National Joint Registry
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NATIONAL JOINT REGISTRY STEERING COMMITTEE (NJRSC)

APPROVED MINUTES

Meeting: NJR Steering Committee **Date:** Thursday 24 July 2008
Location: MLS Venue, 130 Shaftsbury Avenue, London W1D 5EU

Members Present:	Bill Darling	BD	Chair
	Prof Paul Gregg	PG	Vice Chair, Orthopaedic Surgeon
	Mick Borroff	MB	Orthopaedic Device Industry
	Patricia Cassidy	PC	Independent Healthcare Sector
	Mary Cowern	MC	Patient Representative
	Patricia Durkin	PD	Patient Representative
	Peter Howard	PH	Chair, Regional Clinical Coordinators' Network
	Carolyn Naisby	CN	Practitioner with Special Interest in Orthopaedics
	Martyn Porter	MPo	Orthopaedic Surgeon
	Dean Sleigh	DS	Orthopaedic Device Industry
	Keith Tucker	KT	Orthopaedic Surgeon
Regular Attendees:	Richard Armstrong	RA	NJR Programme Director, Northgate Information Solutions (Northgate)
	Charlotte Humphry	CH	NJR Programme Manager, Northgate
Part 2 only	Claire Newell	CNe	NJR Data Quality Manager, Northgate
	Martin Pickford	MPi	NJR Orthopaedic Advisor, Northgate Sub-Contractor
	Mike Swanson	MS	NJR Principal Consultant, Northgate
	Elaine Young	EY	NJR Project Manager, Healthcare Quality Improvement Partnership (HQIP)
Meeting Invitees:			
	Christopher Brittain	CB	Representing Alan Hidderley (MHRA)
Part 1 only	Paul Lelliott	PL	Chairman, HQIP
Part 2 only	Jan van der Meulen	YV	Statistician, Royal College of Surgeons Clinical Effectiveness Unit
Part 1 only	David Nuttall	DN	Economic Advisor, Department of Health

Apologies:	Alan Hidderley	MHRA
	Alex Macgregor	Public Health & Epidemiology
	Christine Miles	Welsh Assembly Government
	Andrew Smallwood	NHS Supply Chain
	Andrew Woodhead	NHS Management Member

REF	ITEM	
	AGENDA: PART 1	
1	**Welcome and Apologies for Absence** The Chair opened the meeting at 10:30 by welcoming all attendees. Apologies were received and noted, and the Chair congratulated, in his absence, Andrew Woodhead on his appointment as Chief Executive Officer of Newham University Hospital NHS Trust.	
	Before moving to Item 2, the Chair welcomed Dr Paul Lelliott, Chairman of the Healthcare Quality Improvement Partnership (HQIP), noting that the Committee was delighted he was able to join the meeting. PL outlined his experience and background in quality improvement, expressing his view that clinical audit should be led by the profession. He explained the background and organisation of HQIP, and highlighted that it was currently a company, limited by guarantee, but was applying to become a registered charity. A Chief Executive, Robin Burgess, had recently taken up post, and HQIP would have 12-15 full time staff. One of HQIP's first tasks was to review the NJR contract with Northgate Information Solutions, which was due to expire in March 2009. In response to MPo's query on whether or not the NJRSC needed to 'market' the NJR to HQIP, PL stated that the Chair had made the need for the NJR very clear to him. He did feel that the NJR data had not been utilised sufficiently, and could provide a valuable tool to support re-certification and revalidation initiatives. PL also confirmed that, after reading the 4th Annual Report, he felt that the NJR was leading the way in quality improvement and patient outcomes. He noted that it appeared the NJR had good support across the country, and a good data system that worked. He noted the amount of surplus levy at year end 2007/08, and encouraged the Committee to be ambitious in its plans for the future. BD noted that the NJR was ahead of the field and that it was now time to look at how to extract the data from the database and use it more effectively; this had been a focus of the Chief Medical Officer's latest report. PG stated that he was encouraged about the increased focus on the use of data for research, and made a personal plea to PL for PROMS and funding for long term research. PL explained that there had been a review of the contract with Northgate, and that a meeting would take place between HQIP, the Department of Health, and the Chair, on the 20th August, to decide the future of the contract. Options included re-tendering the contract, or extending it up to a further two years. The outcomes of the review undertaken by EY would be circulated to members by 30th July, for feedback to BD, to help inform contract discussions. PL also suggested that the Committee draw up a list of strategic objectives which could be turned into a budgeted strategic plan, noting that there would be a review of the levy in September. BD informed the meeting that the next NJRSC meeting would include a strategic review of the NJR. In response to a question from KT about accountability, PL reassured members that the NJRSC would retain its status. He also reported that this would be the last year that ministerial approval would be needed for publication of the Annual Report.	**EY/NJRSC**

2	**Minutes of the Previous Meeting** MB noted two inaccuracies: a. Min ref 5.4: Stated that the Swedish Registry used a general questionnaire when in fact it used EQ5DQuali outcomes. b. Min ref 6: Outliers: The minutes did not reflect the NJRSC decision that manufacturers would have access to record level data when advised of a potentially outlying prosthesis following receipt of an adverse incident report from MHRA. Subject to the inaccuracies being corrected, the minutes of the meeting held on Thursday 31st January 2008 were approved as an accurate record.	**NJRC**
3	**Matters Arising (not appearing elsewhere on the Agenda)** **3.1 Hip Owner's Manual (prev. min ref 5.2)** EY reported that MPi had provided details of the organisation responsible for the original manual but that she had not been able to establish contact with the relevant person, Malcolm Ostwald, by the time of the meeting. **Agreed: That the NJRC would try to locate an electronic copy of the Hip Owner's Manual, and EY would make contact with Malcolm Oswald to establish what assistance he may be able to provide.**	**NJRC/EY**
	3.2 Bulk Upload (prev. min ref 5.6) CH informed the meeting that the NJRC was liaising directly with the suppliers of other applications so they could start end-to-end testing of their applications against the re-developed bulk upload.	
	3.3 Metal on Metal (MoM) Working Group (prev. min ref 5.8) KT reported that a working group, chaired by Mr John Skinner, had been established, and that PH had also been invited to join the group. Following its first meeting, Mr Peter Kay had written to all orthopaedic surgeons in the UK, informing them of the study and the reasons for it. A questionnaire had also been developed, and it was planned to send it to all surgeons who had revised MoM hip replacements. About 550 questionnaires would be distributed. The study would use only linked revisions from the NJR database. Completed questionnaires would be returned to the NJRC where patient and surgeon identifiers would be removed before forwarding to the MHRA for analysis. MPo, KT, and Mr Skinner would then clinically review the data, which may involve additional contact with relevant surgeons, for supporting x-rays and histology. PG raised concern over how practical this would be. KT explained that until this initial study was undertaken, it could not be confirmed that soft tissue necrosis was an issue, and he drew attention to the fact that since the establishment of the study, there had been no further adverse incidents relating to soft tissue necrosis and MoM articulations. BD noted that to date neither he nor EY had received any minutes from the working group meetings, and KT confirmed that he would ensure future minutes were circulated accordingly. KT's suggestion that an update on the MoM study should be included in the NJR session at the BOA Congress in September was approved. CB noted that the MHRA was grateful for the NJR funding contribution of this study. **Agreed:** **KT would ensure all minutes will be sent to EY and BD.** **A MoM presentation would be included in the NJR session at the BOA Congress.**	**KT** **KT**
	3.4 Information Data Sharing Policy (prev. min ref 10 EY noted that at the last meeting it had been reported that there was no NJR Research	

Policy, although there was a formal process by which NJR data could be requested. MPi had provided a draft research protocol, written in 2005, but never presented to the NJRSC. It was agreed that as the NJR wished to encourage applications for research, it was imperative that a transparent process was established.

PG also enquired about progress with circulation of a summary of the data requests which the NJR received, and noted that this information would be useful before the next meeting.

Agreed:

That the NJRC, in consultation with AM, would update the research protocol for consideration of the NJRSC at their next meeting. **NJRC**

That a profile of NJR data requests be circulated to the NJRSC before the next meeting. **NJRC**

3.5 Collaboration with European Registries (prev. min ref 13)

AM was not at the meeting to update the Committee, but BD confirmed his understanding that there was no enthusiasm for formal, ongoing collaboration at this point, but that cooperation was important, albeit the NJRSC were not prepared to alter the NJR dataset in order to align itself with the European registers. The NJRSC approved this view.

3.6 Orthoconsent Forms (prev. min ref 18.1)

MS noted that permission had been granted to Orthoconsent to use NJR consent wording on its consent forms, and that this would appear in its own box with the NJR logo.

3.7 Non-Compliant CEO Letter – Update

BD relayed his conversation with a surgeon who had been led to believe that a colleague had been suspended following their identification as a potential outlier. BD had explained that the NJR had no evidence of this, and it had been acknowledged that this had probably been a rumour. The surgeon had agreed to contact BD if he received any other information, but BD had received no further communication.

3.8 British Hip Society Letter – Update on discussions with Peter Kay

The Chair informed the meeting that he had spoken to Peter Kay, about his letter, which had been presented to the NJRSC at its previous meeting. BD appreciated that Mr Kay had not been expressing his own views, but those of the British Hip Society Council. He had explained that as an Advisory Non-Departmental Public Body (ANDPB), the membership structure of the NJRSC was pre-determined, and members had to apply for appointments through the Appointments Commission. As he had received no further communication, BD assumed that he had addressed the issues raised in Mr Kay's letter.

MPo stated that concern amongst members of the profession was because of a perceived lack of clinical engagement because membership of the NJRSC had moved away from a structure which was representative of professional bodies. The President of the BOA had suggested a more formal interface between the BOA and the NJRSC. MPo also suggested that a smaller executive body, or working groups, be established to oversee the day-to-day business of the NJR, as the profession wished to see more engagement and representation. EY agreed, in principle, with the re-establishment of individual working groups to address current issues between meetings of the NJRSC

PG commented that the councils of BASK and BHS had not been especially proactive but the profession's views were also represented by the RCCs.

BD reiterated his commitment to meet with anyone, at any time.

4	**PROMS** The Chair welcomed David Nuttall, Economic Advisor, DH, who was attending the meeting to provide an update on the national DH Proms study, and agree a formal mechanism for the NJR part funding contribution, in exchange for customised analysis of the resulting linked data to support NJRSC objectives. During the course of the item, a number of comments and concerns were raised by members. It was agreed that, a brief update would be documented in the minutes but a more detailed account of member views would be documented by MS and provided to DN. DN confirmed that the DH PROMS study would include hips, knees, groin hernia, and varicose veins, with data being collected pre-operatively and post-operatively at six months. The reason for undertaking the study was to bridge the perceived gap between clinical information and quality intervention. The NHS Operating Framework had set this out in December 2007, and the study would start to collect data from 1st April 2009, and would be procured using national services, with the Information Centre playing a key role. DN acknowledged the benefits of linking collected data from the DH PROMS study to the existing NJR dataset, but highlighted potential issues around information governance and consent. The Chair also confirmed receipt of a letter from Bob Ricketts, Director of System Management & New Enterprise, DH, seeking to formalise the arrangement between the DH and NJR, and inviting the NJRSC to outline the analysis that would be required on the linked data, so that it could be built into the contracts that were being procured to support the NHS to collect, collate and analyse the PROMs data. It was confirmed that a copy of the letter would be circulated to all NJRSC members who would be requested to submit their views about the kind of analysis and information the NJR would require from the national PROMs study. The Committee agreed that a contract was necessary between HQIP and DH to ensure that the NJR's financial commitment to the study would lead to clearly defined deliverables within a defined time frame. The draft contract would be presented to the NJRSC at its next meeting. It was recognised that there was a limited amount of time to influence the questionnaires to be used for the study and to set the priorities for the research. **Agree:** **That MPi would forward to DN the questionnaire developed by AM for a proposed NJR PROMS study.** **That MS would coordinate a response from NJRSC members and provide this information to EY for submission to DN who would include NJRSC requirements within contract specifications for the PROMs work.**	**MPi** **MS/EY/DN/ NJRSC**
5	**5.1 Outlier Procedure (Surgeon): Stakeholder Communication** BD reported that when the NJRSC had agreed the statistical methodology (5.2 below refers), the President of the BOA, Steve Cannon (SC) would communicate the NJR outlier process to the profession. PG had drafted a summary of the statistical methodology for inclusion in SC's communication, which at the President's request emphasised the Early Warning System. It was noted by BD that he did not mind if his signature was included on the BOA communication, but it was imperative that the NJRSC agreed the methodology, so that SC could notify the profession about the outlier process ahead of the BOA Congress in September. **5.2 Statistical Methodology for Monitoring NJR Outliers** BD reported that a meeting had been held to ensure that PGs summary document reflected the detailed statistical methodology RA reported that the statistical methodology to be used for the identification of potential outliers had been agreed but the NJRC recognised that the methodology would be reviewed going forward. For example, it would be possible, in the future, to use CUSUM to detect short term changes in performance.	

	In response to MPo's concern that the outputs may be affected by missing data, BD reported that this would be highlighted when the proposal to make the NJR a mandatory data collection was taken to ministers. RA confirmed that the data would be updated quarterly and that surgeons would be able to see the same representations of the data as the NJRC. He reported that the agreed methodology was a refinement of the methodology used to previously identify potential outliers. He agreed to use the refined methodology on the same data to compare the results. MB expressed concern that ABHI statisticians had not had a chance to provide him with feedback on the methodology.BD explained that it was too late to wait for this feedback given the urgency of submitting this information to the BOA. **Agreed:** **To approve the statistical methodology and associated summary, and that the summary be submitted to the BOA President for circulation to the profession.** **That MB would notify the NJRSC of any ABHI concerns about the methodology and these would be reviewed at the next meeting** **5.3 Draft Procedure for Handling Outlier Performance- Device** MB reported that ABHI were content that potential outlier performance (Device) was handled as an adverse incident through the MHRA. He reiterated that manufacturers would need access to patient level data from the NJR. It was also noted that AW had agreed to prepare a Non-Disclosure Agreement to enable manufacturers to access patient information within a hospital. Referring to the recent outlier scenario, BD requested the MHRA to report on the outcome of the identified potentially outlying implants. **Agreed:** **That manufacturers would have access to patient level data from the NJR.** **That AW be requested for an update on progress with the NDA.** **That the MHRA provide details of the outcome of the recent outlier scenario.** **5.4 Outlier Surgeon Feedback** The NJRSC received feedback from the clinicians on their role in the recent outlier scenario, and how the relevant surgeons had felt about the process. It was noted that this had generally been positive and the surgeons who were contacted about their results had appreciated the informal call being made by a member of the profession. It was however felt that the outlier process should include a risk assessment of the surgeon contact element, with training provided for NJRSC clinicians to equip them to deal with various scenarios. KT agreed that a risk assessment was necessary and that he personally felt uncomfortable and would have preferred to have some training to handle the various scenarios that could arise. The Chair recognised the sensitivity around the process and requested that it be subject to ongoing review. He expressed his appreciation to the surgeon representatives for their support with this process **Agreed:** **That PH should take the above concerns to the next RCC meeting for their views.** **That further consideration should be given to undertaking a risk assessment of the outlier process with training and support provided for NJRSC clinicians involved in making the initial contact with outlier surgeons.** **That the outlier process be kept under constant review.**	**NJRC** **EY** **MB** **NJRC** **NJRC/AW** **CB** **PH** **NJRC/EY/ BD** **EY/BD**
6	**NJR Data Feedback for Clinicians** RA reported that implementation of Clinician Feedback, a system that would enable surgeons	

	to measure and compare their performance against a number of regional and national benchmarks, was underway. Surgeon members would be asked to pilot the system and provide feedback, prior to launch at the BOA, Congress. It was noted that this would be an initial scoping of the data, and that the system would continue to develop beyond the launch. **Agreed: That surgeon members would be e-mailed a link to the system towards the end of August and asked for feedback and recommendations**	**NJRC**
7	**MDSv3** **7.1 Update on Implementation** CH reported that all issues continued to be reviewed and fixed when required. It was noted that an important request for changes to the inclusion of knee flexion data and primary operation date had been implemented, and that those changes had overcome a number of problems for some hospitals. **7.2 Dataset Modifications** PH reported on omissions in the current dataset, and proposed that the following be considered for inclusion by the RCC Network: 1. Direct thrombin inhibitor (eg Dabigatran).Adverse soft tissue reaction 2. Revising unicompartmental knees 3. Including 'Revision to total from a resurfacing'. **Agreed: That because of these issues there should be an annual review of the MDS by the RCC Network**.	**PH**
8	**Future Business Proposals** MS outlined the following three proposals for which he sought NJRSC approval to develop into full business cases: **a. Extension of the Performance Management System** To extend the Performance Management System to the MHRA and NHS Supply Chain. Although the NJR supplied these organisations with data every year, additional information was always requested. Extending the PMS would enable them to undertake their own analysis and reporting. MHRA could, for example, run their own reports on implant usage and potential issues. BD, as Chair of the PASA Audit Committee, declared an interest in this proposal. **b. Change to the Storage of Data** To change the way data is held on the database. Currently stored using an encryption method, a number of issues are created for users, and surgeons had to download data from the NJR system onto personal or hospital computers. The proposed replacement would provide encryption at two levels. RA reassured PD that Northgate would not propose anything that compromised patient data. **c. Message and Transaction Service Hub** To create a messaging and transaction service hub between external systems and the NJR system. This is required to enable communication with other systems, especially those being delivered under the National Programme for IT (NPfIT). It was also proposed to include Bulk Upload on the hub. **Agreed: That business cases be produced for each proposal and submitted to the NJRSC for further consideration.**	**NJRC**
9	**Cooperation with the US Food and Drugs Administration** MS reported that a request had been received from the US Food and Drugs Administration for data about all ceramic on ceramic bearings. Concern had been raised that the FDA had been reluctant in the past to use the European post market surveillance data, and it was confirmed	

	that no data on ceramic on ceramic bearings had been provided to date. The FDA wanted to use NJR data for research but although they had agreed to submit a more detailed proposal, nothing had been received to date. **Agreed:** **That the NJRSC would wish to consider any FDA proposal if it was forthcoming, but for now no data should be provided.** **The FDA should be notified to liaise directly with the MHRA on this, rather than the NJRC.**	**NJRC**
10.	**Knee Interpositional Devices and the NJR** MPi informed the meeting of a new surgical device which had recently come onto the market. The device was not a joint replacement but was intended to replace the meniscus. As such, it did not qualify as an NJR implant. However, considering the performance of previous similar products, and queries from surgeons, it was proposed that this device should be included in the NJR. KT noted that the history of earlier inter-positional devices had not been good and recommended that its performance be monitored. **Agreed: That the matter would be discussed by the RCCs and included in the consideration of changes to the MDS.**	**PH**
11	**Quarterly Statistics Report Q1 (April to June 2008)** The Quarterly Statistics Report Q1 (April to June 2008) was received and noted.	
12	**Quarterly Management Report Q1 (April to June 2008)** The Quarterly Management Report Q1 (April to June 2008) was received and noted with the following comment: PG requested that the Appendix relating to requests for information should be explicit in regard to the actions carried out. He had been concerned that one request had been actioned when, in fact, it had been rejected. **Agreed: That the NJRC would make the necessary change for future reports.**	**NJRC**
13	**NJR Finance Report (April – June 2008)** The NJR Finance Report (April – June 2008) was received and noted.	
	AGENDA: PART 2	
14	**NJR 5th Annual Report 2008/09** BD expressed concern about the accuracy and quality of the documents submitted to the Committee, noting that the Chairman's introduction was actually that from the previous report. In addition he felt that the emphasis on the four topics agreed in January, had not received the priority that they should, and it was unsatisfactory that he had only learnt of changes to this structure on the 11th July. JvdM stated that, in the time available, it was not possible to produce detailed analysis for all four topics. Only an overview could be provided within the timescales now available. The Committee discussed the layout of the report, noting that some of the statistics and tables would not be included in the printed document, but would be published on the NJR website. MPo noted his disappointment at his offer of help not being taken up, and suggested that in future the data be locked down earlier, to allow detailed analysis to take place in a timely manner. It was noted that a meeting to discuss Part 2 of the report would be held at the end of the meeting. EY confirmed that she and MS would review Part 1 of the Report but members were invited to notify any comments to herself or MS as soon as possible.	**EY/NJRSC/ MS**

	Discussion ensued about the launch of the report. EY confirmed that the report could not go to print until ministerial approval had been obtained. The final draft report would have to go the minister at the end of August if the Report was to be available for the BOA Congress. It was noted that it looked unlikely that the Annual Report would be ready for launch at the BOA Congress, and that the end of September was a more realistic timescale. BD informed the meeting that he was not prepared to recommend an inaccurate report to ministers, and publication would have to be delayed until the analysis was agreed. He confirmed that he had warned the President of the BOA that the report may not now be available for the BOA Congress. With regard to the NJR presentation at the BOA Congress, BD reported that he would Chair the NJR session on the 17 September. In the 90 minute session the clinicians would present the four topics as agreed, RA would present the clinician feedback system and John Skinner would be requested to make a presentation on Metal on Metal. In the 15 minute session the following day RA would make a further presentation of the clinician feedback system.	
15	**Any Other Business** **15.1 Research Request: Mr J Timperley** The Chair referred to a letter from Mr John Timperley requesting that the NJR undertake research on the failures for hip replacements, and that a meeting of surgeon representatives, the NJRC and a statistician be convened for this purpose. It was noted that currently the NJR did not report whether or not the failure was due to the stem or cup, and it was agreed that there would be value in this research. MP offered to support the study if necessary. **Agreed:** **That before a decision was taken, the NJRC would undertake a feasibility study with an estimate of the resources that would be required, for consideration by the NJRSC.** **At the request of the Chair, that the NJRC would report this decision to Mr Timperley in a timely manner.**	 **NJRC** **NJRC**
16	**Date and Time of Next Meeting (previously notified)** Tuesday 21st October 2008 10.30am to 16.00pm	
	The Chair closed the meeting at 16:00 hours	