National Joint Registry
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NATIONAL JOINT REGISTRY STEERING COMMITTEE (NJRSC)

APPROVED MINUTES

Meeting: NJR Steering Committee **Date:** Wednesday 23 April 2008
Location: MLS Venue, 130 Shaftsbury Avenue, London W1D 5EU

Present:	Bill Darling	BD	Chair
	Prof. Paul Gregg	PG	Vice Chair, Orthopaedic Surgeon Member
	Mick Borroff	MB	Orthopaedic Device Industry Member
	Patricia Cassidy	PC	Independent Healthcare Sector Member
	Patricia Durkin	PD	Patients Representative Member
	Colin Esler	CE	Regional Clinical Coordinators
	Allan Hidderley	AH	Medicines & Healthcare Products Regulatory Agency (MHRA)
	Alex Macgregor	AM	Public Health and Epidemiology Member
	Carolyn Naisby	CN	Practitioner with Special Interest in Orthopaedics Member
	Martyn Porter	MP	Orthopaedic Surgeon Member
	Dean Sleigh	DS	Orthopaedic Device Member
	Andrew Smallwood	AS	NHS Supply Chain
	Keith Tucker	KT	Orthopaedic Surgeon Member
	Andrew Woodhead	AW	NHS Management Member
	Elaine Young	EY	Healthcare Quality Improvement Partnership
	Richard Armstrong	RA	Northgate Information Solutions Programme Director
	Charlotte Humphry	CH	Northgate Information Solutions, Programme Manager
	Martin Pickford	MPi	Northgate Information Solutions, Orthopaedic Advisor
	Mike Swanson	MS	Northgate Information Solutions, Principal Consultant
Apologies:	Mary Cowern	MC	
	Andy Crosby	AC	
	Peter Howard	PH	
	Martyn Porter	MPo	Attending p.m.

REF	ITEM	ACTION
	AGENDA	
1	**Welcome and Apologies for Absence** The Chair opened the meeting at 10.30am. He welcomed Dean Sleigh to his first NJRSC meeting as the new orthopaedic device industry member, and Alan Hidderley, MHRA, who would be temporarily representing AC. Apologies were received and noted.	
2	**Minutes of the Previous Meeting** The minutes of the meeting held on Thursday, 31st January 2008, were approved as an accurate record.	
3	**New NJR Management Arrangements** The Chair confirmed that the new management arrangements for the NJR, which had been previously reported, had become effective from 1st April 2008. It was noted that responsibility for the NJR had now transferred from the Department of Health to the Healthcare Quality Improvement Partnership (HQIP), a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing, and the Long Terms Conditions Alliance. This reflected new contract arrangements for the National Clinical Audit and Patients Outcomes Programme which had been expanded to incorporate the NJR. A National Clinical Audit Advisory Group had also been created to be Chaired by Nick Black, Professor of Health Services Research, London School of Hygiene and Tropical Medicine. The Chair advised members that he would be meeting Dr Paul Lelliott, Chair HQIP, the following morning, and would keep members informed of the outcome of discussions.	**BD**
4	**Reorganisation of NJRC Roles and Responsibilities** RA reported that Northgate Information Solutions had been wholly acquired by a private equity company, KKR, in March 2008. As a result, Northgate was no longer listed on the London Stock Exchange, but the acquisition would not result in any change to the way it was managed or undertook its business, and would not affect the NJR. RA also stated that he would be resuming his role as Programme Director for the NJR contract, replacing Kathryn Lehner, who would remain responsible for IT service delivery.	
5	**Matters Arising (not appearing elsewhere on the agenda)** **5.1 Supplier Information – Brand Usage (prev. min. ref 3.2)** EY confirmed DH Legal advice, previously circulated to members, which indicated that there were no legal issues with providing implant manufacturers and suppliers with information about the usage of their own prostheses. **Agreed: To implement the reports which could be accessed, via NJR ReportsOnline**. **5.2 Hip Owners' Manual and Patient Information (prev. min. ref 3.3)** It was noted by EY, that she would be taking over this issue from AMc, who had advised that she had been unable to make further progress due to technical difficulties with amending the original document, and as such had been unable to circulate the working group with a revised copy as agreed. **Agreed: By MPi to provide details of the organisation responsible for the original manual, and that EY would liaise with the NJRC to progress this matter.**	**NJRC** **EY/NJRC** **MPi**

5.3 Consent (prev. min. ref 3.4)

EY reported that there was no generic NHS consent form, and therefore arrangements must be made at local level to incorporate the new NJR consent wording into general consent forms. CH confirmed that RCs were advising units of the revised consent wording, and working with those units that wished to incorporate it into their local forms. The wording had also been publicised in the Spring edition of the NJR newsletter.

5.4 PROMS (prev. min. ref 3.7)

It was reported that BD, PG and EY had met with David Nuttall (DN), DH Corporate Analytical Team, to discuss the DH PROMs study in more detail. BD noted that PG had confirmed that his initial concerns had been addressed by DN.

DN had confirmed that the study would include Oxford Hip and Knee scores and that data would be collected pre-operatively and post-operatively at 6 months. Data collection for the study would be voluntary in 2008/09 and mandatory in 2009/10. PG confirmed the benefits for the NJR which would be able to access this data and link to further NJR PROMs work.

Assurance was sought that the NJR funding contribution would only be used for those aspects of the study relating to hips and knees, and that the NJR would have access to the resulting data, and input into the questions included on the patient questionnaires.

CE felt that the DH study did not address the quality of surgery or enhance the NJR's profile.

AM enquired if there was still time for the NJRSC to influence the DH study, and felt the NJRSC needed more detail about the study plan and the intended outputs. This was supported by MB who stated that the Swedish Registry used EQ5D and Quali outcomes in order to determine the cost effectiveness of patients' whole life quality following hip and knee replacement surgery.

BD confirmed that he would raise the issue with Dr Lelliot, HQIP, and suggested that it would be helpful to have a written response from DN regarding the NJRSC concerns.

Agreed that: EY would write to DN regarding the concerns of the NJRSC, and request a written reply for notification to members. **EY**

5.5 Redevelopment of Website (prev. min. ref 3.9)

CH reported that the new NJR website had gone live on 16 April, and thanked members who had provided input into the design and content review process, notably PD, MC and EY. Members were invited to visit the website and notify any comments to the NJRC

5.6 Bulk Upload (prev. min. ref 5)

CH reported that redevelopment of the Bulk Upload capability was in its final stages, with completion of the interface the following week. A period of development by the application supplier would follow. The NJRC would liaise with them during integration testing. **NJRC**

5.7 MDSv3 (prev. min. ref 6)

CH reported that initial problems with MDSv3 had been resolved and approximately 75-80% of all submissions were now being made using MDSv3. Changes to the dataset, agreed at the previous RCC meeting, relating to 'Knee Flexion', 'Component Brands Removed' and 'Primary Hospital Details' had been scheduled for delivery within the following two weeks.

5.8 NJR Work Priorities and Expenditure Update (prev. min. ref 14)

a. **Inclusion of Northern Ireland -** BD reported that a letter was due to be sent to the Chief Medical Officer, Northern Ireland.

b. **Metal on Metal -** BD reported that the BOA President, and MHRA had expressed their appreciation of the NJR's input and financial contribution into the study of metal on metal hip articulations. A working group had been established to support the MHRA study and

	would call on specialist expertise as required. MPi noted the value of the NJR to this study because it had the largest data base in the world on re-surfacing c.**Inclusion of Ankles/Elbows and Shoulders -** BD reported that professional organisations concerned with elbow, shoulder and ankle replacement surgery had expressed the desire to join the NJR. PG reported that he was aware that the British Elbow and Shoulder Society (BESS) had written to BD and the BOA President, although BD stated that he had not received a letter. It was also noted that PG had been contacted regarding the possible inclusion of wrists into the NJR. **Agreed: That wrists should be included in the NJR, and the NJRC would approach BESS about a copy of their expression of interest.**	**NJRC**
6	**Outliers** **6.1 Outlier Procedure-Stakeholder Communication** BD reported that PG, EY and himself had met with Steve Cannon (SC), BOA President, to discuss communication of the outlier process to the orthopaedic profession. Unfortunately it had not been possible to convene this meeting in advance of the British Hip Society conference, so information could not be formally presented at this event. SC had agreed to a joint communication from BD and himself, to explain the outlier process. However he felt that the full statistical methodology was too long and complex for general circulation to surgeons, and that a one-page summary would be more appropriate for inclusion in a joint NJR/BOA letter. PG agreed to draft an 'executive summary' for this purpose, and the full statistical methodology would be posted on the web site..(min 6.2 below refers) AW noted that the role of the BOA, and assistance of SC, had been crucial to agreeing the outlier process. This view was supported by BD who expressed his appreciation to SC. KT requested confirmation about SCs understanding of the outlier process, as recent correspondence from him had suggested a query about the timing of the involvement of the CEO in the process. Although it was felt that this appeared to contradict SCs verbal understanding and support, it was agreed to seek clarification. **Agreed:** **That clarification be sought from SC about timing of the CEOs involvement and the NJRC would be advised about the detail/timing of posting the statistical methodology on the NJR web site.** **That PG would draft an 'executive summary' of the statistical methodology, and forward to SC for inclusion in the BOA/NJR communication to surgeons.** **That BD/EY would liaise further with SC regarding the communication process.** **That manufacturers would have access to record level date when advised of a potentially outlying prosthesis following receipt of an adverse incident report from MHRA.** **6.2 Statistical Methodology for Monitoring NJR Outliers** The revised statistical methodology for identifying potential outlier performance was discussed, in conjunction with a draft 'executive summary' of the methodology from PG. It was agreed that the full methodology required further redraft to reflect terminology used in the 'executive summary'. Support was also given to a suggestion from KT, that the re-drafted methodology should include examples, and be 'trialled' on selected surgeons, prior to being posted on the web site, and communicated to the profession. **Agreed:** **That the full statistical summary would be re-drafted to reflect the executive summary, and then circulated to the NJRSC with a 7-day turnaround for final comment.**	**EY** **PG** **BD/EY** **NJRC**

	That BD/PG/EY review any final amendments prior to posting the document on the NJR web site.	**BD/PG/EY**
	That PG/KT/MPo obtain informal feedback from surgeon colleagues prior to communication with the wider profession.	**PG/KT/ MPo**
	6.3 Draft procedure for handling Outlier performance-Device MB reported that he had consulted with colleagues about the process, which was agreed in principle, subject to the MHRA specifically notifying suppliers and providing them with the names of the trusts and the affected devices. It was noted that this would be picked up by the Adverse Incident Reporting Procedure. Concern remained about what NJR and unit data suppliers would have access to in order to carry out an investigation, and MB requested written assurance, that relevant data would be available when required. BD advised that the MHRA were still looking at the issue of supplier access to patient data held in units.	
	Agreed: By MB, that he would table the outlier process at the next meeting of the ABHI Orthopaedic Specialist Interest Section (OSIS) on the 8th of May, and report back to EY.	**MB**
	6.4 Recent Outlier Scenario (non agenda item) The Chair advised that information had been received which suggested that the recent handling of a potential outlier had resulted in a suspension pending further investigation. This had been followed up and found to be untrue. KT suggested that those surgeons who had been approached should be contacted informally to obtain their feedback on the process, and how it had been handled. It was agreed that this would provide valuable learning.	
	Agreed: That the NJRSC surgeons would request informal feedback from those surgeons they originally contacted when the outlier process was implemented.	**PG/KT/ MPo**
7	**NJR Data Feedback for Clinicians** RA presented the business case for implementation of a software application that would enable surgeons to measure and compare their performance against a number of regional and national benchmarks. He noted the suggestion to show compliance rates when presenting the information and thanked PG, KT, MPo and PH for their support and comments. Subject to NJRSC approval, it was planned to launch the new capability at the BOA Annual Congress in September. It was agreed that this should be implemented, as it represented a significant development in the quality of data available to clinicians, and would be welcomed by the profession. The potential impact for clinical practice was also recognised. In addition, provision of this data supported the NJR Outlier Process, as it would enable clinicians to view their data within a funnel plot, and assess how this changed over time, thus providing early visibility of any untoward trends. It was considered vital to ensure the continued involvement of the NJRSC clinicians and RCCs in developing and implementing the application. It was noted that RCCs would receive the same presentation at their meeting the following week, and RA confirmed he would continue to liaise with NJR clinical members. CE agreed to provide an update to the next BOA Council meeting, and RA offered to either attend or send CE his presentation. Discussion ensued about the associated costs of the development, and it was recognised that this could either be funded from surplus levy, although this had not been realised for 2008/09, or the NJR Contract development fund. EY confirmed that HQIP would need to be advised of this expenditure commitment.	
	Agreed:	
	To approve the business plan, and that EY would confirm funding.	**EY** **RA/NJRC**

	That the NJRC would ensure continued clinical involvement with development of the application and ensure that it would be operational by 1 September, and officially launched at the BOA conference 16-19 September. **That CE would notify the BOA Council.**	**CE**
8	**Correspondence from Peter Kay, President, British Hip Society-(Non agenda item)** BD circulated a copy of a letter he had received from Mr Peter Kay (PK), President, British Hip Society (BHS), and expressed his disappointment with criticism relating to NJRSC membership, and the apparent misunderstanding about planned NJR development work which PK had been made aware of. Regarding the constitution of the NJRSC, specifically the lack of surgical representation, BD drew attention to the view of the Chief Medical Officer, that the NJRSC should be as representative as possible. Whilst he recognised that the number of surgeons had reduced by one under the new constitution, this had been balanced by his decision to co-opt the NJR RCC Network Chair onto the committee. PG confirmed that surgeon representation on the NJRSC and RCC Network, ensured clinical expertise and opinion was available to the NJR. CE drew attention to the importance of also ensuring representation from the specialist surgical societies covering hip and knee surgery. BD responded that the NJRSC Constitution did not permit the appointment of members from specific professional organisations but as an example Mr Tim Wilton, ex NJRSC clinical member, had agreed to be the unofficial link between the NJRSC and the BOA, and was provided with NJRSC papers for this purpose. BD concluded that the NJRSC had made every effort to retain the goodwill of the surgeons, and he was now concerned about these written comments, which were misinformed and unhelpful to the NJR as it entered a new phase of development. **Agreed:** **That BD would respond formally to PK.** **That PG would ensure that Mr Wilton received NJRSC information.**	**BD** **PG**
9	**NJR 5th Annual Report 2008/09** CH reported that a project manager, David Emsley, had been appointed to manage the production of the 5th Annual Report, and the first draft of Part 1 was almost complete. MPi reported that some of what had been included in Part 2 of the 4th Annual Report would be published on the NJR website rather than included in the printed document. This related to those areas where only numbers, rather than analysis, was being presented. He was confident that the increasing quality of the data submitted to the NJR would result in some excellent results from the analysis. He also reported that mortality of revisions would be included although the emphasis was on the production of survivorship curves. This would be included in the analysis of hip and knee revisions. With regard to the analysis of mortality, thromboprophylaxis, and the incidence of VTE, PG expressed concern that the Royal College of Surgeons Clinical Effectiveness Unit (RCSCEU), had already undertaken work in this area using linked HES/NJR data, and that the work for the Annual Report was duplicating this effort. The NJRC stated they were unaware of this work, but confirmed they would liaise with the RCSCEU who they had sub-contracted to undertake analysis for Part 2. **Agreed: That the draft Annual Report would be reviewed at the July NJRSC meeting but consultation on report sections would be undertaken as they were completed.**	**NJRC**
10	**Information Data Sharing Protocol** EY requested approval of the Information Data Sharing Protocol, previously reviewed by the NJRSC, and now amended to incorporate DH legal advice A minor adjustment was requested to an incorrect date identified on page 13. MB suggested that the protocol should include a paragraph relating to the provision of	

	information for investigating potential outlier scenarios. AM enquired about the process for approving data requests. EY outlined the process which was currently used, and involved initial review by the NJRC before submission to the DH/HQIP for final approval. All data requests were made on a pro-forma which ensured that particular details about the request were provided. EY advised that NJR data requests had been handled in this manner for some time. AM requested that any documentation about this process be circulated to the NJRSC for information. PG supported straightforward data requests being processed this way, but requested that any that raised concerns should be referred to himself and BD, and those relating to research should be subject to peer review. AM suggested that a request for data for research should comply with NJR research aims and include an obligation to feedback information to the NJR. EY pointed out that currently there was no agreed NJR research strategy or clearly defined NJR research objectives so this needed to be addressed. MPi reported that he would provide a copy of a draft policy for dealing with research requests that had been prepared by Momenta the previous NJR contractor. **Agreed:** **To approve the Information Data Sharing Protocol amended to take account of the points raised.** **To circulate details of the process for approving NJR data requests.** **That a research strategy was required and that MPI would circulate a copy of any draft to the NJRC and EY.**	**NJRC** **NJRC/EY** **MPi**
11	**Service Charter** RA presented a proposed 'NJR Service Charter', which outlined a charging mechanism for the management of the data request service, in line with current policy from the NHS Information Centre. He detailed how charges would be made, explaining for example that it would be inappropriate to charge a hospital requesting an extract of the data they had submitted, and this would be provided from the core NJR service. However in other cases such as a commercial organisation undertaking research, it was not appropriate for the NJR to subsidise such requests, and a charge would be levied commensurate with the resource effort required to meet such a request. EY emphasised the importance of applying charges appropriately, and suggested that implementation of the Charter required careful management, monitoring and regular review. BD proposed that the Charter be accepted on this basis, and reviewed after 12 months.. **Agreed: To approve the NJR Service Charter, subject to explicit exclusion of charges relating to units requesting their own data, and review after 12-months.**	**NJRC**
12	**Risk Register** The updated Risk Register was noted and approved.	
13	**Collaboration with European Registries** AM requested the NJRSC to consider the development of formal collaboration with the European Arthroplasty Registry (EAR). Referring to correspondence from the EAR he noted their enthusiasm for collaboration with the NJR, and suggested potential benefits as follows: ▪ The ability to undertake comparative research; ▪ The ability to share information about implants; ▪ The ability to have some influence on European policy; ▪ Potential funding from the EU and ▪ Increasing the influence of the NJR. It was noted that previous requirements for the NJR to conform to European data standards	

	had been dropped, and only dialogue with the NJR was now being requested. PG confirmed that previously he had not supported the issue of standards, but considered that there would be merit in dialogue with the EAR. CE stated that he had attended a meeting of the European Registries whilst at the American Academy. He felt that there were no immediate benefits to be gained by joining, but acknowledged that there may be in the future. **Agreed: To support dialogue with the EAR with the proviso that there would be no further consideration of any changes to NJR data standards, and that progress with collaboration be kept under review.**	
14	**Quarterly Statistics Report Q4 (January - March 2008)** The Quarterly Statistics Report Q4 (1st January – 31st March 2008) was received, and the following points noted; Compliance: 95% (year ended 2007/08 and calculated using levy returns), consent: 86.5% and linkability: 78.6%, were the highest recorded rates to date, as was the level of data submission and the proportion of records submitted with an NHS number. PG noted that 95% compliance meant that approximately 5,000 procedures/year were not being reported. HES data for the last quarter was not yet available.	
15	**Quarterly Management Report Q4 (January – March 2008)** The Quarterly Management Report Q4 (1 January - 31 March 2008) was received and noted. In response to PG's query about action to encourage non-compliant units, the NJRC reported some progress by Regional Coordinators who named poor staffing levels and financial restraints as two major factors for non-compliance. CE mentioned that the RC reports to the RCC Network were useful in highlighting these issues. EY confirmed that the NJRC were compiling information about non-compliant units so that a letter could be sent from the NJRSC Chair to relevant CEO's. Members also suggested a higher level approach to the NHS Confederation and/or SHAs/PCTs, with a view to gaining support for the inclusion of NJR compliance in service contracts. BD noted NJRSC agreement that the NJR should be mandatory. **Agreed: That a letter be sent from the NJRSC Chair to CEOs of non-compliant Units and that progress from this action be monitored in the first instance before further escalation options were considered.**	**EY/BD** **NJRC**
16	**NJR Finance Report (April 2007 – March 2008)** The NJR Quarterly Finance Report (1 April 2007 – 31 March 2008) was received. The year end surplus was noted .BD stated that he would prefer the levy charge to remain unaltered so that funding was available in year 2008/09 for ongoing development of the NJR. He noted that he would raise this with the Dr Lelliott, HQIP. EY commented that the levy was due for review, and the NJRSC would be required to consider this.	
17	**Research Requests** The Chair noted, that due to a delay in acknowledging their data requests, he had spoken to Mr Stockley and Mr Timperley to confirm they would be considered by the NJRSC. **17a Request from Mr I Stockley, Consultant Surgeon** **Agreed: To inform Mr Stockley that subject to confirmation of ethical committee approval, and the submission of a detailed research protocol to the NJRSC the data could be provided.**	**NJRC**

	17b Mr Timperley, Consultant Surgeon MPi reported that his understanding of Mr Timperley's request, based on their discussions at the BOA, was that the provision of data was not the issue, but rather who funds and undertakes the work. **Agreed: To thank Mr Timperley for raising several valid points ,and request further suggestions to enable the NJRSC to properly assess the feasibility of his request.** **17c Ms Charlotte Davies, PhD Student** It was noted that precise data requirements had not been defined in the request from Ms Davies, nor had any indication of time limits. It was also likely that ethical approval would be required. **Agreed: That the request should be re-submitted to the NJRSC once AM had clarified the research objectives and timescales, and the NJRC had confirmed the data required.**	**NJRC** **AM/NJRC**
18	**Any Other Business** **18.1 Orthoconsent Forms** MS outlined a request from Orthoconsent to use the NJR logo and consent wording on their consent forms. It was noted that Orthoconsent forms carried the BOA logo, and their website was sponsored by Finsbury Orthopaedics, a manufacturer and supplier of orthopaedic implants. It was felt that the NJR logo should only appear in a box with the NJR consent form. **Agreed:** **To circulate Orthoconsent forms to the NJRSC, with request for comment within 7 days.** **That pending any objections, Orthoconsent would be granted permission to use the NJR consent wording and logo, with the proviso that the logo only appeared next to the NJR consent text.** **18.2 Data Requests** PG requested a summary of all data requests received by the NJRC	**NJRC** **NJRC**
19	**Date and Time of Next Meeting (previously notified)** Thursday, 24th July 2008 The draft 5th Annual Report would be reviewed	
	The Chair closed the meeting at 15.30 hours.	