



**NATIONAL JOINT REGISTRY STEERING COMMITTEE**

**MINUTES**

Meeting:	Steering Committee meeting		Date: Tuesday 2 November 2004
Location:	BOA, The Royal College of Surgeons, 35 – 43 Lincoln’s Inn Fields, London WC2A 3PN		
Present:	Bill Darling	BD	Chair
	Paul Gregg	PG	Vice chair
	Judy Murray	JM	British Orthopaedic Association (representing the surgical profession)
	Jan van der Meulen	JvdM	Royal College of Surgeons (representing the surgical profession)
	Alex MacGregor	AM	University of East Anglia (representing public health and epidemiology)
	Martyn Porter	MPo	British Hip Society
	Tim Wilton	TW	British Association for Surgery of the Knee
	Mick Borroff	MB	DePuy International Ltd (representing the orthopaedic device industry)
	Chris Dark	CD	BUPA Hospitals (representing the independent sector)
	Andy Crosbie	AC	Medicines and Healthcare products Regulatory Agency (MHRA)
	Andy Smallwood	AS	NHS Purchasing and Supply Agency
	Christine Edwards	CE	Arthritis Care (patient group representative)
	Helen Lovell	HL	Department of Health
	Fiona Davies	FD	AEA Technology (contractor)
	Ian McLean	IM	Representing the Scottish Executive (observer status)

The following AEA Technology staff were also present:

	Leigh Mapledoram	LM	NJR Programme Manager
	Sue Mercer	SM	NJR Project Administrator
	Ian Calcutt	IC	NJR IT Manager
	Claire Newell	CN	NJR Data Quality Manager
	Martin Pickford	MPI	NJR Orthopaedic Adviser
Apologies:	Ken Bateman	KB	Smith & Nephew Healthcare Ltd (representing the orthopaedic device industry)
	Dominic Worsey	DMC	National Assembly for Wales
	Christine Miles	M	Royal Orthopaedic Hospital (representing NHS Trust management)
	Colin Thomson	CT	All Wales Community Health Councils (patient group representative)
	Wendy Walters	WW	National Association of Theatre Nurses

Item	Welcome and Introductions	Action by
1	<p>BD welcomed all attendees to the meeting, and in particular those for whom this was their first Steering Committee meeting. New members of the SC present were:</p> <ul style="list-style-type: none"> <li>- Judy Murray, a consultant based at The Royal Glamorgan Hospital, Llantrisant and representing the BOA</li> <li>- Christine Edwards, the new Information Manager at Arthritis Care</li> </ul> <p>Wendy Walters of the National Association of Theatre Nurses was unable to attend the meeting.</p> <p>Helen Lovell was present representing the Department of Health. Ian Maclean, a consultant on the board of the Scottish Arthroplasty Project, acted as Scottish observer. FD introduced Leigh Mapledoram who is the new NJR Programme Manager, replacing David Carter who recently resigned from AEA Technology.</p> <p>Round table introductions followed.</p> <p><b>[Action 2004/208]</b> A letter should be sent to David Carter on behalf of the SC thanking him for his considerable contribution to the NJR.</p> <p>FD advised that although the Welsh Assembly Government (WAG) were not represented at the November SC meeting, they expected Dominic Worsley to attend the next SC meeting. (Stephen Chamberlain's areas of responsibility had changed.)</p> <p>BD thanked all concerned for their efforts in producing a top quality 1<sup>st</sup> Annual Report.</p> <p>FD advised the SC that – in the period 15 September to 31 October – 7067 copies of the full Annual Report and 1004 copies of the Summary Report had been downloaded from the NJR web site.</p> <p><b>[Action 2004/209]</b> If possible, AEAT to provide a breakdown of UK / overseas accessing of the Annual Report from the NJR web site. (See Appendix 1)</p>	<p><b>AEAT/BD</b></p> <p><b>AEAT</b></p>
2a	<p><b>Progress on actions</b></p> <p>An update of progress on actions had been circulated in advance of the SC meeting. A number of actions linked to items later in the agenda so related discussion was deferred. No questions were asked under the current item.</p> <p><b>Matters arising</b></p> <p>PG reported back on items that the SC had requested be discussed at the October 2004 RCC network meeting.</p> <p><b><i>Inclusion of Trauma procedures in the NJR</i></b> To be discussed under AOB.</p> <p><b><i>Regional roadshows</i></b> RCCs did not feel there was a need for regional roadshows related to the 1<sup>st</sup> Annual Report, aimed at the surgical profession. They had not offered a view on whether regional roadshows aimed at a wider, non-surgical audience might be of value.</p>	

<p><b>Meeting with the Welsh Assembly Government</b>  FD advised that a meeting that had been planned by David Carter had to be cancelled at short notice due to unavailability of NJR Centre staff. It was now known that Dominic Worsley would be the main contact for the NJR. FD would take on responsibility for rearranging the meeting.</p> <p><b>[Action 2004/210]</b> FD to reschedule the meeting with WAG. Ideally, this should include FD, BD, PG and JM. (This action supersedes Action 2004/203.)</p> <p><b>Contact with the European Arthroplasty Register (EAR)</b>  PG advised that he had sent a letter to Gerold Labek (EAR Co-ordinator) indicating that the NJR will not be joining EAR at present but would like to be kept informed of progress.</p> <p><b>Outlier surgeon / hospital performance</b>  BD advised that he wished to use agenda item 9 from the July 2004 SC meeting to report to the Steering Committee. He referred to an email and attachments that had been emailed to all SC members on 29.10.04. This detailed:</p> <ul style="list-style-type: none"> <li>- a meeting at the Department of Health, held on 14 May 2004 and involving BD, Paul Woods, David Carter, FD and Debbie Warren</li> <li>- a subsequent meeting in Middlesbrough on 27 May 2004, involving BD, PG and DC</li> <li>- a letter from BD to Lord Warner, dated 4 June 2004</li> <li>- Lord Warner's reply, dated 10 August 2004</li> </ul> <p>BD advised that he had wanted to raise this issue today as he had hoped to bring something substantive to the meeting. However, it had not been possible to schedule a meeting of the clinicians on the SC in advance of the SC meeting. BD advised SC members that he had not wanted to progress developments in this area further without first informing them.</p> <p>BD briefly reviewed the background to the proposed meeting. The catalyst had been a Channel 4 programme on overseas visiting teams. The purpose of the 14.05.04 meeting had been to determine whether it was technically feasible to use NJR data to identify if there are surgeons with higher than expected revision rates. The conclusion was that it was theoretically feasible but would be reliant on patient consent having been obtained, and NHS number being identified, to link index operations with subsequent revisions. The 27.05.04 meeting centred on considering how 'indicator points' might be identified and then, if they were reached, what the next steps would be. Lord Warner had stressed that patient safety and monitoring outcomes were high on his agenda. He asked that the NJR SC agree a suitable process with the BOA for identifying higher than usual readmission rates after surgery.</p> <p>BD highlighted that subsequent discussions had indicated that the remit of the proposed activity should be expanded. The views of SC members were sought.</p> <p>PG proposed that, in the event that an indicator point was reached, an informal approach be made to the surgeon concerned, indicating that there <u>may</u> be a problem with their performance. It was important to stress that there could be good reasons for the identified performance, for example, related to case mix. PG would initiate discussions with the surgeon, but provide a list of surgeons on a panel from which the surgeon could choose who they wished to talk to. This would acknowledge the importance of a surgeon feeling comfortable about who they would be talking to about very sensitive issues. In simple terms, there are three main outcomes expected: (1) the accuracy and completeness of the data used is challenged; (2) some degree of retraining is required; (3) the surgeon chooses to cease the practice(s) causing concern. Only if the situation cannot be satisfactorily resolved would the duty of care require reporting to the relevant Clinical / Medical</p>	<p><b>AEAT</b></p>
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	<p>Directors. The CD / MD should not be the initial point of contact.</p> <p>PG felt that the above process was similar to the process used in Scotland. IM confirmed this.</p> <p>The Scottish Arthroplasty Project (SAP) now has a comprehensive web site at: <a href="http://www.show.scot.nhs.uk/arthro">www.show.scot.nhs.uk/arthro</a> The Annual Report 2004 can be downloaded from the site. [Post-meeting note: SC members are advised to read the first 5 pages, which provide key points and a summary.]</p> <p>SAP uses Shewart control charts to highlight areas of practice (or data recording) that are at significant variance from the Scottish average. Following publication of the 2003 report, consultants and NHS boards who had higher than average complication rates (i.e.outlier performance) were asked to investigate and explain this anomaly. All 15 consultants provided satisfactory responses. To date, only 2 out of 4 boards have responded. Flowcharts are available to illustrate the procedure for reviewing consultant data outwith normal variation and for reviewing board data outwith normal variation. In earlier reports, a crude case mix adjustment was made by selecting patients aged over 60 with a diagnosis of osteoarthritis when analysing complication rates for NHS board areas. In the 2004 report, further account was taken of the influence of age, sex and diagnosis to allow more sophisticated case mix analysis. A possible disadvantage of the Scottish approach is that reports are currently based on 5 years of data; with delays in information returns, Year 1 is reporting on performance 7 years ago. This is an area that is under review.</p> <p>HL explained that, although relatively new to the NJR programme, this was an area that she found of particular interest. Clearly the NJR needed to develop an appropriate policy. Also, the profession not only need to be 'signed up' to any policy but they must be involved in its development. It would be important to tie in with other developments in clinical governance and performance management. Clearly, different approaches could be considered. For example, reporting back to a hospital on their revision rates (subject to surgeon confidentiality restrictions) and providing national / regional benchmark data for comparison purposes. HL felt it important to examine what was done elsewhere: other national orthopaedic registries (e.g. Scotland, Sweden etc); other UK registries in different fields, e.g. the breast implant registry. The experiences in cardio-thoracic surgery would also be of relevance. HL advised that DH colleagues who lead on clinical governance and audit have shown interest in being involved. They have existing links in to the Healthcare Commission that would be useful for the NJR. It was also felt that involving Medical Directors of SHAs could be beneficial.</p> <p>MB stressed the importance of involving the MHRA and manufacturers in this process to ensure a joined-up approach. For example, there was a need to know whether the MHRA was already investigating the performance of certain components.</p> <p>It was agreed that the representation of the required NJR subcommittee be widened to include representatives from the Department of Health, Scotland, MHRA and ABHI.</p> <p><b>[Action 2004/211]</b> AEAT to liaise with BD and SC members to determine: (a) proposed composition of the required subcommittee and suitable name (one suggestion is NJR Outlier Performance Advisory Group (NOPAG)?); (b) a suitable date for a first meeting of the group (late November?); (c) preparatory activities (and responsible persons) to be carried out ahead of the first meeting.</p>	<p><b>AEAT</b></p>
<p><b>2b</b></p>	<p><b>Approval of minutes – NJRSC (04) 19</b></p> <p>The Committee approved the minutes of the July 2004 SC meeting subject to</p>	

	correcting David Forsythe's company affiliation to Stryker. The minutes would be placed on the NJR website.	
3	<p><b>Quarterly Management Report – NJRSC (04) 20</b></p> <p>FD had no particular issues to raise in relation to contents of the Management Report. She asked if SC members had any queries.</p> <p>In response to a query regarding what NJR data was being provided to PASA (page 8 of report). AS said that PASA were receiving component and hospital data, but no surgeon / patient data was included. This information was required to compare against the submissions received by ODEP (the Orthopaedics Data Evaluation Panel) and thus verify ODEP submissions. The data was proving useful as a cross-check on trust purchasing.</p>	
4	<p><b>The National Joint Registry – The Implementation Plan – NJRSC (04) 21</b></p> <p>FD introduced the Implementation Plan, which had been developed from the NJR strategy for development, that was presented and approved in principle at the July 2004 SC meeting. The Implementation Plan focuses on the strategic objectives identified for the short to medium term and details the associated activities and milestones to July 2005. The milestones are set to coincide with future SC meetings and identify the title of the activity and the key parties expected to be involved. Longer term objectives are included (in the 'Future' column) as they are key to the overall success of the NJR, but it is recognised that the nature and timing of their implementation will be guided by the way in which short term objectives are met.</p> <p>Proposed activities within the implementation plan for which approval to proceed was requested and agreed in principle were:</p> <ul style="list-style-type: none"> <li>- Pilot scale introduction of the Hip Owners Manual – see agenda item 10</li> <li>- Extension of current Regional Audit Coordinators' appointments to end March 2006 (currently, their contracts terminate in July 2005)</li> <li>- Recruitment of one additional RAC</li> <li>- Development and implementation of a Public Key Infrastructure (PKI) system – see agenda item 6</li> <li>- Conducting an initial Patient Reported Outcomes survey and developing the rationale for future surveys – see agenda item 9</li> </ul> <p>FD summarised some of the key activities proposed under the co-ordinated Patient Consent Initiative. This led to discussion on an issue that had arisen at the last RCC network meeting. CN reported that it appears that some Treatment Centres believe they can avoid collection of NJR patient consent as they claim that consent is outside the requirements for meeting minimum care standards. BD pointed out that, if the standards document is deficient, he is prepared to take this issue to Lord Warner.</p> <p>CD advised the SC that the Healthcare Commission is starting a consultation exercise on 29 November relating to merging standards for the NHS and independent sectors. It was agreed that the NJR should contribute to the consultation, BD asking that SC members be prepared to contribute to an NJR response, which should also be forwarded to Lord Warner.</p> <p><b>[Action 2004/212A]</b> AEAT to co-ordinate developing an NJR response to the forthcoming Healthcare Commission consultation.</p> <p><b>[Action 2004/212B]</b> Without waiting for the Healthcare Commission consultation, AEAT to ensure that the independent sector and TCs are alerted to the need to comply with both submitting data to the NJR and putting in place and using an NJR patient consent process.</p>	<p><b>AEAT/SC</b></p> <p><b>AEAT/SC</b></p>

	<p><b>Extending the remit of the NJR</b></p> <p>In relation to the NJR strategy for development and the implementation plan, SC members queried why extending the remit of the NJR to other joints was classified as a longer term objective (5-10 years) and not shorter term. Discussion concluded that there is a strong argument for reaching a steady state in terms of development of the MDS for Hips / Knees and completing major development work including the bulk upload and barcode reading facilities. However, this should not preclude specialist societies starting to think about the potential benefits of a registry for their specialism and requirements of a related MDS. It was agreed that the NJR should take a phased approach in opening up these discussions. As a first step, a letter should be written to the President of BESS (British Elbow and Shoulder Society). Ministers can take a view in the light of the response received.</p> <p><b>[Action 2004/213]</b> A letter to be sent to the President of BESS on behalf of the NJR SC to assess the initial interest in Shoulders and Elbows being incorporated into the NJR.</p> <p>All proposed activities within the Implementation Plan were approved in principle. See agenda items 6, 9 and 10 for detailed discussion on development and implementation of a PKI system, conducting an initial patient reported outcomes survey and a pilot scale introduction of the Hip: Owner's Manual.</p>	<p><b>AEAT</b></p>
<p><b>5</b></p>	<p><b>NJR Statistics Report (Reporting Period: 29 September 2003 to 26 September 2004) – NJRSC (04) 22</b></p> <p><b>Headline statistics</b></p> <p>As previously agreed, the statistics contained within this report are for a 52 week period – 29 Sept 2003 to 26 Sept 2004. Headline figures were:</p> <ul style="list-style-type: none"> <li>- 93.6% of all hospitals listed on the NJR database had submitted data</li> <li>- 82% of returning hospitals had submitted using MDS v2</li> <li>- Patient consent was collected at a rate of 62%</li> </ul> <p>As at 25.10.04, consent levels were up for the 3<sup>rd</sup> consecutive week, with consent levels for MDS v2 submissions in w/e 25 October being 70%. Caution should be applied when interpreting these figures. The rise in consent levels is largely linked to a small number of hospitals with large backlogs of consented proformas inputting them into the NJR system.</p> <p>CN advised that she is in discussion with suppliers and the National Implementation Team (NIT) about obtaining comparator data for the independent sector and TCs, against which NJR data can be compared. <u>[Post-meeting note: Liaison with the independent sector is also being taken forward by CD.]</u></p> <p>TW informed the SC of concerns he had related to teams of visiting overseas surgeons, where individual surgeons may only be in the UK for short periods of time. He requested that the NJR Centre investigate whether the related data entry to the NJR system is carried out in the correct manner. There is anecdotal evidence that surgeon names may not be correctly attributed.</p> <p><b>[Action 2004/214A]</b> TW to provide the NJR Centre with information relating to teams of visiting overseas surgeons, where individual surgeons may only be in the UK for short periods of time.</p> <p><b>[Action 2004/214B]</b> AEAT to investigate whether the related data entry to the NJR system is carried out in the correct manner.</p>	<p><b>TW</b></p> <p><b>AEAT</b></p>

6	<p><b>IT Update, including the outcomes of the Public Key Infrastructure (PKI) scoping study – NJRSC (04) 23</b></p> <p><b>IT update</b>  IC provided a brief update on current IT developments. As agreed, Patient Procedure is being put back into MDS v2 (it was included in MDS v1). This will become a mandatory field in about 3 months' time. The reason for this time lag is to allow hospitals time to enter data they hold on the old proformas (which do not include Patient Procedure).</p> <p>The first testing of Bulk Upload has been completed. By the end of November development is expected to be at a stage where a test version will be released to pilot hospitals and 3<sup>rd</sup> party suppliers for testing.</p> <p>Development of the barcoding facility is progressing on a supplier-by-supplier basis as each supplier has a different standard of bar coding. Testing of the databases being set up is expected to start at the end of November.</p> <p>IT development associated with allowing authorised HDMs to enter default techniques on behalf of surgeons should be complete by end of November. Release of this modification to the data entry system will be timed to dovetail with an associated communications initiative which will also flag up the ongoing development of a wider set of default techniques. The NJR Centre expects that release of the ability for HDMs to enter default techniques will allow a significant number of records in the edit stack to be completed. Currently the edit stack is about 4% of records.</p> <p><b>Public Key Interface System</b>  IC introduced this item by explaining that INSL – who are contracted to provide the NJR security systems – had produced a long and highly technical paper. From this, IC had prepared a management summary and a table that summarised the 4 options, rating them in terms of their pros and cons, indicative costs, security rating, development timeframes, and user experience. The management summary and table were circulated in the meeting and are included here as Appendix 2.</p> <p>For the benefit of new SC members, IC recapped on the potential benefits of developing a PKI system. These include:</p> <ul style="list-style-type: none"> <li>- Secure two way transfer of all NJR data</li> <li>- The ability for surgeons to use the NJR as a resource library</li> <li>- The ability to pass back complete records to surgeons / hospitals</li> <li>- A sense of ownership of the data to surgeons / hospitals</li> </ul> <p>The main aim of proposed security changes is to allow surgeons and hospitals access to patient records (compete with personal data on the patient) on-line from the NJR database. The 4 options put forward were:</p> <ol style="list-style-type: none"> <li>1. <b>Hardware Security Module</b> Introduce a Hardware Security Module (HSM) card (or cards for resilience) as a tamper-proof environment for encryption of patient data. This keeps decryption keys secure and provides a safe container for the decryption process</li> <li>2. <b>Challenge Response Existing Password</b> Replace the existing password mechanism with a challenge process (such as 'type the 1<sup>st</sup> and 4<sup>th</sup> character of your password') to improve protection against keyword sniffing and other data capture techniques. This is typical of the approach taken by Internet banking applications.</li> <li>3. <b>Hardware Authentication</b> Use hardware security tokens to create one-time pass-codes for secure authentication. This offers a secure 2 part process ('something you have, something you know')</li> <li>4. <b>Certificates (PKI)</b> Deploying a certificate-based (PKI) solution for authentication and identity management. Options are included for a 'conventional' client certificate implementation and a packaged solution</li> </ol>	
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	<p>'conventional' client certificate implementation and a packaged solution where certificates and keys are stored and used from within a secure software container.</p> <p>Having summarised the case for / against each of the above options, IC proposed that the NJR pursue Option 1, thereby enabling patient data to be accessed on-line by appropriate users. He also proposed that: (a) Password change be forced every 30 days; (b) Challenge response to password login be reviewed; (c) A risk assessment be completed 3-6 months following HSM implementation; (d) Security options be reviewed upon completion of the risk assessment.</p> <p>IC confirmed that selection of Option 1 did not preclude pursuing any of the other options in the future. In fact it is a building block for whatever else might be done.</p> <p>In response to questioning from SC members, IC stressed that – to allow identifiable data to be given back to hospitals over the Internet – a range of security / confidentiality criteria had to be met. Obviously the Data Protection Act must not be contravened but also, whatever process is proposed, it must satisfy criteria laid down by the NHS Information Authority. NHSIA require sight of a proposal to determine whether or not it passes their criteria – they will not provide approval in advance.</p> <p>IC also confirmed that there would be no apparent change to the front end of the NJR system and also that there was no danger of any hospitals that currently meet NJR IT specifications not being able to use the developed facility.</p> <p>Once all SC members' questions had been addressed, BD confirmed that development of Option 1 would be supported subject to IC first confirming that both the Data Protection Act and NHSIA require this level of security.</p> <p><b>[Action 2004/215]</b> IC to confirm that both the Data Protection Act and NHSIA require the level of security described in Option 1 of SC paper NJRSC (04) 23.</p>	<p><b>AEAT</b></p>
<p><b>7</b></p>	<p><b>Report back from NJR Research Subcommittee</b></p> <p>JvdM apologised for not being able to provide the requested written report ahead of the SC meeting. He summarised the current situation. The NJR Research Subcommittee (RSC) met for the first time on 27 July 2004 and are due to meet again on 10 November. Five key points arose from discussions at the first meeting:</p> <ol style="list-style-type: none"> <li>1. The RSC supports the overall aims and direction of the NJR programme</li> <li>2. The MDS – from the point of view of research – is not ideal</li> <li>3. Care is needed to avoid duplication of effort due to potential overlapping of Terms of Reference of different NJR Subcommittees – in particular, the Terms of Reference of the RSC and of the PROMS (Patient Reported Outcomes Measurement Study) Group</li> <li>4. Determining what the RSC views as the most important tasks – the research priorities – is on the agenda for the November meeting</li> <li>5. Clarification is required on whether there will be funding set aside to stimulate NJR-related research</li> </ol> <p>PG questioned why the RSC felt the current MDS was unsatisfactory for research purposes. JvdM responded that certain important data is not collected, e.g. relating to length of stay, and generally there could be a case for including more data fields related to risk factors for prostheses to help in the understanding of risks. Also, to make full use of patient reported outcomes data, there is a need to know the severity of their condition pre-operation. PG felt that this could be worked on in the future via the PROMS process.</p> <p>PG also reminded the meeting of what had originally been envisaged by the SC in</p>	

	<p>discussions at SC meetings in late 2002 and 2003. Initially, only a reactive approach had been suggested. This would involve teams approaching the NJR with requests for access to NJR data to carry out research. Subject to the proposed research meeting pre-defined criteria – including the required funding already having been identified – and being approved by both the RSC and the SC, it would be supported. Further discussion led to a proactive approach being proposed that would run in parallel to the reactive approach. This would involve the RSC determining what they view as research priorities for NJR stakeholder groups and obtaining SC endorsement for calls for proposals to address the research questions. Both approaches would involve RSC peer review of submitted proposals, with those they wish to see supported being put to the SC for approval. It was also proposed that some level of levy funding should be made available to research that would address the NJR’s defined research priorities (under the proactive approach).</p> <p>HL summarised that the SC needed to see written details of the RSC’s intended mode of operation, draft Terms of Reference, and the case made for funding if any levy funding was expected to be allocated to funding appropriate research.</p> <p><b>[Action 2004/216]</b> Following the RSC meeting currently scheduled for 10 November, a paper to be circulated detailing the RSC’s intended mode of operation, draft Terms of Reference, and the case for funding (if any levy funding was expected to be allocated to funding appropriate research). A timeline should be included in the paper.</p> <p><u>[Post meeting note:</u> Since the SC meeting, discussion between BD, HL, JvdM and FD has indicated that it would be beneficial if the administrative functions of the RSC and its future operations could be undertaken by the NJR Centre. This would free up RSC members’ time to concentrate on those elements that require their expertise, including prioritising research ideas, evaluation of applications received and (in the future) assessing research output. The NJR Centre will work with JvdM to draft a proposed modus operandi for consideration.]</p>	<b>JvdM</b>
<b>8</b>	<p><b>Benchmarking the NJR for compliance and quality – NJRSC (04) 25</b></p> <p>A paper presented at the July SC meeting described the framework currently in place to address issues of NJR compliance, data quality and completeness. Resulting discussion led to AEAT being requested to develop a paper on the levels of compliance, quality and accuracy that are required for the NJR.</p> <p>CN presented the current paper. Her investigations showed that NJR submission rates (both hospital submission rates and operation submission rates) appear to be at least comparable with those of other national registries at this stage of development. Given time, NJR rates are expected to increase to the same levels as the best performing registries.</p> <p>A key issue with the NJR relates to patient consent. Improvement in patient care and the monitoring of prostheses depends on patient consent being given to the levels of other successful registries. This linked in to the co-ordinated Patient Consent Initiative, proposed and endorsed under agenda item 4.</p> <p>MB asked that some work be done on investigating the underlying reasons for the difference between HES estimates and the actual volumes of Hip / Knee procedures entered into the NJR system. CN outlined some of the reasons, including the HES comparison data being for 2002/03, the effects of waiting list initiatives, peaks /troughs in NJR data submission at individual hospitals (eg to meet deadlines for the 1<sup>st</sup> Annual Report or for access to MDS v1 entry).</p> <p>BD thanked CN for a very informative paper that he had enjoyed reading. The report was received.</p>	

<p><b>9</b></p>	<p><b>Report from the NJR Patient Feedback Advisory Group (PROMS) – NJRSC (04) 26</b></p> <p>MPI presented this paper. He advised the SC that the Patient Feedback Advisory Group (PFAG) had been renamed the Patient Reported Outcomes Measurement Study (PROMS) Group. This change of name is because PFAG was often misinterpreted as providing feedback <b>to patients</b> rather than obtaining feedback <b>from patients</b>.</p> <p>The paper provided an update on progress within the PROMS group and made the following recommendations for the SC's approval:</p> <ul style="list-style-type: none"> <li>- That an interim study should be commissioned to start in January 2005, and that decisions regarding choice of survey instrument(s) be delegated to the PROMS group</li> <li>- That support in principle is given to designing and setting up ongoing cohort studies, as described in Section 6 of the paper</li> </ul> <p>Discussion centred on the value of carrying out the interim study ahead of the output being available from the current Treatment Centre study (led by the London School of Hygiene and Tropical Medicine, and also involving the Royal College of Surgeons Clinical Effectiveness Unit). The view expressed by surgeons in the PROMS Group and by the majority of SC members present was that an interim study should go ahead in the short term. This would provide an opportunity to demonstrate patient benefit, test out methodologies / return rates etc ahead of larger scale surveys and provide input to the 2<sup>nd</sup> Annual Report. The associated costs appeared higher than might be expected. AEAT were requested to obtain quotes from organisations that could be subcontracted to cover the more routine elements of the survey – mailout, scanning returns, running preliminary analyses – under AEAT's overall management of the process. CD and MB could provide suggestions for contractors.</p> <p><b>[Action 2004/217]</b> AEAT to obtain quotes from organisations that could be subcontracted to cover the more routine elements of the interim patient reported outcomes survey. CD and MB to provide names / contact details of potential subcontractors.</p> <p>It was also agreed that, following the outcome of the current TC study (possibly by February 2005), the cohort approach would be the subject of a more detailed proposal for SC consideration.</p>	<p><b>AEAT/CD/MB</b></p>
<p><b>10</b></p>	<p><b>Hip: Owner's Manual – detailed evaluation and costings – NJRSC (04) 27</b></p> <p>MPI presented this paper, which had been prepared to provide a detailed evaluation and full costing of the Hip Owner's Manual. It demonstrated substantial potential benefit for the NJR in terms of improved levels of patient consent and compliance as a consequence of adopting the Hip: Owner's Manual.</p> <p>Approval was sought to proceed with development of the manual and to conduct parallel testing of 2 x 5,000 manuals (comparing two different formats).</p> <p>The SC agreed to the proposed parallel testing as described in the paper, subject to obtaining feedback from patients on their views of the manual – e.g. how useful had they found it, might they find it in the future, are there any changes they suggest to the format or the way it is used?</p> <p>AEAT were asked to consider whether the Hip:Owner's manual might also be a conduit for delivering patient reported outcomes forms that are to be completed at a later date.</p>	

<p><b>11</b></p>	<p><b>Determining the levy for FY 2005/06 – NJRSC (04) 28</b></p> <p>This paper was prepared and presented by HL. She presented options for the levy for FY2005/06. The SC were asked to consider the issues highlighted, any other issues considered relevant and make a recommendation to be put to Ministers for final approval. Three options were considered:</p> <ul style="list-style-type: none"> <li>- retaining the levy at £25</li> <li>- reducing the levy to £24.06</li> <li>- reducing the levy to £22.50</li> </ul> <p>Within the above options, scenarios were considered where the number of leviable implants purchased remained constant, and with a 5% year-on-year growth.</p> <p>The paper argued that the levy should be retained at £25 per implant for FY2005/06. Factors taken into account included: (a) the costs involved in changing hospital / supplier systems; (b) savings to individual trusts from, say, reducing the levy by £1.00 will on average only be of the order of a few hundred pounds, which may not even cover the costs of the associated changes to financial systems; (c) if decreasing the levy results in the fund going into deficit, it is extremely unlikely that the Department would be able to provide any additional funding. A probable consequence would be planned work having to be delayed or its scale reduced.</p> <p>The SC agreed with the recommendation that the levy remain at £25.00 for FY 2005/06.</p> <p>There was discussion related to any surplus funds remaining with the Department at 31 March 2005 – would they be carried over into the following FY year? HL indicated that she had consulted colleagues as the levy funds comprise monies from the NHS in England, the NHS in Wales and the independent sector in England and Wales. She is awaiting their response but expects that there will be resulting discussions with the Welsh Assembly Government and the Independent Healthcare Forum.</p> <p>Currently, HL is not aware of any mechanism whereby the Department can carry forward surplus levies into FY 2005/06 if they have arisen from the English NHS. However, she would pursue enquiries further, to determine whether there is an existing mechanism that can be used or if a new one can be put in place due to the special circumstances surrounding the NJR.</p> <p><b>[Action 2004/218]</b> HL to explore whether the NJR can be treated as a special financial case, thus allowing levy monies held by the Department at year end to be carried over to the next FY.</p> <p><b>[Action 2004/219]</b> AEAT to explore whether any novel funding mechanisms that they have experience of may be appropriate to apply to functioning of the NJR in the future.</p>	<p>HL</p> <p>AEAT</p>
<p><b>12</b></p>	<p><b>NJR financial reporting – future format</b></p> <p>HL advised the SC that the DH has a proposal for the format of a routine financial report. This currently consists of a 1 page summary showing the actual and estimated costs of the NJR against estimated income year-by-year. A copy is included as Appendix 3. <b>[Important note:</b> The figures included in Appendix 3 against proposals for new work will require amendment in the light of decisions made by the SC in the present meeting. Once the additional projects have been finalised, a more detailed financial plan will be drawn up.</p> <p>It is proposed that the SC receives at each meeting:</p> <ul style="list-style-type: none"> <li>- the 1 page summary (updated as necessary)</li> </ul>	

	<ul style="list-style-type: none"> <li>- a breakdown showing projected against actual spend for the current financial year</li> <li>- a narrative explanation of any deviation from the projected spend</li> </ul> <p>This routine process would also be the route for the programme management team to draw the SC's attention to any over or under spend, and present proposals for addressing this.</p> <p><b>[Action 2004/220]</b> SC members are asked to forward any comments on the proposed format of financial reporting to Dr Helen Lovell by 19 November 2004.</p>	<b>SC</b>
<b>13</b>	<p><b>Any Other Business</b></p> <p><b>a. Agreeing future meeting dates</b>  SC members are asked to indicate their preferences for SC meetings for the next year. The dates to be selected from are shown below.</p> <p><u>SC meeting 2005 / No.1 – late January or early February</u>  Mon 24, Tues 25, Wed 26, Thurs 27, Fri 28, Mon 31 January  Wed 2, Thurs 3, Fri 4 Feb  [Note: Tues 1 February is booked for an NJR RCC network meeting]</p> <p><u>SC meeting 2005 / No.2 – late April</u>  Wed 20, Thurs 21, Fri 22 April  Mon 25, Tues 26, Wed 27, Thurs 28, Fri 29 April</p> <p><u>SC meeting 2005 / No.3 – mid to late July</u>  Mon 18, Tues 19, Wed 20, Thurs 21, Fri 22 July  Mon 25, Tues 26, Wed 27, Thurs 28, Fri 29 July</p> <p>[Note: There is likely to be a strong preference for the July SC meeting to be held early in w/c 18 July to avoid the start of the school summer holidays]</p> <p><u>SC meeting 2005 / No.4 – late October</u>  Wed 19, Thurs 20, Fri 21 October  Mon 24, Tues 25, Wed 26, Thurs 27, Fri 28 October</p> <p><b>[Action 2004/221]</b> SC members to phone or email their preferred dates for future SC meetings to Sue Mercer ( Tel: 0870 190 6193; Email: <a href="mailto:sue.mercer@aeat.co.uk">sue.mercer@aeat.co.uk</a> ). Deadline – 19 November 2004.</p> <p><b>b. Discussion on including trauma in the NJR</b>  MPi reported back on the situation regarding inclusion of Trauma in the NJR. Trauma is included in both MDS v1 and MDS v2 as an indication for implantation. This may be fresh trauma or previous trauma. Confusion had arisen regarding which – if any – Trauma procedures should be entered into the NJR. MPi clarified that <b>all Total Hip Replacement resulting from Trauma (previous or fresh) should be entered into the NJR</b>. However, Hemiarthroplasties (which frequently are used for trauma situations) are NOT entered into the NJR. No changes to the NJR system are required. Appropriate communication with hospitals and RACs is needed to ensure that in future no trauma-related THRs are lost to the NJR due to misunderstanding the data entry criteria.</p> <p>AS pointed out that a small number of hospitals that specialise in trauma procedures but do not carry out elective THR / TKR may need to be added to the NJR database.</p> <p>There was further discussion relating to whether bipolar procedures should be included in the NJR - currently they are not . If bipolars were to be included, this would have considerable repercussions in terms of modifications to the database,</p>	<b>SC</b>

	<p>communications, the levy etc. It was decided to leave this issue on the table for future consideration.</p> <p><b>[Action 2004/222]</b> AEAT to ensure that appropriate communications are sent to hospitals / RACs clarifying the situation with regards to entry of Trauma procedures in the NJR and encouraging this data entry to take place.</p> <p><b>c. Situation in Harrogate</b>  PG advised the SC of the situation relating to Harrogate Healthcare NHS Trust. They remain a nil returner despite Christine Miles contacting their Chief Executive. His reply detailed a number of reasons why the Trust is yet to comply with the NJR, none of which were felt to be acceptable. BD asked to be provided with the relevant background information to allow him to liaise with North and East Yorkshire and Northern Lincolnshire SHA.</p> <p><b>[Action 2004/223A]</b> AEAT to provide BD with background information on the situation at Harrogate Healthcare NHS Trust.</p> <p><b>[Action 2004/223B]</b> BD to contact North and East Yorkshire and Northern Lincolnshire SHA regarding the situation at Harrogate Healthcare Trust.</p>	<p><b>AEAT</b></p> <p><b>AEAT</b></p> <p><b>BD</b></p>
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**Fiona Davies**  
**Director, NJR Centre**

**10 November 2004**

## APPENDIX 1 BREAKDOWN OF ACCESSING OF THE NJR WEB SITE BY DOMAIN / COUNTRY

The following statistics give a rough indication of the extent to which the NJR web site is used outside the UK.

### September 2004

Listing domains, sorted by the amount of traffic.

reqs: %bytes: domain

----: -----: -----

8698: 58.79%: .com (Commercial)  
6013: 18.77%: .uk (United Kingdom)  
3158: 13.89%: [unresolved numerical addresses]  
786: 4.17%: .net (Network)  
109: 1.54%: .es (Spain)  
134: 0.64%: .ca (Canada)  
71: 0.50%: .au (Australia)  
119: 0.28%: .gr (Greece)  
25: 0.19%: .be (Belgium)  
13: 0.11%: .it (Italy)  
8: 0.11%: .fr (France)  
77: 0.09%: .de (Germany)  
26: 0.09%: .org (Non-Profit Making Organisations)  
41: 0.08%: .fi (Finland)  
48: 0.08%: .tw (Taiwan)  
98: 0.06%: [domain not given]  
7: 0.06%: .ch (Switzerland)  
10: 0.06%: .jp (Japan)  
9: 0.06%: .za (South Africa)  
7: 0.05%: .il (Israel)  
3: 0.05%: .pl (Poland)  
20: 0.04%: .cl (Chile)  
14: 0.04%: .nl (Netherlands)  
6: 0.04%: .sa (Saudi Arabia)  
9: 0.03%: .ee (Estonia)  
8: 0.03%: .ie (Ireland)  
7: 0.03%: .edu (USA Educational)  
2: 0.02%: .pe (Peru)  
1: 0.02%: .mil (USA Military)  
4: 0.02%: .om (Oman)  
7: 0.01%: .my (Malaysia)  
4: 0.01%: .in (India)  
3: 0.01%: .br (Brazil)  
3: 0.01%: .lt (Lithuania)  
4: 0.01%: .nz (New Zealand)  
2: : .bn (Brunei Darussalam)  
1: : .hu (Hungary)  
3: : .dk (Denmark)  
3: : .ge (Georgia)  
2: : .ar (Argentina)  
1: : .sg (Singapore)  
3: : .ru (Russia)  
1: : .se (Sweden)  
1: : .fo (Faroe Islands)  
1: : .mx (Mexico)

## October 2004 Web Stats

Listing domains, sorted by the amount of traffic.

reqs: %bytes: domain

----:-----:-----

8597: 47.02%: .com (Commercial)  
5954: 25.60%: .uk (United Kingdom)  
3348: 17.05%: [unresolved numerical addresses]  
775: 5.12%: .net (Network)  
141: 0.98%: .nl (Netherlands)  
292: 0.57%: .se (Sweden)  
25: 0.48%: .cl (Chile)  
76: 0.44%: .fr (France)  
66: 0.37%: .au (Australia)  
135: 0.35%: .ca (Canada)  
18: 0.32%: .ph (Philippines)  
3: 0.28%: .fi (Finland)  
46: 0.26%: .be (Belgium)  
46: 0.23%: .za (South Africa)  
129: 0.11%: .lv (Latvia)  
11: 0.09%: .org (Non-Profit Making Organisations)  
17: 0.08%: .it (Italy)  
11: 0.08%: .id (Indonesia)  
39: 0.08%: .es (Spain)  
4: 0.06%: .de (Germany)  
8: 0.06%: .sa (Saudi Arabia)  
16: 0.04%: .gr (Greece)  
3: 0.04%: .edu (USA Educational)  
4: 0.03%: .in (India)  
3: 0.03%: .jp (Japan)  
7: 0.03%: .th (Thailand)  
5: 0.03%: .ch (Switzerland)  
5: 0.03%: .dk (Denmark)  
3: 0.03%: .is (Iceland)  
5: 0.02%: .yu (Yugoslavia)  
3: 0.02%: .ie (Ireland)  
6: 0.02%: .nz (New Zealand)  
2: 0.02%: .il (Israel)  
9: 0.01%: .mx (Mexico)  
6: 0.01%: [domain not given]  
4: 0.01%: .sg (Singapore)  
1: 0.01%: .pl (Poland)  
2: : .no (Norway)  
1: : .br (Brazil)  
1: : .cy (Cyprus)  
1: : .ua (Ukraine)

## APPENDIX 2

### OUTCOMES OF THE PUBLIC KEY INFRASTRUCTURE (PKI) SCOPING STUDY

#### MANAGEMENT SUMMARY

#### 1. Overview

This report was commissioned to inform the decision making process around proposed security changes to the National Joints Register. The primary aim of these changes is to allow surgeons and hospitals access to patient records (complete with personal data on the patient) on-line from the NJR database.

#### 2. Options

- Introduce a Hardware Security Module (HSM) card (or cards for resilience) as a tamper-proof environment for decryption of patient data. This keeps decryption keys secure and provides a safe container for the decryption process.

For secure authentication:

- Replace the existing password mechanism with a challenge process (such as “type the first and fourth character of your password”) to improve protection against keyboard sniffing and other data capture techniques. This is typical of the approach taken by Internet banking applications, for that very reason.
- Use hardware security tokens to create one-time pass-codes for secure authentication. This offers a secure two-part process (“something you have, something you know”).
- Deploying a certificate-based (PKI) solution for authentication and identity management. Options are included for a “conventional” client certificate implementation and a packaged solution where certificates and keys are stored and used from within a secure software container.

#### 2.1 Hardware Security Module

##### Advantages

- This is proven technology, widely used in this type of application.
- Decryption keys are kept in a secure, tamper-proof environment.
- Standard programming interface are defined so integration effort is reasonable.
- HSMs use technology compatible with certificates, public key systems and PKI.
- Server SSL private keys can also be held on the HSM, offering improved security over storage on the server hard disk.
- Encryption, decryption and digital signing is performed in hardware so performance is far better than in software.

##### Disadvantages

- Cost.
- Additional programming effort to integrate.
- Additional complexity.

## 2.2 Retain Passwords

### Advantages

- Simple and low cost.
- Already implemented, so known to work.
- Easy to register and enable new users.
- Widely used and understood by anyone likely to use the NJR.

### Disadvantages

- Vulnerable to password guessing, sharing and capture.
- Can be vulnerable to dictionary attacks (where accounts are targeted with an exhaustive list of proper words) and other structured/educated attacks.
- Requires awareness and competence on behalf of the user if security is to be maintained.

## 2.3 Hardware Authenticators

### Advantages

- Very secure, far less vulnerable to compromise than passwords or software tokens.
- Challenge/response variant offers a means to verify individual transactions (probably not relevant to the NJR).
- Easy to use.
- Independent of the client PC – no special interfaces required such as a smartcard reader, USB port, etc.
- Widely used and established technology – used to secure remote access for administrators, remote access for peripatetic users, for high-value financial services and many other applications. [As an example, INSL uses hardware tokens for remote access by staff to email, file sharing and other applications].

### Disadvantages

- Cost – charges per token and generally for the central authentication server.
- Token distribution – they are personalised for a given user so must be delivered securely to that individual.
- Admin overhead – there is an inevitable admin overhead involved with distribution, authentication failures, token failures, user education etc. This can be balanced against the effort involved with dealing with forgotten passwords etc.
- Battery life – tokens are battery powered so have a finite life (usually 3 or 5 years).
- Requires a re-issue of a token (cost and delay) if user loses his/her token.

## 2.4 Certificates (PKI)

### Advantages

<b>Stand-alone Certificates</b>	<b>Certificate + Smartcard</b>	<b>Software Container</b>
<ul style="list-style-type: none"> <li>• Software only – easy to create and distribute</li> </ul>	<ul style="list-style-type: none"> <li>• Secure container for private key</li> </ul>	<ul style="list-style-type: none"> <li>• Software only – easy to create and distribute</li> </ul>
<ul style="list-style-type: none"> <li>• No hardware, scalable and cost-efficient</li> </ul>	<ul style="list-style-type: none"> <li>• Strategic solution for NHS and e-Government</li> </ul>	<ul style="list-style-type: none"> <li>• No hardware, scalable and cost-efficient</li> </ul>
<ul style="list-style-type: none"> <li>• Widely adopted technology</li> </ul>	<ul style="list-style-type: none"> <li>• Offers route to digital signatures and other security techniques</li> </ul>	<ul style="list-style-type: none"> <li>• Portable – can support roaming users (but in less secure implementation)</li> </ul>
<ul style="list-style-type: none"> <li>• Standards-based – could easily be used for other applications</li> </ul>	<ul style="list-style-type: none"> <li>• Could be a basis for security for other NHS applications</li> </ul>	<ul style="list-style-type: none"> <li>• Packaged solution - includes certificate management and user admin tools/interfaces</li> </ul>
		<ul style="list-style-type: none"> <li>• Typically simple per user, per annum charging model</li> </ul>

### Disadvantages

<b>Stand-alone Certificates</b>	<b>Smartcard Deployment</b>	<b>Software Container</b>
<ul style="list-style-type: none"> <li>• PKI deployment can be costly and involves admin overhead</li> </ul>	<ul style="list-style-type: none"> <li>• Involves cost of certificates plus cost of smartcards and smartcard programming</li> </ul>	<ul style="list-style-type: none"> <li>• Requires user (or user's admin) to download and install a client</li> </ul>
<ul style="list-style-type: none"> <li>• Difficult for users to manage and maintain</li> </ul>	<ul style="list-style-type: none"> <li>• Distribution involves secure delivery to an individual</li> </ul>	<ul style="list-style-type: none"> <li>• Roaming option effectively offer only password-level authentication</li> </ul>
<ul style="list-style-type: none"> <li>• Re-issuing certificates after expiry can be painful</li> </ul>	<ul style="list-style-type: none"> <li>• Lack of PC smartcard interfaces so off-board reader required</li> </ul>	
<ul style="list-style-type: none"> <li>• Security for the private key is relatively weak (accessible but protected by a pass-phrase)</li> </ul>	<ul style="list-style-type: none"> <li>• Requires a physical re-issue of card if user's original is lost</li> </ul>	

### 3. Cost Summary

All pricing is indicative at this point for comparison only. Firm costs can be established once a decision has been made on a suitable solution.

Solution		Product Costs		Development		Implementation		Hardware		Support/Service		Momenta PM	Total	
		Upfront	Annual	Upfront	Annual	Upfront	Annual	Upfront	Annual	Upfront	Annual		Upfront	Annual
Pricing in £,000		Upfront	Annual	Upfront	Annual	Upfront	Annual	Upfront	Annual	Upfront	Annual	Upfront	Upfront	Annual
<b>HSM (x2)</b>	<b>Rainbow</b>	20	2.0	30		2						15	67	2.0
	<b>nCipher</b>	20	2.2	30		2						15	69.2	2.2
<b>Password (Challenge/response)</b>				15									15	0
<b>Token</b>	<b>SecurID</b>	235	42.5	20		8		2			100	25	265	142.5
	<b>Vasco</b>	180	0.55	20		8		2			100	25	210	100
<b>PKI</b>	<b>O/Source</b>			120				4			100	25	124	100
	<b>Comm</b>	250	50	20		15		4			100	25	289	150
	<b>Arcot (3yr)</b>	50		20		8		4			100	25	82	100
	<b>Smart Card</b>	240		120		8		4			100	25	372	100

Development includes work by Advent IT and other suppliers on the existing NJR application to integrate with the suggested security solutions.

Implementation is largely infrastructure installation and integration, software installation and configuration and distribution to tokens, certificates etc to users (additional to any existing charges).

Support/service includes technical support and managed services to deploy the technology to the user community and monitor/administer the service.

#### **4. Recommendation**

Patient data can be made available safely over the Internet provided appropriate security measures are taken. The current approach to authentication uses passwords and therefore involves a level of risk, although this risk is mitigated by the rules surrounding password composition (length, non-alpha characters etc) and management. If passwords are to be retained, we recommend either a challenge/response or, at the very least, 30-day password renewal.

Ultimately the risk question is one for the owners of the data (the NHS). Our view is that a more secure authentication mechanism than passwords is appropriate if patient data is made available across the Internet but that a risk assessment should be carried out by the data owners to determine whether passwords are acceptable.

If the secure authentication route is chosen, our recommendation is that a hardware token-based solution is a more pragmatic and manageable option than PKI at this point. Certificates are likely to become the standard within the NHS and beyond, but there are currently too many practical issues at the client end in terms of certificate distribution, installation, portability, renewal and support. A software token using certificates in a packaged form is a lower cost alternative to hardware tokens, can offer largely equivalent security and is far easier to distribute.

Regardless of the option selected, we recommend that a hardware security module (HSM) is installed to perform the decryption of patient data as it is requested. That way, decryption happens in a tamper-proof environment so that the decryption keys are never exposed or vulnerable. Authentication and authorisation has to be completed and data access granted before patient records can be decrypted and presented on-screen. Currently decryption keys are stored on a CD-ROM kept in a safe, so patient data can only be recovered as an exceptional off-line task.

#### **5. Proposed Action**

Install Hardware Security Module within NJR at a Cost of 70 - 90K, thereby enabling patient data to be accessed online by appropriate users.

Force password change every 30 days

Review challenge response to password login (additional 15K development)

Complete a risk assessment 3-6 months following HSM implementation.

Review security options upon completion of risk assessment

**Ian Calcutt**

**NJR IT Manager**

**1 November 2004**

Indicative Cost Table all £000's	Hardware Security Module	Challenge Response Existing Password	Hardware Authenticators	Certificates (PKI)
Development Costs	70 – 100	15	250	275
Annual Support Costs	5	1	100	100
Total Cost	100	16	350	375
Main Advantages	<p>This is proven technology, widely used in this type of application.</p> <p>Decryption keys are kept in a secure, tamper-proof environment.</p> <p>Standard programming interface are defined so integration effort is reasonable.</p> <p>compatible with certificates, public key systems and PKI.</p>	<p>Simple and low cost.</p> <p>Already implemented, so known to work.</p> <p>Easy to register and enable new users.</p> <p>Widely used and understood by anyone likely to use the NJR.</p>	<p>Very secure, far less vulnerable to compromise than passwords or software tokens.</p> <p>Easy to use.</p> <p>Independent of the client PC – no special interfaces required such as a smartcard reader, USB port, etc.</p> <p>Widely used and established technology</p>	<p><b>Certificate + Smartcard</b></p> <p>Secure container for private key.</p> <p>Strategic solution for NHS and e-Government.</p> <p>Offers route to digital signatures and other security techniques.</p>
Main Disadvantages	<p>Cost.</p> <p>Additional programming effort to integrate.</p> <p>Additional complexity.</p>	<p>Vulnerable to password guessing, sharing and capture.</p> <p>Can be vulnerable to dictionary attacks (where accounts are targeted with an exhaustive list of proper words) and other structured/educated attacks.</p> <p>Requires awareness and competence on behalf of the user if security is to be maintained.</p>	<p>Cost – charges per token and for the central server.</p> <p>Token distribution – they are personalised for a given user so must be delivered securely to that individual.</p> <p>Admin overhead – involved with distribution, authentication failures, token failures, user education etc.</p> <p>Battery life - 3 or 5 years.</p> <p>Requires a re-issue of a token if user loses his/her token.</p>	<p>Involves cost of certificates plus cost of smartcards and smartcard programming.</p> <p>Distribution involves secure delivery to an individual.</p> <p>Lack of PC smartcard interfaces so off-board reader required.</p> <p>Requires a physical re-issue of card if user's original is lost</p>
Security Rating 1-5 (5 excellent)	2/3	1	4	5
Development Timeframes	3-6 Months	1 Month	6 – 12 Months	6 – 12 Months
User Experience 1-5 (5 excellent)	3	1	5	5

## APPENDIX 3 – PROPOSED FORMAT FOR NJR FINANCIAL REPORTING- FOR STEERING COMMITTEE COMMENT

National Joint Registry	2002/03	2003/04	2004/05	2005/06	TOTAL
<b>Annual Costs (DH)</b>					
Annual contract					
Expenses					
<b>Total Annual costs</b>					
<hr/>					
<b>Annual contract (AEA)</b>					
Variation costs (exc VAT)					
Variations already agreed					
V1 Additional meeting attendance					
V2 NJR newsletter into Welsh					
V3 Contract amendments					
V4 Contract amendments					
V5 RACs					
V6 MDSv2					
V7 6(b) Bulk upload development					
V8 Barcoding scoping					
V9 Barcode solution					
V10 Component management					
V11 NJR Annual Report (RCS)					
V12 Provide data to Scotland					
V13 Year 3 extension					
<b>Variation Total</b>					
<b>TOTAL AGREED</b>					
<hr/>					
Further Variations to be agreed					
Patient reported outcomes study					
Hip owners manual					
Research Sub Committee					
PKI system development					
Patient consent initiative					
Extension of RAC contracts + 1 RAC					
<b>TOTAL Future Variations</b>					
<b>Total future CV plus variations</b>					
<hr/>					
<b>Income</b>					
Levy					
DH Element		25.00	25.00	25.00	
VAT on DH		18.20	18.20	18.98	
Manufacturers element		3.86	3.86	4.03	
VAT on Manufacturers		2.50	2.50	1.70	
Total Levy		0.44	0.44	0.30	
		25.00	25.00	25.01	
Expected no of implants		143,102	143102	143102	
Annual income - DH		3,156,830.12	3,156,830.12	3,292,777.02	
Annual income - Mfr		420,719.88	420,719.88	286,204.00	
Total income		3,577,550.00	3,577,550.00	3,578,981.02	
<b>Total NJR Income</b>		3,156,830.12	3,156,830.12	3,292,777.02	
<hr/>					
<b>Difference</b>					
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## APPENDIX 4 PROGRESS ON ACTIONS FROM PREVIOUS MEETINGS

Action no.	Progress	Action holder
2003/142 (Revised)	<p><b>Delayed</b> JvdM to produce a paper for the July SC meeting, detailing the Research Subcommittee's proposed constitution and summarising key points of their first meeting. Paper to be provided to FD at the NJR Centre by 30 June. <b>Postponed until November 2004 SC meeting as Research Subcommittee has its first meeting in July (after the July SC meeting).</b></p>	JvdM
2004/184	<p><b>Ongoing</b> JvdM to liaise with the various NJR stakeholder groups to determine what 'early warning' functionality is required for the NJR, what triggers each aspect should set off, resulting actions, and which bodies take prime ownership of each type of scenario involved. JvdM to produce a related paper for the July SC meeting. Individuals to be consulted are: AC, AS, MB, PG, CD and DC. Draft paper to be delivered to the NJR Centre by 30 June 2004. <b>No paper received. Related activity to be carried out as an interim period activity (ahead of work on the 2<sup>nd</sup> Annual Report).</b></p>	JvdM
2004/190	<p><b>Ongoing</b> (a) FD to confirm with Hugh Phillips the timescale for publication of the CSE document. (b) FD to request copies to circulate to SC members, when the document is published (or in advance if possible). (c) AEAT / SC members to determine whether there is a need for the NJR to produce an additional but complementary statement. <b>AEAT to liaise with identified relevant contact (Lavinia Blackett, Head of the Professional Standards Unit at the Royal College of Surgeons)</b></p>	AEAT/ SC members
2004/191	<p>(a) AEAT to send a list of TCs to the National Implementation Team every 3 months, asking them to verify which are operational, and whether there are any to add, and any to remove. <b>AEAT had meeting with NIT representative on 26.10.04. They will keep the NJR informed of developments with new independent TCs.</b> (b) AEAT to facilitate writing to the Healthcare Commission notifying them of the NJR and its requirements and requesting that they inspect against NJR requirements and notify the NJR when they do so. <b>To be linked in to contacting the Healthcare Commission regarding national care standards and NJR patient consent in the independent sector (October RCC meeting refers).</b> (c) AEAT to request that prosthesis suppliers notify the NJR Centre when a new hospital / TC starts purchasing hip and knee components. <b>Being addressed.</b></p>	AEAT
2004/197	<p><b>Ongoing</b> AEAT to develop outlines for one (or perhaps more) approach to enabling HDMs to enter surgeons' default techniques, cost the approach(es) and determine timeframe(s). To be submitted for approval when ready (i.e. do not wait until October SC meeting.)</p>	AEAT
2004/198	<p><b>Completed</b> AEAT to carry out a scoping study on implementing a PKI security system on the NJR, including costings. Cheaper alternatives, eg system used on tonsillectomy audit, and emailing the NJR Centre and being sent CDs of their own data. <b>See SC paper NJRSC (04) 27</b></p>	AEAT

2004/201	<p><b>Completed</b>          AEAT to draft a letter to be sent to EAR on behalf of the Steering Committee indicating that the NJR will not be joining at present but would like to be kept informed of progress.  <b>Carried out by PG</b></p>	AEAT
2004/203	<p><b>Ongoing</b>          AEAT to arrange a meeting involving SCh, BD, PG and DC to ensure that there is a full, common understanding of the situation in Wales; and agree what steps need to be taken.  <b>Meeting being rescheduled due to changes in responsibilities</b></p>	AEAT
2004/205	<p><b>Ongoing</b>          AEAT and MPo to work up a full set of questions from the set provided by John Timperley, draft answers and circulate to the SC for review.  <b>Action to be rescheduled for November 2004.</b></p>	AEAT/ MPo

**Fiona Davies**

**3 November 2004**