National Joint Registry
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NATIONAL JOINT REGISTRY STEERING COMMITTEE (NJRSC)

APPROVED MINUTES

Meeting: NJR Steering Committee **Date:** Thursday 31 January 2008
Location: MLS Venue, 130 Shaftsbury Avenue, London W1D 5EU

Present:	Bill Darling	BD	Chair
	Mick Borroff	MB	Orthopaedic Device Industry Member
	Andrew Crosbie	AC	Medicines & Healthcare Products Regulatory Agency (MHRA)
	Mary Cowern	MC	Patients Representative Member
	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
	Carolyn Naisby	CN	Practitioner with Special Interest in Orthopaedics Member
	Martin Pickford	MPi	Northgate Information Solutions, Orthopaedic Advisor
	Martyn Porter	MP	Orthopaedic Surgeon Member
Part 1 only	Andrew Smallwood	AS	NHS Supply Chain
	Keith Tucker	KT	Orthopaedic Surgeon Member
Part 1 only	Andrew Woodhead	AW	NHS Management Member
	Anne Macleod	AMa	Department of Health
	Elaine Young	EY	Department of Health
	Charlotte Humphry	CH	Northgate Information Solutions, Programme Manager
	Kathryn Lehner	KL	Northgate Information Solutions, Service Manager
Part 1 only	John Martin	JM	Northgate Information Solutions, Statistician
	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 Work Priorities and Expenditure (Item 14):

	Gerard Hennessy	GH	Department of Health

Apologies:

Patricia Cassidy	PC
Christine Miles	CM

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.	
2	**Minutes of the Previous Meeting** The minutes of the meeting held on Wednesday 7 November 2007, were approved as an accurate record.	
3	**Matters Arising (not appearing elsewhere on the agenda)** **3.1 Appointment of NJRSC Industry Member (prev. min ref 5.2)** The Chair confirmed that Dean Sleigh, Biomet UK, had been offered the post of NJRSC Industry member to replace Anthony Lowther. Although he had verbally accepted, the appointment had to be formalised by the Appointments Commission. **3.2 Supplier Information – Brand Usage (prev. min ref 6.4)** EY reported that this matter was still under review with DH Legal, and she would confirm whether Suppliers could receive brand usage reports as soon as the advice was available **Agreed:- EY to circulate any update to the NJRSC** **3.3 Hip Owners Manual and Patient Information (prev. min ref 8)** It was reported that a meeting of the Hip Owners Manual special interest group had taken place on the 30 January 2008. Aims, target audience, content, format, access to patient information and the potential to link to NHS Choices had been discussed. **Agreed:- That AMa would produce a revised format of the manual for discussion by the NJRSC, before the end of March 2008.** **3.4 Consent (prev. min ref 18.2)** EY reported that on DH Legal advice, further changes to the NJR consent text had been made, and the text could now be circulated for use. She also reported that the possibility of incorporating the NJR consent wording into general NHS consent forms was still being investigated. **Agreed:- That EY would liaise with Andy Smallwood, NHS Supply Chain, about whether consent forms were printed centrally.** **3.5 Procurement of the National Clinical Audit and Patients Outcome Programme (NCAPOP) (prev. min ref 5)** EY confirmed that an announcement about award of the NCAPOP contract was imminent, and that she would circulate the NJRSC with details.	**EY** **AMa** **EY/AS** **EY**

	3. 6 NJR/Cancer Registry-Genotoxicity (prev. min ref 12) It was noted that work was ongoing in liaison with the MHRA	**AMa NJRC**
	3.7 PROMS (prev. min ref 13) EY reported that the PROMs business case was still awaiting ministerial submission. However the new national requirement for PROMs reporting for electives (Hip and Knee, Varicose Veins, and Groin Hernia's), was announced in the Standard NHS Contract for Acute Services, recently published as part of the NHS Operating Framework for 2008/09. This encouraged voluntary participation in PROMs during 2008/09, to become mandatory in 2009/10 for all NHS patients undergoing the chosen study procedures. It was noted that the business case confirmed the financial contribution from the NJR for the Hip and Knee element of the study only. In the light of this, there was expressed concern about the benefits of the national study for the NJR, and a view that the NJR should be able to influence the detail of the proposed questionnaires relating to Hip and Knee element of the study. **Agreed: That the NJRSC be kept informed on this issue**	**EY**
	3.8 NJR ReportsOnline – Surgeon Reports (prev. min ref 15.3) Noted by CH that the facility to measure the number of times the website was accessed did not currently exist; but could be incorporated into the website redevelopment project.	**CH**
	3.9 Re-development of the NJR website (prev. min ref 11) CH updated members on the re-development of the NJR website. It was noted that a focus group, with DH, patient and surgeon representation, would be established to ensure user feedback.	**CH**
4	**Outliers** **4.1 Recent Outlier Scenario** The Chair updated the NJRSC on the management of the 'outlier' scenario that had arisen since the previous meeting. He explained the background relating to notification of the outliers by the NJRC, and delay with submission of a formal report to himself and the DH. He noted that the first opportunity to review this report on the 8 November 2007, had identified the need to take immediate action. However, in the absence of an agreed outlier procedure and statistical methodology, this had required Chairman's action on behalf of the NJRSC, to ensure the matter could be progressed. Thanking PG and KT for their support, the Chair outlined the process which had then followed to ensure clinical review of the statistical methodology used to identify the potential outliers, establish if there was a 'case to answer', and agree an 'interim' procedure to be followed. This had allowed the first NJR outlier scenario to be handled thoroughly and effectively. Learning from the process had been subsequently incorporated into the 'interim' statistical methodology (item 4.2 below) and outlier procedure (item 4.3 below) for further consideration and approval of the NJRSC.	

	4.2 Statistical Methodology for Monitoring NJR Outliers JM presented a revised paper on the statistical methodology for monitoring NJR outliers. It was discussed and noted that: a. Survivorship analysis should be carried out for 1, 3, 5, 7 and 10 years. b. MP requested that adjustment be made to account for different compliance rates. JM confirmed that adjusted and non-adjusted rates could be provided to show the impact of compliance. Noted that this could influence units and surgeons to comply, as the methodology would weigh against non-compliance. The Chair noted the relevance of making the NJR mandatory, and this was supported by the NJRSC who felt this should be pursued with the DH. c. AC felt that decisions reached at the 'Outlier' meeting of 17 January 2008, should be incorporated into the methodology, and offered to liaise with JM regarding this. d. Funnel plots should be the preferred method for graphical illustration of data e. Reference to 're operations' should be deleted and replaced with analysis of all 'revisions' once PH had confirmed this with the RCC Network on the 7 February. A review of the decision not to include recording of this information within MDSv3 would be required. f. PG considered the methodology and tolerance levels to be robust g. MP considered information/data should be posted on the NJR website to allow surgeons to review their own performance for governance purposes h. In response to a query from PG regarding reporting timescales, JM confirmed that the next report could be produced within three months, applying the agreed statistical methodology to all NJR data **Agreed that:** **The methodology be amended to include the above points, and then e-mailed to NJRSC members prior to the next meeting, for further review/comment, before submission to the next NJRSC for approval** **The NJRC produce the next report within three months (by the April NJRSC meeting), and quarterly thereafter.** **The NJRC consider what information could be posted on the NJR website to allow surgeons to access more detailed information regarding their performance and make recommendations to the NJRSC for consideration** **As an advisory body to the DH the NJRSC should recommend that the NJR be made mandatory, and that the Chair pursue this through appropriate channels** **4.3 Draft Procedure for Handling Potential Outlier Performance (Surgeon)** EY presented a further draft of the procedure for handling outlier performance which had been updated to take account of learning from handling the recent outlier scenario (item 4.1 above refers) It was felt that reference to the surgeon being 'requested to confirm whether NJR data is correct'-Stage 8-Detail, should be deleted from the process It was also agreed that NJR responsibility as outlined in Stages 10 and11 i.e. to notify the CEO and Surgeon, and request confirmation that an audit had been undertaken, was appropriate. The importance of timing between Stages 8-10 was considered crucial. PH confirmed the general support of the RCC's for the procedure, but it was noted	**PH** **JM/AC NJRSC** **NJRC** **NJRC** **BD/EY**

	by MP that most surgeons had no knowledge of this outlier process, and as such communicating the procedure would be vital to gaining acceptance. The Chair noted that Steve Cannon, BOA President, had supported the handling of the recent outlier scenario, using the 'interim' procedure, and he would contact him for advice about communication to the profession, and the possibility of a joint approach between the BOA and NJR. The Presidents of the BHS and BASK would also be advised. KT mentioned that he had been requested to write an article for the BOA newsletter, BONNE, which would also provide an opportunity to mention the outlier process. The Chair agreed, but requested that this be deferred pending discussion with the BOA President. **Agreed That:-** **The NJRSC approve the draft outlier performance procedure with requested amendment to Stage 8, and recognition of the timetabling of Stages 8-10. .** **The Chair would arrange to meet with Steve Cannon, BOA President, regarding a joint communication to the surgeon profession, after which KT would include reference to the outlier process in his article for BONNE.** **The BHS and BASK would be notified** **4.4 Procedure for Handling Potential Outlier Performance (Device)** MB enquired about a further draft of the procedure for handling outlier performance of devices. EY reported that the NJRSC had approved this at their last meeting, pending amendment to include reference to the MHRA informing the manufacturer. AC raised an additional issue requiring resolution prior to agreement of the procedure. This related to data confidentiality when the MHRA notified a manufacturer of a potential outlying prostheses, in order to protect the identity of the surgeon who had experienced problems with the relevant component(s) It was accepted that a manufacturer would require this information to investigate an outlying device, and the Chair requested advice from surgeon NJRSC members about the release of this information. It was agreed that in an outlier scenario, the manufacturer should be given the identity of both unit and surgeon to facilitate an investigation, but the information should be treated in strictest confidence. **Agreed to:-** **Approve the procedure for handling outlier performance (device), pending amendment to reflect MHRA disclosure of unit and surgeon identity to a manufacturer.** **Forward the amended document to MB for information of the ABHI**	**BD** **EY** **EY/MB**

5	**Bulk Upload** The NJRSC considered a business case and request for funding, in respect of changes to bulk upload, which would improve the facility. It was noted that to phase out MDSv2, bulk upload needed to be redeveloped for MDSv3, that Bluespier had confirmed they would redevelop their system and participate in the project at their own expense, and that the production of an interface would be provided to all suppliers for integration with their systems. Project costs were queried, namely the project manager rate. The NJRC confirmed that the work required specialist resource in addition to core contract provision. **Agreed:-** **To approve the business case, and associated funding of £91,227 (incl of VAT), for re-development of bulk upload;** **That the NJRC would produce an explanation of what would be provided to suppliers.** **That the NJRC would e-mail the NJRSC to explain how bulk upload would work within MDSv3, for communication at local level.**	 **NJRC** **NJRC**
6	**MDSv3** CH reported implementation of MDSv3 on 30 November 2007. She noted that 50% of operations were now being entered via MDSv3, and that unit feedback had been positive. Approval was sought for the addition of a "not available/not known" option within the following mandatory data fields, to facilitate the ease of accurate data entry: a. Knee flexion- Data often unavailable in patient notes. b. Component brand removal.- Identification of brand often difficult. c. Primary hospital location/primary operation date.- Data often un available. **Agreed:- By the NJRSC to accept the changes, subject to agreement by the RCC Network at their 7 February meeting**	 **RCC/ NJRC**
7	**NJR Data Entry Issues** CNe presented a paper on the issues surrounding data entry, as requested by the RCC Network, which was noted and accepted. The Chair considered that information relating to the assessment of compliance factors, could be used to support the case for mandating data entry to the NJR.	
8	**NJR 5th Annual Report 2008/09** It was accepted that the 5th Annual Report should focus on the following four topics with supporting data posted on the website: a. Survivorship of conventional hip replacement by bearing surface (metal/poly, ceramic/poly, metal/metal, ceramic/ceramic) b. Extension of last years work on unicondylar knees and resurfacing prostheses to a later timeframe c. Early results of total hip and knee re revisions, with the length of stay for both procedures, to include causes and revision cohort.	

	d. Examination of admissions for VTE events following hip/knee replacement **Agreed:** **That the NJRSC would review initial work at their meeting on 23 April**	**NJRC**
9	**Quarterly Statistics Report Q3 (October – December 2007)** The Quarterly Statistics Report Q3 (1 October to 31 December 2007) was received and noted, with the compliance rate for 2007 confirmed at 91%	
10	**Quarterly Management Report Q3 (October – December 2007)** The Quarterly Management Report Q3 (1 October to 31 December 2007) was received and noted.	
11	**NJR Finance Report (April – December 2007)** The NJR Quarterly Finance Report (April – December 2007) was received and noted, but deferred for further discussion within the afternoon workshop session.	
12	**Any Other Business** **12.1 Information Governance** The NJRSC accepted details about how the NJRC complied with handling, storage and transfer of sensitive data, but noted that these arrangements should also apply to all NJRC sub-contractors. **12.2 Collaboration with European Registries** AM proposed that the NJRSC consider greater collaboration with existing European Registries, or countries requiring assistance to start a Registry. **Agreed:- That AM would prepare a paper on the implications of such collaboration, to include original documentation from Gerold Labek, Head of the European Arthroplasty Registry, for further consideration by the NJRSC** **12.3 NJRSC Agenda Items.** The Chair invited all NJRSC members wanting an item included on the agenda, to make their request through the appropriate channels.	**NJRC** **AM** **NJRSC**
	AGENDA: PART 2	
13	**Risk Register** The Chair explained that the revised Risk Register was now set up to reflect risks for the NJR/NJRSC rather than solely for the NJRC. Members identified the following potential NJR risks for inclusion in the register; a. False/positive identification of 'outliers' - Poor perception of NJR data quality; b. Non-mandatory NJR compliance-Difficult to achieve 100% data input and unit funding for appropriate data input staff; c. Data Protection/Loss - Protection arrangements confirmed (see agenda Item 12.1 Information Governance), back up support undertaken nightly by the NJRC, and information stored off site within a secure environment; d. Change to status of NJR contractor (financial/merger) - Northgate assurance about their recent merger with KKR;	

	e. Transfer of NJR management from the DH to a new provider, 'Healthcare Quality Improvement Partnership' f. Lack of funding support for the NJR; g. Change of government/abolishment of the NJR; h. Lack of belief in the NJR - Positive high profile vital for the NJR; i. Meeting supplier expectation; j. Frequency of NJRSC meetings- Quarterly NJRSC meetings unable to deal with detail of all issues. NJRSC sub groups to be convened as appropriate; k. Handling of Outliers - Agreed procedures to be constantly reviewed **Agreed:-** **That the NJRC would incorporate the identified risks into the Register and circulate to NJRSC members for further review and comment, in advance of the next NJRSC meeting, when the updated version would be given additional consideration.**	**NJRC/ NJRSC**
14	**NJR Work Priorities and Expenditure** NJRSC members participated in a workshop, facilitated by Gerard Hennessy, Head of People Development, DH, ,to consider short, medium and long-term NJR priorities, and identify expenditure for funding before the end of the financial year. The following ideas were proposed:- a. Improve Data Quality, to include: CUSUM and development of continuous monitoring; dynamic publication of data on the website for stakeholders; audit of accuracy of data entry into the NJR; facility for smaller outcome studies b. Improve stakeholder Communication/Engagement/Information c. Resource research programmes independent of Annual Report, d. PROMS study on revision and whether the patient benefited.. e. Incorporate ankles, elbows and shoulders into the NJR database (when practical) f. Include Northern Ireland (NI) into the NJR database g. Support and fund a study of the biological implications of metal on metal articulation in total hip replacement (as agreed by the Chair at a recent meeting with the MHRA/BOA) . **Agreed:** **To support the listed proposals with the following priority;** **Short/Medium Term: Data Quality/Continuous Monitoring** **Feedback/Information to Stakeholders** **Metal on Metal study** . **Inclusion of NI into the NJR** **Longer Term: Hip Owners Manual** **Inclusion of other joints into the NJR** The Chair thanked Gerard Hennessy for facilitating the session.	**/**
15	**Election of NJRSC Vice Chair** The Chair proposed PG for a further one-year term of office as NJRSC Vice Chair, and this was seconded. No other nominations were received, and PG was confirmed in post for a further year, from the 1 February 2008 to 31 January 2009.	

16	**Date and Time of Next Meeting (previously notified)** Wednesday 23 April 2008 (10.30am - 4.00pm). N.B. Agenda to include a review of initial work on the 5th Annual Report. MP and KT requested the meeting be rescheduled, as they would be unable to attend due to commitments at the London HIP meeting on the 23 April.The Chair moved to maintain the scheduled date, on behalf of other NJRSC members who had the meeting date diarised. **Agreed:- That PG would liaise with MP and KT regarding their input.**	**PG**
17	**NJRSC Meeting Schedule 2008/09** **Agreed:-** Thursday 24 July 2008. (Agenda to include review of the 5th Annual Report) Tuesday 21 October 2008. Thursday 29 January 2009.	
	The meeting closed at 4.00pm. The Chair acknowledged Kirsty Smith's departure, conveying best wishes for the future, and thanking her for her contribution and attention to detail	