

NATIONAL JOINT REGISTRY STEERING COMMITTEE (NJRSC)

MINUTES

Meeting:	NJR Steering Committee		Date: Tuesday 27 th April 2010
Location:	MWB, Golden Cross House, 8 Duncannon Street, Strand, London, WC2N 4JF		
Members Present:	Prof Paul Gregg	PG	Acting Chair, Orthopaedic Surgeon
	Mary Cowern	MC	Patient Representative
	Prof Alex Macgregor	AM	Public Health & Epidemiology
	Carolyn Naisby	CN	Practitioner with Special Interest in Orthopaedics
	Martyn Porter	MP	Orthopaedic Surgeon – <i>attended morning session</i>
	Dean Sleigh	DS	Orthopaedic Device Industry Representative
	Keith Tucker	KT	Orthopaedic Surgeon
	Andrew Woodhead	AW	NHS Management Member
Regular Attendees:	Richard Armstrong	RA	Programme Director, Northgate
	Alex Henderson	AH	Committee Administrator, Healthcare Quality Improvement Partnership (HQIP)
	Mike Swanson	MS	NJR Principal Consultant, Northgate
	Yvonne Tse	YT	Development Officer (NJR), HQIP
	Melissa Wright	MW	Development Officer (NJR), HQIP
	Elaine Young	EY	National Development Lead, HQIP
Meeting Invitees:	Dr Crina Cacou	CC	Medicines & Healthcare Products Regulatory Agency (MHRA)
	Peter Howard	PH	Chair, NJR Regional Clinical Co-ordinators' Network
	Robin Rice	RR	Welsh Assembly Government Representative
Apologies:	Mick Borroff	MB	Orthopaedic Device Industry Representative
	Robin Burgess	RB	Chief Executive, HQIP
	Andy Crosbie	AC	MHRA
	Charlotte Humphry	CH	Programme Manager, Northgate
	Khalid Razak	KR	MHRA
	Andy Smallwood	AS	NHS Supply Chain Representative

REF	ITEM	Action
1.	<p>Welcome and Apologies for Absence</p> <p>PG opened the meeting and welcomed all those present.</p> <p>Apologies were received and noted.</p>	
2.	<p>Minutes of the previous meeting held on 28th January 2010</p> <p>The minutes were accepted as a true and correct record.</p>	
3.	<p>Appointment of Chairman and status of Steering Committee</p> <p>EY reported on the status of the NJRSC following the formal notification received from the Department of Health (DH) which EY had previously notified members of.</p> <p>The NJRSC would no longer be classified as a Non-Departmental Public Body, but would be reclassified as an Expert Committee, subject to confirmation from the Cabinet Office. Due to the change of status, the NJRSC would no longer report to Ministers, but would instead report to Sir Bruce Keogh, NHS Medical Director. The reason given by the DH was the NJRSC's success in making the data collection, and the setting of the levy for the NJR, non-contentious in the modern NHS.</p> <p>Appointments to the NJRSC would no longer be conducted through the Appointments Commission, but through HQIP following a similar process. The appointment of a new lay Chair would be handled by HQIP, and an advert would be placed during June/July.</p> <p>It was noted that the DH had recognised the work of the NJRSC and the status that the NJR had. Members were thanked for their contribution to its success.</p> <p>During the process of the Committee's change of status, EY noted that it would be a useful time to review the structure of the NJRSC. Members discussed the current role of the NJRSC and the support of the sub-committees. When the structure of the sub-committees was introduced, the workload was intended to be distributed, with issues being covered outside of the NJRSC and reported back. It was noted that the agendas for the sub-committees had become very lengthy and intense. It was suggested that the sub-committees should be given the authority to make decisions to reduce the level of discussion which currently occurred in the NJRSC meetings during each sub-committee update.</p> <p>Members discussed the benefits of setting up a Management Executive Committee to oversee any issues raised in the sub-committees, and report to the NJRSC. It was felt that this would be useful as the strategic and executive work was currently combined during the NJRSC meetings.</p> <p>EY would email members with further information on the proposed restructure, and would invite members to email comments and feedback to her. The committees would undergo a review to identify how the structure could be improved. She noted that it should be considered whether the restructuring process should be completed prior to, or following the appointment of a new Chair.</p> <p>PG expressed his thanks, on behalf of the NJRSC, for the hard work that the HQIP</p>	

	<p>representatives assigned to the NJR.</p> <p>Agreed that:</p> <p>1. EY would email members regarding the restructuring of the NJRSC. Members would reply to EY with their comments and suggestions.</p>	EY / All
4.	<p>Matters Arising (not appearing elsewhere on the Agenda)</p> <p>4.1. Addition of Temporomandibular Joint Replacement (TJR) [Previous minutes: Item 3.2. Matters Arising]</p> <p>MS and CN had attended a meeting at the National Institute for Clinical Excellence (NICE) with Hannah Patrick (Consultant Clinical Advisor) and Professor Bruce Campbell (Chair, Interventional Procedures Advisory Committee) to look at the dataset for the TJR, and discuss the proposal of TJR joining the NJR.</p> <p>NICE had not shown support for the proposal, and the NJRSC agreed that it would not proceed at the current time. HQIP would inform Andrew Sidebottom, who had presented the proposal to NJRSC members in October 2009, of the decision.</p> <p>Agreed that:</p> <p>2. EY would write to Andrew Sidebottom to confirm that the NJR would not proceed with inclusion of TJR onto the NJR at the present time.</p> <p>4.2. Component Management System Project [Previous minutes: Item 12. Component Management System]</p> <p>MS confirmed that work on the project was underway, and it was estimated to be completed within 3 months, in line with elbows and shoulders. Initially there had been a problem with classifying implants due to the new products available on the market, so the process was being reviewed to allow new categorisation of components. The surgeons offered to review the system when it had been completed.</p> <p>4.3. Metal on Metal (MoM) Study [Previous minutes: Item 15. Metal on Metal Study]</p> <p>CC informed members that the report on the MoM issue had not yet been finalised. MHRA had published interim advice on patient management which had been supported by the British Orthopaedic Association (BOA). The Joint Working Group would reconvene to finalise the report, after which it would be published.</p> <p>EY queried the involvement of the NJR in the report and sought clarification on who had set up the Joint Working Group, and who was responsible for the report. Members felt that clarification from Dr Sue Ludgate (Medical Director, MHRA) would be welcomed, which CC would follow up.</p> <p>Members expressed their concern that the MHRA would not grant indemnity to the authors of the report, and CC agreed to take the issue forward.</p> <p>Members discussed the MHRA alert and felt it was important for a clear and consistent message to be given to NHS Trusts to inform them of the action they would be required to take when the MHRA alert was issued, which CC would follow up.</p> <p>PG stated that the MoM issue had highlighted the method of how new prostheses were introduced and controlled.</p>	EY

5.1.1. Minutes of the previous RCC Network meeting

The minutes were noted.

5.1.2. Hemi-arthroplasty Procedures

Following further discussion on which form should be filled out when hemi-arthroplasty procedures were carried out, members were in agreement that conversion from a hemi-arthroplasty to a total hip replacement should be entered onto the H1 form.

Members felt that the H2 form should be amended to state that it was not to be used for conversion of hemi-arthroplasty.

Agreed that:

- 7. Conversion from a hemi-arthroplasty to a total hip replacement should be entered onto the H1 form. For clarity, the H2 form would be amended to state that it was not to be used for conversion of hemi-arthroplasty.**

PH / Northgate

5.2. Outliers Sub-Committee

5.2.1. Minutes of the previous Outlier Sub-Committee meeting and update

PG updated members on the previous Outlier meeting where reports 003 and 004 had been reviewed. MW had produced summary charts which monitored progress on each surgeon which had been identified as a potential outlier. The report would be sent out on a fortnightly basis to all members for their information.

There had been a long discussion during the Outlier Sub-Committee meeting regarding the process of identifying potential implant outliers. The MHRA were concerned with the process and the speed with which the outlier information was reaching them.

MC stated that patients would be appalled if they discovered they had been fitted with a device which had been highlighted as a potential outlier, regardless of whether there was firm evidence to support the claim. If there was doubt, the device should not be fitted. MPo agreed that in the case of patients being fitted with a device that was a potential outlier, there was a greater concern for the patient’s wellbeing.

Members then reviewed the issue from the view of the suppliers whereby evidence should be sought before announcing a device as a potential outlier as there was a danger of creating unnecessary panic.

Although the MHRA had initially been involved with the process of identifying implant outliers, they no longer were and expressed a wish to be involved again going forward.

Members discussed creating an additional sub-committee to deal specifically with the identification of proposed implant outliers, and include the involvement of the MHRA in the process. Members agreed with the proposal, and HQIP would make arrangements to formulate the new sub-committee.

MPo felt that potential implant outliers was the responsibility of the MHRA. Until the new sub-committee had been formed and the new process was underway, the NJR would inform the MHRA of potential implant outliers and they should quickly proceed to follow up with the supplier, as the welfare of patients was at risk.

<p>Agreed that:</p> <p>8. An additional Outlier Sub-Committee would be formed which would involve MHRA to specifically review the process for identifying potential implant outliers.</p> <p>5.2.2. CUSUM and real-time monitoring</p> <p>At the previous Outlier Sub-Committee meeting, Lightfoot Solutions had been invited to give a presentation regarding an early warning system which could be used for the identification of potential outliers. At the meeting, members had felt that it would be useful for Lightfoot to conduct a pilot study, and to give a more detailed presentation to NJRSC members. The system focussed on signals from noise which would allow subtle changes in data to be identified in real-time. The system would be an addition to the current NJR monitoring system, and would be based at Northgate so there would be no breach of confidentiality. The system would identify the low volume issues that were not currently identified. Northgate were in contact with Lightfoot Solutions to arrange another meeting to discuss the system in further detail.</p>	<p>PG / HQIP</p>
<p>Agreed that:</p> <p>9. A follow up meeting would be organised with Lightfoot to meet with the Outlier Sub-Committee. A request would then be made for Lightfoot to produce a more detailed presentation for the NJRSC.</p> <p>5.2.3. Letters to Trusts with a compliance rate below 80%</p> <p>AW and PG had produced a draft letter which PG discussed with Sir Bruce Keogh (BK) when they met. BK had offered to submit a paragraph regarding quality accounts to include in the letter to Trust CEO's with a low compliance rate. RR reminded members that Wales did not have Quality Accounts, and MC suggested an alternative paragraph should be added from the Welsh Chief Medical Officer. EY would follow up with RR and MC.</p> <p>BK was complimentary of the work the NJR had achieved. Although the British Orthopaedic Association (BOA) were supportive of the NJR's work in the outlier identification process, he suggested written support from the BOA should be sent to the Department of Health (DH). Mike Bell (President, BOA) had previously agreed to do this, and MPo offered to follow up on progress.</p> <p>BK approved of the process whereby the NJR initially contacted the identified outlier surgeon to validate their data before contacting their CEO.</p> <p>The issue of mandation was raised, but was made clear by BK that it would not go ahead.</p> <p>BK was surprised that the NJR Annual Reports did not present survivorship data by named units.</p> <p>EY informed members that HQIP were working on a general guidance on the outlier process as commissioned by the DH which would be issued across all national audits.</p> <p>BK had stated to PG that he felt the NJR should feed data back to Trusts, and a named individual in each Trust should review the data, address any issues that</p>	<p>MS</p>

<p>arose, and report back to the NJR with the actions that had been taken.</p> <p>The Outlier Sub-Committee had discussed the following suggested process in relation to reporting outliers on a Trust basis:</p> <ol style="list-style-type: none"> 1. Every six months, a letter would be sent to the Chief Executive Officer (CEO) of each Trust (the frequency may be reviewed at a later date). The letter would provide a commentary which would: <ol style="list-style-type: none"> a. Inform the CEO of where their unit was as a whole, in relation to other units b. Indicate where individual named hip surgeons from their unit were in relation to each other, and to state if they had been identified as a potential outlier or not c. Indicate where individual named knee surgeons from their unit were in relation to each other, and to state if they had been identified as a potential outlier or not. 2. A letter would be sent to the surgeons, who had been identified as an outlier, 6 weeks before the letter (stated above) would be sent to their CEO, which would allow them to review their data and approach their CEO in advance. The letter would provide a commentary which would: <ol style="list-style-type: none"> a. Inform the surgeon of the NJR process for reporting outliers b. Advise the surgeon that their data suggests that they are an outlier c. Identify their position on a funnel plot graph d. Request that the surgeon validates their data e. Provide details of specialist societies, eg the British Orthopaedic Association, which were available for the surgeon to contact if required. <p>Members supported the proposed principle and agreed that MPo could report back at the BOA Council meeting he was due to attend that afternoon.</p> <p>A draft proposal would be drawn up and circulated to members for review ahead of the next NJRSC meeting where the draft would be finalised. It was anticipated that the new system could be introduced in April 2011 in line with the 006 Outlier Report.</p> <p>The NJR had been asked to produce another article for the British Orthopaedic News (BON). KT and PG had previously agreed to discuss what would be included in the article.</p> <p>Agreed that:</p> <ol style="list-style-type: none"> 10. EY would follow up with RR and MC regarding the letters which would be sent to all Trusts with a compliance rate below 80%. An alternative paragraph would be required for the letters to the Welsh Trusts, as Quality Accounts was not relevant to them. 11. MPo would follow up with Mike Bell (President, BOA) regarding the letter he had agreed to send to the DH on behalf of the BOA to formally express their support for the outlier monitoring and management work of the NJR. 12. The principle proposed by the Outlier Sub-Committee for reporting outliers on a Trust basis was supported by the NJRSC. 13. A draft proposal on the outlier process would be reviewed by the Outlier Sub-Committee and distributed to the NJRSC members for comment, prior to the next NJRSC meeting where the proposal would be finalised. <p>5.3. Stakeholder Engagement and Communications - addition to the agenda</p> <p>AW and MW updated members on the progress of initiating the Stakeholder Engagement and Communications Sub-Committee. The aim of the committee would be to connect</p>	<p>EY / RR / MC</p> <p>MPo</p> <p>PG</p>
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	<p>5.5.2. Research Meeting: NJR, Research Capability Programme/Connecting for Health, Arthritis UK and the British Orthopaedic Association</p> <p>The minutes from the Research meeting with Arthritis UK, the BOA and the Research Capability Programme were received. The meeting had been organised by Sir Alex Markham to discuss the national research project which was attempting to connect all NHS related databases together to facilitate research. Another meeting had been scheduled for July for further discussion.</p> <p>Sir Alex Markham had been invited to attend the current NJRSC, but was unable to due to his diary commitments. He was also unable to attend the NJRSC meeting scheduled for July. Members suggested inviting him to October's NJRSC to discuss the Research programme, or request a paper for the NJRSC to review if he was unable to attend.</p> <p>EY informed members that the NJR Research post remained vacant as the contact they had approached was unable to assist with taking the process forward. EY was continuing to find a solution.</p> <p>Members queried whether the proposal by Alistair Hart on the metal on metal study with the NJR had been circulated. EY confirmed it had, but would recirculate.</p> <p>Agreed that:</p> <p>17. HQIP would contact Sir Alex Markham to invite him to the NJRSC meeting in October. If he was unable to attend, a request would be made for him to produce a brief paper for the NJRSC to review.</p> <p>18. EY would recirculate the research proposal from Alistair Hart to members.</p> <p>5.5.3. NJR PROMs</p> <p>RA stated that the draft protocol document was being produced which would outline the proposed capture of 12 month follow up questionnaires for the patients who had participated in the National PROMs programme and consented for their data to be stored on the NJR. Patients would undertake a survey for a 12 month period, with a 3 year and then 5 year follow up. The Department of Health (DH) had shown their support of the programme during a meeting held with Northgate. Costs for the programme were being finalised and would be circulated to members ahead of the next NJRSC where further discussion would be held.</p> <p>PG stated that an application had been received from Mike Reed to conduct a PROMs study on the 5 most commonly used knee implants. He had also received a verbal request from another contact and would forward both requests to AM for consideration at the next Research Sub-Committee meeting.</p> <p>KT stated that Norfolk and Norwich were developing a web-based PROMs which would allow access by patients and GPs. Members discussed the advantages of web-based against paper-based forms.</p> <p>Agreed that:</p> <p>19. Northgate would circulate the estimated costs to members ahead of the next NJRSC, where the survey would be further discussed.</p> <p>20. PG would reply to a verbal request he had received and ask for the request to be made in writing. He would then forward the request, along with an application from Mike Reed to AM for consideration at the next Research Sub-Committee meeting.</p>	<p>EY / AH</p> <p>EY</p> <p>Northgate</p> <p>PG / AM</p>
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	<p>5.6. Development Sub-Committee</p> <p>5.6.1. Update on the Ankle Inclusion Project</p> <p>The data collection was launched on 1st April 2010 following approval from the Review of Central Returns (ROCR). The levy had been agreed and would start on 1st June 2010.</p> <p>The Welsh Assembly had been written to, and the NJR were waiting for their authorisation.</p> <p>All forms had been updated to include the ankle joint, and implant suppliers had been notified. The Memorandum of Understanding (MOU) had been updated and signed.</p> <p>The latest NJR newsletter included an update of the inclusion of ankles to the NJR, and a patient case study.</p> <p>5.6.2. British Elbow and Shoulder Society (BESS)</p> <p>Northgate and HQIP had conducted initial meetings with BESS, and the business case had been signed off. The draft project initiation document was under review. The levy rate would remain the same cost for shoulders as for hip and knees joints.</p> <p>Ankles were now part of the NJR, although their representation on the NJRSC was still to be confirmed.</p> <p>Discussion was required as to how ankles and shoulders would participate in the outlier process.</p> <p>Further meetings were due to be held, and updates would be given to the NJRSC.</p> <p>Agreed that: 21. The next Outlier Sub-Committee meeting would include a discussion on how ankle and shoulder joints would participate in the outlier identification process.</p> <p>5.6.3. Incorporation of Northern Ireland KT contacted James Nixon who confirmed that Northern Ireland were still keen to join the NJR. EY informed members that Mike Bell (President, BOA) had been in contact associates in Northern Ireland and there was now some confusion over the levy and other implications of Northern Ireland joining the NJR. EY would clarify the issues with Mike Bell and follow up on the process.</p> <p>Agreed that: 22. EY would contact Mike Bell (President, BOA) to clarify the issues surrounding the delay in the incorporation of Northern Ireland to the NJR and to agree a co-ordinated approach.</p>	<p>MW</p> <p>EY</p>
<p>6.</p>	<p>Strategic Plan</p> <p>6.1. DNA Biobank Study</p> <p>Members received a draft version of the protocol for the development of a NJR DNA Biobank Study. MPo informed members that the study was a pilot study and was being</p>	

	<p>led by Mark Wilkinson, an orthopaedic surgeon in Sheffield who was interested in understanding disease processes and the genetics behind it.</p> <p>The NJR had been approached to assist with the funding of the study. Any funding approval from the NJR would be conditional upon approval from the National Research Ethics Service (NRES) and from the Ethics and Confidentiality Committee (ECC) being granted.</p> <p>Members felt they should seek advice from an external peer review before making a decision on the funding, and agreed that 3 peer reviews would be satisfactory. Members were supportive of the proposal, subject to the peer review. Once the peer reviews had been conducted, the feedback would be circulated to members who would then be contacted prior to the next NJRSC meeting to agree a response.</p> <p>MPO stated that his name would be removed under the 'Details of Applicants' section of the proposal, as there was an issue regarding conflict of interests.</p> <p>Agreed that: 23. AM would select 3 external reviewers to conduct a peer review on Mark Wilkinson's proposal. 24. The NJRSC were supportive of the proposal, subject to external peer review. Members would be contacted in advance of the next NJRSC meeting to agree a response.</p> <p>6.2. HES/NJR linkage Audit Project</p> <p>Members discussed the need for the NJR to validate HES revisions. Jan van der Meulen and Susan Charman had previously stated they would give their expertise on HES data and its statistics.</p> <p>The project plan was not available for distribution at the meeting, but would be available at the next NJRSC meeting.</p> <p>Members supported the principle that the issue should be reviewed and further discussion would be undertaken.</p> <p>Agreed that: 25. Northgate would produce a project plan for review at the next NJRSC meeting. 26. MS, MPO and PH would meet to discuss the process.</p>	<p>AM</p> <p>AM / All</p> <p>Northgate MS / MPO / PH</p>
<p>7.</p>	<p>NJR Finance Report Q4 (January – March 2010)</p> <p>The Finance Report for Q4 was received and noted. There had been an under-spend on the strategic plan.</p>	
<p>8.</p>	<p>Orthopaedic Departmental Audit Meeting using NJR data</p> <p>KT had produced a paper which listed 5 queries surrounding:</p> <ul style="list-style-type: none"> a) orthopaedic departmental audit meeting using NJR data b) trainees and identifier numbers c) double data upload d) trainees using NJR data for MDs 	

	<p>e) annual report to surgeons.</p> <p>Northgate produced a paper which had responded to KT's queries, and members reviewed the paper.</p> <p>Agreed that: 27. KT and MS would meet to discuss the idea of having a single log-in for multiple applications/systems.</p>	KT / MS
9.	<p>NICE – Total Hip Replacement (THR) using minimally invasive approach</p> <p>PG advised members that he had received 2 letters from representatives at the National Institute for Health and Clinical Excellence (NICE) thanking the NJR for its support in its preparation for gathering mandation.</p> <p>Members discussed the ongoing issue of managing the different barcodes used by suppliers.</p> <p>Agreed that: 28. Northgate would:</p> <ol style="list-style-type: none"> a. conduct a survey to establish which suppliers were using which barcodes b. suggest an approach to accommodate the existing systems in place c. investigate the costs and implications involved. 	Northgate
10.	<p>Mandating the NJR Project</p> <p>This was incorporated under item 5.2 (update on the Outliers Sub-Committee meeting).</p>	
11.	<p>Quarterly Statistics Report (QSR) Q4 (January – March 2010)</p> <p>The QSR for Q4 was received and noted.</p>	
12.	<p>Quarterly Management Report (QMR) Q4 (January – March 2010)</p> <p>Members noted the QMR for Q4.</p> <p>MC stated that she had received positive feedback on the recent NJR newsletter which was more patient focussed than previous editions.</p> <p>MC queried the response which had been given to the patient of the data request listed at the bottom of page 21 of the QMR ('no data was supplied to the patient because the information was available within the Annual Report'). She noted that patients who were advised to refer to the Annual Report should be guided on which section to find their information. MS would ensure that patients would be effectively advised.</p> <p>PG advised members that the new CEO of Arthritis Research UK had approached PG for an article about the NJR, to publish in the Arthritis Research UK newsletter. PG would provide a brief history, aims, and the importance of the NJR.</p> <p>CN informed members of an issue with accessing data on the NHS Choices website. When patients attempted to retrieve data on hip or knee procedures for their local Trust, collective data for all procedures within the Trust was given, instead of data which was relative to a certain type of procedure. MS stated that he had a telephone call scheduled with NHS Choices the following day and would mention the issue, as well as discussing</p>	

	outcome revision rates and compliance consent rates.	
13.	<p>Any Other Business</p> <p><u>a) British Orthopaedic News (BON) article</u> KT requested that members should email him with any suggestions for the article that he was producing for the BON. Overall, members felt that a summary of the NJR developments in progress would be useful.</p> <p>Agreed that: 29. Members would email ideas for the BON article to KT.</p> <p><u>b) Suppliers Feedback System Project</u> DS informed members that the data supplier access had not been perceived to be on the original project plan. Upon investigation, he was informed that it was allegedly delayed due to the inclusion of ankles on the NJR. He stated that he was concerned that this would occur again when shoulders and elbows were included on the NJR. HQIP confirmed that this was not the case and would speak with Northgate outside of the meeting to clarify the issue.</p> <p>Agreed that: 30. YT and MS would liaise outside of the meeting to discuss any related issues.</p> <p><u>c) Strategic Plan</u> YT reminded members that she had circulated ideas on the strategic plan, but was yet to receive feedback from the majority of members. Although there was no urgent deadline for response, it would be useful to have ideas in preparation for next year.</p> <p><u>d) Combined Orthopaedic Associations Congress, 12th – 17th September 2010, Glasgow</u> KT advised members who planned to attend the congress to book their accommodation as soon as possible. There had been a high demand for accommodation due to the scheduled visit from the Pope during the same week.</p>	<p>All</p> <p>YT / MS</p>
14.	<p>Change of date for the first meeting of 2011</p> <p>In order for the NJRSC to meet quarterly, the first meeting of 2011 would be held on Tuesday 18th January 2011. This would replace the previously proposed date of 24th February 2011.</p>	
15.	<p>Date and Time of Next Meeting</p> <p>Wednesday 28th July 2010, 10.30 am – 4.30 pm Mary Ward House, 5-7 Tavistock Place, London, WC1H 9SN</p>	