National Joint Registry
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# NATIONAL JOINT REGISTRY STEERING COMMITTEE (NJRSC)

## APPROVED MINUTES

**Meeting:** NJR Steering Committee **Date:** Wednesday 22nd April 2009
**Location:** MLS Venue, 130 Shaftsbury Avenue, London W1D 5EU

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| **Members Present:** | Bill Darling | BD | Chair |
| | Prof Paul Gregg | PG | Vice Chair, Orthopaedic Surgeon |
| | Andy Crosbie | AC | Medicines & Healthcare products Regulatory Agency (MHRA) |
| | Peter Howard | PH | Chair, Regional Clinical Coordinators' Network |
| | Prof. Alex Macgregor | AM | Public Health & Epidemiology |
| | Martyn Porter | MPo | Orthopaedic Surgeon |
| | Keith Tucker | KT | Orthopaedic Surgeon |
| | Andrew Woodhead | AW | NHS Management Member |
| | Mary Cowern | MC | Patient Representative |
| | Patricia Durkin | PD | Patient Representative |
| | Dean Sleigh | DS | Orthopaedic Device Industry |
| | Patricia Cassidy | PC | Independent Healthcare Sector |
| **Regular Attendees:** | Elaine Young | EY | National Development Lead, HQIP |
| | Yvonne Tse | YT | Development Officer (NJR), HQIP |
| | Richard Armstrong | RA | NJR Programme Director, Northgate Information Solutions (Northgate) |
| | Charlotte Humphry | CH | NJR Programme Manager, Northgate |
| | Mike Swanson | MS | NJR Principal Consultant, Northgate |
| **Meeting Invitees:** | Robin Burgess | RB | Chief Executive, HQIP |
| | Kalid Razak | KR | Medicines and Healthcare Products Regulatory Agency (MHRA) |
| **Apologies:** | Mick Borroff | MB | Orthopaedic Device Industry |
| | Carolyn Naisby | CN | Practitioner with Special Interest in Orthopaedics |
| | Andy Smallwood | AS | NHS Supply Chain |

| REF | ITEM | Action |
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| | **AGENDA** | |
| **1** | **Welcome and Apologies for Absence**<br>The Chair opened the meeting and welcomed back Andy Crosbie who had been temporarily covering another post within the MHRA. The Chair also welcomed Kalid Razak, a colleague of AC's, who had recently taken up the post of Principal Medical Device Specialist, Biosciences and Implants.<br>Apologies were received and noted. | |
| **2** | **Minutes of the Previous Meeting**<br>PG asked that the name of his hospital be corrected to 'James Cook University Hospital' from 'Memorial Hospital'<br>Subject to that correction being made, the minutes of the meeting held on the 29th of January 2009 were approved as an accurate record. **The corrected minutes will be published on the NJR website.** | **NJRC** |
| **3** | **Matters Arising (not appearing elsewhere on the Agenda)**<br>**3.1 National PROMS (prev Min ref 3.2)**<br>EY congratulated Northgate on its successful bid for the national PROMS study. RA explained that Northgate had won Lots 1 and 2 of the contract which were related to data collection and aggregation. Lot 3, which related to the analysis of the data, had been won by the Royal College of Surgeons Clinical Effectiveness Unit (RCS CEU).<br>**3.2 US Food and Drugs Administration (prev Min ref 3.3)**<br>EY requested firm direction from the Committee about the continuation of discussions with the US FDA following its request for data from the NJR.<br>Both MB and DS raised concerns about controlling the data once it had been released to the FDA and the fact that the FDA would be sub-contracting to a number of organisations to undertake analysis of the data. DS felt that it would be more appropriate to cooperate with the European registry that was currently under consideration.<br>AC felt that there may be a risk to compliance with the NJR if surgeons became aware that their data was being analysed by an agency external to the NJR.<br>MPo raised the issue of data quality and expressed his view that, without a definitive statement about the quality of the data, it should not be released. He commented that the FDA should have submitted a properly defined research proposal, which would be treated in exactly the same way as any other similar request; his comment was supported by members.<br>RA outlined the process developed by the Information Centre (IC) for the use of HES data. Requestors were required to provide a statement about the purpose for which the data would be used, the sub-licensing of the data, and include a licence fee. EY reported she had had discussions with the IC and that development of a similar model would require the involvement of the Department's legal team.<br>In summary, BD directed that the dialogue should continue with the FDA and consider 3 points:<br>• The data quality could not be quantified.<br>• A formal research request should be submitted with a clear statement on the purpose of and usage of the requested data.<br>• That sub-letting of work based on the use of NJR data or sub-licensing the data itself was out of the question. | |

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| | **3.3 MDSv3.1 Dataset**<br>**3.3.1 Inclusion of Surgeon Grades (prev Min ref 10.1)**<br>CH provided an update on the development to the meeting, informing them that testing was due to commence in the next 2 weeks.<br>**It was agreed that: PG requested confirmation of the surgeon grades that would be used and it was agreed to cover this outside of the meeting.**<br>**3.3.3 Individual Surgeon Portfolio (prev Min ref 10.2)**<br>MS reported that he had met with trainee surgeons at the Annual Meeting of the British Hip Society and that discussions had focused on the ability of trainee surgeons to know the outcomes of those procedures that they had either participated in or observed. This would require the ability to include trainee surgeon details on the NJR data collection forms. The information could then be made accessible through *NJR Clinician Feedback*. Both MPo and KT expressed support for the idea although consideration needed to be given as to how it could be implemented, especially if the data were to be linked to a surgeon's electronic training record. MPo felt any implementation would engage surgeons with the NJR at an early stage in their training.<br>**It was agreed that: A document outlining possible implementations should be presented at the next meeting of the NJRSC.**<br>**3.4 NJR Levy 2009/2010 (prev Min ref 8.3)**<br>EY reported that the Department of Health had returned the 2007/08 surplus to HQIP for the purpose of supporting the NJR Strategic Plan. On this basis it had been agreed, contrary to the recommendation from the previous meeting that the levy remain at £20 for 2009/10. | **PG/CH**<br><br>**NJRC** |
| **4** | ***NJR Clinician Feedback* System**<br>**4.1 RCS CEU - Review of the Statistical Methodology**<br>PG reported that the RCS CEU had undertaken a review of the methodology, implemented by Northgate, for the identification of potential outliers. A paper had been produced which was offered to members. PG confirmed that the way in which the Patient Time Incidence Rate had been calculated was correct, and that this was now being compared to an expected revision rate based on a 'national benchmark'. The report concluded that it would take 2 years to develop a robust system and that a dedicated team would be required.<br><br>BD drew members' attention to Paragraph 29 of the report which stated that it was not acceptable to ignore potential outlier performance even if the evidence was imperfect. BD expressed his agreement with this, and reiterated the NJRSC's commitment to the surgeons and its responsibility to patients. He also expressed that a 2 years wait for the methodology to be implemented was unacceptable.<br><br>PG supported BD in this, but felt that the only surgeons who would be identified were those submitting data to the NJR. He expressed that further action was needed to deal with non-compliant surgeons and units.<br><br>PH raised an issue with the method proposed in the RCS CEU report because it was based on an expected revision rate of 1 per 100 patient years, which meant that only one third of the surgeons were included in its analysis. Surgeons who had less than approximately 50 procedures were not included in the method and this meant that only surgeons with high volume operations would be detected as potential outliers. AW stated that this was unacceptable.<br><br>RB expressed the view that the RCS CEU report required further scrutiny and validation. He stated that if it was felt that there were issues with it, then it could not be signed off and that the NJRSC should be considering a process for signing it off.<br><br>RA observed that, whilst nothing had been said that would undermine the work of the RCS CEU, a further review of the deficiencies highlighted by PH was required. The additional review could consider other, complimentary methods to overcome the perceived deficiencies.<br><br>**It was agreed that: The method used in the report will be implemented by Northgate on the** | **PG/PH/ KT/MPo** |

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| | **proviso that all of the NJR data is plotted and that Northgate builds in additional data fields to include surgeons with low procedure volumes.** | **NJRC** |
| | MPo was asked to consider whether or not an upper limit of 2 expected revisions per 100 patient years should be used as the threshold rather than 1 and to report back to BD and PG. | **MPo** |
| | RA confirmed that Northgate would be able to implement the method proposed in the report but that NJR/HES linked data could not be used. This would require further discussion with the Information Centre (DH). | **NJRC** |
| | **4.2 Specification for Surgeon's Report**<br>MS reported that, following discussions with PH, a report enabling surgeons to look at revision rates at year one and year three had been developed and demonstrated at the Annual Meeting of the British Association for Surgery of the Knee (BASK).<br>Action was underway to transfer the report from the test system to the production system. PH confirmed that *NJR Clinician Feedback* had been well received by surgeons attending BASK. | |
| | **4.3 Supplier Requirements**<br>MS updated the meeting on discussions held with MB to define the requirements for *NJR Supplier Feedback.* A business case had been prepared and forwarded to HQIP. The development would be funded from provisions within the core contract although there would be an additional licence fee.<br>MS agreed to DS' request for close collaboration during the requirements definition phase.<br>**It was agreed that: The Committee supported the business case and the development of *NJR Supplier Feedback* and approved the additional funding.** | **NJRC** |
| **5** | **Outliers**<br>**5.1 Current Outlier Scenario**<br>BD stated that the report from the RCS CEU, identifying potential outliers, could not be ignored and that further discussions with the surgeons had taken place. PG reported that there had been only a provisional review of the data to date and that a further meeting was planned for 7th May 2009 following the Editorial Board meeting to determine "case to answer". | **PG/PH/ KT/MPo** |
| | **It was agreed that:**<br>**1. PG would lead the review process and the meeting would include both Northgate and the RCS CEU.**<br>**2. BD and EY would be informed of the outcome immediately following the meeting for the management of potential outliers.** | **PG** |
| | **5.2 Process for Handling Potential Outliers**<br>Consideration was given to a letter from Clare Marx, BOA President, outlining an alternative proposal for the management of potential outliers to the one currently operated by the NJR.<br>In summary her suggestion was for every Unit performing joint replacement to have a designated lead, who would be a member of the local Trust Clinical Governance Committee, and be responsible for ensuring that the processes for collection and inputting of data to the NJR were maintained, and that reports from the NJR were routinely submitted to the Governance Committee. In the case of identification of a potential outlier, the NJR would notify this designated Trust lead, who would undertake an initial investigation, and bring the matter to the attention of the individual concerned. A summary of the investigation and any recommended action would then be presented to the Trust Clinical Governance Committee.<br>EY noted that the BOA President had acknowledged the NJR may have other views about the process to be followed, and was only offering this proposal as a preliminary suggestion. She drew attention to the fact that the main difference to the existing NJR process was that the Chief Executive would not be notified of a potential outlier directly by the NJR, the expectation being that s/he would be made aware of the potential outliers through the designated lead and Trust clinical governance structure. However, this would require careful consideration by the NJRSC as | |

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| | notification to a Trust Chief Executive had been the key issue of previous debate between the NJRSC and Department of Health, when the current process had been agreed.<br><br>EY considered that the operational issues associated with the NJR securing and maintaining an accurate and up to date data base of all Trust leads were complex. Chief Executives would be requested to nominate Trust leads but some may self nominate creating a two-tier system. Further, possible changes to Trust personnel, posts and structures, with the exception of statutory Trust Board posts, could put the NJR at future risk when reporting outliers. PC also highlighted the importance of ensuring the correct reporting level within the independent sector i.e. general manager or group Chief Executive?<br><br>PG supported the value of embedding the NJR within the Trust Clinical Governance structure. AW agreed that this was a positive approach but was concerned that clinical governance arrangements differed within Trusts, but the constant factor was that Chief Executives were the accountable governance officers and needed to be informed in the first instance, whatever delegated arrangements they subsequently put in place to ensure that appropriate action was taken. It was also noted that to by-pass a Chief Executive in the outlier process could place the NJR at risk of inadequately discharging its governance responsibilities. RB agreed that notification of the Chief Executive was essential. PH also emphasised the importance of ensuring that a potential outlier surgeon was included in all early communications with the Trust. The current NJR process of managing potential outliers ensured this was the case but the suggested process of notification to a designated lead could delay this. MPo added that a surgeon must be given the opportunity to explain their data.<br><br>**It was agreed that: The current NJR procedure for investigating potential outliers continues, and that the BOA President be notified.**<br><br>AC apologised for the length of time taken to consider the appropriate action for the four implants communicated to them as potential outliers. They had encountered a number of difficulties around trying to establish whether the issues were with the implants or the surgeons and working out what data was required to support the analysis. AC was confident that those issues had been resolved.<br><br>The performance of two devices was associated with potential outlier surgeons and the suppliers were not aware of those issues.<br><br>The supplier of the third device was only aware of 1 out of 27 revisions in the UK, indicating that hospital units were not reporting revisions and that the company's post-market surveillance was inadequate. Data from international registries did not indicate an issue with this particular device and the MHRA would therefore not be taking any action with regard to it. They would, however, be following up the poor post-market surveillance results with the supplier.<br><br>The fourth implant was supplied as two variants and analysis determined that whilst one variant was successful, the other was not. A device alert was currently under discussion and there would be a need for patient follow up. AC reported that the manufacturer would no longer be marketing the affected product.<br><br>PG was concerned that surgeons had not been reporting the revisions to the manufacturers and stressed that it was a big plus for the NJR to have picked these up. He suggested that it would be good for the NJR to receive acknowledgement for its work in detecting these implants through the British Orthopaedic News. | **HQIP** |
| **6** | **NJR Strategic Plan 2009-2010**<br><br>EY provided an update on the Strategic Plan and explained that it had undergone a number of revisions following suggestions and comments received since the previous NJRSC meeting. EY drew members' attention to three specific items:<br><br>• A proposal to have funding for full time statistical support which could be provided from a number of different sources. For example, this support could include analysis to support the MHRA or potential outlier analysis.<br><br>• The need for a PROMS study to consider different age groups was no longer necessary as it | |

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| | was included in the national PROMS study.<br>• The need for a dedicated infrastructure for handling research proposals and requests.<br>The proposal for statistical support was welcomed by AC as it would have been of considerable benefit when considering the outlying implants.<br>**It was agreed that: The topics of work would be put out to tender as and when it was required. AM asked that more than one organisation be used in order to provide a sensible quality measure and avoid any accusations of favouring one organisation over the others.**<br>In considering the objectives included in the Strategic Plan, the following comments were made:<br>**(a) Making the NJR Mandatory**<br>MS reported to the meeting that he and YT had had a very useful meeting with Steve Webster from the Review of Central Returns (ROCR). In addition to the application to collect ankle, elbow, and shoulder data, the NJR was required to re-new its licence which will expire at the end of June 2009. ROCR had agreed to a 6 month extension (ends in Dec/09) to that licence so that the additional data could be included in a single application. Despite the fact that there was a Government directive to reduce data collection within the NHS, Mr Webster, did not foresee any difficulty with the increased data collection of the NJR and recommended that the application should include a request to make the data collection mandatory. He also advised seeking support from Ministers and Monitor prior to submitting the application.<br>**It was agreed that: As a minimum, support should be sought from the CMO, the NHS Medical Director, Lord Darzi and the Care Quality Commission.**<br>**(b) Links with the National Hip Fracture Database**<br>In response to a query, RB reported that the NJR will provide some funding support to undertake a study to see how the two datasets could be linked.<br>**All the items included on the Strategic Plan received the support from the Committee.**<br>AC raised a new item for consideration, relating to a report in July 2007 that recommended linking the NJR to cancer registry data.<br>**It was agreed that: EY will put this proposal into the Strategic Plan.**<br>EY thanked all members for their input and informed the meeting that the next steps were to formulate plans for implementing the strategy and deciding upon priorities. | **HQIP**<br><br>**EY** |
| **7** | **Editorial Board**<br>MPo reported that the minutes of the previous Editorial Board had been circulated and thanked all those involved with the editorial process for their efforts. The aim was to have a draft of the annual report in time for the NJRSC meeting in July. MPo was satisfied with the progress made to date on the Annual Report and thanked Claire Newell for having already submitted material for review.<br>MPo informed the Committee that the HES data used in the report would include data up to November 2008 which is two months more than had been expected. Additionally, the analysis would include, for the first time, NJR/NJR linked revisions as well as NJR/HES linked revisions.<br>He also suggested that a request could be made to the BOA and other professional societies for formal feedback and suggestions on the content and style of the Annual Report.<br>The Editorial Board minutes were noted by the Committee. | |
| **8** | **Research Request Protocol**<br>AM outlined a paper, highlighting the high level process for research requests received by the NJR and proposing ideas for refining the process. There were two basic flow charts: one for dealing with straightforward requests for data, the other for dealing with research requests.<br>AM informed members that the process still required further thought and the purpose of the paper was to provide a broad outline in order to gain approval in principle for this to be taken forward for | |

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| | implementation by the Editorial Board. He also raised an issue of funding to support the establishment and managing of the processes and the ongoing governance review.<br>KT stated that a named study sponsor was necessary for each research request to ensure that all proposals had been carefully thought through before submission.<br>RA observed that the process should cover both the provision of data for 3rd party research and research to be undertaken by the NJR itself.<br>MPo thought that the paper provided an excellent starting point and suggested that fellowships could be funded by the NJR to encourage the use of the data and to promote the NJR more widely.<br>**It was agreed that: In principle, the Editorial Board would take this forward and implement the necessary processes.**<br><br>BD thanked AM for his work. | |
| **9** | **Extension of NJR to Northern Ireland**<br>YT reported that the initial meeting had been postponed. It was hoped to arrange a meeting for June. | |
| **10** | **Inclusion of Elbows and Shoulders into the NJR**<br>PG reported on a meeting held with President and Immediate Past President of the British Elbow and Shoulder Society (BESS), attended by YT, RA and MS. The meeting was very positive and started with some concerns about the NJR both Mr Stanley and Mr Bunker were encouraged by the end of the meeting.<br>BESS confirmed that they were already collecting data and, although further review would be required, the data collected is similar to that collected by the NJR. Their main concerns appeared to be around the share of and access to funding for research, and whether they would be able to use their preferred research organisation. BESS were also concerned about having representation on the NJRSC.<br>Mr Stanley and Mr Bunker would be reporting back on the outcome of the meeting to the Council of BESS at its next meeting in June. | |
| **11** | **Inclusion of Ankles into the NJR**<br>MS reported that the dataset for ankle joint replacement surgery was almost complete and asked that approval be given outside of an NJRSC meeting.<br>**It was agreed that: The draft dataset could be circulated by email for approval.**<br>MPo acknowledged that the current number of ankle replacements taking place was low but stated that such procedures would increase significantly over the next 5 years. Although it would be some time before any analysis could be undertaken, now was the right time to start collecting data. | |
| **12** | **NJR Finance Report**<br>EY sought confirmation that all members had received the amended financial report. The reported figures for the financial year 2008/09 and the expected budget for 2009/10 were received and noted. | |
| **13** | **Quarterly Statistics Report Q4 (January – March 2009)**<br>The quarterly statistics report was received and noted. | |
| **14** | **Quarterly Management Report Q4 (January – March 2009)**<br>CH proposed closure of two risks on the risk register. The proposed closures were agreed and CH was to update the risk register.<br>The report was received and noted. | **CH** |
| **15** | **Any Other Business**<br>**15.1 Anaesthetic Data** | |

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| | PH offered to draft a letter in response to a letter from an anaesthetist at the RUH in Bath who were preparing a paper on the quality of the anaesthetic data recorded by the NJR.<br>**15.2 British Hip Society**<br>KT informed the meeting that the next annual meeting of the British Hip Society would be from 24-26 February 2010 in Sheffield. He extended an invitation to all members.<br>**15.3 Gwen Fish Memorial Lecture**<br>KT extended an invite to the Gwen Fish Memorial Lecture which would be taking place at 1800 hours on 3rd of July in Norwich. Mr John Skinner would be presenting on metal on metal. If members would like to attend, they should contact KT. | **PH** |
| **16** | **Date and Time of Next Meeting**<br>**Thursday 9th July 2009 at 10.30-16.30**<br>MLS, Shaftesbury Avenue, London W1D 5EU | |