 NJR 5th Annual Report 2008/09 – Planning** The following comments about drafting the next Annual Report were noted: • That the format should include four main topics to form the printed version of the report, with accumulated analytical information being posted on the website, and the printed version to have a detailed index for ease of use and reference; • MP's suggestion that the views of stakeholders, with highlighted benefits, be incorporated; • AW's suggestion that the report was an ideal vehicle to make links to the experience of Commissioners; • That JvdM's input to the production of the 5th Annual Report would be valued, but the decision to utilise the Royal College of Surgeons for this purpose would be the decision of the NJRC; and • AM's view for a scientific publication to coincide with the Annual Report **Agreed: That the NJRSC would provide the NJRC with suggested topics for the 5th Annual Report so that a paper could be prepared for discussion at the January meeting of the NJRSC**. **Action Ref Nov 07 (6.3a)**.	**NJRC**

7	**MDSv3** CH reported that the scheduled launch of MDSv3 for the end of November 2007 was on target. Noted that RC's had released proformas to units in mid October, and the NJR website had been updated to keep users informed.	
8	**Quarterly Statistics Report Q2 (July – September 2007)** The Quarterly Statistics Report Q2 (1 July to 30 September 2007) was received and noted with the following comments; CM queried the use of different quarters when dealing with data for England and Wales. It was noted that this was due to accessibility of comparative data. It was noted that information that may have financial implications, such as joint replacement figures levelling out, would be welcomed by the Trust Chief Executives, particularly in relation to applications for Foundation Trust status.	
9	**Quarterly Management Report (QMR) Q2 (July – September 2007)** The Quarterly Management Report Q2 (1 July to 30 September 2007) was received and noted with the following comment; **Data Submission** Regional variations with data submission, and plans to deal with nil returning units were queried, as the QMR contained no detail about how these issues were being tackled. The NJRSC confirmed the importance of the NJRC dealing with any problems that the QMR may identify, and having an associated action plan included in the report. KT suggested that Special Advisory Committee (SAC), which oversees the training of doctors in orthopaedics, be notified of the top and bottom performing units. PH indicated that the RCC's could communicate this information. **Agreed:** **That the NJRC submit additional details of nil returning units, and regional variations, and a proposed action plan for dealing with this, to the January NJRSC meeting**; **Action Ref Nov 07 (9a)** **That PH would raise the issue of Special Advisory Committee at the next meeting of the RCC Network. Action Ref Nov 07 (9b)**	**NJRC** **PH**
10	**NJR Finance Report Q2 (July – September 2007)** The NJR quarterly Finance Report Q2 (1 July to 30 September 2007) was received and noted with the following comments; That a positive balance of £750,000 was recorded at the end of quarter 2 and that the NJRSC needed to consider how these surplus funds could be appropriately utilised. **Agreed: That the afternoon session of the January NJRSC meeting would be split into two sessions; one to cover risk management, as previously agreed, and the other to prioritise projects and workload that may be funded by the surplus balance. Action Ref Nov 07 (10)**	

11	**Re-development of the NJR Web-site** Referring to Chairman's action which had been taken in respect of the joint decision with the DH to approve the use of development funds for implementation of MDSv3, the Chair confirmed that both the NJRSC and DH were responsible for decisions surrounding authorisation of the NJR contract development fund. KL presented a business case for re-development of the NJR website, with request for associated funding. Noted by the NJRSC that the 2007/08 contract development fund had been utilised for implementation of MDSv3, but the NJR levy budget could support this expenditure. **Agreed: By the NJRSC, to approve the appropriate funding for this purpose**.	
12	**NJR/Cancer Registry-Genotoxicity** The DH informed the NJRSC about discussions with the MHRA, about the possibility of linking outcomes from the NJR and UK Cancer Registry. It was noted that further work was necessary to establish if a link was possible, what resource would be required to achieve it, and any cost implications, to the NJR.. **Agreed: That the NJRSC would be kept informed of progress. Action Ref Nov 07 (12).**	**DH/AMc**
13	**PROMS** The DH updated the NJRSC on the proposed plans for a national PROMS study. It was noted that a DH business case was to be submitted for ministerial approval. It was proposed that the study would introduce PROMS for Hip and Knee replacement, and for Varicose Vein and Hernia patients as soon as possible, and acknowledged that this would necessitate close collaboration with the NJR, as well as a funding contribution from the NJR towards the hip and knee element of the study. It was recognised that there was significant benefit to the NJR being part of a national PROMS study. The Chair confirmed that due to the timescales of the case submission for ministerial approval, it had not been possible to address the issue of funding through the NJRSC. As such he had taken Chairman's action to authorise an NJR contribution of £150,000 in relation to the project, subject to ministerial approval being received. **Agreed:** **By the NJRSC, to support Chairman's action to approve a funding contribution towards the Hip and Knee element of the national PROMS study.** **That the NJRSC be kept informed about whether ministerial approval had been received for the PROMS study. Action Ref Nov 07 (13).**	**DH/EY**
14	**Independent Sector Treatment Centre (ISTC) Audit** JvdM presented details of the government commissioned ISTC audit and proposed collaboration with the NJR. He explained that the audit was of fixed duration, and designed to answer specific questions regarding comparable outcomes between ISTC's and NHS Units. Concern was expressed regarding the different case mix of ISTC and NHS patients, and JvdM confirmed that an 'Audit Steering Committee' would monitor the outcome data and ensure fairness. The audit would not include any review of the cost element of care.	

	Noting that JvdM had written to invite a member to represent the NJRSC on the Audit Steering Committee, the Chair invited nominations, indicating that the first meeting had been scheduled for the 20 November 2007. **Agreed: AW would represent the NJRSC on the Audit Steering Committee.**	
15	**Any Other Business** **15.1 Title of the NJR Regional Coordinators** KL informed the NJRSC of the RCC Network decision to retain the title of 'Regional Coordinator'. **Agreed: By the NJRSC, to accept the decision of the RCC network.** **15.2 Role of the NJR Regional Coordinators** MP raised concern about whether the current level of RC manpower was adequate to support their role given the large geographical areas they were required to cover. KL confirmed that an internal review of RC staffing indicated that manpower resource was adequate to cover the required workload, although further review of improving working practices would be considered in more detail. MP mentioned that some RCC's rarely saw their RC. KL explained that the RC's undertook detailed reports of progress in their areas, which were made available to all RCC's through their network meetings, although this level of detail was not reported to the NJRSC. **Agreed: That the NJRC would liaise with the DH about an action plan to improve communication and working relations between RC's and RCC's. Action Ref Nov 07 (15.2)** **15.3 NJR ReportsOnline – Surgeon Reports** It was reported that whilst current reports were good, they required development. The NJRC confirmed that work to improve data levels was underway. **Agreed: That information relating to the number of 'hits' to the ReportsOnline section of the website be reviewed, and communicated back to the NJRSC. Action Ref Nov 07 (15.3)**	**NJRC** **NJRC**
	AGENDA: PART 2	
16	**Discussion and Resolution of All Outlier Issues** **16.1 Statistical Methods for Monitoring NJR Outliers** Consideration was given to a re-drafted paper outlining statistical methods for monitoring outliers. **a. Statistical Reporting Format** It was agreed that the funnel plot analysis be adopted as the statistical methodology for the identification of NJR outliers, relating to brand, unit, and surgeon. However, it was felt to be crucial that survivorship analysis was also used to support the process. JvdM's recommendation that the data should reflect revision rates after one year and then three years, was accepted, but it was noted that as it was not currently possible to report on three year revision rates, the next step must be to install an	

	ongoing monitoring system. The NJRC reported that inclusion of survivorship statistics required fine tuning of the data processing element of the funnel plots, but could be undertaken within a two week time period. **b. Trigger Point for potential outlier identification** It was agreed that an initial trigger point of 99% was acceptable, but should be subject to constant review. **Agreed that:-** **Funnel plot analysis should be accepted as the initial process for identification of outliers, but must include supporting survivorship analysis, and be subject to constant review. Action Ref Nov 07 (16.1a)** **The NJRC would redefine the funnel plot data to incorporate survivorship analysis. Action Ref Nov 07 (16.1b)** **A trigger point of 99% be adopted to identify outliers, but that this be subject to constant review.** **JvdM would send NJRC the Cusum reporting paper previously produced for information. Action Ref Nov 07 (16.1c)** **16.2 Draft Procedure for Handling Outlier Performance** The DH tabled a further draft procedure for discussion, with apologies that it had not been previously circulated. It was noted that due to different requirements, any procedure would require re-draft for the Independent Sector and Wales. Concern was expressed that the re-draft procedure had changed significantly from the draft previously agreed in principle with the BOA. Specifically two key points were raised: the involvement of an independent panel ("gang of 10"), and the point at which the CEO was notified of a potential outlier. MP stressed that the suggested escalation of data to the CEO before an independent panel ("gang of 10") were notified, could lead to negativity within the surgeon community, and cynicism about how NJR data could potentially be used. The Chair reminded members of two significant changes which impacted on the draft procedure previously agreed by the BOA: responsibility of a CEO for clinical governance arrangements, and indemnity for investigating surgeons which could only be covered at Trust level. Both factors required a CEO to be informed about a potential outlier at the beginning of the process. Surgeon members advised that as the BOA had approved the previous draft process in principle, they should be notified of any changes. It was accepted that the NJRC data should be reviewed by a clinician to establish whether there was a 'case to answer', and the 'outlier' surgeon should be contacted by the reviewing clinician and advised to contact their CEO who would also be informed. Outstanding issues included, the acceptable timeframe between contact with the 'outlier' surgeon and the CEO, to allow the surgeon time to provide an explanation and/or make initial contact with their CEO, and whether a CEO could be 'instructed' or 'advised' to use an independent reviewer, or left to make internal Trust review arrangements.	**NJRC** **NJRC** **JvdM**

	Agreed:- That the DH would further review the policy in the light of the NJRSC discussion, but that nothing discussed could be taken as approved until this review had been undertaken. Action Ref Nov 07 (16.2) **16.3 Draft Process for the Investigation of Outlier Implants** The DH tabled a further draft procedure for discussion, with apologies that it had not been previously circulated. Attention was drawn to the objective to maintain current arrangements with MHRA responsibility for dealing with devices and implants, but to notify Trust CEO's to facilitate investigations. The following points were noted: • That the major change to the current MHRA arrangements, involved an escalation process to be followed should a Trust CEO fail to cooperate with an investigation. • That the draft process made no reference about notification of implant manufacturers/suppliers. Although under current arrangements the MHRA would undertake to do this, it was agreed that this should be identified as a specific MHRA requirement. • Concern that outlier implant and performance processes, should not be viewed in isolation as frequently one may impact on the other. **Agreed:- That the DH would redraft the process to include reference to the MHRA notifying implant manufacturers/suppliers about outlier devices, and then undertake further review before finalising. Action Ref Nov 07 (16.3)**	**DH** **DH**
17	**Date and Time of Next Meeting (previously notified)** Thursday 31 January 2008 (10.30am - 4.00pm)	
	The meeting closed at 4.00pm	