National Joint Registry
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NATIONAL JOINT REGISTRY STEERING COMMITTEE (NJRSC)

MINUTES

Meeting: NJR Steering Committee **Date:** Wednesday 24th October 2012
Location: Burroughs Room, Wellcome Collection, 183 Euston Road, London, NW1 2BE

Members Present:	Laurel Powers-Freeling	LPF	Chair
	Prof Paul Gregg	PG	Vice Chair / Orthopaedic Surgeon
	Mick Borroff	MB	Orthopaedic Device Industry Representative
	Mary Cowern	MC	Patient Representative
	Dr Jean-Jacques de Gorter	JG	Independent Healthcare Sector Representative
	Prof Alex Macgregor	AM	Public Health & Epidemiology
	Martyn Porter	MPo	Orthopaedic Surgeon
	Carolyn Naisby	CNa	Practitioner with Special Interest in Orthopaedics
	Dean Sleigh	DS	Orthopaedic Device Industry Representative
	Keith Tucker	KT	Orthopaedic Surgeon
	Andrew Woodhead	AW	NHS Management Member
Attendees:	Richard Armstrong	RA	Programme Director, Northgate
	Rebecca Beaumont	RBe	NJR Communications Lead, Healthcare Quality Improvement Partnership (HQIP)
	Paul Dieppe	PD	Bristol
	Alex Henderson	AH	Committee Administrator, HQIP
	Peter Howard	PH	Chair, NJR Regional Clinical Co-ordinators' Network
	Khalid Razak	KR	Medicines and Healthcare Products Regulatory Agency (MHRA)
	Robin Rice	RR	Welsh Government Representative
	Mike Robinson	MR	Research Officer (NJR), HQIP
	Peter Rottier	PR	Northgate
	Andy Smallwood	ASma	NHS Procurement Representative
	Mike Swanson	MS	NJR Principal Consultant, Northgate
	Melissa Wright	MW	Development Officer (NJR), HQIP
	Elaine Young	EY	National Development Lead, HQIP
Apologies:	Ashley Blom	AB	Bristol
	Robin Burgess	RBu	Chief Executive Officer, HQIP
	Dr Crina Cacou	CC	MHRA
	Sue Musson	SM	Patient Representative

REF	ITEM	ACTION
1	**Welcome and Apologies for Absence** LPF opened the meeting and welcomed those present. Apologies were noted.	
1.1	**'Implant Scandal' News Headlines** Following a recent publication highlighting an undercover investigation by the British Medical Journal and The Daily Telegraph, which had exposed loopholes in the EU system to approve devices, it was noted that 'Beyond Compliance' – an initiative to improve post market surveillance – was due to be implemented by the BOA/MHRA/NJR to improve device monitoring and regulation. [Item 3 below refers.]	
2	**Minutes of the previous meeting held 24th July 2012** The minutes were accepted as a true and correct record.	
3	**'Beyond Compliance' [BC]** KT briefed members on the proposed BC process as follows: a. Data would be uploaded at unit level as per the entry process for NJR data. b. The NJR database would recognise the BC device and deposit into a separate BC repository which would store a range of data including PROMs, x-rays. c. A BC Scrutiny Group would advise on risk, rate of introduction to market, and review results. d. The BC initiative would be a separate bolt-on system linked to the NJR database. e. The NJR would not be responsible for the initiative, which was being led by the MHRA and the BOA, but would be represented on the BC Steering Committee. f. Northgate would run the system as a service that users would pay to use. g. A pilot study was being arranged, with manufacturers eager to participate. h. The BC initiative would not be mandatory, but it was anticipated that if successful, it had the potential to become mandatory, as with the NJR. i. Patient consent for the initiative would be the responsibility of the hospital surgeon. It was suggested that it would be useful for the patient to be given a card when they provided their consent stating that if they had a revision done at a different hospital, the other unit should upload the data. j. Initially the initiative would be run without PROMs data pending further discussion.	
4	**Matters Arising** It was noted that a report updating members on matters arising from the previous meeting had been previously circulated for information (see appendix).	
5	**NJR Structure and Governance Review** LPF reported that the DH had confirmed the status reclassification of the NJRSC from 'Advisory Non-Departmental Public Body' to 'Departmental Expert Committee', effective from the 22nd October 2012. Members reviewed the outcomes from the NJR Structure and Governance Review Workshop held in July, and EY presented three draft structure options for consideration. The following was noted/discussed: a. <u>Resources</u> Development of the NJR meant that core workload now exceeded available resources and needed to be addressed. b. <u>Roles and Responsibilities</u> • Executive and Non-Executive roles should be clearly defined. • Chairmen of Sub-committees should be Non-Executives. • Succession planning was paramount as some members involved with multiple sub-committees, had terms of office due to expire. c. <u>Executive Committee</u> An Executive Committee should be created to support the work of the NJRSC. d. <u>Devolved Administrations</u> The NJRSC status change should not affect how the NJR process worked for Wales, and in future Northern Ireland, and decisions and communication should reflect geographical differences.	

	e. Future Representation The RCC Network could provide a forum where additional joints and geographical locations could be represented, rather than increasing the size of the NJRSC. f. Sub-Committees • The sub-committees were working well, but needed to interact more. • The recently established Patient Forum was valued. • The future of the Editorial Board required further consideration. • The current arrangement of the two individual Implant and Surgeon performance sub-committees worked best, but it was recognised that greater interaction between the two would be beneficial i.e. possibly combining for two meetings a year to discuss overlapping issues. It was noted that the Implant Performance group also encompassed the Scrutiny Group, although members queried why the NJR (a non-regulatory body) managed this when it would perhaps be a more appropriate role for the MHRA. • The Data Quality Working Group should continue to exist but have a defined role that was more closely aligned with the outlier groups. **Agreed: LPF/EY would discuss these proposals with DH and work on new arrangements based on an Executive and Steering Committee.**	**LPF/EY**
6	**Clinician Feedback [CF] Phase 2 Development** EY noted that the current CF system had not been upgraded since 2009, and required further development to ensure that it continued to meet stakeholder expectations. PR mentioned that Supplier Feedback currently allowed manufacturers greater access to information in some areas than clinicians, in particular identifying which patients had undergone revision. He outlined the following suggestions to upgrade the CF system: a. Enhancing existing functions • 5 and 7 year survivorship to be added to the existing 1 and 3 years; • Include a funnel plot trail instead of only the most recent position; • Trainees to be able to view all units they had worked in on one screen, without having to look up individual units. b. New Features • Download Raw Data button to include current outcome status (unrevised, revised, deceased), which was currently laborious to access; • Surgeon Performance Report button that would produce a single surgeon standardised report that would be ideal for surgeon appraisal and include details of individual compliance, survivorship and funnel plot data. c. Ad Hoc Additional fields • Not currently provided. d. Future consideration • PROMS linkage. CUSUM PG enquired about progress with the development of CUSUM. EY confirmed that Bristol would be looking at continuous monitoring arrangements. PG suggested that the new Data Quality Group, which was being considered as part of the NJR restructure, could possibly take a wider remit in terms of what the NJR were doing with data. It was agreed that a meeting be convened with Bristol to discuss CUSUM. User Friendliness RR requested that the user friendly aspect of CF was improved as part of the development, as the majority of Welsh hospitals used Internet Explorer 6 which was one of the browsers that the interface did not support. Cost of CF Phase 2 development Northgate confirmed a cost of approximately £14,000 for the Phase 2 development.	

	Agreed: • **A meeting would be arranged with EY/PG and Bristol to discuss CUSUM.** • **Analysis work would be undertaken by Northgate on the Clinician Feedback V2, with involvement from EY, JJ, RR and PH (PH representing surgeon views). Enhancements to the current functionality were approved in principle. A proposal for any new developments to Clinician Feedback would be brought to January's NJRSC.**	**PG/HQIP Northgate/ HQIP**
7	**International Collaboration**	
7.1	**International Society of Arthroplasty Registries (ISAR) Conference 2013** KT outlined the provisional programme for the 2nd International Congress of Arthroplasty Registries which would be held 1st – 3rd June 2013 in Stratford-upon-Avon, and encouraged those who wished to attend to take advantage of the 'early bird' rate of £275. LPF stated that there would need to be a limit for the number of people the NJR would sponsor to attend the event. The provisional programme, submissions information and further details were available on the ISAR website: www.isarhome.org	
7.2	**Unique Device Identifiers (UDI)** KT reported on the news that the Food and Drug Administration had reported that all implants were to have a Global Trade Item Number (GTIN), with the aim that each implant could be traced to each patient. He reported that Johnson & Johnson (including DePuy) was involved with a UDI linked with GS1, and the International Consortium of Orthopaedic Registries (ICOR) was currently undertaking a UDI project led by Stephen Graves of the Australian Registry. EY confirmed that the NJR were currently working with Australia to undertake a provisional comparison of knee data held by both registers. **Agreed: The NJRSC would be kept informed of progress and any further work.**	**EY**
7.3	**a) Arthroplasty Watch** KT reported that he had been invited by Lars Lidgren to participate on an Advisory Board set up by Lund University, Sweden, to look at poorly performing joint replacements on an international basis and to provide an early warning system. **b) Swedish Meeting of Registries** KT reported that Goran Garellick had invited the NJR to contribute to a meeting 27th & 28th May called by the Swedish Ministry of Health and Social Affairs in Stockholm. To this meeting, representatives of health departments in all European countries had been invited. The study to which we were being invited to contribute was available. Personal participation by NJR members was not required. It was noted that the Swedish Registry had also contacted the NJR requesting information associated with this study. **Agreed:** • **KT would accept the invitation to participate on the Swedish Advisory Board.** • **HQIP would provide the information that the Swedish Registry had requested.**	**KT** **HQIP**
8	**Information Governance: NJR Data Access/Use**	
8.1	**Freedom of Information [FOI] Request and Information Commissioner** EY reported that an FOI request received from a firm of solicitors, and rejected for reasons of commercial sensitivity, had been referred to the Information Commissioner for investigation. **Agreed: EY would keep the NJRSC updated.**	**EY**
8.2	**Use of Supplier Feedback [SF]: Provision of NJR data analysis as part of procurement** Members noted that in June 2012, a request from DePuy for approval to submit an analysis of SF data, to support a tender submission, had been rejected by HQIP on the basis that it represented marketing. However MB and AS considered that this was an	

	appropriate use of SF which would enhance the procurement process and asked that the principle be given further consideration. **Agreed:** • **Data to be used for decision making as part of procurement within the UK healthcare environment, could be approved for use.** • **A standard template application form should be drawn up.**	 **MB/HQIP** **HQIP**
9	**NJR Finance Report Q2 (1st July to 30th September 2012)** The finance report was received and noted. LPF acknowledged the income and the expenditure variance with respect to the Lot 1 contract.	
10	**Update from the NJRSC Sub-Committees**	
10.1	**Regional Clinical Coordinators Network** Noted that PH would raise Clinician Feedback System and the Minimum Dataset at the next RCC meeting on 6th December.	**PH**
10.2 **10.2.1**	**Data Quality Working Group (held 10th October)** **Data Quality letters and process** It was noted that approximately 151 letters had been sent to Trusts in England, Welsh Health Boards and private groups, requesting they nominate an NJR data quality lead, but to date only 55 responses had been received. For Trusts that had not responded, a copy of the original letter would be resent to the Clinical Director, requesting them to respond to their RC by a prescribed date. Trusts that continued to fail to respond would be informed that data from their Trust that was put into the public domain would remain un validated and a list of non-responders would be included in future annual reports. For Trusts that had responded, an acknowledgement letter would be sent. Data validation work should commence in the near future with the nominated data lead.	 **HQIP/PG**
10.2.2	**Data Quality Audits** PG reported that following an earlier audit in South Tees to compare information entered onto patient forms compared to information entered on to the NJR database, Paul Baker had conducted a larger sample of 160 cases. Although the essential information was accurate, it appeared that the default technique on systems brought about inaccuracies if surgeons changed their thromboprophylaxis technique but not their default setting. MS confirmed that the default setting would be removed in the future. **Agreed: PG would ask Paul Baker to send his project paper to AM.**	 **N/Gate** **PG**
10.2.3	**Device Audit** EY reported that 13 Trusts had been contacted to undertake an audit commissioned by the MHRA. To date only two had completed although most were scheduled to do so by the end of November, after which the position would be further reviewed with the MHRA.	
10.3 **10.3.1**	**Outlier Sub-Committee – Surgeon Data (held 10th October)** **Care Quality Commission (CQC)** It was noted that EY had invited Christine Bennett and Chris Sherlaw-Johnson from the CQC to attend the meeting. The collaboration with the CQC was discussed, along with the escalation process for surgeon and unit outliers.	
10.3.2	**Annual Clinical Report** The majority of Trusts had acknowledged receipt of their Annual Clinical Report letter. Letters sent out with the next report would be reviewed and amended.	
10.3.3	**Reset Button** Agreed in principle, that 3 years after prosthesis was removed from the market, due to poor results, the cases would be removed from the databases of all surgeons, and funnel plots recalculated. For surgeons who had changed their practice, a plot would be	

	produced up to, and post, the change in practice. These updates should go on Clinician Feedback, but it was recognised that this would incur development costs.	
10.3.4	**Hybrids** It was agreed in principle that Hybrid data would be included on Clinician Feedback for hips and knees, subject to the cost.	**N/Gate**
10.4 **10.4.1**	**Implant Performance Sub-Committee (held 18th October)** **Streamlined data access** KT noted that the process of obtaining the necessary data when implants had come under scrutiny was not always efficient. The sub-committee felt that the Chair should have unrestricted access to the data to answer any enquiries, and could possibly be added as a Supplier Feedback user for this purpose. The NJRSC understood the need for streamlined data access, but they considered that appropriate processes had to be in place. **Agreed: Further discussion would be held outside of the NJRSC.**	**EY/MS/KT**
10.4.2	**Availability of declared Level 1 and Level 2 reports to other registries** Sharing implant alerts with other registries had been discussed by the sub-committee, and would be discussed at ISAR 2013. **Agreed: A proposal would be drafted for the next NJRSC detailing in what circumstances the NJR should be expected to provide data to other registries.**	**KT**
10.4.3	**NJR and HES revisions** How to tackle the issue of NJR recorded revisions in comparison to HES was discussed. **Agreed: A one-page outline of the issues and associated action plan would be drafted for the next NJRSC.**	**EY/KT/MS**
10.4.4	**Reset button** When an implant with a high PTIR was withdrawn from the market, there was discussion about whether the PTIR of that implant should be removed from the group PTIR. Also, when an implant was a Level 1 or Level 2 potential outlier (but this was only due to a small number of surgeons) should there be an option of resetting the PTIR if those surgeons ceased using the implant. For transparency purposes, it was considered advisable for two funnel plots to be produced, one with the original PTIR and one with the reset PTIR. **Agreed: A detailed proposal for the reset button would be submitted to the next NJRSC.**	**KT**
10.4.5	**PROMs on implants** KT requested support for analysis of PROMs data for implants **Agreed: KT would draft a proposal for consideration at the next NJRSC meeting.**	**KT**
10.4.6	**Important Studies** AM noted that there was a lot of important data relating to patient safety that should be progressed for further analysis and presentation, but there had been a delay for the progression of some studies. **Agreed: AM would produce a plan of the items currently being studied by the NJR, and the items to be pursued, for review and assessment at the next NJRSC.**	**AM**
10.5 **10.5.1**	**Editorial Board** **Launch of the NJR Annual Report** MPo reported that the 9th NJR Annual Report had been extremely well received at the British Orthopaedic Association conference in September.	
10.5.2	**Annual Report Part 4: Unit Performance** EY confirmed that the CQC had been very interested in Part 4 of the NJR Annual Report and were working with the NJR to review the associated data that would allow further investigation of poorly performing units. She added that this was a credit to the NJR and the excellent standard of reporting at unit level data for the first time.	

10.5.3	**10th NJR Annual Report: Format, Launch and Promotion** Reflecting general support for reducing the size of the current printed report, consideration was given to the following options: • Part 1 could be published online earlier in the year and launched at ISAR 2013; • Part 2 & 3 data could be grouped together by joint and launched online at the NJR's 10th anniversary event rather than the BOA conference; • Special Topics could be reviewed in further detail at the BOA conference; • Part 4 could be published online; and • As more data was published online, when available, the Annual Report could be changed to the format of an Annual Review. Though not everyone had home internet access, public access was available in libraries. MPo suggested that a stakeholder consultation exercise should be undertaken to obtain views about what presentational improvements could be made. **Agreed:** • **The Editorial Board would decide on the format of the 10th Annual Report.** • **A stakeholder consultation exercise would be undertaken.**	**MPo** **HQIP**
10.5.4	**9th NJR Annual Report Patient & Public Guide [PPG]** RBe noted that a draft version of the PPG would be available at the next Editorial Board. The NJR Patient Focus Group had been consulted on the content and format of the guide and had provided valuable advice. EY confirmed that a future event would be arranged for the NJRSC to meet the NJR Patient Focus Group.	
10.6	**Research Sub-Committee (RSC)** The minutes of the previous meeting (held 4th October) were circulated.	
10.6.1	**British Medical Journal Article: McMinn** AM informed the group that the RSC had agreed that the initial correction published by the BMJ in respect of the research paper by D J W McMinn, was insufficient. He confirmed that he had written again to express concern and a further correction had since been published on the BMJ website. It was agreed that this was a satisfactory outcome.	
10.6.2	**NJR Research Officer** AM reported that MR was leaving to take on a new role at the London School of Hygiene and Tropical Medicine. The NJRSC acknowledged the achievements MR had made to the NJR Research Process. **Agreed: EY would circulate a copy of the Job Description for this post and members would notify her of any potential candidates.**	**EY/All**
10.6.3	**NJR PROMs Project** EY noted that it was previously agreed that the NJR would conduct 1, 3 and 5 year PROMs, but funding had only been granted for 1 year due to the timing of re-tendering the NJR contract. The 1 year PROMs was now completed and under review and 3 year PROMs was now due to be undertaken by January 2013 but required additional funding of £178k. AM reported that he was meeting with AB on 9th November to discuss and agree analysis plans from the data. **Agreed that:** • **AM would resend the original NJR PROMs proposal to the NJRSC.** • **The PROMs Working Group would discuss the outcome of the data analysis of the 1 year PROMs. The NJRSC agreed in principle that 3 year PROMs should go ahead.**	**AM** **AM**
11	**Quarterly Statistics Report Q2 (1st July to 30th September 2012)** The QSR report was received and noted.	
12	**Quarterly Management Report Q2 (1st July to 30th September 2012)** The QMR report was received and noted.	

13	**Any Other Business**	
13.1	**NJR Engagement with Clinical Commissioning Groups** In order to drive forward best practise in hospitals, PG suggested engaging with clinical commissioning groups. MS advised that some initial work had been undertaken and he would update EY/PG on this. **Agreed: EY and PG would explore engagement with Clinical Commissioning Groups**	**EY/PG**
14	**Next meeting** Tuesday 29th January 2013, 10.30 am – 4 pm. Note different venue: Friends House, Euston.	

APPENDIX

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MATTERS ARISING FROM 24 JULY 2012 NJRSC

1. **Data Sharing with the Care Quality Commission**
   [Previous min ref: 3 – Matters Arising ref: 1]
   Following sign off of the data sharing agreements, the first tranche of NJR data was sent to the CQC in August, based on the initial agreed indicators.
   Currently awaiting confirmation of how the CQC plan to present the data which will be referred to NJRSC for sign off.

   In addition, HQIP have been liaising with the CQC regarding an agreed process for the escalation of surgeon and unit outliers as identified in the NJR Annual Clinical Report and NJR Annual Report Part 4 Unit performance tables. The CQC attended the surgeon performance outlier committee to discuss these issues in more detail and will be working with us to determine how our data can form part of the CQC QRP information and be used in their hospital inspection process. This is a very positive outcome for the NJR and our collaboration with the CQC.

2. **NJR data for publication on NHS Choices**
   [Previous min ref: 3 – Matters Arising ref: 2]
   The NJR is still waiting for confirmation from NHS Choices that they agree to the proposed data sharing agreement. Once this was finalised the NJR will share the data related to the agreed indicators, for publication on the NHS Choices web site. The NJRSC would be kept updated on progress.

3. **Compliance with NJR v's. HES – private sector issue**
   [Previous min ref: 3 – Matters Arising ref: 3]
   Re. Pilot study of providing individual surgeon feedback on compliance:
   Northgate have applied for the Consultant Code within the Annual Report application for HES data but have not yet heard whether this field will be approved for usage. CN to keep the NJRSC updated.

4. **NJR Research Strategy**
   [Previous min ref: 3 – Matters Arising ref: 4]
   A draft Research Strategy is still under discussion with ARUK, BOA and the NJR.
   With respect to NJR's own Research Strategy, this will emerge through the listing of prioritised topics. A working group was being established to produce the list of prioritised topics, with the first draft available for review in November. In addition the group will also discuss an Annual Research Plan that would allow the NJR to stagger activities over the year and enable us to update and communicate on NJR work periodically rather than annually through the NJR Annual Report. AM to keep NJRSC updated.

5. **NJR Research Fellows**
   [Previous min ref: 7]
   The advert for x 2 research fellows had been placed on the Royal College of Surgeons (RCS) fellowship website and the NJR website. Each post would be for a period of 12 months in the first instance, renewable for a second year subject to satisfactory performance. NJR funding for each post would be up to £60,000 per year, managed through the established RCS fellowship framework.
   The fellows would report through the NJR for mentorship and work programmes, and be supported as necessary by the University of Bristol NJR statistician.

The closing date for applications was 16th November 2012.
The interview panel to be arranged thereafter, would be led by HQIP/NJR representatives and representatives from the BOA, BHS and BASK would be invited to participate.

6. NJR Economic Model
[Previous min ref: 3 – Matters Arising ref: 8]
It had been necessary to cancel a second meeting with manufacturers which had been scheduled for 20th August to pursue options for a cost sharing arrangement with the NJR. This meeting was to be re-scheduled pending comments from DH about suggested proposals. The NJRSC would be kept updated.

7. NJR/DH Price Benchmarking Pilot Study
[Previous min ref: 3 – Matters Arising ref: 9]
The NJR was now working with the DH Procurement Division as the pilot study had commenced, and work was on-going with the initial three Trusts that had agreed to participate. The pilot would then be extended to a further x 30 hospitals before overall evaluation by the end of the year. The NJR was providing regular updates to the DH. It had been agreed that if the pilot was rolled out to the NHS generally that an NJR group would be convened to oversee aspects of NJR system development and governance. EY/RA would keep the NJRSC advised about progress.

8. Incorporation of Elbow and Shoulder Joints: Shoulder PROMs
[Previous min ref: 6]
LPF had written to Andy Carr/BESS regarding a contribution towards the cost of implementing shoulder PROMs. This was currently being reviewed by BESS who had confirmed that they would come back to the NJR on this matter in the near future.

9. Geographical Extension of the NJR
[April 2012 min ref: 12]
Northern Ireland
Work to incorporate Northern Ireland into the Registry was nearing conclusion. A contract between Northern Ireland and the NJR had been drafted by both parties, and would now be submitted to the DH for approval. Once this was finalised, manufacturers would be instructed to implement collection of the NJR levy. Completion of this project was scheduled for end October/November 2012 after almost 5 years of negotiation.

It was intended to communicate this as widely as possible. Interest had already been expressed from BBC Northern Ireland. NJR literature and stationary would also need to be amended. How Northern Ireland would be represented on the NJR would be addressed as part of the NJR structure review, but it had been provisionally agreed that one of their surgeons would participate in the NJR RCC Network.

EY would inform members when a date had been confirmed for the NJR to become the NJR for England, Wales and Northern Ireland.

Channel Isles and Isle of Man
Following extension to Northern Ireland, work would commence to incorporate the Channel Isles and Isle of Man, all of which were extremely keen to join the NJR. Associated work and costs for this work would be minimal.