

Mary  
Newman/POLICY/DOH/GB  
05/03/2012 19:47

To "Ludgate, Susanne" <

cc

bcc


Subject Re: FW: Meeting with DePuy

Susanne

My view - but would welcome cc recipient views:

- Manufacturers of these MOMs are not subject to a recall and the MOM performance is still within NICE guidelines so trusts cannot look to a manufacturer for reimbursement
- clinicians are expected to react to evidence from clinical audit, and have long adapted post operative surveillance to the needs of the patient and to what experience and evidence has shown about the performance of various prostheses. We could argue that the evidence to support the MDA was first published in the NJR annual report last year, and trusts should already have been acting on it - and arranging follow ups - as a matter of good clinical practice. Bottom line is, they cannot look to the centre for reimbursement.
- patients cannot look for reimbursement of travel costs. This surveillance is not mandatory on them, although it needs to be offered. 'Free at the point of care' means 'free from when they get to the clinic' (unless they already qualify for patient transport services).

Mary Newman ACMA  
Head of Clinical Strategies  
CPSD (NHS Medical Directorate)  
423 WEL

Please contact  if you want to set up a meeting with me

"Ludgate, Susanne" <



"Ludgate, Susanne"

05/03/2012 06:03

To Mary Newman/POLICY/DOH/GB@DOH

cc

Subject FW: Meeting with DePuy

Dear Mary

Grateful for advice on para 2. Best wishes, Sue

05/03/2012 13:52

To Mary Newman/POLICY/DOH/GB@DOH  
cc  
bcc  
Subject Re: Fw: Cancer Risk and Metal on Metal Hip Replacements  
E46F038BF82A728C802579B8004C09D7

It looks like it. Many thanks

Kind regards

Office of the NHS Chief Executive  
Department of Health,  
Room 428 I Richmond House | 79 Whitehall | London | SW1A 2NS  
Office:  
Blackberry:  
Mary Newman/POLICY/DOH/GB

Mary  
Newman/POLICY/DOH/GB  
Sent by:

To  
cc

05/03/2012 13:51

Subject Fw: Cancer Risk and Metal on Metal Hip Replacements

I trust that the submission below is the one that you were seeking.

Regards,

, PA to  
Mary Newman ACMA  
Head of Clinical Strategies  
CPSD (NHS Medical Directorate)  
423 WEL

Please contact [REDACTED] if you want to set up a meeting with me

---

Mary  
Newman/POLICY/DOH/GB  
Sent by

To  
cc  
bcc

05/03/2012 13:27

Subject Fw: Denmark halts use of all metal hips

asked me to forward this to you,

PA to  
Mary Newman ACMA  
Head of Clinical Strategies  
CPSD (NHS Medical Directorate)  
423 WEL

Please contact if you want to set up a meeting with me

----- Forwarded by I

on 05/03/2012 13:24 -----

Mary  
Newman/POLICY/DOH/GB  
05/03/2012 13:22

To Susanne Ludgate  
cc

Subject Fw: Denmark halts use of all metal hips

Sue

what do you think ?

We have a cunning plan to get you some central help with 'beyond compliance' but need to talk about on-costs in NHS - any idea of how much might be involved? Can we speak next week about that ? I want to get the letter out first

Mary

Mary Newman ACMA  
Head of Clinical Strategies  
CPSD (NHS Medical Directorate)  
423 WEL

Please contact if you want to set up a meeting with me

----- Forwarded by Mary Newman/POLICY/DOH/GB on 05/03/2012 13:19 -----

Mary  
Newman/POLICY/DOH/G  
B  
05/03/2012 13:19

To I, Bruce  
Keogh/OIS/DOH, Gerard Hetherington/HPIHSD/DOH/GB  
cc  
Subject Fw: Denmark halts use of all metal hips

For info. I have discussed with Gerard and think we shouldn't accelerate our planned date of 14 March for the letter. This is the equivalent of the Danish BOA giving this opinion - if the BOA here want to announce the same then we should let them but otherwise stick to plan

Mary

Mary Newman ACMA  
Head of Clinical Strategies  
CPSD (NHS Medical Directorate)  
423 WEL

Please contact if you want to set up a meeting with me

----- Forwarded by Mary Newman/POLICY/DOH/GB on 05/03/2012 13:14 -----

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29/02/2012 16:15

To

MARY NEWMAN,  
GERARD HETHERINGTON

cc

bcc  
Subject Update MHRA briefing on metal on metal (MoM) hip implants, 2010/004/019/291/007

History: This message has been forwarded.

Dear

You asked for updates on the metal on metal (MoM) issues below:

1. scientific research projects

As set out in submission of 24 February (please see attached) , who is part of Arthritis UK, is considering a number of scientific research proposals to address some gaps in our understanding of the biological mechanisms which may put patients with MoM hip replacements at risk of cancer. This work is independent of the MHRA. These proposals will need to go through a rigorous evaluation and selection process before they are started. We have spoken with [REDACTED] today clarifying his current timelines for his proposed work. He has informed us that an Expert Working Group has now been set up to consider research priorities to understand the basis of any pathological hazards resulting from MoM hip replacements. The Group has met to discuss the list of possible areas to study and is currently in the process of short listing the key questions. He will also need to secure funding. This process will take approximately four months. Following this selection and validation process the group aims to invite project proposals. The selected projects could range from non-clinical studies (which may be completed in months) to biological and clinical studies which could take several years to fully complete. We would keep regular contact with [REDACTED] to obtain progress updates on this work.

2. Timeline of relevant submissions (and copies of emails) to Private Office on the MoM issues:

**A) 27 January 2012 - Possibly increased cancer risk from ASR metal-on-metal hip implants.**

Informing ministers about emerging information on a possible increased cancer risk in a small group of patients from one local area implanted with ASR MoM hip implants.

Outcome: PS(Q) would like to see an update before further advice goes on the MHRA's website.

**B) 30 January 2012 - Alleged Poisoning risk from metal-on-metal hip implants.**

Updating ministers about the background to a recent report in the Sunday Telegraph – now picked up elsewhere in the press - which alleges that MoM hip implants may cause





"Ludgate, Susanne"  
[Redacted]  
[Redacted]

Sent by:

To Mary Newman/POLICY/DOH/GB@DOH

cc

bcc

Subject FW: URGENT: MHRA Briefing on Metal on Metal Hip Implants

29/02/2012 08:49

Mary:

Please see below a copy of an e-mail that was sent earlier this morning to Ellen Graham.

With best wishes.

Susanne Ludgate

**Dr Susanne Ludgate**

BSc (Hons) MB ChB DMRT FRCR FRACR MBA  
Clinical Director  
Medicines and Healthcare products Regulatory Agency  
Floor 4-Y  
151 Buckingham Palace Road  
LONDON  
SW1W 9SZ

Telephone:

E-Mail:

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“poisoning”. This appears to be based on a handful of reports from the US (Alaska) and Australia suggesting an association between MoM hip implants and a number of different clinical symptoms.

Outcome: Cleared by ministers

**C) 7 February 2012 - Failure rates of stemmed metal-on-metal hip replacements: data analysis from the National Joint Registry.**

Informing ministers of a forthcoming scientific publication on failure rates of stemmed (also known as Total Hip Replacement (THR)) MoM hip implants. The article concludes that MoM THR have an unacceptably high revision rate compared with other types of hip implants.

Outcome: Cleared by ministers

**D) 24 February 2012 - Metal-on-metal hip implants: update on associated cancer risks and patient monitoring and management**

Updating ministers about the actions taken on:

- a possible increased cancer risk in patients implanted with MoM hip implants;
- monitoring and management of patients implanted with MoM hip implants;
- MHRA's press office reactive lines about a cancer risk in patients implanted with MoM hip implants and MHRA's media handling proposals for the monitoring and management of patients implanted with MoM hip implants.

Outcome: Ministers noted the submission. PS(Q) has requested a further submission in a month's time covering in particular the work to consider the cross-correlation between the NJR data and Cancer Registries and the work looking at the cross-correlation between the NJR and the MHRA GPRD. Ministers would also like a read-out of the results of the work with the Swedish and Australian National Hip Registries as soon as it is available.

Should you have any questions, please contact Dr Sue Ludgate (tel:

With kind regards,

01/02/2012 20:49

To Mary Newman/POLICY/DOH/GB@DOH,  
"Susanne Ludgate"

cc [REDACTED], Bruce  
Keogh/OIS/DOH@DOH, Gerard  
Hetherington/HPIHSD/DOH/GB@DOH,

bcc

Subject Re: MOM submissions and briefings  
77303FB39DA1E47B8025799700682718

I did have a brief discussion with [REDACTED] earlier about scope to do data linkages and he confirmed should be possible but hurdles like ethics approval to sort.

Message sent from a Blackberry handheld device.  
Mary Newman

----- Original Message -----

From: Mary Newman

Sent: 01/02/2012 20:42 GMT

To: [REDACTED] Susanne.Ludgate [REDACTED]

Cc: [REDACTED] Bruce Keogh; Gerard Hetherington;

Subject: MOM submissions and briefings

Susanne, [REDACTED] cc colleagues here and BOA

I'm sorry to add to your load but I've been chasing material on metal on metal over the last day or so since for some reason NHS MD have been out of the loop. I think [REDACTED] and [REDACTED] have been on some copy lists for their interest in clinical audit and the NJR but not everything has got through to Bruce (the wrong email address was used), Gerard,

total HES population. Revisions were identified and analysed additionally. This analysis showed no increased incidence of cancer relative to the entire population in any of the metal on metal group (inclusive of the ASR group; the resurface group or the revised group).

6. Next steps will rely on whether the \* cohort study finds wider local evidence to support the local cancer concern raised, and on whether the story gets media legs - either before that or as a result. I suggest it may be sensible to consider **now** what we will do if the story does get legs (even if unfounded, although is at least a risk of worrying evidence from \* ). The PIP saga has raised media appetite for implant scare stories regardless of what the research evidence shows.

I apologise if some of the following questions are gormless:

- Susanne: I assume MHRA will keep us briefed on \* developments?
- [REDACTED]: it is helpful to know that if we have to, MHRA and we can quote the Bristol study even though it is brand new, not yet peer reviewed, and unpublished. But can CMO consider whether there is any way to accelerate the necessary peer review and get it out there?
- Susanne, [REDACTED]: am I right to assume that comparison between NJR and cancer registries is likely to be more accurate than comparisons with HES? I understand that previous discussions about the benefits of establishing information linkages between the NJR and cancer registries have now been revived and will be pursued with vigour by [REDACTED]. But I understand they think this will take around 6-months. Is there a way we could accelerate this? I note [REDACTED] of the National Cancer Intelligence Network has worked with John Parkinson of MHRA in the past. Might they be able - if asked - to help [REDACTED] move faster?
- Gerard, [REDACTED]; if patients do get worried about risk and start bombarding their GPs for advice or referral, is there anything we can commission that can help them through decisions about whether to go for revision? It will be a predominantly elderly frail population, so should we investigate what it would take (and how long) to commission a patient decision aid on revisions for a perceived increase in cancer risk? We've already got these tools published now on NHS Direct for knee and hip arthritis (ie do you really need a replacement to begin with), and DH has now placed £3m of contracts via Right Care with three different organisations to get them developed. See attached for background

[attachment "Right Care - patient decision aid.doc" deleted by [REDACTED]].

All the best

Mary

\* = a site in Wales

Mary Newman ACMA  
Head of Clinical Strategies  
CPSD (NHS Medical Directorate)  
423 WEL

Please contact [REDACTED] if you want to set up a meeting with me

---

  
01/02/2012 16:20

To Mary Newman/POLICY/DOH/GB@DOH

cc

bcc

Subject Fw: Ministerial submission - Alleged poisoning risk from  
metal-on-metal hip implants 2012/001/025/291/008

01/02/2012 12:48

To

cc

bcc

Subject Fw: Metal on Metal: Welsh Analysis AITS record  
2012/001/025/008

Dear All,

Please see the email below from MHRA, which updates on the current position with the metal-on-metal hip implant work. CMO has seen this and is happier with how this will be handled (I sent an email yesterday detailing her concerns).

⋮

----- Forwarded by

H on 01/02/2012 12:39 -----