MICHAEL R. REED

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

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In re Bair Hugger Forced
Air Warming Products
Liability Litigation,

MDL No. 14-2666 (JNE/FLN)

- -

- -

VIDEOTAPED DEPOSITION OF

MICHAEL R. REED

- -

London, United Kingdom

Taken December 4th, 2016 By Rose Kay

Job No. 115951

APPEARANCES:

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Allen Dyer

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I N D E X

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MICHAEL R. REED

Sunday, December 4, 2016

THE VIDEOTAPED DEPOSITION OF MICHAEL R. REED is taken on this 4th day of December 2016, at Faegre Baker Daniels, LLP, 7 Pilgrim Street, London EC4V 6LB, United Kingdom, commencing at 12:30 p.m.

THE VIDEOGRAPHER: We are on the record in the deposition of Michael Reed, in the matter of Bair Hugger Forced Air Warming Products Liability Litigation; in the High Court of Justice, Queen's Bench Division, job number 15-2666 (JNE/FLN).

The deposition is being held at Faegre Baker Daniels, 7 Pilgrim Street, London, U.K. on December 4, 2016. The time is half past 12.

My name is Gerlando Scaffidi. I am the legal video specialist from TSG Reporting, Inc, headquartered at 747 Third Avenue, New York. The court reporter is Rose Kay, also in association with TSG Reporting.

Would counsel please introduce themselves and the parties they represent?

MR. GORDON: Corey Gordon, on behalf of the defendants 3M and Arizant in the U.S. proceedings.

MR. ASSAAD: Gabriel Assaad, on behalf of the plaintiffs.

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MS. ZIMMERMAN: Genevieve Zimmerman, on behalf of the plaintiffs.

MR. HOLL-ALLEN: Jonathan Holl-Allen, counsel for Mr. Reed.

MS. OKONEDO: Ediri Okonedo, solicitor for Mr. Reed.

THE EXAMINER: Allen Dyer. I am the court appointed examiner.

Mr. Reed, could you repeat after me?

MR. MICHAEL R. REED.

having been sworn.

testified as follows:

THE EXAMINER: Could we have your full names and your professional address?

A. Mike -- Michael Richard Reed. I work for Northumbria Healthcare, which is in Northumberland, U.K.

THE EXAMINER: Thank you. Yes, Mr. Gordon.

EXAMINATION BY MR. GORDON:

Q. Good afternoon, Mr. Reed; and I understand by now that Mr. is the appropriate title for a senior physician in the U.K.

A. It's an exam. That's all.

Q. It's really hard, because in the U.S. to call a physician Mr. would be a real insult; so I am adapting, but it is a challenge.

You are an orthopaedic surgeon; is that correct?

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A. Yes.

Q. When did you become a consultant orthopaedic surgeon?

A. I think 13 years ago. That sort of order.

Q. Approximately --

A. 2004, I think. 2003, 2004.

Q. And how long was your period of what we would call residency?

A. Okay. So we do it slightly differently in the U.K., the residency thing. But we do a junior residency, which is about four years; and then a senior residency, which is just in orthopaedics, which is another six years. I took a year off of my six years, because I did research, which is sort of recognized by a lot of that.

Q. So you would have left medical school some time in, like 1994?

A. Yes. So we leave medical school at 23. So we don't do anything generally before medical school over here.

Q. All right. And since you -- well, strike that.

Where did you do your junior residency and your senior residency?

A. So junior residency, I did in the North East; and then I did two years of research in Sheffield. And then I did the rest of the time in the North East on the senior training program. And then I did a year in New

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Zealand or eight -- no, 15 months in New Zealand, doing joint replacement essentially in ... and I came back.

Q. What do you mean by the North East, for whose of us who are not familiar with it?

A. So the North East of England, which is -- we border onto Scotland, if that helps. So we are just at the very top of England, on the East Coast.

Q. Is that where Northumbria is now?

A. Yes.

Q. Okay. And is it the Northumbria Hospital Trusts; is that ...?

A. Yes, so Northumbria Healthcare NHS Foundation Trust.

Q. Explain what the trust is?

A. So the trust is an organization of hospitals which have the same management structure and the same financial mechanism, if you like; the same employment structure.

So my hospital, my trust has, I think, a total of 11 or 12 hospitals, of which some will be community hospitals and some will be more like hospitals with operating theaters, and some will be trauma hospitals, or just one now, one trauma hospital out of all of that.

Q. How many of those hospitals do you perform surgery in?

A. Now, three.

Q. Let's start with now. Three?

A. Yes.
Q. What are they? How are they identified?
A. So one is called the Northumbria Hospital. It is the new one. One is called Hexham General Hospital. And one is called Wansbeck Hospital.
THE EXAMINER: Sorry?
A. Wansbeck.
THE EXAMINER: Wansbeck.
A. Yes.
BY MR. GORDON:
Q. How new is the Northumbria one?
A. It opened in June last year, so that must be almost 18 months.
Q. And prior to that, were you practicing just at Hexham and Wansbeck, or did you replace something with Northumbria?
A. So immediately prior to that, I was operating just in those two. But I have done some operations in North Tyneside Hospital, which is another one of our hospitals in North Shields.
Q. How long have you been affiliated with the Northumbria Trusts?
A. So I have been a consultant the whole time I have been with Northumbria, although I did do some training there

as well. So I think it's about 2004 since I was appointed, 2003. And I have been at Northumbria since then.
Q. And do you have any additional administrative responsibilities or titles, with respect to overall orthopaedic surgery?
A. So I am head of training currently.
Q. For orthopaedics?
A. For the North East, for orthopaedics; so 67 orthopaedic trainees. So I am currently head of quality for Northumbria, although I am stepping down. My wife is ill, so I am stepping down from that.
What other jobs do I have? I am Chair of the Education Committee for the Orthopaedics Association, British Orthopaedic Association.
Q. Do you currently serve on any NHS committees?
A. Well, I am on the NICE committee, so that's one of our guidelines generators. Well, it is our guidelines generator, if you like.
Q. What does NICE stand for?
A. So the National Institute for Health and Care Excellence. And I am on a committee currently for venous thromboprophylaxis.
THE EXAMINER: You'd better repeat that last word.

A. Yes, Thromboprophylaxis. So this is stopping clots in the legs, essentially, that go to the lungs.
And I am on the NICE guidance committee for avoiding hypothermia in theater. And I have previously served on them, doing a quality standard for avoiding surgical site infection. And I did the evidence update for NICE on surgical site infection prevention.
BY MR. GORDON:
Q. All right. Let's go backwards.
When did you do that evidence update on avoiding surgical site infections?
A. I would estimate 2013.
Q. And when did you serve on the committee for avoiding -- for providing guidance for avoiding hypothermia?
A. That is currently running, so it runs for maybe a year. You have several meetings, you look at all the evidence; so that's currently in process, if you like.
Q. Is this the first time you have served on that committee?
A. Yes.
Q. Okay.
A. So what happens is they update the guidance every few years. So when they are updating it, there are several meetings and you review lots of evidence and then it

stops. The guidance comes out, and then maybe in five years time they will do it again and it might be a different committee next time.
Q. Okay. And the venous thromboprophylaxis committee, is it the same thing, about a year?
A. Same thing. And it's, I think, slightly more advanced than the other one, down that road. They are running parallel, but they are not related.
Q. The reason I am asking is: for some reason, I thought you had some responsibilities with NICE, going back several years.
A. So the surgical site infection prevention update was 2013, I think. And the quality standard was about the same time, maybe 2014, something like that; but that sort of order. I don't think I have done anything with NICE before that.
Q. Okay.
I apologize in advance for having thrust in front of you four volumes of material. We have pre-marked them, the volumes 1 through 4 as exhibits 1 through 4.
These are documents that were provided to you a couple of weeks ago, under the High Court's requirements.
MR. ASSAAD: I would like to make an objection at this time,

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just for the record, for the court.

THE EXAMINER: It is not an objection, I don't think. It is something that you want to put on the record.

MR. ASSAAD: Well, I have an objection as well. First of all, I am going to have an objection to globally offering these exhibits as 1 through 4; because as we have realized, within each binder, there's multiple exhibits, multiple different documents and he has not laid any foundation for whether or not they are authentic documents. And to just globally limit it as 1 through 4, it is not commonly done in the United States and I don't think it is done either under English law in trial, to take a whole stock of miscellaneous documents and exhibits and maybe mark it as one big exhibit.

Second, I also object to the use of any of these documents, because we received these documents only a few days before; we received 1,700 pages two days before the date of this deposition, which I think is untimely and goes against the spirit of the sealed order.

THE EXAMINER: Does it not go against the words of the sealed order?

MR. ASSAAD: Well --

MR. GORDON: It does not.

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MR. ASSAAD: It does not go against the words. But, you know, as we have realized, the sealed order was created and written by defense counsel for now --

THE EXAMINER: Okay. You have put your objection on the record.

MR. ASSAAD: I do object. For the purposes of going forward, it is going to be very difficult, unless you identify each document being used and what the exhibit number is for the U.S. court.

It is also improper, unless you want to go through every single page in exhibits 1 through 4. And whether or not he lays the foundation for each document, and whether or not it is authentic, I think each document that's within the binders should be labeled as a different exhibit for ease of use going forward in this deposition, as -- so the court in the United States could rule on the admissibility of each and every document.

MR. GORDON: Counsel, as we have done in the last two depositions, I am identifying, by the specific pagination within each of these group of exhibits, those documents that I am examining the witness on and that is the evidence -- the documents that I am offering.

And if the court finds foundation lacking for any

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particular subset of this, that I specifically enumerate and identify, then so be it. And to the extent that I have adequately identified the specific pages and only those specific pages, that's what we are offering.

These binders correspond to the documents that we have provided to Mr. Reed and to the other deponents, pursuant to the requirements of the London High Court.

So for ease of review and going through the materials in the manner that they were provided to the witnesses and marking them as group exhibits and identifying by specific pagination.

THE EXAMINER: Okay. Have you put on the record -- and this was the question. Have you put on the record an objection to lack of foundation for all of these documents?

MR. ASSAAD: I have a lack of foundation, a lack of --

THE EXAMINER: So you don't have to repeat it.

MR. ASSAAD: But I have one more thing. I just want to say that in accordance with the sealed order, it also refers to the Federal Rules of Evidence and the rules of being at trial. And this is -- we are supposed to conduct this deposition as being a trial before the English courts, as well as the U.S. courts, and this is not how we identify documents by showing 1,700 pages without

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establishing authenticity or foundation.

THE EXAMINER: Okay. Carry on.

MR. HOLL-ALLEN: Sir, may I just say this. For the purposes of the record, the order states --

THE EXAMINER: Hang on. Let me just get my copy. Yes. Paragraph?

MR. HOLL-ALLEN: Subparagraph (f):

"The documents in relation to which Mike Reed is to be questioned by either the defendants or the plaintiffs shall be provided to him in a tabbed and paginated bundle at least 14 days before the date listed in paragraph (b) above."

And I, in the interests of my client, am bound to put on the record this: that a specific inquiry was made by me before the Senior Master as to the likely volume of the material, and the indication was that it would be one or perhaps two Lever Arch files, and I acknowledge that the defendants have not produced anything greater than that in relation to any of the other effective witnesses. But certainly the volume of material that Mr. Reed has been served with is significantly in excess of what we were led to believe.

THE EXAMINER: Well, it grows from time to time. That's one of those things.

I think the order is perhaps a bit mean, when it provides for him to get them 14 days before and not the other parties, but there we are. That is a matter of hindsight. Gabriel should have been ordered to get them 14 days in advance. I have sympathy for Mr. Reed. There are a number of files.

Anyway, let's get on with the real event.

MR. ASSAAD: Can I have a ruling to identify documents and the foundation, because --

THE EXAMINER: You have put it on the record for the U.S. court. I really think that spending time identifying each document as an exhibit is unnecessary. You have put it on the record. You can say that this was -- you see, we don't have a procedure like this in England. So there's no trial procedure you can follow and rely on in this country. You are restricted to the new -- the federal rules, because we don't do it this way.

MR. ASSAAD: Well, I have a standing order for --

THE EXAMINER: Fair enough. We have a procedure by which all documents are presumed to be authentic unless someone challenges them specifically. And by the time we get to trial, we can have a trial bundle agreed by everyone.

MR. ASSAAD: But each document is labeled as different

exhibit numbers.

THE EXAMINER: We don't have exhibit numbers.

MR. ASSAAD: Well, whatever number. In the United States, that is the way it is done.

THE EXAMINER: I understand. But you have put your objection on the record for the U.S. court.

MR. ASSAAD: Fair enough.

MR. GORDON: I bet you wish you had gone to law school, huh?

A. I didn't get 14 days either, but we will press on.

BY MR. GORDON:

Q. If you take exhibit 1, which is volume 1. It is in front of you.

(Exhibit Reed 1 marked for identification.)

THE EXAMINER: He needs to have enough space at least to have each file open before him.

BY MR. GORDON:

Q. If you could turn to page 505.

MR. HOLL-ALLEN: Volume 1?

MR. GORDON: Volume 1. Page ...

A. I don't have a 505 in volume 1.

MR. GORDON: The pagination is in the lower right hand corner.

THE EXAMINER: Not on mine. So you'd better tell me which tab number.

MR. GORDON: They are not paginated?

MR. HOLL-ALLEN: Volume 1 only goes to ...

A. 300 and something.

MR. HOLL-ALLEN: 387.

MR. GORDON: I apologize. Volume 2.

(Exhibit Reed 2 marked for identification.)

THE EXAMINER: I have an unpaginated version.

MR. HOLL-ALLEN: Just for the avoidance of any doubt, there are five files.

THE EXAMINER: Five?

MR. HOLL-ALLEN: Four of them are the -- what we understand to be the defendants' documents, and they are continuously paginated throughout those four files.

THE EXAMINER: Not mine. Not mine.

MR. HOLL-ALLEN: Not yours? I am sorry to hear that. The fifth file is the plaintiffs' documents and those are not -- those are tabbed, but not paginated.

THE EXAMINER: Well, I don't have that either.

MR. GORDON: These are paginated.

THE EXAMINER: It's all right.

MR. GORDON: These are.

THE EXAMINER: I can cope. Just tell me where they are.

MR. GORDON: Where did these come from?

THE EXAMINER: No idea.

MR. GORDON: Here is 1 and 3.

MR. ASSAAD: These are our 4 to ...

MR. GORDON: Are those paginated?

A. There's numbers on them.

MR. HOLL-ALLEN: These are paginated. It is a complete set, I think.

MR. GORDON: Why don't we switch that out.

(Off the record remarks.)

A. What page are we on, sorry?

MR. GORDON: 505.

THE EXAMINER: 505, yes.

BY MR. GORDON:

Q. And I specifically want to ask you about the document that runs from 505 to 510.

Could you tell us what that -- this particular document is?

A. So this is a paper which looks at the forced air warming machines, if you like, and the potential for them to have bacteria build-up within them; and also to have, sort of, emissions of particles out of the -- out of the hose at the end.

Q. And are you the first listed author in this one?

A. I am, yes.

Q. And when was this published?

A. August 2013.
Q. Okay. So with your permission, I am going to refer to this particular study as "Reed 2013".
A. Okay.
Q. Now --
THE EXAMINER: What does it mean, that you are the first named author on this one?
A. So it means various things, actually. So the very traditional route is that the junior author, if you like, goes first.
THE EXAMINER: That is what we have heard to date.
A. Yes. And the senior author would go last. In this particular instance, I went first because I was keen to get this to, if you like, an orthopaedic community, to get the message to the orthopaedic community. So that's the basis of me going first on it.
THE EXAMINER: And what is the AANA Journal?
A. It is a nursing journal, I think. I think it's anesthesia ...
THE EXAMINER: It is in the area of anesthesia and nursing?
A. Yes. That's my recollection.
THE EXAMINER: Okay. Yes.
BY MR. GORDON:
Q. If you could turn to pages 533 through 538.

And if you could just briefly identify what this is?
A. So this is a paper which I am a sort of middle author, if you like, and it's a paper that looks at the disturbance of laminar flow with forced air warming during a simulated knee replacement.
Q. And when was this published?
A. This was published in -- actually, I can't read that on the copy. I think 2013.
MR. HOLL-ALLEN: I see --
THE EXAMINER: August 2013, at the top of page 534.
MR. HOLL-ALLEN: Accepted for publication, April 16, 2012, I see at the bottom of 533, copyright 2013.
BY MR. GORDON:
Q. And the first author on this is Belani, sir?
A. Yes.
Q. Again with your permission, I will refer to this study as "Belani 2013"; okay?
A. Okay.
Q. Then I would like you to turn to pages 540 through 547. And again, I will ask you to briefly identify this?
A. Okay, so this is a paper which looks at two things. One is the disturbance of laminar flow using forced air warming in a sort of experimental set-up, and it also has some clinical data. I would like to discuss the

clinical data with you actually. I am sure we are going to do that, anyway.
Q. I can assure you, your wish will be granted.
A. Yes, but there is something specific I want to bring to your attention. So when we get there, I will bring that to you.
Q. Okay. When -- strike that.
The first author on this is Paul McGovern?
A. Yes.
Q. And you are the last author?
A. Yes.
Q. And by convention, that makes you the senior author?
A. In this stance, yes.
Q. When was this published?
A. I think 2011.
Q. So I will again, with your permission, refer to this study as "McGovern 2011" and I will probably spend the lion's share of my examination on this study.
So you said you looked at two things; the disturbance and then some clinical data.
Did you do both things essentially simultaneously or around the same time, or was one done first and the other done with some separation of time in between?
A. So my recollection is that the sort of experiment, if

you like, the mocked-up experiment was done in the summer of 2010, which would be sort of in the middle, almost in that transition phase of when we were moving between the clinical -- you know, the two different clinical types of warming.
Q. And the clinical part of it was done later; is that correct?
A. No. So it sort of straddles it, I think is how I would describe it. Because my recollection is that, looking at the timings, the theater experiment with the warming, et cetera, was done, I think in May of that year, which would be 2010.
Q. When the McGovern study was initially conceived, did you initially plan on doing the two different components?
A. No, I don't think we did.
Q. What was the one you initially planned to do?
A. Well, you know, the theater-based, lab-based one, if you like, of those two, would be the one that we specifically set out. The other one was more opportunistic.
Q. Okay. And so the one that was, sort of, the progenitor of this study was the airflow disruption component; is that right?
A. Yes.

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Q. Okay.
How did you come to be interested in that subject?
A. Okay. So I have been trying to recollect the exact order of events; but I am pretty sure I saw a video, which I am sure will be used in some of the evidence, which was smoke coming out of the bottom of a draped theater which was being shown around by Augustine, and I think that was in 2009, perhaps at one of the orthopaedic meetings.
I then heard David Leaper, who I think is another one of your witnesses, speaking at a conference in 2009. And following that, I contacted him by e-mail, actually, and we had an e-mail discussion about his anxiety about the fact that laminar flow was potentially disrupted by forced air.
And then --
THE EXAMINER: Was that the topic of his talk that you heard?
A. I did make some notes on it. I am actually not sure it was. There must have been something in it, in all honesty, because I did e-mail him and the conversation went that way. I have got that e-mail. But there must have been something in his talk that set me off with that discussion.

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And so -- and he at that point, I think, was a consultant for Augustine.
BY MR. GORDON:
Q. Are you talking about Professor David Leaper?
A. Yes. And in late 2009, we did an experiment in our theater, which was comparing forced air warming with conductive fabric warming, which was the Augustine product.
Q. Also known as the Hot Dog?
A. The Hot Dog. And that involved getting a -- essentially sucking air in, onto culture plates, to see whether there was an increased bacteria load in the theater.
And we did that with a microbiologist. There was a minor celebrity microbiologist who was a bit of a TV personality at that time who came up and did that with us, and they went off and cultured the air, if you like, that sucked onto these plates.
Q. What --
A. So --
Q. What were the results of that?
A. So what that showed was that there was no difference in contamination, whether you use forced air warming or not.
Q. Who financed that study?

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A. So that was financed by Augustine. He gave our department £5,000 for that.
Q. How did you connect with Dr. Augustine for that financing? In other words, did he come to you, did you go to him? Was there some other ...?
A. Yes, I am not even sure I had met him, but it was through David Leaper. David Leaper essentially arranged that. But I know the money was coming from Augustine. I don't think I had met him at that point.
Q. Okay.
So Professor Leaper arranged for funding from Augustine for you to do a microbiological study?
A. Yes. And David Leaper came as well and we did it on a weekend in theater.
Q. I have to ask. How does a microbiologist become a TV celebrity?
A. So my recollection is, it was something about the sort of -- where bacteria grow and everything. She wasn't a celebrity for that long actually, but she was a slightly colorful character and she was good for TV, I think.
Q. Was this done at one specific hospital?
A. Yes.
Q. Which one?

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A. Wansbeck.
Q. Okay. Is Wansbeck your primary hospital or was it back then?
A. Yes.
Q. Is it still today?
A. It is much more gray now, but it's where my office is. But I am not sure I operate any more there than I do anywhere else.
Q. Back in that 2009 timeframe, that would have been where you did more surgeries?
A. Yes.
Q. Did -- at that time period in 2009, did Northumbria Hospital Trust have its own microbiology staff?
A. Yes.
Q. Did you involve any of them in this project?
A. No. I think they probably wouldn't have been too keen because, you know, these things involve costs and hassle for the lab techs. So they are not too keen on doing ad hoc experiments like that in the microbiology department.
Q. So the people involved in this were you, Professor Leaper, this -- the celebrity microbiologist; and anyone else?
A. Yes. There would be one or two trainees, of which

I can't actually recollect who they were.
Q. Do you recall if Paul McGovern was involved in this project?
A. Yes, I think he probably was. He was actually. He was definitely involved, because subsequently he submitted the abstract.
THE EXAMINER: Because?
A. Because he submitted the paper. So when you do the work, you send it to a meeting and hopefully someone listens.
BY MR. GORDON:
Q. Did you send it to --
A. The Hip Society.
Q. The British Hip Society?
A. Yes.
Q. As a -- for a publication or a presentation or for something else? We have learned that there are different ways of presenting research.
A. Yes, so it would have been for a presentation. So you stand up for ten minutes and you tell everyone about your paper. And I think there's a sort of downgraded category which is a poster, so that's just -- you get to stand next to a laminated sheet about what you did.
Q. So this was submitted to the British Hip Society as

a proposed presentation, presumably to a meeting of the British Hip Society?
A. Yes, so 200 or 300 people, probably. Hip surgeons go to that meeting.
Q. And Dr. McGovern was the primary author of this presentation?
A. Yes, I think so.
Q. Was Augustine, as the funder, notified of the results of this -- of your test?
A. So I don't know about officially. I would be surprised if he didn't know. I mean, that paper, it wasn't accepted by the Hip Society, because it didn't -- negative papers unfortunately don't tend to get a lot of air time.
Q. Let's -- I want to make sure that, when the U.S. jury hears this, they understand what you mean by that. What -- in science medical research, what does a negative paper mean?
A. So what we are saying there is that that paper showed there was no difference between the two warming methods. There was no bacterial contamination between the two that we could ascertain; based on what we did.
Q. So -- and what would a positive paper mean?
A. Where one is better than the other.

Q. So in your experience, a paper that shows a difference is more likely to be accepted for publication or presentation or posters or something; is that basically what you are saying?
A. I think that's true, yes. Well, that's definitely true. That's well known.
Q. Did you or anyone connected with this research attempt to submit the results of this study to any other forum or journal or anything else?
A. So it may have been submitted to other meetings. I wouldn't necessarily know. Sometimes trainees do submit things; particularly when they have been submitted once, they do submit them to other places. But it wasn't presented, I am pretty sure, anywhere in the end, because it was -- if it was submitted elsewhere, it was rejected.
Q. So would Dr. McGovern have been the person --
A. Yes.
Q. -- doing that? So he is the best person to ask?
A. Exactly.
Q. We will get to do that later this week.
When you actually did this study and found out that there was no difference in bacteria, did that have any impact on how you viewed the issue of disruption of --

potential disruption of airflow?
A. So certainly it had an impact, because you have to look at it and say: well, okay, there's no difference. But we had seen, you know, the videos of the -- of air moving from outside of the, you know, essentially the Augustine smoke videos which I am sure you have seen, which show that air is mobilized out -- from the floor, for instance, up into the theater.
So I mean, yes, it's reassuring. And you know, the abstract is pitched as such. But I didn't -- it didn't put it to bed for me, if that's the question.
Q. So after you had done this microbiology study, Dr. Leaper and Dr. McGovern, or Professor Leaper -- or Mr. Leaper, I think. I get the term --
A. He is a Dr. again actually. A bit more confusing, but ...
Q. Okay. If I call you guys "Dr.", please, this is no disrespect. It is just my default position; it is my default salutation of respect.
When the three of you and anyone else -- microbiologists did this study, was there a discussion amongst any of you, after the negative results came out from the British Hip Society that it was not interested in a presentation that: maybe we should look at

something else, some other aspect of this?
MR. ASSAAD: Objection to form.
THE EXAMINER: You may answer.
A. Well, I think we did go on. With that particular group, and the microbiologists, we did not take it any further. But we did go on quite separately, it must have been seven or eight months later, to do the experiment we talked about before, in the -- but it wasn't related as such.
THE EXAMINER: Which experiment was that?
A. That was the one that's in this McGovern et al paper. That's the one that was in the theater, in the middle of 2010.
THE EXAMINER: Okay.
A. But it was -- yes. I mean, that was then, at that point, unfunded. I was already asking -- well, I had asked in 2009 for a randomized trial to be funded by Augustine, but that wasn't forthcoming.
BY MR. GORDON:
Q. How would you have communicated it to Augustine?
A. Through David Leaper.
Q. What was the reason you were told that Augustine wasn't going to fund a randomized trial?
A. I think I wasn't particularly told that. I think I was

told that we would start with the smaller stuff, like the sort of bacteria one that we just talked about. And then that was negative.
MR. ASSAAD: I will make an objection to the last question as hearsay.
THE EXAMINER: You may answer.
A. Sorry, what was the question again; sorry?
BY MR. GORDON:
Q. I forgot too.
A. Okay. We have all forgotten.
Q. I am just trying to understand the sequence. So -- well, let's step back for a second.
What's a randomized trial?
A. Okay. So a randomized trial is when you essentially -- you design the experiments, so things happen at random, so they are not being driven by anything else. So then you can decide ultimately what the effect -- what the effect of that is, and then you can ascribe it to a particular thing.
So these, in fact, are randomized trials, these experiments in the operating theaters, because you are essentially doing things at random and then you are measuring the effect of that and you will come to the conclusion that one thing is better than the other.

But what I was asking Augustine for was a randomized clinical trial, where you essentially take a patient and you -- before you do the operation, you assign them at random to having forced air warming or an alternative, and then you measure what happens to those patients.
Q. In the hierarchy of research, where does a randomized clinical trial fall?
A. So a randomized clinical trial falls almost at the top. So the very best level of evidence is when you get multiple randomized trials and you see the effect of them; better analysis of randomized trials. But a randomized trial, you know, a large well constructed randomized trial would be a very good level of evidence.
Q. Are they costly?
A. Yes. I would have thought a trial to look at this particular thing would be probably 1.5, £2 million to do.
Q. Is that typical for a randomized clinical trial?
A. Of that sort of scale, I mean, you would need lots and lots of patients. So yes, that would be pretty typical. It would be cheaper in the U.K. than it would be in the U.S.
Q. Why would you need -- I will strike that.
Was there something about this, where you would need

more patients than other kinds of randomized trials, or just that -- that's the nature of the beast; you need lots of patients?
A. It is because infection is relatively unusual. You need to have lots of patients to show the effect of different intervention. So an infection that occurred in half the patients, you wouldn't need many patients to show that one treatment was significantly better than the others.
Q. And when you say "infection" and "usual", are you speaking specifically in joint arthroplasty?
A. Yes.
Q. Had you ever done any estimate of the number of patients who would have to be involved, to have a valid randomized clinical trial that would look at the issue of the impact of warming modality on joint infections?
MR. ASSAAD: Objection. I am going to object that this is outside the scope of the subject areas on the list of the sealed order. Unless he is discussing about the stuff that he's done in the past in respect to his own studies, if he has ever done that kind of analysis. But a reference to a hypothetical and future study, I don't think that is part of the sealed order about calculating sample sizes. And if counsel would wish to point to a certain area, I would be happy to review it, but

I have not seen it in the order.
A. Do you want me to answer or ...?
MR. ASSAAD: Hold on.
A. Hold on.
THE EXAMINER: Mr. Gordon?
MR. GORDON: Yes?
THE EXAMINER: Well, do you accept that objection or do you say it is within the scope?
MR. GORDON: No. It's -- we are trying to get his background and his involvement in the development of these studies. And he sought funding from Augustine for a randomized clinical trial. He was denied it.
THE EXAMINER: Yes.
MR. GORDON: And I am trying to find out what, if any, additional steps he took to gain funding and to -- I will let the matter drop.
THE EXAMINER: I don't think your question had anything to do with that at all. If you had restricted to that, then I don't suppose there would be an objection. So shall we treat that question as withdrawn and go to -- something which goes to: what steps he did take to secure funding?
BY MR. GORDON:
Q. Sure. When Augustine said "no", was that the end of

your interest in a randomized clinical trial on this issue?
A. No. I think -- I don't think we got to specific numbers with Augustine or even a specific cost, but it was like an expression of interest, I would say.
So yes, over the years, I have done quite a few trials now, looking at infections at the end point and it depends on what -- as well as how rare the outcome is, like infection, it's also --
MR. ASSAAD: Objection. He's answered the same initial question as before. This is going into something that he has done in the past -- the studies that are the subject matter of this case, the subject of his work.
MR. GORDON: I am guessing that even in England, it's considered improper to interrupt a witness in the middle of an answer.
THE EXAMINER: Well, if this question shouldn't have been asked, then he is entitled to ...
The schedule B does seem to be, apart from a few items at the top about useful knowledge of the patient-warming device and factors that influence infection control practices, restricted to specific studies; not studies that weren't done or funded. It's studies that have been produced.

MR. GORDON: It also -- and this was a vigorous point of discussion. It relates to the relationship with funding sources and the fact of Augustine and Augustine companies.
THE EXAMINER: Where is that? Unless I am missing a page, which I am not.
MR. ASSAAD: Just for the record, I assume that we could all rely on the draft order that's been submitted to the Senior Master, as the current live ...?
THE EXAMINER: I assume schedule B has not been touched?
MR. HOLL-ALLEN: Schedule B has not been touched. And in fact, the order that was sent to the Master on Friday was made by the Master. So it is not a draft.
THE EXAMINER: No, no, no, but we have to rely on the previous version.
MR. HOLL-ALLEN: Yes, indeed. So if I can intervene at this point. It is correct that if one turns, for example, to the second page of schedule B, within the scope of this deposition are communications or any potential communications with Dr. Augustine, Augustine Temperature Management and the like.
THE EXAMINER: About the studies?
MR. HOLL-ALLEN: Well, that was the point that I was moving on to make. Every paragraph is qualified in that way.

THE EXAMINER: Well, I assume that was part of your objections you were taking at the time the order was made, to tie it down to specific published studies.
MR. HOLL-ALLEN: And to be fair to the defendants, the way in that respect, in which they were putting it.
THE EXAMINER: Okay.
MR. HOLL-ALLEN: As I understood it.
THE EXAMINER: So Mr. Gordon, can we stick to the studies that were done, rather than the studies that were not done?
MR. GORDON: Actually, no. With all due respect, and I can get to the documents where Mr. Reed is pushing the issue of a randomized clinical trial, e-mails back and forth with Dr. Augustine, with Mr. Albrecht, about: the better way to go would be a randomized clinical trial. We will get to those.
THE EXAMINER: But that is not within the scope of the schedule B.
MR. GORDON: With all due respect, sir, it is, because --
THE EXAMINER: Where?
MR. GORDON: It relates to the communications, relating to these studies; the ones that were published.
THE EXAMINER: Yes. Well, I don't understand how communications about unpublished studies relates to

communications about published studies.
MR. GORDON: The communications about published studies relate to criticisms of the published studies and the way to respond to and address those criticisms and why things were or were not done on a particular --
THE EXAMINER: Let's look at the e-mails.
MR. GORDON: That is what we are --
THE EXAMINER: Let's get to the e-mails. I am not persuaded at the moment. If you show me relevant e-mails, I may be persuaded.
MR. GORDON: I will get to it, but you know --
THE EXAMINER: No, I am not going to allow this type of questioning to continue, unless you lay a basis with proper e-mail references to this witness. I am simply not going to allow it to continue.
MR. GORDON: That is fine. I appreciate that Mr. Reed is kind of cutting to the chase and getting things out, that I will get to eventually. So I will stick to the documents. I apologize. This is going to take a little bit longer this way.
BY MR. GORDON:
Q. Let's go to the McGovern paper, and I want to focus on the second part of the study, the comparison or the -- what you described as the clinical component.

A. Yes. I would like to speak to you about that.
THE EXAMINER: Well, let's get to it first, where it is; so that those of us who are not familiar with this document can identify it.
A. So 540.
THE EXAMINER: Yes, I have got that. Where in the document are you talking about?
MR. GORDON: I think the discussion begins on page 543 and it kind of intertwines a little bit, but --
THE EXAMINER: Can I suggest, Mr. Reed, that you allow Mr. Gordon to ask his questions and answer them and then before we leave this document, you can make any point you wish to make about it, unless you think it is essential for you to lay down your marker before you answer questions about it.
A. I would prefer to do that, if that is okay.
THE EXAMINER: Fine. Do it that way.
A. So when I was reading this documentation yesterday and going through e-mails, it's clear to me that some of the data on the clinical side of the paper is wrong, slightly wrong. It doesn't affect the conclusion of the paper and there's still a significant difference. But there is, in fact, one more infection in each group.
Now, this was e-mailed to Mark Albrecht and he did

reply to it and, in fact, it's in your documents; the e-mail correspondence. And he says he will put it into the main paper and, in fact, he then says he has put it in the main paper, but unfortunately it's slightly old data that is in the main paper. It does not affect the conclusion in any way, but nevertheless it is not the latest data they have got in there, and I don't know why that is.
THE EXAMINER: If Mr. Gordon points you to that specific section, then you can identify it for us.
A. I will ...
BY MR. GORDON:
Q. I am sure we will get to those details.
Just broadly speaking, the clinical component of it was a retrospective observation analysis of infection data; is that correct?
A. So I mean, the data is collected prospectively. So it is not that we look back. It is collected live. So it is prospective in that sense, but I would say it is opportunistic, because we had made the change and then we looked to see what happened. The data is prospective.
Q. Was the data being collected -- were the data being collected for purposes of doing this study?

A. No. We collect data routinely and we have a surveillance team, so that is essentially nursing staff, of which I think we had three at that time, whose job it is purely to look at infection rates, if you like.
Q. Okay. So just again, in broadbrush terms. You had and have a body of infection data and what this study did was to look back at a particular time period; is that correct?
A. Well, we collect --
MR. ASSAAD: Objection, misstates the prior testimony.
THE EXAMINER: You may answer.
A. We collect the data as we go, if you like, and we have done since probably, I think, 2007/2008.
BY MR. GORDON:
Q. What is the reference on page 533 to --
THE EXAMINER: 543?
BY MR. GORDON:
Q. 543, thank you. For demographic information on relevant risk factors for surgical site infections, SSI, collected for primary hip and knee replacement procedures performed at our hospitals -- hospital during a 2.5-year period starting 1st July, 2008?
MR. ASSAAD: Where are you reading? I am sorry.

THE EXAMINER: At the top of --
MR. GORDON: At the beginning of the text on page --
MR. ASSAAD: Oh, thank you.
THE EXAMINER: Sorry, what was the question arising out of that?
BY MR. GORDON:
Q. What does that refer to?
A. Well, that's essentially the data that we collect on patients as they come in and have a joint replacement.
Q. Did you just start collecting that data on 1st July, 2008?
A. I think that's probably about right, yes. That's when we went to full-time surveillance. We didn't have a surveillance team. We had part-time surveillance. So in England, there's the -- the NHS law is that you have to submit the one quarter every year, one operation infection rates. And we moved to full-time surveillance in that time. So we had a complete handle on infection rates from that point.
Q. And at the end of that 2.5-year period, did you stop collecting data?
A. No. We still collect data.
Q. The 2.5-year period is the -- would be the time period of the McGovern paper; right? That's -- it's just

a finding that what -- the book-ends of the study?
A. Yes.
Q. Okay.
So when you -- at the start date of 1st July, 2008, patients were being warmed with the Bair Hugger; is that correct?
A. Yes.
Q. And at some point, you transitioned over from warming patients with the Bair Hugger to warming them with the Hot Dog; is that correct?
A. Yes.
Q. And at some point, you were fully transitioned and only had -- were only using the Hot Dog?
A. Yes.
Q. Is that correct?
A. Yes.
Q. So there were really three periods in that 2.5 years. The first period being Bair Hugger only; the second period being transition; and the third period being Hot Dog; is that correct?
A. Yes.
Q. What was the period of Hot Dog only use?
A. So that's in the paper. It's from -- it was something like June till -- until the end of December.

Q. Of ...?
THE EXAMINER: Where is this?
A. So this is page 546. And it's the chart which has been written on.
THE EXAMINER: Oh, I see.
BY MR. GORDON:
Q. So June to December 2010?
A. Yes, I think it's June.
MS. ZIMMERMAN: What page was this?
MR. HOLL-ALLEN: 546. This is the table ...
BY MR. GORDON:
Q. Would that be seven months?
A. It feels about right. Six or seven months.
MR. ASSAAD: There's markings on this page. Did you mark ...
THE EXAMINER: I am a bit confused to where the proper lines are, in the light of all these ...
So you used the Bair Hugger from July 2008 to March -- February/March 2010?
A. No. So the -- what's the best way to explain this chart? So if you can try and ignore the scribbles.
THE EXAMINER: Yes, I am trying to.
MR. HOLL-ALLEN: Sir, I am sorry to interrupt. In the plaintiffs' file, there is a clean copy of the same

document.
THE EXAMINER: Thank you. I don't have the plaintiffs' file.
MR. ASSAAD: And I would prefer to use that, because it seems that this document was used during the Albrecht deposition that was taken in October(?) 2016 and I had to have -- these markings could influence the witness's testimony today. So I would rather have a clean copy.
THE EXAMINER: That is another reason. The principal reason is that it's virtually impossible to understand, with all these markings on it.
MR. HOLL-ALLEN: Would you like to use my copy, sir?
THE EXAMINER: No, it is more important that you have it than I do.
BY MR. GORDON:
Q. Well, let's skip that chart. If you go back to page 543 --
MR. ASSAAD: Are you moving on to the ...
MR. GORDON: No, that was the ...
THE EXAMINER: Which one of these is ...?
A. I think --
BY MR. GORDON:
Q. Under "Joint infection data", there is a reference to: a transition of warming -- forced air warming to

conductive fabric was made in all pre-selected orthopaedic theaters starting on 1st March, 2010, and ending on 1st June, 2010.

A. Yes.

Q. So that the transition period would be March, April, May of 2010; correct?

A. Yes.

Q. So that would be three months?

A. Yes, that looks right.

THE EXAMINER: So prior to March 1st, 2010 it was Bair Hugger. And after 1st June, it was Hot Dog.

A. Yes.

THE EXAMINER: Thank you.

BY MR. GORDON:

Q. So the Bair Hugger only period was July --

A. July 2008.

Q. July 2008 to the end of February 2010?

A. Yes.

Q. And --

A. Yes.

Q. And after those three months, there was use of both Hot Dog and Bair Hugger.

A. (Nods.)

Q. Is that right? You have to say "yes" or "no".

A. Oh sorry, yes.

Q. That is all right. And the last seven months of the period you looked at, it was Hot Dog only; is that right?

A. So is it seven months or six?

Q. June, July, August, September, October, November, December.

MR. HOLL-ALLEN: Seven.

A. Seven. There you go.

BY MR. GORDON:

Q. So the Bair Hugger only period was 20 months; is that right?

A. Well, it was that time, certainly. That feels right.

THE EXAMINER: 20 months.

BY MR. GORDON:

Q. How -- were the data that you looked at collected at more than one hospital?

A. No.

Q. Which hospital were these data from?

A. Wansbeck Hospital.

Q. Do you recall how you initially gathered the data for analysis?

A. So the data is gathered by a team of nurses, surveillance nurses. That's their job. That's what

they do. That's all they do.

Q. I was being a little bit more ministerial in my question. If you go to the file cabinet and pull it out, is it computerized data, is it ...?

A. Ah, so I asked them to -- I mean, the way this works is that we have a report which is produced, of which there's some in here actually, which is all the various operations that are done, the risk factors those patients have and then the outcomes they have; which is generated by the hospital systems.

But infection is a difficult one. You can't rely on computers to sort of diagnose that, or you can't rely on coding. So it's a specific -- you need a specific team. So they have got that and then they have added their call on whether there is an infection or not, to that.

Q. Let me ask you to take a look in volume 3, at pages 788 through 1081.

(Exhibit Reed 3 marked for identification.)

MR. ASSAAD: 7 ...?

BY MR. GORDON:

Q. 788 through 1081.

Does that look familiar to you?

A. Yes.

Q. Is that the form of the data on infections that you

would have pulled and provided to your co-authors?

A. Yes.

Q. Who did the actual data analysis?

A. For this paper, Mark Albrecht.

Q. So were these data, pages 788 through 1081, provided by you to Mr. Albrecht?

MR. ASSAAD: Objection, lack of foundation.

THE EXAMINER: You may answer.

A. I expect so. I don't remember that, but I imagine I did. There was nothing on here that would -- you know, there is no data governance issues with this. So I think, I am almost certain I would have provided it.

THE EXAMINER: Well, it starts on 1st October, 2007, according to page 788.

A. Yes. I mean, he wouldn't have analyzed that; but this data goes back, in fact, to 2002.

MR. ASSAAD: I would just like a clarification for my objection. I am uncertain whether or not this witness is saying that this is exactly what he gave or used, or whether he says it looks like it, but he is not clear. I just want a clarification.

THE EXAMINER: Which is it, Mr. Reed?

A. In all honesty, it looks like it. I don't know if it is what I gave. But I don't know where he would have got

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it, if it wasn't from me.
MR. ASSAAD: Do you know whether or not it is accurate?
A. I don't know.
MR. ASSAAD: All right. Objection, lack of foundation with any questions regarding this -- this spreadsheet, without authenticity or proof that it is accurate -- an accurate picture of the data that Mr. Reed may have used --
THE EXAMINER: We have your objection. Yes, Mr. Gordon.
MR. GORDON: Now I know why you have those paginated ones. That was my set.
THE EXAMINER: No, they came from ...
MR. GORDON: The two that I ...
THE EXAMINER: You can have it back.
(Off the record remarks.)
BY MR. GORDON:
Q. On exhibit 10 -- actually, strike that.
In volume 3, exhibit 3, the data spreadsheet from 788 to 1081; under column B, "Site", there are a series of two letters. Do you know what those letters stand for?
A. So this is the -- the hospitals that are performing joint replacements. So "HX" would be Hexham. "NT" would be North Tyneside. And WG would be Wansbeck.

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Q. So these are the data for all three of those hospitals for the time period --
A. It looks like that, yes.
Q. I think if you turn to page 1082 and 1083, this is a document -- we can tell by the Bates numbers, let's say Augustine 0005490 and 5491. This was sequentially accompanying the spreadsheets that were produced, pursuant to the subpoena to Dr. Augustine, produced by Dr. Augustine.
Does pages 1082 through 1083 look familiar to you?
MR. ASSAAD: Objection to the -- objection, assumes facts not in evidence. Another objection as to speculation.
THE EXAMINER: You can answer.
A. Yes. It looks familiar to me.
BY MR. GORDON:
Q. There is a reference to a Mike Reed database. Do you know what that maybe refers to?
A. Well, this is the explanatory table, if you like, for all of those dots and dashes that we have just been looking at.
Q. Are you talking about pages 788 through 1081; is that right?
A. Yes.
Q. So what columns in the large spreadsheet tell us when

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a given patient has had an infection?
MR. ASSAAD: Objection, lack of foundation. I would like to have a standing objection with regards to the foundation. Is that acceptable?
THE EXAMINER: Yes.
MR. ASSAAD: So this document --
THE EXAMINER: You have your objection on the record. It applies to the whole document. I understand.
MR. ASSAAD: Well, and every question. I don't want to waive any objections.
THE EXAMINER: No. Sorry, repeat the question, Mr. Gordon? Which column is in the ...
BY MR. GORDON:
Q. In the 788 through 1081 that we looked at, do we find an indication that there has been an infection?
A. So as I said before, there's -- this database is looking at the -- where it was done, the complications and the co-morbidities.
This database is then given to the surgical site infection surveillance team and then they populate it with a field at the end. This is what they have done in this -- certainly some of these cases.
So it is an additional field. Like I said, it is not collected by computer. It is done by an actual

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surveillance team whose job it is just to do that. So it is not from hospital episode statistics, which is where this has come from.
THE EXAMINER: This is a record of all hip and knee operations, is it?
A. Yes, yes.
THE EXAMINER: Where do we find an identification of which ones resulted in an infection; which column?
A. I am not sure it is on this. It might be on this.
MR. GORDON: On the --
A. There are some. If you look at page 1051, it's -- unfortunately it is not very helpful, because it's printed out across many, many pages.
THE EXAMINER: Yes, I understand that.
A. But if you see in cell 4602 --
THE EXAMINER: 1051.
A. There is one identified there and the bugs are next to it.
MR. GORDON: So since this is an Excel spreadsheet, it is -- rather than having it over half the length of the table, it is printed on multiple pages. But if we look back for the identifier 4602 --
THE EXAMINER: If you look back at what?
BY MR. GORDON:

Q. On page 1047, 4602, that coding would indicate that this was something that was done at Wansbeck General; is that right?
MR. ASSAAD: Objection, leading.
A. Sorry, what page are you on; sorry?
MR. GORDON: 1047.
A. What was the cell number?
BY MR. GORDON:
Q. Let's track 460 to -- all the way through; and I won't ask a leading question.
What hospital was 4602 performed at?
A. Well, it's a little tricky to tell, given they are all -- running from the sheets. But 4602? I can't really see it, with the quality of this print.
Q. On 1047 you can't, under column B?
A. Yes. On 4602, I can't identify it. 4602. Yes, I think I can read it here. It was Wansbeck General. Patient aged 76. Is that right?
Q. And what type of procedure was it?
A. A hip replacement.
Q. What was the date of the surgery?
A. The --
THE EXAMINER: Is yours a very poor copy? Because mine is quite clear.

A. I am struggling to focus, unfortunately, with the light in my eyes. It is very small. I probably need to wear glasses. 15 September, 2010, I would say.
BY MR. GORDON:
Q. And when -- if we go back to the page that I pointed out, 1051, under 4602, under the column "BF", what does that tell us?
A. What page are you on now?
Q. 1051.
A. On 4602, it says: "infection Staph Epidermis".
Q. Is there a date indicated there?
A. Yes. It looks like -- sorry, I can't really focus.
THE EXAMINER: 3rd October.
A. 3rd October, 2010.
BY MR. GORDON:
Q. And what does that date refer to?
A. I suspect -- I don't know. Probably the diagnosis date.
Q. What was the -- in the McGovern study, what was the time period of surveillance that you included? In other words, how long after the surgery was an infection one that got counted in your study?
A. 60 days.
Q. So if the surgery -- if 4602 was performed on 15th September, 2010 and diagnosed on 3rd October, 2010,

would that have been included or excluded in your count?
A. When was the surgery done, sorry?
Q. It was done on 15th September, 2010.
A. It would be included.
Q. Okay. And what is staph epidermis?
MR. HOLL-ALLEN: Epidermis.
A. So yes, it is a bacteria. It is a fairly common sort of infection in a joint replacement.
BY MR. GORDON:
Q. How was that column, the "BG" column populated? Is it before or after this has been reviewed by the surveillance team?
A. Well, they populate it.
Q. Okay.
A. They populate it.
Q. So if there's a "yes" and a date and a bacteria indicated, does that indicate that that has already been identified and confirmed by the surveillance process?
A. Yes. I mean, that's -- they have written it. The only caveat, I would say, is that some people will be ultimately removed if they are hip replacements for trauma. That is the only caveat, I would say, but ...
THE EXAMINER: If there is ...?
A. If it is a hip replacement that has been done for

trauma. So if they have fallen and broken their hip, then they fall in a different classification system because they are much higher risk. So generally they have got their own surveillance. We do still measure them, but they don't fall into planned joint replacement territory.
BY MR. GORDON:
Q. It appears at 1060, there is a category under "AZ" that describes the -- whether it is trauma or non-trauma?
MR. ASSAAD: What page?
MR. GORDON: 1060.
MR. ASSAAD: 1060.
A. I am not sure that would be a reliable way of saying whether it was trauma or not. It seems to me, that's the way the hospital is paid. And it's -- I think, do you have DRGs in the States? But it's essentially -- it's the way they are paid. I wouldn't necessarily rely on saying that's trauma or not.
THE EXAMINER: Well, every one on the page, I think, apart from one, refers to a non-trauma category. Is that a fairly accurate indication?
A. I mean, it might be. But I think there are sometimes operations that fall into different groups, because that's a very wide group.

THE EXAMINER: Okay.
A. I mean, there is an enormous amount of operations that fall into those groups. You are probably right, but I don't -- I think a coder wouldn't rely on that to say whether it was trauma or not.
BY MR. GORDON:
Q. When you initially saw a printout of data for use in the McGovern study, did you limit it to non-trauma, hip and knee surgeries?
MR. ASSAAD: Objection, misstates the prior testimony. Lack of foundation. He never stated he saw a printout.
THE EXAMINER: You can answer.
A. So normally, the patients you get on here are elective. So there will be some that come on, that are not elective, and then they will be removed by the surveillance team and put -- not actually removed, but put into a different category of joint replacement.
BY MR. GORDON:
Q. When you compiled the data for the McGovern study, did you in any way try to separate the trauma and the non-trauma patients?
MR. ASSAAD: Objection, misstates the prior testimony.
THE EXAMINER: You may answer.
A. I mean, we definitely attempted to do that, because this

database is meant to be just planned cases, just elective cases.
BY MR. GORDON:
Q. Okay. And by --
A. But we do know that other ones get in through coding and then they will be taken out in the sort of data cleaning process.
Q. By this database, you mean the 788 through 1050 -- 1081?
A. So you know, before we would publish, if you like, on infection rates, then we would go through it, we would check every case is as -- you know, every case, whether the infection is trauma or not. You might by chance end up pulling one out, you might not. I am not aware whether we did with this study.
Q. Okay. The data here, on 788 through 1081, as Mr. Dyer pointed out, began on 1st October, 2007. What was your reasoning for commencing the Bair Hugger only period on 1st July, 2008?
A. So my recollection is that we got a full-time surveillance team at that point. So as I said, previously in the U.K. you only have to do a quarter. Actually, you can choose which operation you do. So you might not have full-time surveillance prior to that.
THE EXAMINER: So one operation, one quartile, per annum?

A. Correct. That's the national standard. But we have moved to doing every operation full-time; and that's why we have got that reliable data. So there would be big gaps in the period. If you looked at 2006, you might only have a quarter of the year populated, which would be very unreliable data.
THE EXAMINER: Yes.
BY MR. GORDON:
Q. So I really want to drill down on the timing; and that is critical. I am going to ask you to take a look at volume 2, pages 487 through 490.
A. Okay.
Q. Have you seen this before?
A. I saw it yesterday.
Q. Is that the first time you saw it?
A. I'm not sure.
MR. ASSAAD: I am going to object for lack of foundation for any questions being asked, if he hasn't established foundation. He has written this document -- the authorship of this document --
THE EXAMINER: You have made your objection. Keep objections short.
MR. ASSAAD: Well, I need to put all the objections for the U.S. court.

THE EXAMINER: I know.
MR. GORDON: They are all preserved.
THE EXAMINER: I am familiar with how U.S. attorneys --
MR. ASSAAD: They are --
MR. GORDON: The only objection is: waives form or foundation.
MR. ASSAAD: I am only doing it for trial --
BY MR. GORDON:
Q. Do you know who Julie Gillson is?
A. Yes. Julie Gillson was one of our matrons.
Q. What is a matron?
A. So it is a senior nurse, essentially.
Q. Was she one of the SSI surveillance nurses?
A. No. So Julie is a matron, so the senior nurse within surgery, if you like. Gail Lowdon leads the surgical site infection surveillance team.
Q. And if you look at the front page of this document. At page 71, the very last paragraph, it says during --
THE EXAMINER: Where are you?
BY MR. GORDON:
Q. Page 71. Oh, I am sorry.
THE EXAMINER: 487.
MR. GORDON: 487, thank you. Page 487, the last full paragraph on the page:

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"During the last two quarters of 2008/2009, Northumbria Healthcare NHS Foundation Trust was reporting SSI rates in the combined total of surgeries in the THR/TKR and repair neck of femur between 3.5 percent and 5.7 percent and was regularly receiving letters from the HPA informing the trust of its high outlier status for SSI."

First of all, did I read that correctly?

A. Yes.

MR. ASSAAD: Objection. Move to strike for hearsay.

BY MR. GORDON:

Q. Did --

THE EXAMINER: (Overspeaking.) ... moving on to a question --

MR. ASSAAD: He can't read evidence in, without establishing a foundation. I am saying this is hearsay. He is reading someone else's words into the record. He is basically advocating this point. Objection for hearsay.

BY MR. GORDON:

Q. Do you recall there being a period of time when the Northumbria Healthcare Trust was getting letters from the HPA about SSI rates?

A. Yes.

Q. And what were those -- first of all, what is the HPA?

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A. So the HPA is the Health Protection Agency and they are the group that collate the national database, based on people collecting it locally. So Gail Lowdon who leads our surgical site infection surveillance team, a member of her team will be uploading that information nationally, if you like, to the Health Protection Agency.

The issue with that is that not every trust puts in the data as we have established; and the infection rates that they quote are very low and, in fact, they have -- I mean, the government advisers on infection have publicly written to say that their quotes -- they quote very low infection rates, unrealistically low, because the surveillance system is poor in many trusts?

THE EXAMINER: Do you have a recollection of these letters being received?

A. Yes.

THE EXAMINER: Okay.

BY MR. GORDON:

Q. And what did Northumbria do in response to those letters?

A. So I mean, we have done lots of things, as I think has become clear. We have made loads of changes over a period, a sustained period, to try and reduce the

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infection rates.

Q. Was there any type of a committee or a working group formed?

A. Yes. So there was a surgical site infection prevention committee, which I chair.

Q. And when was that formed?

A. It may actually even be on here. About 2008, maybe even 2007. That sort of timescale.

Q. And that's your independent recollection?

A. Yes.

Q. So the reason I say that is that on page 548, it says that the multiple -- a multi-disciplinary team formed the trust SSI group and the first meeting took place in December 2008.

A. There you go then.

Q. Well, if you --

THE EXAMINER: What is the --

BY MR. GORDON:

Q. If your recollection is different than what is here --

A. Yes, I think that feels right and she would know. What I would say is that we may have been doing stuff before that, before we did a formal meeting, but it would not have been long before that.

Q. And there is a reference in the next paragraph to:

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"The first action point of this meeting was to place a successful bid to appoint two full-time SSI nurses on a 12-month secondment."

MR. ASSAAD: Objection, hearsay.

BY MR. GORDON:

Q. And my question is: was there -- were there full-time SSI nurses prior to whenever this multi-disciplinary group first met?

A. Yes, so the -- the surveillance was done -- I mean, we should probably go back one step.

So we were named in the paper, based on the 2007 data, as having a high infection rate. And after that, we went to full-time surveillance, some time probably in early 2008, but we didn't have the business case and people -- and people formally appointed to those rules. They were being done, I think, by infection control, rather than by a surveillance team. Same methodology.

MR. ASSAAD: I am going to object again to those line of questions. It is not part of the subject matter of the sealed order. It has nothing to do with the studies that he has been performing, that it has been limited to -- by the Senior Master.

THE EXAMINER: He is still in the --

MR. ASSAAD: I mean, we -- well, it really isn't. It is

dealing with what these two people wrote, regarding infection control that they set up a committee to do a bunch of stuff, that has nothing to do with the McGovern study, the Belani study or any of the other studies.

THE EXAMINER: Well, at the moment, it seems to me that it relates to the McGovern study.

MR. ASSAAD: How does it relate --

MR. GORDON: It relates exclusively to the McGovern study and it is the category of the infection control procedures.

MR. ASSAAD: Procedures, but not how they set it up, who is on the committee, what the history is --

MR. GORDON: Well, your objection is noted, Gabriel. Let's start this game playing.

THE EXAMINER: Let's proceed.

MR. ASSAAD: Stop what?

MR. GORDON: Game playing.

MR. ASSAAD: Okay. Don't accuse me of playing games, sir.

THE EXAMINER: Let's get on with the questions.

BY MR. GORDON:

Q. Mr. Reed, if you turn on to page 421 of the same ...

THE EXAMINER: Where are we?

BY MR. GORDON:

Q. 421. Can you identify the people in that?

A. So the lady in red is a nurse and the lady in black is the surgical site infection coordinator, if you like. I am in that photo. And the other guy is -- I couldn't tell you his name, but he was from one of the companies.

Q. Do you know what he is holding?

A. Yes. Some -- it is like an award for reducing infection rates.

Q. And the award from whom to who?

THE EXAMINER: I must say, I do not think this is assisting our progress very much, studying this photograph.

MR. GORDON: No, I agree.

THE EXAMINER: Let's get back to the paper.

MR. GORDON: Again, I keep getting diverted. I want to get the timeline of the infection control changes. That is the sole interest I have --

THE EXAMINER: How does looking at this photograph advance that?

MR. GORDON: We are going to get foundation objections up the wazoo about everything else, all -- piece by piece.

BY MR. GORDON:

Q. Mr. Reed, in this photograph, what's behind you, behind them, on the wall?

A. Well, it is a timeline of the changes we have made.

I think it is the same one that's in the paper you just showed here.

Q. Now, if you would turn to page 436. This document actually goes from 436 up to 457 -- excuse me, 451. It's a copy of a July 2012 operating theater journal. Are you familiar with that publication?

A. Yes, probably, yes.

Q. And if you turn to page 446 --

MR. ASSAAD: Objection, lack of established foundation for use of this document in questioning the witness.

BY MR. GORDON:

Q. Is that you in that picture?

A. I think it is the same picture.

Q. Okay. And do you recall seeing this publication?

A. I saw it yesterday. I may have seen it at the time. I don't -- I don't remember it. I remember the photograph being taken, I think.

Q. Do you remember receiving an HAI Watchdog Award in 2011?

A. Yes. I think that's what he's got in his hand.

Q. Do you remember being interviewed by anybody about that award?

A. Not explicitly, but it's -- it's not unlikely.

Q. How did the award come to be awarded to Northumbria? Did it come out of the blue? Did somebody apply for it?

MR. ASSAAD: Objection. How is this award within the scope of the McGovern paper?

THE EXAMINER: I don't understand, I confess, Mr. Gordon, how what you have been doing for the last ten minutes assists us with accurate dates at all.

MR. GORDON: Because I want to get back to the chart with the dates, but I have got these --

THE EXAMINER: Where do you get a date that assists from this page?

BY MR. GORDON:

Q. Well, let me ask you, Mr. Reed. Did you submit an application for an award, an HAI Watchdog Award for success for reducing infections?

MR. ASSAAD: Same objection.

A. So I may have done. It would have been me or the nursing staff that did it, I imagine. I mean, we applied for lots of awards over the years. That would be not unusual.

BY MR. GORDON:

Q. Would you have expected that application to have said: the only thing we did to reduce infections was to change from forced air warming to the Hot Dog?

MR. ASSAAD: Objection, calls for speculation. Lack of foundation.

THE EXAMINER: Do you remember what you included in the application for the award?
A. I don't remember. I don't actually make any application, but I may have done.
THE EXAMINER: Well, you may have done anything. We are dealing with probabilities, rather than what may have happened.
A. Yes. Well, it would have been made by me or by Gail Lowdon, I imagine. Would we have said --
MR. ASSAAD: I would like a ruling. I don't think he should answer that question, if he doesn't recall --
THE EXAMINER: No, fine. No, I am ruling that he does not need to answer that question.
BY MR. GORDON:
Q. Was the only thing that you -- you won the award for, was for changing the warming modalities, or were there other infection control things that you did in the --
MR. ASSAAD: Objection, outside the scope.
THE EXAMINER: Let's get back to the documents, rather than the award.
MR. ASSAAD: Ask him not to answer that question.
THE EXAMINER: That has no part within schedule B.
BY MR. GORDON:
Q. Did you change -- I will direct your attention to

page 425.
MR. ASSAAD: Sorry, what page?
MR. GORDON: The document is 425 through 431.
A. Yes, I have got that, yes.
BY MR. GORDON:
Q. And specifically page 427. Again, it says "Mike Reed as a consultant orthopaedic surgeon." Do you see that?
A. (Nods.)
Q. Is this something you recall ever seeing before?
A. Well, I definitely saw it yesterday. I don't recall if I have seen this before or not. It's obviously written about me, rather than by me. Whether I would have given -- been given the opportunity to sign it off, I don't know.
Q. Well, do you recall being interviewed by the Clinical Services Journal?
A. I don't think this was an interview. I think this was -- this is based upon a presentation, I think, rather than an interview.
Q. Okay.
A. I could be wrong, but that was my impression yesterday.
Q. Well, let's turn to page 453. The document goes from 453 through 457. Do you recognize that?
A. Yes.

Q. Okay.
THE EXAMINER: What is the JTO? Journal of Trauma and Orthopaedics?
A. Yes.
BY MR. GORDON:
Q. You were one of the authors of this?
A. Yes.
Q. If you turn to page 454.
MR. ASSAAD: Just for the record: when you use these documents, can you identify the Bates number, the title of the document and establish foundation before asking questions? Page number and title, so we know for the record, so the record is clear and clean?
BY MR. GORDON:
Q. On page 454 in that box, that column, what are those -- under "Management", what are each of those items contended to be?
A. So essentially there's risk factors for infection, so this is identifying certain patient groups that are more likely to get infections; so patients who are obese, patients who smoke.
Q. Let's focus on the second --
A. And then perioperative factors. These are things maybe that you can influence, as opposed to not.

Q. And you describe this as a summary table of common prevention tactics; is that right?
A. Yes.
Q. And towards the bottom, you say you maintain normothermia as one of the prevention tactics; right?
A. Yes, I think that's right, one of the ... yes.
Q. And your skin prep, you say you use an alcohol pre-wash, followed by a 2 percent chlorhexidine-alcohol scrub; is that right?
A. Whereabouts is that? Yes, okay. Well, that's what we said.
MR. ASSAAD: I am going to object to the --
A. Actually, we said -- or betadine actually, so --
MR. GORDON: Okay.
MR. ASSAAD: Lack of foundation to his --
THE EXAMINER: Did you say lack of foundation? That is fine. That is the standard objection made by U.S. attorneys.
MR. ASSAAD: Okay. Well --
THE EXAMINER: They don't go on and explain the basis for it, in my experience.
MR. ASSAAD: In depositions, no. But I say the --
THE EXAMINER: This is a deposition.
MR. ASSAAD: To be raised at trial.

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BY MR. GORDON:

Q. Did there come a time when you switched the skin prep that you used at Wansbeck?

A. Yes. It is on the timeline somewhere.

Q. What did you switch from and what did you switch to?

A. So we would have switched from a variety of things. It is surgeon preference. To -- I think we switched maybe at the end of 2010, the very end of 2010.

Q. Do you recall there being a period of time that the laminar air system at Wansbeck required repair?

A. Yes.

Q. What was wrong with it?

A. Well, this was -- it wasn't in all theaters, but in particular theaters, essentially it wasn't functioning properly.

Q. How did you come to learn that?

A. We had a guy come and assess it, an expert.

Q. Was -- had you noticed some problem or was this a routine assessment?

A. So I mean, I think as we made clear, we were trying to reduce the infection rates. We made a number of changes. We made -- you know, we were looking everywhere we could, trying to get a marginal gain on reducing infection rates. And that's the basis for

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getting them all checked.

Q. Were any of the procedures in the Bair Hugger only period performed in the operating room that needed repair of the laminar airflow system?

A. In truth, I am not sure when those dates are. It might be on the timeline; is it?

Q. Did you have any hand in preparing the timeline?

THE EXAMINER: I am sorry. I missed the question.

BY MR. GORDON:

Q. You --

THE EXAMINER: I just did not hear it.

A. Did I have a hand in preparing the timeline?

THE EXAMINER: Right.

A. Certainly over the years I have.

BY MR. GORDON:

Q. There's no way you can read the one in that -- in the article. So I took the liberty, for my sake, if you have -- of printing out a larger version of it.

THE EXAMINER: How does this relate to the studies that we are concerned with?

MR. ASSAAD: I agree.

THE EXAMINER: I have not been able to have a copy that I can read.

MR. GORDON: I understand that. I am going to pass you

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a copy that you can read.

MR. ASSAAD: Can I have a copy that I can read?

THE EXAMINER: If other counsel in the room could have a copy of it, so that they can read.

MR. GORDON: Well, they are younger. They can probably read that one.

MR. ASSAAD: I want the same copy that you are giving him.

MR. GORDON: Okay. Well, I don't have it.

THE EXAMINER: My question is: how does this relate to any of the studies with which -- to which this witness's evidence is confined?

MR. GORDON: Mr. Dyer, with all due respect, this is a --

THE EXAMINER: No, it is a simple question.

MR. GORDON: Yes. And if you -- the timeframe that the Bair Hugger only was compared to the Hot Dog only, and resulting in a 74 percent reductions in infections, happens to coincide with a whole bunch of other infection control practices.

THE EXAMINER: Why don't you put that to the witness?

MR. GORDON: That is what I am trying to get to.

THE EXAMINER: Dear God, we must have been trying to do it for about an hour now.

MR. GORDON: Well, I am sorry I don't have the exquisite skills to go right to the point.

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THE EXAMINER: Well, then, get right to the point --

BY MR. GORDON:

Q. Is this the timeline you have been referring to, Mr. Reed? And we will mark this separately as, I guess, exhibit 5. So we will put copies in the record.

(Exhibit Reed 5 marked for identification.)

MR. ASSAAD: We have --

THE EXAMINER: I am sure you do.

A. Yes. I mean, I am sure this was produced in my department. I am not sure when or how up to date it is. I can't verify it. But I imagine it's correct there or thereabouts.

MR. ASSAAD: Can we mark this as an exhibit, since we have produced this?

THE EXAMINER: I think Mr. Gordon --

MR. GORDON: I just said we will mark it as an exhibit.

MR. ASSAAD: I am going to object to whatever exhibit this is, based on the lack of foundation. The witness has just said he didn't create it.

BY MR. GORDON:

Q. Just to clarify, and I think the record is clear. But did you -- were you involved in the creation of the timeline?

A. I definitely have been involved in the creation of the

timeline over the years. It is a live document; that is what I would say. So it's not fire and forget. It is kind of updated as we go. So this is quite -- probably quite a recent one.

Q. But maybe not the most recent one?

A. Yes.

MR. ASSAAD: Leading.

BY MR. GORDON:

Q. Was there a switch in your hospital's -- in the antibiotic use for hip and knee replacement surgeries, where you switched from cefuroxime to gentamicin?

A. Yes, so this is obviously made clear in the paper that we wrote, with -- you know, this is based on caveats and this is all in the paper that we wrote.

THE EXAMINER: Which paper are you referring to?

A. The McGovern paper.

THE EXAMINER: Right, okay.

A. The one that has got the clinical data, if you like. These riders are clear in the paper that we have --

THE EXAMINER: Some of us haven't had the opportunity to look at the paper before today at any time; so that is why, Mr. Gordon, your route is somewhat unclear to me. So you are saying the paper contains caveats as to other matters that have changed during the period?

A. Yes.

THE EXAMINER: Thank you.

BY MR. GORDON:

Q. Is it correct that the cefuroxime was switched to gentamicin in August 2007; is that correct?

A. The dates that are in the paper -- actually, that isn't in the paper. That's beyond -- that's well beyond it. That is before the paper. Yes, so that feels right.

Q. And is there any reference in the McGovern paper to the hospital having switched from cefuroxime to gentamicin in 2007?

A. I don't think so, but it's before the -- it's well before the time period, isn't it?

Q. Well, there is a reference in the paper to switching from gentamicin only to the lower dose of gentamicin and adding teicoplanin?

A. Mm-hm, which was in the time period of the paper, of the ...

Q. Well, the switch from cefuroxime to gentamicin, that occurred before you started the Bair Hugger only period that you were looking at; right?

A. Yes.

Q. So what -- and the gentamicin reduction and addition of teicoplanin, is it correct that that occurred in the

beginning of March 2009?

A. The data in the paper, if you've got the paper there in front of you, then that will be right.

Q. Okay.

THE EXAMINER: Just remind me where the McGovern paper is?

MR. HOLL-ALLEN: 540.

THE EXAMINER: Thank you.

MR. HOLL-ALLEN: There are details of the changes in the antibiotic regime at 543, reflected in the column ...

MR. GORDON: Thank you.

BY MR. GORDON:

Q. So when did the switch from gentamicin only to gentamicin plus teicoplanin take place?

A. So from July 2008 to February 2009, a single dose of gentamicin was given, 4.5 milligrams per kilogram. In March 2009, this was changed to teicoplanin, 400 milligrams, and gentamicin, 3 milligrams per kilogram. And then I go on to talk about the gentamicin and the cement.

THE EXAMINER: The gentamicin, briefly, is ...?

A. It is an antibiotic which is effective against many of the bacteria that cause infections.

BY MR. GORDON:

Q. And in fact, though, you have said it should not be used

as a prophylactic -- by itself as a prophylactic antibiotic in hip and knee arthroplasties; correct?

A. So the main reason for our switch, in fact, was renal failure; because it is a high dose of gentamicin that we were having to give, 4.5 milligrams per kilogram. And that was, we felt, damaging a proportion of our patients. So we switched to gentamicin because we had to move -- we had to stop using cefuroxime. That became, if you like, almost illegal in the U.K., to use --

THE EXAMINER: To use?

A. The cefuroxime change in 2007 was driven by the NHS, the big NHS, if you like, and it's because it has an association with Clostridium difficile infection. So the big NHS --

THE EXAMINER: I think that is a terminology that is familiar in this country, but not necessarily to the U.S. attorneys. Could you repeat that?

A. So it is a diarrhoeal infection which is associated with antibiotic use. And there is a big government campaign to reduce Clostridium difficile rates, a bit like MRSA maybe in the United States. So the executives of the trust are charged with reducing rates of Clostridium difficile. One of the ways of doing that would be to

stop using cefuroxime in the hospital. So that's what happened to us back in 2007.

THE EXAMINER: So that came from above?

A. It was driven from above.

THE EXAMINER: But your change to a gentamicin mix, what, came from active patient experience?

A. Yes. So there was two things. We -- we have written a paper on this, which is probably somewhere in there. But that, from memory, showed an increase in infection rates and an increase in renal failure rates; and a significant reduction in Clostridium difficile, reduced by three patients.

BY MR. GORDON:

Q. Are you talking about the switch from cefuroxime to gentamicin; it reduced the Clostridium difficile, but you had an increase in infection and ...?

A. Yes, I don't know -- I genuinely don't know, but I am sure you have got the paper, whether we had an increase in infection, but I am sure it was in that direction. It wasn't significant.

Q. Take a look at pages 527 through 531.

And it is in the abstract, the findings. Can you just summarize them?

MR. ASSAAD: Objection. I just want to be clear. Based on

Mr. Jonathan's objection earlier on about using documents that are not part of the scope of this, you know -- the scope of this sealed order. Are we saying he is allowed to go to other documents by the --

THE EXAMINER: Well, yes, because he is -- as I understand it, because I have not had the opportunity to read the McGovern paper, so I don't know what its conclusions are. But as I understand it, Mr. Gordon is seeking to establish other operative factors during the relevant period. Do I have that right, Mr. Gordon?

MR. GORDON: Yes.

MR. ASSAAD: I just want to be clear, based on what Mr. Holl-Allen was saying earlier about other documents.

THE EXAMINER: If Mr. Holl-Allen will point us to a different one.

MR. HOLL-ALLEN: It was --

A. So in summary, there was what would be said to be an insignificant fall in Clostridium difficile rates, although very close to significance. But there was an increase in pneumonia, which -- cefuroxime probably protects the chest; that's why that happened. Renal failure, which required critical care admission and return to theater, and return to theater for infection.

BY MR. GORDON:

Q. That RTT for proven infection; what does that mean?

A. Return to theater for proven infection increased.

Q. And what did it go from and to?

A. Well, 0.66 to 1.52.

Q. So it went from 0.66 percent infection to 1.52 percent infection when you switched from cefuroxime to gentamicin by itself; am I reading that right?

A. Yes.

Q. And that switch occurred prior to the start of the Bair Hugger only period; is that right?

A. That switch occurred, yes; the switch from cefuroxime to gentamicin, yes. The switch beyond that occurred in -- as we have said in the paper, occurred during the Bair Hugger period.

Q. And, well, the switch occurred, I thought you -- at the end of -- you were using gentamicin only up until February 28, 2009; is that right?

A. Well again, that's in the McGovern paper, when we changed. There is detail on that.

Q. And if you start at the McGovern -- the Bair Hugger only period in the McGovern, on 1st July, 2008, that would mean July, August, September, October, November, December 2008, February and March of 2009?

THE EXAMINER: No, January and February, I think.

BY MR. GORDON:

Q. What did I say?

THE EXAMINER: It started -- it ended on 1st March.

BY MR. GORDON:

Q. January and February. I will do that again.

July, August, September, October, November, December, 2008. January 2009, February 2009; eight months.

For eight months of the Hot Dog only period, the only antibiotic that was being given to patients was gentamicin; correct?

A. Yes. That sounds plausible.

Q. And --

A. That's written in the paper.

Q. Once you switched to a combination of gentamicin and teicoplanin, were there any further changes to the antibiotic regimen through the remainder of the study period?

A. So we changed from gentamicin to gent/teic. That was the change we made.

Q. And that remained the same through the remainder of the balance of the study period; is that right?

A. Yes. It is the same today.

Q. Yes. Was there -- wasn't there a point in time after

the study period, where you actually lowered the gentamicin further or increased the teicoplanin a little ...? It doesn't matter. I am not going to --

A. I don't think so.

Q. Obviously that is beyond -- that is beyond the scope, I think.

A. It's 3 milligrams per kilogram that we used. That's what we've always used, I think.

Q. Okay. During the seven months of the Hot Dog only period, what antibiotic regimen was used?

A. Gent/teic.

Q. So all of the Hot Dog patients, Hot Dog only patients, had the combination of gentamicin and teicoplanin; is that correct?

A. Mm-hm.

Q. And for eight months of the 20 months of the Bair Hugger only period, Bair Hugger only patients had only gentamicin; right?

A. I mean, I am not sure about the exact dataset in evidence, but certainly there was a period when -- during that Bair Hugger phase, if you like, where one group was on the antibiotic gent, and one was on gent/teic. That is in the paper.

Q. Right. And there were 12 months of the Bair Hugger only

period where the Bair Hugger patients were receiving the same antibiotic regimen as the Hot Dog only patients were; correct?

A. Sorry, say that again?

THE EXAMINER: What period was that?

BY MR. GORDON:

Q. From March 1st, 2009 until the end of the Bair Hugger only period. That was the same gentamicin and teicoplanin that continued on into the Hot Dog period?

A. That feels right, yes.

Q. So it's only the -- the first eight months of the Hot Dog only period, where there was a different antibiotic regimen?

A. Do you mean the Bair Hugger only period?

Q. I mean the Bair Hugger only period, yes.

A. Well, again, I would need a bit more time to work out exactly how many months. But you're right, in principle, in that there was a period in the Bair Hugger group when you are on the gentamicin and a period when you are on the gent/teic.

THE EXAMINER: Is that right? As I understand it, the change to gent/teic occurred right at the end of the Bair Hugger only period, but at the beginning of the transition period.

MR. GORDON: No, I think it is a year on.

MR. HOLL-ALLEN: Yes. The transition period was beginning in 2010.

THE EXAMINER: Oh sorry, I apologize. I'll withdraw that. Sorry, that explains my confusion.

BY MR. GORDON:

Q. In addition to the change in the antibiotics you also changed the venous thromboprophylaxis regimen; right?

A. (Nods.)

Q. You need to say "yes" or "no", just to ...

A. Yes, yes.

Q. What was that change?

A. So again, I wouldn't be able to cite dates for you, but we went for a period on rivaroxaban, which again is in the McGovern paper. We have put the dates in there. And yes, we had an increase in our return to theater rates when we were using that, and we published that.

Q. And what happened? Did you continue with the rivaroxaban or change to something else?

A. Yes, we changed to tinzaparin; something else, yes.

Q. What were you using before you changed to rivaroxaban?

A. Heparin, I think. I am not entirely sure.

Q. I don't want to -- I am not trying to test your memory. If you go back to the paper on page 540 through 547 --

if you --

THE EXAMINER: You have got about five minutes left on the tape.

BY MR. GORDON:

Q. Let's see if we can at least pin down the thromboprophylaxis change.

We have the -- before you switched to rivaroxaban, you were using tinzaparin; right?

A. Yes.

Q. You switched to rivaroxaban for a seven month period; right?

A. Yes, that feels right.

Q. And then went back to tinzaparin; right?

A. Yes.

Q. What were the months that you switched from tinzaparin to rivaroxaban?

A. Well, I think as you said, August 2009 to February 2010. That's when we were on rivaroxaban.

Q. So that would be August, September, October, November, December of 2009. January, February 2010. Seven months of rivaroxaban; is that right?

A. Yes.

Q. And those seven months occurred solely in the Bair Hugger only period; right?

A. It may be six months, but yes.
Q. And you switched from tinzaparin to rivaroxaban, why?
THE EXAMINER: Sorry, are you asking about the first switch?
MR. GORDON: Yes, the first switch.
THE EXAMINER: Okay.
A. I am not sure why we switched. I mean, I think it's -- it's an oral treatment, so you can have a tablet, rather than injections. So there's an advantage for the patients and maybe for compliance. That would be the rationale, if you like, for switching.
BY MR. GORDON:
Q. And regardless of the rationale for switching to rivaroxaban, you switched back after six or seven months, because of all the complications with rivaroxaban; right?
A. Because they were bleeding essentially, yes.
Q. And returning to theater; correct?
A. Yes.
Q. And --
THE EXAMINER: Rectal bleeding?
A. No, just bleeding from the wound.
THE EXAMINER: Oh right.
A. Well, and bleeding into the wound specifically. So they were getting what we call hematomas. So collections of

blood that just continued to leak and cause trouble.
THE EXAMINER: So after six or seven months, it would have been sufficient to justify a change back; that must have been a fairly marked sequence of events?
A. Yes. I mean, well, we certainly -- we picked it up. And we weren't the first. In fact, subsequently there were ten other trusts, and I think you have got that paper in there, that had that issue. And internationally as well, since then.
THE EXAMINER: Shall we change the tape?
MR. GORDON: Yes. Let's do that.
THE VIDEOGRAPHER: This is the end of tape number 1, in the deposition of Michael Reed. We are going off the record at 2:28.
(2:28 p.m.)
(Break taken.)
(2:37 p.m.)
THE VIDEOGRAPHER: This is the beginning of tape number 2, in the deposition of Michael Reed. We are going on the record at 2:37.
THE EXAMINER: Yes.
BY MR. GORDON:
Q. Mr. Reed, I am not sure where we were. What was the period of rivaroxaban; what were the months?

A. So from August 2009 to February 2010, rivaroxaban was provided from Day 1 post-operatively.
Q. Was it at the beginning or at the end of February?
A. I couldn't tell you from here. I mean, we would have that somewhere.
Q. It says "in February", but ...
A. Sure, I appreciate that. Based on what I have got in front of me, I can't remember.
THE EXAMINER: "In February" suggests a change some time during the month, as opposed to at the beginning or at the end, doesn't it?
MR. GORDON: Well --
THE EXAMINER: Perhaps we can --
MR. GORDON: Let's look at another paper.
BY MR. GORDON:
Q. If you turn to page 521 through 525, that's -- is that the paper you were referring to earlier, where you were the co-author about the switch to rivaroxaban?
A. (Nods.)
Q. If you look on page 522, the first very full paragraph, it says:
"Group 2 had their primary operation between 1 August, 2009 and 28 February, 2010."
Seven months.

A. (Nods.)
Q. So would that be the rivaroxaban only period?
A. On the basis of what we have here, yes, I think it would, yes.
Q. Okay.
Well, I have been trying to track this now, over the chart. The Bair Hugger only period went from July 2008 to the end of February 2010. The transition period was March, April, May of 2010 and then the last seven months of 2010 was the Hot Dog only.
Now, in the comparison between Hot Dog and Bair Hugger, you didn't use the three months of the crossover; right?
A. Correct.
Q. Okay.
So the surgical site infection rate for the Bair Hugger only included eight months where you were using gentamicin only; right?
A. Okay.
Q. And it included seven months where you had switched from tinzaparin to rivaroxaban; right?
A. Okay.
Q. And those two periods actually didn't coincide. In other words, the switch -- the antibiotics switch to

gentamicin plus teicoplanin had occurred prior to the rivaroxaban?

A. I will take your word for it. I am sure you have got the data -- you have got the advantage of having mapped it out. I can't think of ...

Q. Well, I'm more than happy -- if you want to see my scribble, or you can map out for itself.

A. I don't disagree with what you're saying. I'm sure you have got that ...

Q. Just those two factors, the antibiotic and the proper(?) thromboprophylaxis or the common(?) thromboprophylaxis. There were five months during the Bair Hugger period when the Bair Hugger patients had the same antibiotic regimen and thromboprophylaxis regimen, as in the seven months of the Hot Dog period; right? That being March of 2009 to the end of July 2009?

A. I cannot think that fast, I am afraid, but you are probably right.

Q. Well ...

A. So are you saying that there was a crossover when they had rivaroxaban and gentamicin; is that what you are saying?

Q. No, there wasn't; was there?

A. Well, I don't know. You have got the data there.

Q. We spent a lot of time on this. The gentamicin only period, for Bair Hugger, was from July 2008 to the end of February 2009; but the rivaroxaban switch did not start until August 2009 and ended in February of 2010, and there was no overlap.

A. Okay.

Q. So there are two discrete periods; right?

A. Right. Sounds fair.

Q. But both those discrete periods occurred in the Bair Hugger period?

A. Yes.

Q. But there was five months in the middle essentially of the Bair Hugger only period, when the Bair Hugger patients were getting the same antibiotics and the same thromboprophylaxis as the Hot Dog only patients got?

MR. ASSAAD: Objection, leading.

A. Was there? Weren't they on different antibiotics?

BY MR. GORDON:

Q. Okay. What antibiotics were the Bair Hugger patients on in March to July 2009?

A. I am going to have to go back to the paper. We could just map this out and ...

Q. Well, how about -- why don't you map it out. So that's your conclusions. Yes.

A. Do you want me to borrow your sheet where you have written it all out or ... just in the interests of time?

Q. Well, I would love to, but I know I am going to get an objection.

THE EXAMINER: Well, if we had clean copies of the chart on page 546, which I understand are in the plaintiffs' bundle, it would make everyone's life much easier, wouldn't it?

MR. GORDON: Right, but I am getting huge objections on foundation for that, so I --

MR. ASSAAD: I have no objection if you want to use my copy.

THE EXAMINER: He can't object to a document that they have included in their bundle.

MR. ASSAAD: And I would never make an objection.

A. Do you want me to go to that?

MR. ASSAAD: We have a clean copy in our --

MR. GORDON: Oh, I see what you are saying. Oh yes. I don't have an objection to that.

MR. HOLL-ALLEN: Do you want to take my page?

A. Thank you.

MR. HOLL-ALLEN: I am supplying the witness with page 1543 of the McGovern article, which corresponds with page 546 in the marked copy.

THE EXAMINER: Okay. And what is it, Mr. Gordon, you want

him to mark on it?

MR. GORDON: I guess we will have to mark this as a separate exhibit, if he is writing on it. So this could be exhibit 6.

(Exhibit Reed 6 marked for identification)

BY MR. GORDON:

Q. If you could just draw the line, draw a line indicating when the -- you switched from gentamicin to gentamicin plus teicoplanin.

A. Just excuse me. I am just going to draw the rivaroxaban because I have got the page, to save us time.

Q. Perfect.

A. And then the next one was the gentamicin switch.

Q. Yes.

A. The McGovern paper. Could you give me a page for that? Just give me the ...

MR. ASSAAD: So 543, I think is the information; the left hand column.

A. 543.

MR. GORDON: Yes.

A. Actually, I can just copy it off here.

THE EXAMINER: This is what he was being asked to do, as I understand it, as well.

MR. GORDON: I think page 543 does give the --

THE EXAMINER: What are you looking for, Mr. Reed?
MR. GORDON: The antibiotic switch dates.
A. The antibiotic switch dates. So --
BY MR. GORDON:
Q. In the middle of that first paragraph?
A. So in February 2009, they switched.
Q. Well, it looks like it says that in March 2009, this was changed to teicoplanin 4 milligrams and gentamicin 3 milligrams per kilogram.
A. Yes, okay. My chart looks like that. Is that what you are expecting?
Q. Yes. And you -- based on what you have done now, is there a period of time in the Bair Hugger only time period, when the Bair Hugger patients were receiving the same antibiotics and the same thromboprophylaxis as the Hot Dog patients?
A. Yes.
Q. What was that period?
A. Well, it's from February 2009 till July 2009.
Q. Five months?
A. So it was March, April -- no, it wasn't. It was February, March, April, May, June. Five months.
Q. Okay. So if you had compared the SSI rate for that five month period, in the middle of the Hot Dog only period,

to the seven month Hot Dog -- excuse me. Did I say Hot Dog?
If you had compared the five months in the Bair Hugger only period, when the same antibiotic and thromboprophylaxis regimens were used, to the seven months of the Hot Dog period, then you would have eliminated the possibility that the differences you were seeing could have been influenced either by the antibiotics or the thromboprophylaxis; correct?
MR. ASSAAD: Objection, lack of foundation, misstates the prior testimony. Assumes facts not in evidence.
THE EXAMINER: You may answer.
A. It would be a pretty small series to compare, but you could compare them, yes.
BY MR. GORDON:
Q. In your rivaroxaban study, what was the period of time of the series that you compared?
A. Could you tell me that?
So ...
Q. It looks to me like it was six months versus seven months.
A. Okay. Bearing in mind there is a different end point he is looking for. He is not looking for infection as an end point.

Q. Did you assess infection in the rivaroxaban study?
A. We did, I think, assess infection.
Q. And --
A. My recollection is: there was no difference in the infection rates.
Q. Let's take a look at that. That is an important point. 521 through 525?
A. There was no significant ...
THE EXAMINER: Where are we looking now?
MR. GORDON: The rivaroxaban study.
THE EXAMINER: Which is page what?
MR. GORDON: 521 through 525.
BY MR. GORDON:
Q. If you look at 523, the very last paragraph on that page, where it says:
"Our rate of infection increased from 1 percent to 2.5 percent, following RBC ... following the introduction of rivaroxaban and infection rate of 1 percent is similar to that reported in the literature following hip and knee replacements."
Did I read that correctly?
A. Yes.
Q. And the six month period that you compared the rivaroxaban to -- or the six month tinzaparin period

where you found a 1 percent infection rate, that you said was similar to that reported in the literature following hip and knee replacement, that six month period in your rivaroxaban study coincides with five of the six months of the Bair Hugger only period, where the antibiotics and the thromboprophylaxis was the same. There is one month difference; right?
MR. ASSAAD: Objection, lack of foundation. Misstates the document.
THE EXAMINER: Is that correct?
A. Could you repeat that for me? I am sorry. I am not picking up on exactly what you are saying there, so ...
BY MR. GORDON:
Q. The period of time that you -- in your rivaroxaban study.
A. Yes.
MR. ASSAAD: Which one are you referring to? Because there's two.
MR. GORDON: 521 through, whatever, 525.
BY MR. GORDON:
Q. Actually, page 521.
"Between February 2009 and February 2010, all patients who underwent(?) THR/TKR in our hospital ..."
And there you were using a 30 day period instead of

60 days for follow-up; right?
A. Okay. If that's what it says, yes.
Q. So the first six months of the rivaroxaban comparator was tinzaparin only; and that was February 1st, through the end of July 2009; right?
A. Yes.
Q. And that coincides with five of the six months of that period of Bair Hugger, when the same antibiotic regimen and thromboprophylaxis regimen was being used?
A. Yes.
Q. As in the Hot Dog only period.
So in that six month timeframe in your rivaroxaban study, you found a 1 percent infection rate. In the next seven months of rivaroxaban, which was also during the Bair Hugger only period, the infection rate jumped to 2.5 percent and then you went back to tinzaparin; right?
A. Yes. So what is clear in the rivaroxaban paper is that there is no significant difference in infection rates. I think that was what it showed. It wasn't far off significance, I will give you that; but if you -- we couldn't link rivaroxaban to infection.
Q. Who did the statistical analysis for your rivaroxaban paper?

THE EXAMINER: "For your"; which ...?
MR. GORDON: The rivaroxaban paper.
MR. ASSAAD: There's two of them. Can we be clear which one we are talking about?
MR. GORDON: The one we are looking at. The one from page 521 to page 52 -- whatever. You can ask him about another paper later.
MR. ASSAAD: You have a paper right after that, sir. That is the same thing.
THE EXAMINER: We are on 521 to 525. We will stay on there until we move.
A. I don't know. I was not lead author on that. I don't know.
BY MR. GORDON:
Q. Okay. And when you say it is not statistically significant, the jump from 1 percent to 2.5 percent, it had a P value of 0. -- 0.102. So you are saying that didn't meet the test for statistical significance.
A. Yes. So it doesn't meet, if you like, the sort of accepted test; although in reality, it is a continuum, I accept that. So ...
Q. And from a clinical standpoint, jumping from 1 percent to 2.5 percent --
A. Sure.

Q. -- in a short period of time like that was sufficiently concerning that you switched back?
A. Yes, that's --
MR. ASSAAD: Objection, leading.
A. That's why we put it in the paper. That's why we referred to it in the McGovern paper.
BY MR. GORDON:
Q. Okay. And the 1 percent timeframe, 1 percent infection rate, covers that five month window in the middle of the Bair Hugger period, that you could compare apples to apples, at least with respect to thromboprophylaxis and antibiotics; correct?
MR. ASSAAD: Objection, leading.
A. I think, yes. I think on the basis of what you are saying, that is a reasonable thing. The groups are very small, then. You can't -- it is easier to compare a big group to a small group than it is a small group to a small group, when you are looking at the significance of testing.
BY MR. GORDON:
Q. Well, it would be even bigger to compare a big group to a big group; right?
A. Yes.
Q. Was there a period of time when you adopted some sort of

a color coding system in the OR, in terms of what people wore?
A. Yes.
Q. What was that? What was the purpose of that?
A. So we -- essentially when you are in theater, you wear purple, what we would call scrubs, so the sort of pajamas. When you are out of theater, you wear blue. And it's just a way of making sure that people don't go out of theater and contaminate people on the ward and vice versa.
Q. Was there --
THE EXAMINER: Are there changing facilities before you leave the operating theater area?
A. Yes.
BY MR. GORDON:
Q. Was there some change in the footwear that occurred?
A. Yes. So we made lots of changes, as we have detailed here.
Q. When you say "As we have detailed", are you talking about the McGovern paper?
A. So you mean, there's presentations in here. There's papers we have written on it and ...
Q. And the reason I am asking about the McGovern paper is that you say on page 546:

"This study does not establish a causal basis for this association. Although the demographics were similar between the patient groups in terms of risk factors for infection, the data are observational and may be confounded by other infection control measures instituted by the hospital. For example ..."

THE EXAMINER: Where are we?

MR. GORDON: Page 546.

THE EXAMINER: Yes, but where?

BY MR. GORDON:

Q. On the left hand side, the first full paragraph that begins:

"This study does not establish a causal basis ..."

But you say:

"For example, changes were made to the antibiotic and thromboprophylaxis protocols used during the study, although no infection control changes were made after February 2010."

And my -- I am emphasizing the words "For example". You've got thromboprophylaxis and antibiotics specified in here.

But my question is: are there -- did I miss it or are there any other places within there, where you actually -- within the McGovern paper, where you talk

about what other changes had occurred or when?

A. So we did -- we obviously listed that there were changes, so we chose two specific ones, because they are the ones really with the evidence base or the concern around them.

So to turn that on its head, if I was to say, you know: we changed the color of theater blues in the article here on infection, they would say: well, where is the evidence for that, that influence? And you wouldn't find a reference for that either.

So a lot of the things we have done are on the basis of common sense, rather than evidence that it will help infection. I would accept that.

Q. Did you change the dressings?

A. That's -- at one point we changed the dressings, yes.

Q. From what to what?

A. So I am struggling to think if we had a policy before we changed, in terms of -- I think it was probably certain preference. But after we changed, it was to something called Aquacel Surgical.

Q. Is that the same thing as Jubilee?

A. Jubilee, yes. Jubilee is --

Q. The hospital?

A. The hospital that invented it. The Golden Jubilee.

Q. Was there any evidence to support switching to the Jubilee dressing?

A. So they had evidence.

THE EXAMINER: "They" being?

A. The Golden Jubilee had done a small trial on it.

BY MR. GORDON:

Q. The hospital in Glasgow?

A. Yes.

Q. What did their trial demonstrate?

A. So they looked at a variety of outcome measures, but the ones I remember were blister rates. So you can sometimes get blistering around a wound. And they were reduced with that dressing, and infection rates were reduced. I can't remember whether that was superficial and deep or whether it was just deep. But there was a -- there was an effect.

Q. And when did you switch to the Jubilee dressing?

A. It's probably on the timeline, I think.

Would you care to point it out, to speed me up? There is a lot on here.

Q. If I am reading correctly, it is the October 2009.

THE EXAMINER: Right at the bottom left hand side, at the bottom, in the yellow box.

A. Okay. So ...

THE EXAMINER: Well, that's audit.

A. Yes, it's audit. I am not quite sure what that means. It may well have changed well ahead of that. There is another wound dressing audit you see underway, I think, at the beginning of 2008.

THE EXAMINER: I see, yes.

A. So I couldn't say with any certainty when we changed, but it was a pretty early change, I think, that we made.

BY MR. GORDON:

Q. Would it have been before or after the audit?

A. Well --

THE EXAMINER: You can't audit something you are not using.

A. No, so I mean, I think -- I am struggling to know whether in quarter 1 2009 we introduced it or whether it was before that. I don't know.

BY MR. GORDON:

Q. Okay. But it was before --

A. It probably is written somewhere in your documents.

Q. It was before the switch to Hot Dog; right?

A. I mean, my recollection is that it was, but I couldn't say with any certainty.

Q. Did there come a point in time when, at Wansbeck, you started screening hip and knee patients for methicillin resistant staphylococcus aureus, MRSA?

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A. No. We have always done that, but I think you are alluding to sensitive staph aureus.
Q. That was my next question. So you have always done the first screening?
A. Yes, I can't remember when we didn't.
Q. But my next question -- yes. So did there come a time when you -- was there a time when you had not been screening for methicillin susceptible staphylococcus aureus, and you started screening for that?
A. So that was in early 2010, I think we started screening for that.
Q. And was it just screening, or did somebody who had -- did you take some action?
A. So we would decolonize patients to -- essentially what you are trying to do is to reduce the load of this particular bug in someone's nose or on their hands or whatever.
Q. So some of the Bair Hugger only patients would have not had the benefit of MSSA screening; some of them would have? Either way -- did you say February 2010?
A. I think it was January, but ...
Q. Okay. So at the very end of the Bair Hugger only period?
A. Yes.

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Q. So if you were the Bair Hugger -- some of the Bair Hugger patients at the very end would have had MRSA screening and all of the Hot Dog only patients had the benefit of MSSA screening?
A. That is due. But what I would say is that there is no evidence that it reduces infection rates in this group; certainly at this point. That may not be the case now, six years down the line. But yes, it was introduced with that intention.
Q. Did there come a point in time when you instituted pre-warming of patients for hip and knee ...?
A. Yes.
Q. When was that?
A. It will probably be on the timeline.
THE EXAMINER: What does it mean?
A. So essentially, if you warm someone up before their operation, then they are less likely to get cold during their operation. If you are less likely to get cold during the operation, then it reduces your complications of bleeding, heart attacks and perhaps infection.
BY MR. GORDON:
Q. Well, had you seen any studies before you implemented the pre-warming, to address that specific issue; does it have any impact on infection?

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A. So it does have an impact on infection. But I think what's less certain is whether it has an impact on infection if you warm them in theater as well. So isolated pre-warming has an impact on infection.
In fact, David Leaper, who you are going to meet, published that in a very good large study. But my recollection is that those patients weren't warmed during surgery.
Q. Are you talking about the Melling paper from 2001?
A. Yes.
Q. Was there a study closer in time, so when you switched to pre-warming that you had seen ...?
A. So I have certainly seen a study that shows that if you pre-warm people, they are less likely to get cold, so that's like a proxy. So I have certainly had that in some of my presentations.
Q. Have you ever indicated that in your presentations, that you read the New England Journal and found some article about a significant reduction in infection rates by adding pre-warming, and then you decided to do that as part of your routine procedures?
MR. ASSAAD: Objection, leading.
A. That was David Leaper; David Leaper's study, I think. I think that was in the Lancet, actually, David Leaper's

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study. Is pre-warming in the New England Journal of Medicine? I am not aware of that.
BY MR. GORDON:
Q. Okay. I am not going to take time going into too many more ...
A. There is now good evidence evolving, but it is coming into practice as a definite now, compulsory. This is six years down the line.
Q. When did you start pre-warming patients?
A. It is probably on the timeline. Can you point that out for me?
Q. I think it is probably the second quarter of 2010.
A. Okay. It is likely to be correct if it is on here.
THE EXAMINER: Yes, it is part of the entry in the yellow box.
BY MR. GORDON:
Q. The yellow box up on the top bit.
A. Yes, I am not sure that the Lancet study -- and I am genuinely not sure. But I think that is not based on the people who are warmed during the operation as well. I think in David's study, they were only pre-warmed.
Q. The 2001 Melling --
A. Yes.
THE EXAMINER: So in your hospital, as from June 2010 they

were both pre-warmed and warmed during the operation?
A. Yes, yes. And the major benefit of that would be reducing bleeding, reducing anxiety, reducing pain perhaps as well, reducing transfusion rates. It has a lot of advantages. It does not relate specifically to infection and I am not sure that warming and pre-warming together reduce infection rates. Either is probably fine.
BY MR. GORDON:
Q. Now, at some point you switched to chlorhexidine as a skin prep; is that right?
A. (Nods.)
Q. When was that?
A. In my recollection, late 2010, right at the end of the -- I will save you some time. Right at the end of the -- actually, I can't remember which period it was.
THE EXAMINER: Look at the little red box for Q4/2010.
A. Okay, there you go, right. At the end of 2010. So -- yes.
BY MR. GORDON:
Q. Did there come a point in time when you instituted a root cause analysis of infections?
A. Yes. I think that was pretty early on, actually.
Q. Like the first quarter of 2009?

A. Yes, or even before that, I suspect, actually.
THE EXAMINER: It says "underway", which is not exactly very precise.
BY MR. GORDON:
Q. I just want to cut to the chase. Would you agree that there were -- that there was, first of all, a serious problem with infections in the knee and joint area, in the late 2008/early 2009 timeframe?
MR. ASSAAD: Objection to form, argumentative.
THE EXAMINER: You may answer.
A. So I mean, I would definitely agree, we were trying to reduce our infection rates. And it's a devastating complication and we were trying to reduce them. And you know, I think as we have made very, very clear publicly, we have tried lots of things to reduce it.
BY MR. GORDON:
Q. And over a period of time, you implemented a whole variety of infection control procedures?
A. Yes.
Q. And it wasn't just switching from Hot Dog -- or from Bair Hugger to Hot Dog; right?
A. So in the time period that we have put in the paper, I don't think there's anything significant that we haven't mentioned in the paper, which is the gentamicin

and the rivaroxaban, in terms of -- in terms of affecting infection rates.
You know, there are other things like MSSA screening which was introduced.
But at the time of this paper and still, there is no evidence to say that it reduces infection rates, staph aureus infection rates in joint replacement patients. Now, we are doing a piece of work now that does actually, I think, show that. But that is not in the literature at all, even six years down the line.
Q. Just looking at the timeline and the picture of you standing in front of that thing, the graph that starts out very high and goes down very quickly. Was that reflective of what was happening to the SSI rates?
A. So I mean, this chart is the SSI rates, but it is not -- you need to understand, it is not the Wansbeck primary joint replacement infection rates. This is --
Q. The whole system?
A. -- the conglomerate of superficial and deep revision, hip fracture patients, hemiarthroplasties, DHSs, and it is a large group. And the value of that is that you can make a change and hopefully track the advantage of that.
Q. There came a point in time when you stopped using one particular operating theater; correct?

A. Yes.
Q. Why was that?
A. That was, I think here.
Q. I think it was a little later in time.
A. The laminar flow repaired in Wansbeck. Is that the one you ...
Q. And that was when? That was -- it is kind of hard to tell from the timeline, other than that it was --
A. That was quarter 3/2008. Quarter -- at the start of quarter 3.
Q. Now, I --
A. To June 2008.
Q. From memory, I think it is in the orange box on the far right.
A. Okay.
Q. After the --
THE EXAMINER: That is Q4 of 2013, theater 2, WGH, closed to all TKH joint replacements.
A. Yes, so there was a brief period. That is not actually my theater, but there was a brief period that it was closed.
BY MR. GORDON:
Q. Okay. It was not a permanent closure? I don't want to talk about that, then.

THE EXAMINER: Before we go on, the air conditioning, whatever you have done --

MR. HOLL-ALLEN: Have I made it worse?

THE EXAMINER: I heard it behind me cease to come out of the vents.

(Off the record remarks.)

THE VIDEOGRAPHER: Going off the record at ten past 3.

(3:11 p.m.)

(Break taken.)

(3:11 p.m.)

THE VIDEOGRAPHER: Back on the record at 3:11.

THE EXAMINER: So you want to go to volume 4 now?

BY MR. GORDON:

Q. Yes, please. Can I direct your attention to page 1584?

(Exhibit Reed 4 marked for identification.)

Q. It is actually a full e-mail chain. The full e-mail chain goes from 1584 to 1589.

A. Okay.

Q. Got it? And the bottom half of that page, 1584, is that an e-mail from you to Mark Albrecht and Paul McGovern?

A. Yes.

Q. And is this -- it concerns what ultimately became the published McGovern paper; right?

A. I would have to read that, but it sounds likely. Yes,

that would be right.

Q. If you look at the second full paragraph under your comments, could you just read that one? It starts with "the infection reduction data".

A. So I have said:

"The infection reduction data has been given too much prominence. Whilst the data is real and can be used in the discussion, it is potentially controlled by many factors and I am not prepared to imply that this is solely a forced air warming effect. We have made lots of interventions -- it could be any, although I agree it could largely be a forced air warming effect."

Q. By whom was the infection reduction data being given too much prominence?

A. Well, I think I am referring to the first draft, which I think was done by Mark Albrecht.

Q. And based on the e-mail at the top of that, after a -- a week after you sent that e-mail about infection reduction data being given too much prominence, Albrecht sent back to you and Paul McGovern, with a carbon copy to Scott Augustine and Christopher Nachtscheim, what he describes as the first official rough draft of the paper. Do you know what that means?

A. Well, it is a rough draft of the paper, yes.

Q. Was Mark Albrecht the primary writer of the paper?

A. He had the first go at this paper and I think many other papers.

Q. Do you know why Scott Augustine was copied on this?

A. I think he was on the payroll at that time. Mark -- in fact, he's got an Augustine e-mail address.

THE EXAMINER: So over the page at 1585, when he wrote to you on 22 December, saying:

"I've started getting serious about getting your manuscript done."

What does that mean, as you understood it?

A. I think he was going to do a draft of the paper.

THE EXAMINER: So he actually did the initial first draft?

A. Yes; I am 90 percent sure he did that.

THE EXAMINER: Okay.

BY MR. GORDON:

Q. If I could now move you to 1601 through 1607; another e-mail chain.

It looks like this is a few days later than the one we just looked at. In particular, I want to draw your attention to page 1602, where you say -- at the top, where you say:

"Mark, the paper reads well and (until the reviewers complain!) I am happy to include both the spinal data

and the infection plots. Could you have a read through and I would be very grateful if you could address comments and add references. I will also need a new deep infection chart drawing up and stats when I have up to date data. Same message but a couple of infections under CFW with many more numbers of primaries. It makes the data much more credible with the same message."

What did you mean by that?

A. Well, it's just a longer follow-up in the forced air warming group.

Q. What was the reference to making it more credible?

A. Well, the more patients you have in it, the more credible it is. I mean, that's what that ...

THE EXAMINER: What does the sentence:

"Same message but a couple of infections under CFW with many more numbers of primaries."

What does that mean?

A. It means we have had infections under forced air warming -- sorry, under conductive fabric warming. So I was more or less telling him that it wasn't going to be data that he would particularly love, but nevertheless it probably still shows an advantage. That was my view at that point. So we had had more infections.

THE EXAMINER: As many more numbers of primaries?
A. So that means that the -- so essentially, "primaries" means the primary joint replacement. So we had done --
THE EXAMINER: Primary?
A. Primary joint replacement. So we had done lots of operations. We had two more infections. So that's -- compared to the data we had seen before, I think it's presumably saying ...
BY MR. GORDON:
Q. If you could turn to page 718 through 739.
THE EXAMINER: What is this, sorry?
MR. GORDON: I think that goes back to volume 2.
THE EXAMINER: 718?
MR. GORDON: 718 through 739.
A. Okay.
BY MR. GORDON:
Q. And on the cover page of 718, it shows as authors: Mike Reed, Mark Albrecht, Oliver Kimberger, Mark Litchy and David Leaper.
Do you know what this is?
A. So I think this is an early version of the -- of Reed et al, as you call it.
Q. The one that we find at page 505 through 510, are the authors Reed, Kimberger, McGovern and Albrecht?

A. I think so. To be clear, I have not -- I think that probably -- yes, that will be this paper, sent in Vienna.
THE EXAMINER: So this is what you would call Reed 2013?
MR. GORDON: Yes.
BY MR. GORDON:
Q. So what was David Leaper's involvement in that paper?
A. So I don't know, is the truth of it. My recollection of this, when I was going through this last week, is that he was on early versions of this paper, but he wasn't on the final version.
Q. You don't know why?
A. I don't know why. He would be the best person to tell you. I can speculate, but that would be speculative.
THE EXAMINER: No.
BY MR. GORDON:
Q. Okay. If you could turn to pages 741 through 754. On page 741, it identifies authors of this paper as Leaper, Reed, Wim -- W-I-M -- Amsterdam and Mark Albrecht. Do you have any idea what this is?
A. I don't have any recollection of this, I am afraid. I don't know whether I should, but ...
Q. Do you have any idea who "Wim" refers to?
A. No.

Q. Okay. One more.
A. This paper was never published, as far as I am aware.
Q. Did you participate in writing it?
A. I don't think so.
Q. Are you even aware that -- strike that.
Was it the practice for somebody else to author something with your name on it and then ask you to sign on as an author?
A. No. I mean, the involvement, if you like, of the clinicians was to have a clinical context to the data. So in the paper that I eventually -- the Reed et al, you know, my involvement was really to put some -- add some weight to it, essentially, and that's the reason that I was on that.
I think my recollection of that particular paper was that it was pretty well written. I think that -- just let me get this clear in my ...
The Reed paper, I actually put quite a lot of time into. Is there a copy of that?
MR. HOLL-ALLEN: 505, I think we said.
THE EXAMINER: 505.
A. Was it in here as well?
MR. HOLL-ALLEN: Yes, it is in the same volume, 505. Ah no, sorry. That is the plaintiffs' bundle. You want

volume 2.
A. I think, isn't it in here as well?
MR. HOLL-ALLEN: It may be.
A. I was just going for an easier ...
So the forced air warming evaluation and intake filtration actually, I put quite a lot of work into, in terms of the paper, because it took quite a lot of understanding. I don't know if you read that paper. It is a complicated paper.
THE EXAMINER: That is why it is well written. I have not read it, because I was not given the task.
A. So I had quite a lot of input into that, albeit after the experiments were done. But the concept there of filters and the likes took quite a lot of understanding for me.
BY MR. GORDON:
Q. The experiments were done in Minnesota; right?
A. That one was done in, I think, Minnesota and in Vienna. So there were two aspects to that study.
Q. If I could have you turn to page 1479 now. It is an e-mail chain, 1479 to 1480. I want to ask you about --
MR. ASSAAD: On exhibit 3?
MR. GORDON: It is in exhibit 4, actually. Sorry.

THE EXAMINER: 1479?
MR. GORDON: Yes.
BY MR. GORDON:
Q. What I want to direct your attention to is the top of 1479 and just really -- it doesn't show you as being copied on it, so I just really want to ask you if you are aware of any discussion about the line:
"Ok, Scott, that leaves you with a decision to make."
MR. ASSAAD: Objection.
BY MR. GORDON:
Q. "Pick 1 of 3 options.
"1) We ask Mike Reed to take lead on this abstract also."
MR. ASSAAD: I am going to make an objection before you enter it into the record. Something -- you failed to establish foundation. He is not even on the e-mail. You are just testifying here. This is not proper.
MR. GORDON: Gabriel, are you going to be okay with me interrupting you in the middle of a question?
THE EXAMINER: Carry on, Mr. Gordon.
MR. ASSAAD: If I am reading an e-mail from somebody else, feel free.
THE EXAMINER: He has ...

MR. ASSAAD: He does not. He is not copied on it.
THE EXAMINER: It does not matter.
MR. ASSAAD: It does matter.
THE EXAMINER: What rules ...
MR. ASSAAD: The Federal Rules of Evidence.
THE EXAMINER: All right. You make your objection.
MR. ASSAAD: That is what I am doing.
THE EXAMINER: Carry on.
BY MR. GORDON:
Q. I will go back. The line I am asking back:
"Ok, Scott, that leaves you with a decision to make. Pick 1 of 3 options:
"1) We ask Mike Reed to take lead on this abstract also (maybe preferred choice).
"2) We ask Bob Gauthier to take lead on this.
"3) You take the lead author role (I also like this option equally to #1)."
Have you ever seen this before?
A. No.
Q. Were you privy to any discussions with Mark Albrecht or Scott Augustine about Scott Augustine deciding who was going to be asked to be --
A. No.
Q. -- an author of the paper?

A. No.
THE EXAMINER: Were you asked to take the lead on this abstract?
A. I am not entirely clear what this refers to, to be honest. It could be almost anything, in terms of papers. There's no attachment.
THE EXAMINER: Well, it is. It is a forced air warming abstract document.
A. Have we got that?
THE EXAMINER: I don't know where the document ...
MR. GORDON: Well, when I find it, I will circle back to this.
THE EXAMINER: Okay.
MR. GORDON: You see the crud and bug. Just put that into the back of your head. We will come back to that.
BY MR. GORDON:
Q. Since we are in this volume, I just want to deal with one small thing and get it done with.
If you look at 1494 through 1505 -- correction, 1492 through 1505.
And at the beginning of this, there's an e-mail chain and then an attached draft of a presentation.
Is this at all familiar to you?
A. I mean, I have certainly read it in the last couple of

weeks; and I have probably read it at the time I was copied in. It is my e-mail address.
Q. You know, I apologize. I lumped together in that, the e-mail and the attachment. The e-mail chain just goes from 1492 to 1498; and then 1500 to 1505 is the attached draft. That's what I'm talking ...
Oh, I am sorry. Before we leave that e-mail chain.
If you look at 1496, please. In the middle of the page, there is an e-mail from Mark Albrecht to Paul McGovern with a carbon copy to Mike Reed, Scott Augustine, Brent Augustine and "Nach001" and the text of that is:
"Much better Paul. You did a good job of hiding the 'agenda' and making this look much more impartial. I'll give you an updated infection graph and summary tomorrow."
What was your understanding of what "agenda" Mark was praising Paul for doing a good job of hiding?
MR. ASSAAD: Objection. Calls for speculation.
THE EXAMINER: Did you have an understanding?
A. I can speculate, I can speculate on it.
THE EXAMINER: No.
A. I mean, I wasn't --
MR. ASSAAD: We don't want you to speculate.

MICHAEL R. REED

A. -- engaging in that conversation, so I would be speculating.

BY MR. GORDON:

Q. So as you sit here today, you don't remember any discussion of an agenda that you wanted to hide, with this presentation that you and Dr. McGovern gave?

A. No, I don't think -- I am speculating, but I don't think the agenda is referring to Paul McGovern.

Q. Okay. One other question before we leave the e-mails. At the very bottom of 1496, Brent Augustine sends an e-mail to Mark, CCed to others, but he specifically says:

"Dr. Reed, it was nice to see you in San Diego. The research was extremely well received by those that saw it."

Do you know what that was referring to?

A. Just let me check the date. So -- sorry, which page are you on?

Q. 1496.

A. So -- well, I mean, I had been to San Diego once. It was for the American Academy of Orthopaedic Surgeons. It must have been there. Did I present there? Probably.

Q. Do you recall what you presented?

MICHAEL R. REED

A. No. I could find out, probably. As far as I am aware, it wasn't on anything related to this.

Q. Okay. That was going to be my question.

Did you ever speak at a conference on anything related to forced air warming where Scott Augustine or his company helped you with travel costs or lodging costs?

A. Me? No.

Q. Someone else?

A. Well, Paul McGovern, I think, went to Minneapolis and my recollection was that I advised him to get receipts and just get them reimbursed and not to take anything financial. That's my recollection of it.

Q. Okay.

Now, I want to flip to 1500 through 1505. It is titled "Outline of BHS presentation". And if you look at the comment boxes on the right, on that first page, 1500, the very first comment is:

"Comment: MRR1."

A. Mm-hm.

Q. Who is MRR1?

A. Very likely to be me, I would say.

Q. And you -- this outline indicates that the presenters of this BHS presentation are Paul McGovern and Mike Reed.

MICHAEL R. REED

Was there ever such a presentation?

A. Yes. So I think this is a presentation at the Hip Society, which was in Bournemouth or the south of England somewhere, in about -- well, it was the meeting in probably 2011, 2012, something like that. It was the same meeting that we got declined the other -- the original piece of research we did. That was declined at this meeting. This one was accepted.

Q. Okay.

This presentation doesn't reference that negative microbiology study, does it?

A. Correct, that was declined. So the two separate -- I mean, he may well have put lots of papers in. I think at that particular meeting, I personally and my team had loads and loads of papers in. That -- so the first one wasn't accepted. This one was accepted. So he gave this presentation.

Q. If you drop down to the bottom comment on page 1500, "M3". First of all, do you know who the "M" comments are coming from?

A. I am speculating, but it's probably Mark --

MR. ASSAAD: Objection.

A. Well, I don't know, no, is the answer.

THE EXAMINER: I don't quite understand these commented

MICHAEL R. REED

boxes. "MRR1", you say, is you?

A. I think it is my first comment.

THE EXAMINER: But "M2", which continues the sequence, is obviously from someone else, because it says "I agree with Mike".

A. Yes.

MS. ZIMMERMAN: Just the ...

THE EXAMINER: No, I don't think it is M1, because it is that person's first comment.

MR. GORDON: There might have been an M1 that, you know, he deleted before it got sent.

MR. ASSAAD: No, because there is MR5 after M4.

MR. GORDON: I have seen, I ...

THE EXAMINER: I saw this the other day and I was very confused by it.

BY MR. GORDON:

Q. Looking at comment "M3" where it says:

"I suggest you add this as an additional slide to focus the direction of where you are going in the broader context, that you are only looking at one potential factor among many possible ['many' or 'may possible'] culprits. This makes it look impartial and hides our agenda, so to speak..."

MR. ASSAAD: Objection, hearsay.

BY MR. GORDON:
Q. Do you recall any discussion with Mr. Albrecht about the need to make this presentation that you were and Dr. McGovern about to give --
MR. ASSAAD: Objection. Sorry.
MR. GORDON: Gabriel, let me finish.
MR. ASSAAD: I thought you were done. You had a question --
THE EXAMINER: Okay, let him finish.
MR. ASSAAD: I thought he had finished.
A. Just to be clear, that is not my comment, M3.
BY MR. GORDON:
Q. I understand, I understand. I am just wondering: when you saw the back and forth on these comments, did you even read that one?
A. I probably haven't -- I mean, I have probably read this once and commented. And he's made comments after I've read it, because I don't -- well, is there any of his things that I have commented on? I suspect he's commented after me.
MR. ASSAAD: I would like to make an objection to the last question. It assumes facts not in evidence. You said this was Albrecht's comment and that has not been established.
MR. GORDON: That is what Mr. Albrecht testified to, so

I consider that a fact established in evidence already.
MR. ASSAAD: That is not --
MR. HOLL-ALLEN: May I intervene to say this. Mr. Gordon said a moment ago to the witness:
"When you saw the back and forth in relation to these comments."
With respect, I don't know whether it has been established that at the time, Mr. Reed saw the back and forth in relation to these comments; in the sense that it seems to me to be perfectly plausible that he made comments, and then M made comments which he did not subsequently see.
So it seems to me that there has to be a better foundation for the questions, and an assumption is being made about a factual issue which has not been accepted.
THE EXAMINER: So we would have to see an MRR response to an M comment.
MR. HOLL-ALLEN: I think we would, or the witness would have to accept that he had seen the M comments at the time; and I don't believe that he has accepted that.
BY MR. GORDON:
Q. If you turn to page 1501. At the very bottom, there is a comment, MRR8:
"Are there any pictures of this in use with models?

Ideally an attractive one."
Comment, M9:
"I know the exact picture Mike wants ... I'll get it to you."
Comment, MRR10:
"Need to mention the improved efficiency. Watts spend etc. Mark will have figures in comparison to FAW."
Does that refresh your recollection as to whether you only made comments once and did not review any responsive comments?
THE EXAMINER: No, I am sorry, Mr. Gordon. That does not work.
A. No, I don't think so. No, that is a separate --
THE EXAMINER: If you look at the dotted line, it is clear that M9 responds to MRR8, but MRR10 is a separate comment. It is not responsive to M9.
MR. GORDON: Right. But it is sequentially current.
THE EXAMINER: Well, that is -- it is in the document.
MR. GORDON: It is not sequentially referring to his first comment. Comment MRR10 does not respond sequentially to MRR8. In other words, they weren't done at the same time. I am not going to belabor the point. It is --
THE EXAMINER: They may have been done a minute later,

I don't know, but ...
A. I think the way track changes works is to -- they have all got different numbers. Every comment has got a different number. That doesn't mean that I have seen -- there is nothing in here that makes me think I have seen the conversation. I have seen it once, I suspect. It would be unlikely that I would do it twice, to be honest.
BY MR. GORDON:
Q. So when you commented, MRR6:
"I'm tempted to say the driver for this was the need to verify the smoke DVD produced by Augustine ... remind them that this DVD was posted to all orthosurgeons in U.K. last year (assuming that is correct)."
So the comment, M7:
"I'd be careful here. That might imply a strong corporate agenda behind these activities and raise questions as to the credibility of the results."
You never saw that response?
A. I don't think so. I mean, I couldn't honestly say I saw it. It would be unlikely that I would review a trainee presentation twice, before going. But it's possible I did.
Q. Okay.

If you turn to the final page. I'm sorry, 1505. It is your comment, MRR20, I want to ask you about. It is -- at the bottom, there's somebody saying:

"Notes -- for discussion, or to fit into main body."

And one of them is:

"Mention infection data from Northumbria."

And the dash line goes over to your comment, MRR20:

"Suggest you hold this as the very last slide -- one that is placed after your thank you slide at the end. If you are lucky you can steer a question into exposing it. Normally work a treat and can be introduced with 'I thought you might ask that...'"

What did you mean by that?

A. So when you give your presentation, you have essentially being accepted to give a presentation on a particular topic. And that was on the -- from my recollection, that was on the difference between forced air warming and conductive fabric warming that we did on the experimental -- on the experimental sort of one in theater.

But a common question after that sort of thing is: how does this apply to clinical practice? That would be the next question.

So you can't really present on it in your main

presentation, because that's not what they have given you permission to do. But if then someone in the audience asks, that's when you can show, you know, a relevant slide.

And that's something that I will do fairly routinely, is to try and anticipate a question that I think will be -- that will be asked, and then you can answer it. Rather than with a sort of a bumbling statement, you can actually have something to show.

THE EXAMINER: So the slide is on the screen?

A. Yes.

THE EXAMINER: And you are hoping that someone is going to say: "I want to ask questions about that"?

A. Yes and I might hold two or three slides that I might get asked and so my thank you slide is up and someone asks me. I say: "Well, I thought you might ask. I have got a slide on that." And just -- it is a fairly common practice.

BY MR. GORDON:

Q. Why didn't you want to have the issue of the infection data presented during the --

A. Because the abstract that had been accepted was not a clinical paper. It was a specific experiment. That's what the -- you know, if they accept that, you can't

really go with something else. You need to go with what they have accepted and present that. It would be -- because otherwise you could just turn up with anything and say anything in your slot.

Q. Had you submitted the infection data part of the study?

A. I think that was too early at that point. That was, I think -- I forget when this was, but this was probably 2010. So there might have been a hint towards some data at that point.

Q. Okay.

If you turn now to the e-mail chain, 1529 through 1535. The top page, 1529, is an August 20, 2010 e-mail from Mark Albrecht to you and Paul McGovern, with a CC to Nachtscheim, Gauthier and Scott Augustine.

Do you recall seeing this before?

A. I saw it the other day, but I am sure I did receive it at the time.

Q. Yes.

At the bottom, he says that:

"Bob is more than happy to assume the lead authorship role and verify the fidelity of our research (he has seen it first hand). Further, I'm sure Chris will also vouch for that since we brought him over to take a look at it too. If we take the burden off of

both of you as being lead authors, would you be comfortable with submitting the current publication as is with a role as secondary authors? The only reason I ask is that I've got a backlog of these things to get in that are just sitting here -- without any clue as to when the bubble generator will clear customs. I'd like to target an anesthesiology journal with this article anyways, so Bob is a natural choice for lead author."

What does that refer to?

A. So --

MR. ASSAAD: Objection, calls for speculation.

A. I am just trying to think about the timeline, 2010.

That -- I am speculating, and I know that's not allowed, but ...

THE EXAMINER: No, thank you.

A. Okay, fine.

THE EXAMINER: See if you can reword the question, Mr. Gordon.

BY MR. GORDON:

Q. Okay.

Was there -- we have probably talked about this earlier -- some study that had been done in Minnesota that you didn't actually see?

A. The Belani study, yes.

MICHAEL R. REED

Q. Okay, so that refers to the Belani study. And the co-authors on that were Albrecht, McGovern, you and Nachtscheim; right?
A. Yes.
MS. ZIMMERMAN: And that binder is going behind tab 4.
A. Yes.
Do you want me to comment or ...?
BY MR. GORDON:
Q. Go ahead.
A. I am not sure, in honesty, whether this e-mail refers to this paper. I don't know how you have linked that. It may be so. If you could help me out, that would be good.
Q. No. I know that I can't help you any more than that. If you don't know, you don't know.
But if you turn to page 1532 in the e-mail chain -- no, in that one. There appears, at the top, an e-mail from Robert Gauthier to Mark Albrecht, Mike Reed, Paul McGovern, CCed to Nachtscheim, Gauthier and Scott Augustine. It says:
"Mike and Paul. As Mark mentioned, I have worked closely with these guys."
I am not going to read the whole thing, but do you recall seeing that?

MICHAEL R. REED

A. Well, I recall reading the whole transcript yesterday, which was interesting.
Q. What was interesting about it?
A. Well, it looked as if the e-mail text had been authored by my recollection and here was -- by Albrecht, or by somebody else.
Q. In your experience, was that unusual for Mr. Albrecht to ghost write, if you will, communications on behalf of other people?
A. I never saw him write any communications. Well, obviously -- I mean, I have just seen this now and that was to me; so it obviously happened. But I wouldn't be aware of that happening, no.
Q. Was there ever a time he drafted a letter to the editor for your signature, concerning criticisms of flaws in the McGovern study?
A. Yes. So I mean, like the papers, he would tend to do the first draft and he did draft a letter which actually, I think ultimately I didn't send. But he did draft a letter.
THE EXAMINER: And that was criticizing ...?
A. My recollection is that it was a letter commenting on a paper criticizing my paper.
THE EXAMINER: Right.

MICHAEL R. REED

A. I think.
BY MR. GORDON:
Q. Why did you decide not to send it?
A. I think there was a couple of reasons.
One initially was that I was concerned that it was double publishing the same data, which is kind of frowned upon. That was my main concern.
As time went on, there was more data I could have put in it and a sort of extended follow-up, but it was a particularly busy time of year.
In fact, I was doing a lecture tour in the States that summer and by the time I came back, that was never being pushed. I don't know if Albrecht was no longer working for Augustine or something had happened, but I was pushed -- not pushed, but I was reminded constantly to do it, and then the reminding stopped and I never got round to it.
Q. I am going to flip to the e-mail chain that goes from 1519 to 1522.
And at the bottom of the first page, 1519, there is an e-mail from you to Mark Albrecht with a CC to McGovern, Nachtscheim, Scott Augustine -- two S. Augustines -- T. Neils. You go on:
"Thanks Mark, very impressive. The transfusion data

MICHAEL R. REED

is unreliable, I'm afraid -- it just shows errors we are making in coding/billing. It is actually about 10 percent. I can get the reliable data but it would take quite a lot of work. Likewise I can get ASA grade but possibly BMI by pulling the charts/notes. I suggest we don't do that as I don't have the resource -- what do others feel?"
What are you referring to there?
A. So do you remember, we started today with that big long spreadsheet that has codes collected by professional coders on what happened to the patient? So you can reliably get data on whether they either had a heart attack or whether they had a chest infection. But we know that the transfusion box on that, even though we collect the data, we know it's unreliable.
So the best way of getting that data is to go to the transfusion lab and cross reference with their data. So I could get it, but actually it would be quite a lot of work and insofar as our paper was concerned, not of much relevance.
So that is the transfusion data.
Likewise, for ASA grades, anyone know what the ASA is?
Q. Why don't you explain what that is?

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A. So the American Society of Anesthesiologists. It is their grading system, which essentially is a grading system to see how healthy you are. So ASA grade 1 is very healthy and ASA grade 5 is very unhealthy. So we do have that data. It is collected, but it is not collected electronically. So I would have to go back to each patient's notes, which would be several hundred sets of notes.

THE EXAMINER: It would be a massive job.

A. A massive job. So for the value it was going to give us ...

So I suggested, I think, perhaps in this conversation, that we do something called Charlson scoring.

BY MR. GORDON:

Q. If you turn to 1521 at the bottom.

THE EXAMINER: How is it this gentleman can print out these e-mails running in date order, as opposed to reverse date order?

(Off the record remarks.)

BY MR. GORDON:

Q. "Mark, I agree hypo and hyperthyroidism and COPD would be useful but only if the list was more complete. I think it would highlight the fact that we don't have

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ASA data, obesity and transfusion. We should leave out."

Why -- what is the reference there to highlighting the fact that: "We don't have ASA data, obesity and transfusion"?

A. Well, if we did not have it in the dataset, we would have to go and look for it. So it would be a big piece of work, so I was not keen to embark on that. You might embark on that if the reviewers really wanted it. If they are saying: "We will publish your paper if you get that", then it would be worth pulling 1,000 sets of notes or whatever.

But for the benefit, it probably wasn't worth it.

Now, what I have suggested is that we did have robust data on those three things; hypo, hyperthyroidism and COPD. But in itself, if you put that in, people would say: "Why are you collecting that and not other things that are more obviously linked, like ASA, obesity and transfusion?" So it would just alert the reviewers to the fact that we haven't got that data.

Q. I recognize that it was a whimsical statement, but what did you mean by:

"It is fair to say my assassin may be funded by Bayer or Arizant!"

MICHAEL R. REED

A. Because both of those companies -- so Bayer make rivaroxaban. Well, we know what Arizant made. So you know, it was clear to me that they wouldn't like what I was saying.

Q. Okay. Maybe I do need to be more specific. What was the concern with respect to Bayer?

A. Because we published our paper on rivaroxaban. Do you remember, the one we discussed at length earlier, about --

Q. Okay.

A. -- the return to theater rates?

THE EXAMINER: That was the --

MR. GORDON: Separately.

THE EXAMINER: That was the short period for which you used it.

A. Yes. And also we wrote a paper about ten other hospitals, which we have not discussed today, I think it is in the package, showing the same effect. So --

THE EXAMINER: What is Charlson scoring?

A. So the Charlson score is a predictor of likelihood to die, essentially. So it looks at a variety of measures like: have you got heart disease, have you got lung disease, have you got HIV? All of these things. And it produces a scoring system for your chance of dying. So

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it is useful -- if your paper is, for instance, on mortality, then it is useful to be able to grade the patient's Charlson score, so you can compare big groups of patients.

And we can do that from the spreadsheet, you know, that exhaustive spreadsheet we had before. I can turn that into a Charlson score for any individual patient, so you risk assess them.

BY MR. GORDON:

Q. Do you currently use the Hot Dog?

A. No, I don't, actually.

Q. When did you stop using the Hot Dog?

A. In -- certainly earlier on this year.

Q. What do you use now?

A. So we are currently undergoing an evaluation of different systems.

So in the last six months -- well, certainly this year, I have used the Hot Dog. But we had some difficulties with them beginning to bubble and sort of melt; "melt" is an overexaggeration, but they began to bubble along the seams and we were anxious that the patient was going to get injured. So we stopped using them, we pulled them.

And we are currently trialing different conductive

fabric systems, different companies; and sometimes used forced air warming if there was nothing else available.

Q. Which forced air warming system do you use, if there is nothing else available?

A. Bair Hugger.

Q. Have you yourself used Bair Hugger in the last six months?

A. Yes.

Q. How about the other surgeons at Northumbria? Have any of them used Bair Hugger in the last six months?

THE EXAMINER: Do you know --

A. Yes.

THE EXAMINER: -- what other surgeons use?

A. They will have used Bair Hugger and they will have used conductive fabric, because we are doing -- we are sort of evaluating different systems and we haven't always got conductive fabric available. So yes. There are some surgeons I know who are refusing to use Bair Hugger, but I am not one of them.

BY MR. GORDON:

Q. I think we need to go back to volume 1, which is exhibit 1.

(Off the record remarks.)

Q. Mr. Dyer, I think you might have my volume 1.

THE EXAMINER: Volume 1?

MR. GORDON: Yes. Is there an extra volume 1 over there?

MR. ASSAAD: Mr. Videographer, what is the current time? The current time, for the record?

THE VIDEOGRAPHER: We have been on the record for three hours and 21 minutes.

MR. ASSAAD: Thank you.

MR. GORDON: How much of that time was Mr. Assaad spending making his speaking objections? You don't have to answer that.

MR. HOLL-ALLEN: Does anyone want this folder, volume 1?

THE EXAMINER: If someone can tell me which tab and which internal Bates stamp, I am perfectly happy.

MR. GORDON: I am actually winding up pretty quickly, but I guess I didn't understand the order to say three and a half hours, regardless of how much time the plaintiffs consume with --

THE EXAMINER: Three and a half hours is what you get. I do not notice that there have been an excess of interventions which would have -- in that time. Believe me, I have heard much longer interventions, with much more frequency.

Which tab are we going to?

MR. GORDON: I will start with -- it is under tab 5, but it

is page 371.

THE EXAMINER: Yes, but what is the internal Albrecht reference?

MR. GORDON: I am sorry?

THE EXAMINER: What is the internal Albrecht reference? The Bates stamp?

MR. GORDON: Oh, 0018360.

Did you not have a paginated one? Because there is another ...

THE EXAMINER: Oh, there is one here.

MR. GORDON: That is all I am using.

THE EXAMINER: So page number now, 3 ...

MS. OKONEDO: 371.

THE EXAMINER: Thank you.

MR. GORDON: Page 371.

A. Ah, 371.

BY MR. GORDON:

Q. Yes, yes. Sorry.

A. Oh, sorry.

THE EXAMINER: This is a back to front order.

MR. GORDON: Sorry?

THE EXAMINER: This is a back to front order.

BY MR. GORDON:

Q. It is an exchange of e-mails with you and Scott

Augustine and Brent Augustine, Paul McGovern. It is really just one line I want to ask you about, at the very bottom. You said:

"I don't have a great appetite for writing to the editor, though. I think there is probably enough background concern, so it is reaching people's consciousness. What we need here is an RCT."

First of all, do you know what letter to the editor that refers to?

A. I think it's probably the letter which we discussed ten minutes ago, that Mark Albrecht had started and drafted.

Q. What did you mean by: "There is probably enough background concern, so it is reaching people's consciousness"?

A. I think people were talking about it. People --

Q. What is "it"? What were people talking about?

A. I think people accept that it affects laminar flow. I think it is much more contentious, whether it affects infection rates. I think it is pretty accepted that forced air warming will affect your laminar flow, because of the way it affects air movements and the heat. It is very fragile.

Q. And then the last line:

"What we need here is an RCT."

What is that a reference to?

A. So this goes back to the thing I have been saying since 2009. We had a randomized control trial. We needed a big trial to show if there is a difference between forced air warming and conductive fabric warming, in terms of infection rates.

Q. Are you aware of any such trial, either underway or planned?

A. So there is a planned trial, which I am a principal investigator for, which means that I am not leading it; but I am, if you like, on the grant and I am on the team that are hopefully going to run the trial.

Q. How were you recruited to be part of that?

A. So the chief investigator has, I think, probably seen me show the videos of how it disrupts laminar flow or something similar, at least. He -- he is not an orthopaedic surgeon. He is an infectious disease consultant.

Q. That is Professor Scarborough?

A. Yes, I think so.

THE EXAMINER: Professor?

A. Scarborough. Dr., I think.

BY MR. GORDON:

Q. Scarborough. I am sorry. He asked you to be part of

the research team?

A. I think -- I can't remember. Well, I suppose he did, because I haven't led it. He has come to me. I would be a reasonably natural person to come to, because we do a lot of randomized trials and I have clearly got an interest in this.

Q. And what is the randomized trial going to be comparing?

A. So it's a pilot study, which means it is a study where we are trying to gain information to see what we would have to do for a big trial. But it's randomizing patients with a hip fracture, who are having a hemiarthroplasty with a very high rate of infection. So if you break your hip in your 70s and 80s, then you have a much higher rate of infection. So we've chosen that group deliberately. Because of the high infection rate, you need smaller numbers.

THE EXAMINER: That is in trauma situations specifically?

A. In trauma.

BY MR. GORDON:

Q. What is the intervention that you're going to be examining?

A. Conductive fabric warming versus forced air warming.

Q. And the end point is?

A. Infection.

Q. So when you talked about an RCT, is that --

A. That is the Holy Grail.

Q. That is the Holy Grail. Who is funding this?

A. 3M. Well actually, 3M and a charity. But 3M are certainly funding the pilot.

THE EXAMINER: A U.S. charity or a U.K. charity?

A. Are we ...?

THE EXAMINER: A U.S. charity or a U.K. charity?

A. Oh, a U.K. charity. It is something like the Infection Prevention Society or something like that. It is on my CV somewhere.

BY MR. GORDON:

Q. And this study that 3M is funding, that's similar to what you had wanted to do earlier and Augustine declined to fund; is that right?

A. Yes.

MR. GORDON: Thank you. I have nothing further.

THE EXAMINER: Right. Let's go off the record briefly.

THE VIDEOGRAPHER: Going off the record at 4:06.

(4:07 p.m.)

(Break taken.)

(4:17 p.m.)

THE VIDEOGRAPHER: Back on the record at 4:17.

EXAMINATION BY MR. ASSAAD:

Q. Mr. Reed, my name is Gabriel Assaad and I am one of the attorneys that represent hundreds of plaintiffs in the United States litigation with respect to Bair Hugger. We have never met before; correct?

A. Correct.

Q. Have you met any attorneys that are representing plaintiffs in the United States with respect to this litigation?

A. I am not sure I understand the wording, but I haven't met any attorneys from the United States if that makes it easy.

Q. Have you met any attorneys that are representing the plaintiffs or the claimants with respect to this litigation?

A. No.

Q. Have you met with any attorneys that are representing 3M or Arizant with respect to this litigation?

THE EXAMINER: Before today?

BY MR. ASSAAD:

Q. Before today.

A. No.

Q. Have you been in contact with anyone from 3M regarding this litigation?

A. So I do randomized trials; that is one of the things

I do. And I am doing a randomized trial on a 3M product, which is completely unrelated to this. And they did contact me six months ago, essentially just agreeing that this was -- they were nothing to do with each other. And -- but it clearly was on their radar that this was going on. But apart from that, they wanted to hire me to do one of their studies on something completely different.

Q. And that would be the Crebbs(?); is that correct?

A. Yes.

Q. During those conversations or those meetings with 3M, did you have any substantive conversations about your viewpoint regarding this litigation or the substantive parts of this litigation?

MR. GORDON: Object to the form of the question.

THE EXAMINER: You may answer.

A. No, I don't think I did.

BY MR. ASSAAD:

Q. Now, before we get into the substance -- I am going to start off with the background, but I just want to go over a few ground rules, just so we are clear.

I am going to ask you numerous questions. If you do not understand my question, please let me know. Fair enough?

A. Yes.

Q. If you answer the question, we will assume that you understood the question I asked; fair?

A. Okay.

Q. And any time you want to take a break, please let me know. This is not an endurance contest, so please speak up.

And I'd ask you, as you have heard before, please do not speculate or guess to any questions. If you don't know the answer, it is okay to say "I do not know"; fair?

A. Okay.

Q. And also try to be verbal with a "yes" or "no", so the court reporter can take a clear record. So she can't take down you nodding your head; okay?

A. Okay.

THE EXAMINER: And if it is possible, because Mr. Gordon may want to put an objection on the record, pause for a moment before you start your answer to the question. I know it is very difficult.

A. Okay.

BY MR. ASSAAD:

Q. I would like to mark this as exhibit number 7, please.

THE EXAMINER: This is?

MR. ASSAAD: The CV.

(Exhibit Reed 7 marked for identification)

BY MR. ASSAAD:

Q. Mr. Reed, can you please describe what has been marked as exhibit number 7?

A. It is my curriculum vitae.

Q. Why was this prepared?

A. About two weeks ago.

Q. And it is dated November 21st, 2016. Is that when it was prepared?

A. Yes. That feels about right.

Q. Is this the most up to date version of your CV?

A. Yes.

Q. Is there anything in this CV that is not included, with regard to your education, training, background, employment?

A. I don't think there is anything major excluded that I am aware of. Everything big, I have put in.

THE EXAMINER: Was it prepared in response to the order in this case, or do you have one which you keep running all the time?

A. Yes, I have one that I update when needed.

BY MR. ASSAAD:

Q. On page 2, it has an index of your publications. Do you

see that?

A. Yes.

Q. And unfortunately, as I've got a PDF copy, I could not click here. Where is the link going? Is it going to PubMed?

A. Google Scholar.

Q. Google Scholar, okay.

And I, in fact, printed off a copy of the Google Scholar and I have approximately 214 publications that you have been part of; does that sound correct?

A. In terms of Google Scholar, yes, probably.

Q. Are there more than 214?

A. No. But Google Scholar is very inclusive. So there will be abstracts. So for instance, if you present at a meeting, like the Hip Society one, then it may well get onto Google Scholar when it wouldn't get onto PubMed.

Q. Okay. So they might not all be peer reviewed articles?

A. Yes.

THE EXAMINER: I am a little lost. PubMed?

A. So PubMed -- so PubMed is a website where you can look for papers that have been peer reviewed, if you like; so they are in a journal and they are peer reviewed. Whereas Google Scholar has a wider net and they will

pick up maybe so-called abstracts from meetings, so just short pieces of work that are not necessarily peer reviewed.

THE EXAMINER: So Google Scholar is produced as a result of searches by someone else?

A. Yes, by --

THE EXAMINER: PubMed, do you post information to it, or is there some sort of search?

A. So I think Google Scholar searches the whole internet for your name. PubMed will only go to journals that are peer reviewed and search their databases.

THE EXAMINER: Fine, thank you.

A. So probably I have 130, 140 on PubMed, I would think.

BY MR. ASSAAD:

Q. And according to Google Scholar, it is my understanding that your peer reviewed articles have been cited over 2,700 times; does that sound about right?

A. I have never looked, but it does tell you. So that's -- you are probably right.

Q. Now, I just want to go briefly to your educational background.

If you could start from the beginning, just so we have a clear picture of -- a chronological picture of your background, starting with your education, through

your training, through your employment.

So let's start with your education. Could you just go briefly through your education?

THE EXAMINER: Which level; starting at which level?

BY MR. ASSAAD:

Q. The level right after what we would call high school.

A. Okay.

THE EXAMINER: From 18?

MR. ASSAAD: Yes.

THE EXAMINER: From 18 on.

A. Right. So I went to Newcastle University to do medicine. They give you two degrees for that in our country, MBBS. And then I did some training, further training in the North East.

BY MR. ASSAAD:

Q. I don't mean to interrupt you. Could you just provide dates, so we have a chronological picture of when you started your training and finished?

A. Right, okay. I have got my CV, so this helps. In 1992 I started training, having qualified as a doctor. And then I, two years later --

THE EXAMINER: Training as a surgeon?

A. Yes, training as a surgeon. But the first few years is quite general.

And then I sat my first surgical exams in 1994. I did the second part of my surgical exams in 1996.

I then joined a specialist training scheme in trauma and orthopaedics, having first completed two years of orthopaedic research in Sheffield. So I did six -- in fact, five years on the training scheme in trauma and orthopaedics in the North East.

Then I went on a fellowship to New Zealand and did a specialist joint replacement and revision and infection fellowship; and then did some trauma training in New Zealand as well on a fellowship.

And then just before I went to New Zealand, I sat my sort of consultant exams, I would say; maybe the equivalent of your boards, in 2002.

And then I have been a consultant since 2002. It looks like I was awarded a fellowship of the English College of Surgeons without examination a couple of years ago. So you -- in your early career, you tend to have to sit an exam to get in. And then later on, if they like you, then they will let you into a different college without having to sit the exam. So that's what that is.

BY MR. ASSAAD:

Q. Okay. And so FRCS is the equivalent of maybe the U.S.

boards; correct?

A. I would say FRCS trauma and orthopaedics is equivalent to the U.S. boards.

Q. Okay.

A. So FRCS part 1 and 2 are maybe more junior surgeons. It takes a very long time in the U.K. to train as an orthopaedic surgeon, compared to the U.S.

Q. And to take your FRCS exam for trauma and orthopaedics, do you have to have a certain qualification like so many surgeries or so much experience?

A. Yes, you do.

Q. Can you please describe to the ladies and gentlemen of the jury and the judge what qualifications and experience is required to sit for the FRCS for trauma and orthopaedics?

A. Right. So the -- there are rules around that, which are soft rules. But to finish as an orthopaedic surgeon, you have to have your trauma and orthopaedic FRCS exam and then you have to have done so many types of surgery. So you need to have had so many cases in your logbook, et cetera, et cetera.

So actually, when I went through, it was not as regulated. It is now very regulated.

Q. Right. And then you have -- I think you have mentioned

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it, but FRCS England awarded ad eundem, in England. Is that without an exam?

A. Yes.

Q. And is that a special recognition when you get admitted or get qualified for FRCS England without an exam?

A. I -- in a way, I would say it was. That was how it was sold to me.

THE EXAMINER: So these previous --

A. They still make you pay.

THE EXAMINER: These previous FRCSs, were they not English?

A. So they are the College of Surgeons of Edinburgh. So there are several surgical colleges, all of which you can join; they are all of equal ranks, so --

THE EXAMINER: So you were Scots qualified until 2014?

A. Yes, and I am still Scots qualified. I am now doubly, if you like, if you want to call it a qualification.

BY MR. ASSAAD:

Q. For us that are not around here: what does that mean, "Scots qualified", as ...?

THE EXAMINER: Edinburgh.

A. So we have -- there are several colleges of surgeons. So there is the College of Surgeons of Ireland, one of Edinburgh, one of England, and I think the Glasgow one is physicians and surgeons. It is quite confusing.

MICHAEL R. REED

But you have to be -- by law, you have to be a fellow of one of them, in order to -- because it is by exam and you have to pass your exam. And all the exams are actually the same exam. They have all joined up and do the same exam. And then you just -- one college will hold your -- take your money, essentially.

BY MR. ASSAAD

Q. It doesn't limit where you can practice; correct?

A. Correct. I mean, trauma and orthopaedics is where I practice. But yes, I can operate right across the breadth of trauma and orthopaedics, based on that qualification.

Q. I meant the geographical region as well. It does not limit the geographical region?

A. No, so that is completely universal. So I can take that to New Zealand.

THE EXAMINER: I was going to say: Edinburgh and Glasgow are in Scotland, if you don't know, so that is why I referred to it as "Scots qualified".

BY MR. ASSAAD:

Q. Now, after you -- following 2002, you said that is when you became a consultant?

A. Yes.

Q. And --

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A. Maybe 2003, I think I became a consultant.

Q. And before that, what would your title have been before a consultant?

A. A specialist registrar, I think we were called.

Q. And what is the difference between a special registrar and a consultant?

A. So as a specialist registrar, you are still working under the governance of a consultant; whereas once you are a consultant, you are an independent practitioner, albeit within the constraints of the health service and its given governance structures. But I am an autonomous practitioner.

Q. Okay. So if we had to relate it to -- are you familiar with the United States system, with a -- with the trainee, the residency, and then there's also an attending at a university hospital?

A. Yes, so it would be an attending position. If I have now -- I think that's what you would call it. And the resident would be the specialist registrar. The difference is that your residency is very short, whereas ours is very, very long in comparison.

Q. Understandable.

And as a consultant, do you train specialist registrars?

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A. Yes.

Q. And do you currently train?

A. Yes; and I am currently training program director, so I am head of training in the North East. So that's 67 trainees that are, if you like, under my auspices.

Q. And those 67 trainees are trainees for trauma and orthopaedics?

A. Yes.

Q. You said "program director". Are those individuals that are in the hierarchy below you, but assist you in training those 67?

A. Yes, so there are people -- I wouldn't say they are below me, but there are people, attending surgeons of equal rank who will generally train one individual each, if you like; that sort of make-up.

So we have got a wide body of attending surgeons who train specialist registrars in my region and I am head of training. I would not say I am in charge of them. I think they have made that pretty clear, that I wasn't.

Q. And those program directors are also consultants; correct?

A. Yes. So I am a program director and I am a consultant, yes.

Q. Okay.

Are you a member of any national organizations, in respect to trauma and orthopaedic surgery?

A. Yes. So I am a fellow of the British Orthopaedic Association and the -- I am a member of the British Hip Society as well.

Q. Are you a member of any international organizations?

A. Not from memory.

Q. Just out of curiosity. I remember you mentioned during Mr. Gordon's questioning to you that you gave a presentation to the American Academy of Orthopaedic Surgeons in San Diego; is that correct?

A. Yes, it sounds like it's correct. I can't remember -- I actually can't remember what it was. But I did say I gave one. I did go to that meeting for sure. I don't remember what presentation it is. I give a very -- I do a huge amount of presentations.

Q. And have you given many presentations -- or have you given any other presentations in the United States?

A. So in 2012, I represented Britain in a traveling fellowship of orthopaedic surgeons; so there was four surgeons from Britain selected to tour round the United States, giving talks.

Q. Do you know Dr. Parvizi?

A. Yes.

Q. Do you know him personally?

A. Yes.

Q. Were you part of the consensus that was formed among the orthopaedic surgeons internationally?

A. I was not part of the last one, but I am part of the one that is coming up.

Q. And you know the consensus I am speaking about?

A. Yes, the peri-prosthetic joint infection consensus, yes.

THE EXAMINER: Sorry, can you repeat that?

A. Okay. So there's probably now -- I think in 2013, there was a meeting held in the United States to agree on risk factors for peri-prosthetic infection; so infection of a joint replacement. And in fact, I didn't go to the consensus meeting but I did contribute to it, actually on theater and laminar flow. Maybe even on forced air warming. But certainly on laminar flow.

So I wrote some of the text for it, which I think they subsequently voted on in the big meeting. And that meeting is coming round again, and I will be going -- I think it is next year or the year after.

BY MR. ASSAAD:

Q. We are talking about work group 4, correct, dealing with particles and laminar flow and forced air warming?

A. Sounds correct.

Q. I think you cited two before in some of your articles?

A. Right, yes. I did provide some text for it. I don't genuinely know how far that got.

THE EXAMINER: It is a consensus document, is it?

A. Yes. So it is -- it is a sort of highly publicized consensus document of, if you like, world experts, mainly U.S. focused, but still there's a few U.K. people that go.

BY MR. ASSAAD:

Q. And have you seen the consensus, the final version of it, the one that was prepared in 2013?

A. Yes, I have seen it.

Q. And do you understand that 3M was a sponsor of the consensus?

A. I hadn't realized that, but ...

Q. And it's -- based on your CV, you have received awards in the event; correct?

A. I have received awards.

Q. Yes.

A. Yes, I suppose I have. I am trying to think what.

THE EXAMINER: Where are they listed?

MR. ASSAAD: It might not be on his CV. I know we talked about it, but I thought I saw it on his CV.

BY MR. ASSAAD:

Q. Well, I don't see it on your CV, but have you received any awards in orthopaedic surgery?

A. I received the Program Director of the Year Award last year. So that's the national award for theoretically the best program director in that job we just talked about, of training the trainees.

I can't remember any others. You will have to prompt me.

Q. All right. And I can tell you, you have had publications, such as peer reviewed articles. You have done presentations, book chapters and you have been a reviewer for publications and given lectures; correct?

A. Yes.

Q. All on orthopaedic surgery; correct?

A. Yes.

Q. And did any of them have to do with peri-prosthetic joint infections?

A. Quite a large number of book chapters and papers would relate to that.

Q. Just so we are on the same definition. Is there a difference between a wound infection in your mind and a peri-prosthetic joint infection?

A. I mean, I think a wound infection is a more general term that can refer to someone that's had surgery generally

and has got an infection; whereas a peri-prosthetic joint infection, we will call it "PJI" maybe, PJI, is specific to when you have an implant in place, a hip replacement, for instance.

Q. Like, for example, the McGovern study which we discussed a lot today, or you discussed a lot today. That dealt with PJIs; correct?

A. Correct.

Q. Not superficial wound infections; correct?

A. Correct, yes.

Q. And that is a big difference to treat a superficial wound infection, as compared to a PJI; correct?

A. Yes. I mean, it is a world apart.

Q. And we talked about peer review. And just in your own words, would you agree -- or strike that.

Would you agree that the peer review process is a rigorous process?

A. Yes.

Q. And based on my review of your -- of the literature that was on Google Scholar, it is my understanding that you have done research on methods to reduce peri-prosthetic joint infections?

A. Yes.

Q. And you have done research on operating theater methods

to reduce peri-prosthetic joint infections?

A. Yes.

Q. And you have actually done research on draping methods to reduce peri-prosthetic joint infections?

A. On what methods?

Q. Draping methods?

A. Draping methods. Certainly gowning methods, yes.

THE EXAMINER: That is slightly different?

A. Well, draping I think is what you put on a patient; whereas gowning is what you put on yourself.

THE EXAMINER: Quite.

A. But yes.

BY MR. ASSAAD:

Q. You have also done research on prophylactic antibiotics to reduce PJIs; correct?

A. Correct.

Q. You have done research on thrombo-prophylactics to reduce PJIs; correct?

A. I am not sure about to reduce it, but its impact on, yes.

Q. And going back, because I am not sure if we have discussed this, or if you discussed it in the direct.

Just for the ladies and gentlemen of the jury back home, what is peer review and why is it important?

A. So peer review is when you send an article that you have written. You send it to the journal and they will send it, normally anonymously, to several people who will -- who are also experts in that area, who will read it and decide. Normally they will decide that it's not good enough for publication. If they -- if they like it, then they will generally send it back for changes, suggestions. And very, very rarely, they will take it first, first hit. So it is important obviously; it is a quality indicator. It is a quality measure.

Q. Quality control for an article?

A. Yes.

Q. Reaching the -- your other colleagues in the field; correct?

A. Yes.

Q. Do you follow any certain -- or do you subscribe to any certain peer review journals?

A. So I subscribe to the Bone and Joint Journal, and have access to a large number of journals through my university network and the hospital network.

Q. And you said you were a reviewer for some of those journals?

A. I am a reviewer for, in the last year, the Bone and Joint Journal. Yes, I think I review for probably three

or four journals. Certainly in the last three or four years, I've reviewed for three or four journals.

Q. Would it be fair or accurate to state that you devoted most of your research to PJIs?

A. Certainly to joint replacement. I would say a large amount is PJI. I do also do other things on outcomes, but yes, largely -- quite a large body of work would be prosthetic joint infections.

Q. And the purpose of that is you are trying to make joint replacements safer for the patient?

A. Yes.

Q. Because safety is paramount to any methods you ascribe to, with respect to the patient; correct?

A. Yes.

Q. And you would expect that safety should be paramount to a medical device manufacturer that markets and sells devices to your hospital; correct?

A. Yes.

Q. And PJI is a serious complication and can be catastrophic; correct?

A. Yes.

Q. You can have multiple surgeries?

A. Yes.

Q. You mentioned before, amputations?

A. Rarely, but to get to that point, there is a huge number of surgeries normally as well.
Q. And potentially it could cause death?
A. Yes. Well, it does cause death. I mean, there is a definite association with mortality. It reduces your life span.
Q. Do you consider yourself an expert in peri-prosthetic joint infections?
A. Well, in, you know, the view that I have been invited to the international consensus perhaps, and I do speak frequently on it at meetings. I spoke yesterday in Manchester on it. So yes, I speak quite frequently on it.
THE EXAMINER: And my understanding is that it is not that there is a significant percentage or proportion of infections in this surgery. It is because of the severity of the cost to --
A. Exactly. So it is the severity of the complication which is just game changing for most patients. It is a terrible, terrible complication.
BY MR. ASSAAD:
Q. And do you consider yourself an expert with respect to the causation of peri-prosthetic joint infections?
A. I think "expert" is maybe for someone else to judge, but

I do know a lot about it and I have spent a lot of time researching it.
MR. ASSAAD: We need to go off the record, because of the change of CD.
THE VIDEOGRAPHER: This is the end of tape number 2 in the deposition of Michael Reed. Going off the record at 4:44.
(4:44 pm)
(Break taken.)
(4:49 pm)
THE VIDEOGRAPHER: This is the beginning of tape number 3 in the deposition of Michael Reed. Going on the record at 4:48.
BY MR. ASSAAD:
Q. Mr. Reed, we can agree that you need a bacteria to cause a peri-prosthetic joint infection; correct?
A. Yes.
Q. And we can agree that because of the implant, you need very few bacteria to cause a peri-prosthetic joint infection; correct?
A. Correct.
Q. Contrary to a wound infection, where you might need millions; correct?
A. So if you don't have an implant in situ, then you can

have many, many more bacteria on the wound without getting an infection. So yes, it is much more important when you have got an implant.
Q. So an implant is highly susceptible to a bacteria and the cause of a peri-prosthetic joint infection mainly because of biofilm; correct?
A. Yes, so biofilm is a slime that the bacteria produce that protect it from antibiotics and other mechanisms the body might have to rid the infection. So yes, it is very -- it is driven by biofilm, we think, the difficulties in getting rid of the infection.
Q. And you would agree with me that as a result -- strike that.
You would agree with me that most, if not all of the peri-prosthetic joint infections occur when bacteria gets to the implant during the perioperative period; correct?
A. I am not sure we know that. That's -- but that is sort of an accepted philosophy. But I don't think we know that for sure, in actual fact. But that is the dogma.
THE EXAMINER: You referred to the peri ...?
BY MR. ASSAAD:
Q. Peri, during the surgery.
THE EXAMINER: I see, during the operation.

BY MR. ASSAAD:
Q. When you say that is the accepted philosophy, that is the main consensus among most orthopaedic surgeons; correct?
A. Yes.
Q. And because of the biofilm, it is very difficult to treat these peri-prosthetic joint infections through medication; correct, such as antibiotics?
A. Yes. Essentially you can't get rid of an infection with antibiotics alone.
Q. Because there is no vascularity to the joint?
A. Yes, because -- because bacteria and biofilm become very protected by the slime, and so you need about a thousand times the dose of the antibiotic for it to work, and you can't deliver that much antibiotic to the patient.
Q. Have you heard of the term "chain of infection"?
A. Can you -- can you rephrase that?
Q. Yes, I can actually. Basically, for an infection to occur, you have to have an infectious agent, a reservoir, a portal of exit, a mode of transportation, a portal of entry and a susceptible host. Have you heard that described before?
A. Yes.
Q. And for example, so with respect to the infectious

agent, that would be bacteria; correct?
A. Yes.
Q. And the reservoir in the operating room, that could be the patient; correct?
A. Yes.
Q. It could be the surgeon?
A. Yes.
Q. It could be the assistant?
A. Yes.
Q. It could be the scrub nurse?
A. Yes.
Q. It could be the Bair Hugger?
A. Yes.
THE EXAMINER: It is just the source of the infection.
MR. ASSAAD: Yes.
THE EXAMINER: It could be hundreds of things probably.
MR. ASSAAD: The most likely things I am talking about, actually.
THE EXAMINER: Right.
BY MR. ASSAAD:
Q. And you would agree with me that the mode of transit -- the transmission of the bacteria in the operating room would be particles; correct?
A. Yes, I think that would be fair.

Q. Such as skin squames; correct?
A. (Nods.)
Q. You have to say "yes".
A. Yes.
Q. Or another name for it might be "fomites"; correct?
A. Yes, I don't think we have a definite understanding of actually where the infection comes from. But these are the commonly accepted things.
THE EXAMINER: What about if you had a dirty instrument? Would that involve particles or not?
A. Well, I mean, there would be -- in particle form, I guess on the instrument; but yes, you could certainly spread infection by instruments that haven't been sterilized and that does happen from time to time.
BY MR. ASSAAD:
Q. But that wouldn't meet the standard of care; correct?
A. Correct.
Q. The standard of care would have sterile conditions; correct?
A. Yes.
Q. Now, with respect to a peri-prosthetic joint infection to reveal itself, that might take a couple of years; correct?
A. It can take that long. It is relatively rare, but it

can.
Q. And that's because of the biofilm; correct?
A. Well, I think it's because some bacteria are slow growing, that you can get infections that last that long. But what sustains them is the biofilm. That's what -- that's what allows them to continue to grow and become problematic, is that with being in biofilm, they are not able to be treated by antibiotics or by the host defenses. That is why they can take so long.
Q. In your practice, have you ever had a patient come in that had a peri-prosthetic joint infection that had the primary surgery done more than six months?
A. Yes.
Q. More than a year?
A. Yes.
Q. More than two years?
A. Yes.
Q. How long?
A. Well, people can present at any point with an infected joint replacement.
THE EXAMINER: I think he was asking: what was the longest period between primary and return?
BY MR. ASSAAD:
Q. If you know. If you don't know, it's ...

A. Well, I have certainly seen plenty of people that had a joint replacement 15 years ago that come in with an infection. But then the question is whether it was caused during the primary operation or not, or whether it is a new infection which has gone through the bloodstream. But yes, it can present at any time, but it commonly presents early, in the first few months.
Q. Okay.
THE EXAMINER: Is there an alternative to removal of the implant and replacement?
A. So there's various criteria that you might use to make decisions. But one operation you can do is to open up the wound and literally scrub it and clean it and cut away all the affected tissue. The idea is to try to get rid of the biofilm, and then give them antibiotics which hopefully are targeted on the bacteria.
And in a proportion of cases, perhaps 60 percent of cases, you might be able to make that the only extra operation. But many patients will go on to having further very significant surgery to remove the implant.
THE EXAMINER: So if you try that route and it doesn't work, the patient is faced with at least four operations; a third to remove the implant and a fourth to replace, and a fifth implant?

A. Yes, at least, yes.
THE EXAMINER: I hope my hips remain in one piece.
BY MR. ASSAAD:
Q. In your practice, you have had patients that may have had more than five or six surgeries to remove an infection; correct?
A. Yes.
Q. Though it is uncommon, it is not rare to have that many surgeries?
A. It is not rare. I think my record is about 14 or 15 operations.
Q. Now, we're going to get into discussing your publications that we have discussed before, and I am going to ask you many questions. And if you give an opinion, I am not asking for an expert -- but just if you give an opinion, I want to make sure that it is within a reasonable degree of medical probability, similar to a medical diagnosis. I don't want you to guess or anything. Is that fair?
A. So, just so I am clear. Are you saying that if it is more than 50 percent, you want me to say "yes", or more than 20 percent?
Q. For example, you were asked questions like: does, for example, MSSA screening reduce infections? And you

said: well, there is no evidence. When you give that opinion, I want that to be with a reasonable degree of medical probability.
The reason I am asking that is because under our Federal Rules of Evidence, without having that limit as a standard, it would be inadmissible in court. So it is greater than 50 percent; fair enough?
A. Okay.
Q. And if you can't make that opinion, if you are unsure, please let me know and we don't have to -- you don't have to answer the question. Fair enough?
A. Yes. And just so I am clear: are you talking about now or in 2010 or '11?
THE EXAMINER: You are not here to give opinion evidence today. You are here to give evidence about the facts and matters surrounding the production of these papers.
A. So my answers relate to what we knew in 2010 or '11?
BY MR. ASSAAD:
Q. Or whatever period the article was.
A. Okay.
Q. Fair enough?
A. Yes.
Q. Now, part of the McGovern study dealt with disruption of the unidirectional airflow; correct?

A. Yes.
Q. Are you familiar with the Legg studies?
A. Somewhat familiar.
Q. Do you know Andrew Legg?
A. I have met him.
Q. Do you know Mr. Hamer?
A. Yes, I do.
Q. Have you had any discussions with them about their studies?
A. We have definitely discussed it in the past. We haven't discussed it in any detail recently, in the last probably three or four years. I don't think we have discussed it.
Q. But you are aware that their studies showed an increase in particle count on the surgical site; correct?
A. Yes.
Q. And I think in some of your articles, you cite those studies; correct?
A. (Nods.)
Q. Is that correct?
A. Yes.
Q. And would you agree with me that the longer the surgery exposure, there's more -- there is likely more exposure to particles?

A. So the longer the operation, the higher the infection rate. That is accepted. We don't know quite why that is and whether that is linked to obesity.
But yes, in broad terms, if your wound is open and that's when the particles get into it, then clearly there will be a temporal link between the wound being open for a length of time and an infection.
THE EXAMINER: What sort of -- if there can be an average hip replacement operation, what sort of time are we talking about?
A. For a slim patient, probably an hour, an hour and a quarter, something like that.
THE EXAMINER: And with an obese patient, it increases?
A. Yes.
BY MR. ASSAAD:
Q. And speaking about patients themselves, the patient is a susceptible host, right, to the infection; correct?
A. Yes, yes.
Q. And some hosts, some patients have more difficulty fighting off infections than others; correct?
A. Yes.
Q. Obese patients or underweight patients have more difficulty fighting off bacteria; correct?
A. Yes.

Q. Perhaps smokers?
A. Yes. I mean, I would say definitely smokers, if you base it on the RCTs.
Q. Diabetics. In one of your papers, you cited to a study that showed there was no difference in PJIs in people with type 1 or type 2 diabetes; is that correct?
A. Yes, so in our own series we have not actually found a link with diabetes and infection. But most series would show a link.
Q. And with all these co-morbidities that we are discussing, at the end of the day, you still need the bacteria to enter into the host to cause the infection; correct?
A. Yes.
Q. Okay. Smoking does not cause bacteria to get into the implant; correct?
A. Correct.
Q. So does --
MR. HOLL-ALLEN: Forgive me for interrupting. It does seem to me that we are getting into the area of opinion evidence which is not clearly related to the individual studies. I question whether these issues are within the scope of the defined studies or whether the answers to these questions are required in order to understand the

studies.
MR. ASSAAD: If you look at my tab 7, which is one of the studies that I have -- which he has authored. It talks about obesity, diabetes, smoking.
THE EXAMINER: Yes, but just because he has authored an article on that topic, it does not necessarily bring it into the scope.
MR. ASSAAD: Okay.
THE EXAMINER: Hang on, hang on. That is not necessarily an end of the matter.
MR. HOLL-ALLEN: Sir, the order, as with the orders in the other cases, identifies certain specified other studies. This is paragraph 25.
THE EXAMINER: Yes, it does refer at 4 and 5 to factors that influence infections in general orthopaedic surgery and 5, infections and general practices. I think that we are in the area of factors that influence infection. Does smoking influence infection? It does seem to me a proper question. I -- you have put a marker down.
MR. HOLL-ALLEN: And may I very briefly, because I don't want to hold up matters, say that I specifically objected to paragraph 4 in front of the hearing before the Senior Master; and the Master let it in, in part on the understanding that it might well include matters of

opinion evidence, but that was a matter that could be taken up at the time of the deposition.
So I have registered my concerns.
THE EXAMINER: You have. I am sure Mr. Assaad has heard and I am sure he will --
MR. ASSAAD: I am --
THE EXAMINER: -- restrict himself to paragraph 4 of the schedule B.
MR. ASSAAD: I will, and ...
BY MR. ASSAAD:
Q. You are familiar with the Belani study; correct?
A. Yes.
Q. And you are an author in the Belani study; correct?
A. Yes.
Q. With respect to the McGovern study, that just dealt with the primary, total knee and total hip arthroplasty; right?
A. McGovern was hip and spine. Belani was knee. That's my recollection.
THE EXAMINER: Where is the Belani?
MR. ASSAAD: Tab number 1.
THE EXAMINER: I don't have ...
MR. ASSAAD: I am sorry, McGovern.
THE EXAMINER: McGovern?

MR. ASSAAD: Yes.
BY MR. ASSAAD:
Q. We could keep that in there, but just for the record, I would like to mark tab 1, exhibit number 8. If you would like to put a sticker on the McGovern study in tab number 1?
THE EXAMINER: It is already exhibited.
A. This is the McGovern study, not the Belani study.
MR. ASSAAD: That is in a different case or a different deposition. I am going to mark it in this deposition for the court, so I can ...
A. This is McGovern?
MR. ASSAAD: Yes.
(Exhibit Reed 8 marked for identification.)
THE EXAMINER: She is marking the one in your file.
MR. ASSAAD: Yes.
BY MR. ASSAAD:
Q. If you look at Reed 5 at the bottom, there is a graph at the top of the page, table 1.
The data that was provided is here(?); is that correct?
A. Yes. Sorry, I thought you were referring to the lab-based study in this paper, as opposed to the clinical study.

Q. I am sorry?
A. I thought when you were referring to the lab-based study -- because in the McGovern paper the lab-based study, if you like, the one not involving patients, was on -- was on hips.
Q. Sure, the airflow or the bubble tests.
A. Yes, those tests. But the clinical paper, you are quite correct, is on both.
Q. And if you don't understand my question or you are getting confused, let me know. We will try to be on the same page, because I want to have a clear record here.
A. Yes.
Q. And those surgeries that had been dealt with: primary, total knee and total hip arthroplasty?
A. Yes.
Q. Which is less time for surgery than revision; correct?
A. Correct.
Q. Revision surgeries have higher infection rates; correct?
A. Correct.
Q. In some of your articles, you have also referred to the Sessler study. Are you familiar with the Sessler study?
A. Yes. So --
THE EXAMINER: How is that spelt?
MR. ASSAAD: S-E-S-S-L-E-R.

A. You will need to tell me which Sessler study, because he has been --
MR. ASSAAD: The Sessler Olmsted 2011 study.
A. What is the title of the paper?
Q. 2011?
THE EXAMINER: No, the title.
BY MR. ASSAAD:
Q. Oh, the title.
A. He has been fairly prolific over the years.
Q. Do you know Dr. Sessler personally?
A. I don't.
Q. Do you --
A. I know -- I know he has done some studies for Arizant. I don't know him.
Q. It is titled:
"Forced-air warming does not worsen air quality in laminar flow operating rooms."
Do you know that study?
A. I am not very familiar with it, I am afraid. Have you got it here?
Q. I don't think I -- since your name was not on it, I didn't ... you have cited two, but I can give you a blank copy.
A. Sure.

Q. If you -- going back to ...
I want to turn to tab number 13.
THE EXAMINER: I ...
MR. ASSAAD: You are not going to have this one.
THE EXAMINER: Not even what you sent me electronically?
MR. ASSAAD: Oh, electronically, yes. It would be page number -- I would like to mark this as exhibit 9.
(Exhibit Reed 9 marked for identification.)
BY MR. ASSAAD:
Q. If you go to the second page.
THE EXAMINER: So the index is a blank document. The other says that the -- oh, the document. Yes, sorry.
Where are we going?
MR. ASSAAD: The second page. Do you know what page it is on? I gave you an index. It is Reed 116.
BY MR. ASSAAD:
Q. Have you seen this e-mail before?
A. I saw it in this -- this week or two.
Q. This is an e-mail dated March 8, 2012.
A. Yes.
Q. Oh I am sorry, December 2nd, 2011, from you to --
A. Yes, I do remember sending it, yes.
Q. Can you please describe this e-mail?
A. Right. I wish it was a bigger font. So my recollection

is that this was an inquiry that I had from a center in the U.S. I think actually in Minneapolis. And they are asking about a study we have done and I am providing them with some updates. I think I have taken the trouble to put my disclosures in and where it's been presented. And I have offered to put them in touch with Mark Albrecht, who could come and demonstrate the issue, which I think would probably be fairly easy to demonstrate in a theater.
Q. And were you in Minneapolis at any point in time during this period?
A. So I was in Minneapolis in 2012, so maybe in, I think, May 2012.
THE EXAMINER: Look at the last sentence of your e-mail.
A. There you go. June 2012. That was when I mentioned I was doing a lecture tour of the States and I knew it was going through their town in June, by the look of it.
BY MR. ASSAAD:
Q. Okay. And you are aware that this e-mail was forwarded on to 3M?
A. I wasn't aware of that until yesterday.
Q. Okay. At any point in time, when 3M was made aware, I guess they were made aware in March 13, 2012, did you ever get a phone call or any type of e-mail from 3M

saying: "Hey, we want to know more about the data that you have obtained in the McGovern study"?
A. No.
Q. And you talk about more data on 400 more patients, around 400 more patients; correct?
A. Yes.
Q. And you -- and if you look at your e-mail, you write: "You will see the effect is present for knees (0.6 vv 1.6%) as well as hips (1.3 vv 5.5%). The effect has been sustained."
What did you mean by "The effect has been sustained".
THE EXAMINER: Sorry, where is that?
A. So it just meant that we continued to see low rates of infection.
BY MR. ASSAAD:
Q. For the Hot Dog?
A. Yes. Well, yes.
Q. Okay. Or the conductive warming device which was the Hot Dog; right?
A. Yes.
Q. So even after you published the McGovern study, you continued to obtain data to see whether the effect could be sustained; correct?

A. Yes.
Q. And at any time, did you run the statistical analysis regarding that data?
A. Yes. Well, yes, I did.
Q. Okay. Did you get the same -- a P value that still showed that the results were significant?
A. So my recollection is that the P value at that point was very significant. I think it is somewhere in this documentation.
Q. If you look at it, in the following tab, 14. Reed 118.
A. Yes. So I haven't seen this before, although it was interesting as an analysis. But ...
Q. Okay. Can we mark this as exhibit number 10?
THE EXAMINER: "This" being?
MR. ASSAAD: Reed 118.
THE EXAMINER: Just that page?
MR. ASSAAD: Yes.
(Exhibit Reed 10 marked for identification.)
BY MR. ASSAAD:
Q. Why do you say this was very interesting?
A. Well, it is the first time I have seen this, in different centers, being collated, if you like. So it was interesting that on the face of it, at least, they have had a similar experience. But of course, what you

don't have here is peer review. But on the face of it, it looks, you know, like an impressive reduction.
Q. There was discussion with respect to -- during the direct examination, about the change in antibiotics during the study period, with respect to forced air warming and the conductive fabric device. Do you recall that testimony, that discussion?
A. Yes.
Q. Were you aware that Mr. Albrecht ran the numbers to determine the differences in the reduction rate between the different antibiotic protocols?
A. Only when I read this, you know, in the last couple of weeks.
Q. Were you aware that there was no statistical difference between antibiotic protocol 1 and protocol 2?
A. Not prior to the last couple of weeks.
Q. If that's true, would you agree with me that the change in antibiotic protocol had no statistical significance in the infection rates in the McGovern study?
A. So on the face -- on the basis that you have only got those two things involved, the antibiotics -- one antibiotic versus another, then this appears to show that.
Q. And if that statement is true, you would agree with me

that the change in antibiotic protocol would not be considered a confounding factor in the McGovern study?
MR. GORDON: Object to the form of the question.
THE EXAMINER: This is getting perilously close to asking him to give his opinion.
MR. ASSAAD: In the McGovern study, he spent much time showing --
THE EXAMINER: I know he did, but you are now introducing an additional factor which is something which has only come to his attention recently.
MR. ASSAAD: Fair enough.
THE EXAMINER: And asking him how, in his opinion, it affects matters, which I think is teetering on the edge.
A. So on the basis of the information we have got in front of us, it looks as if there wasn't a difference between the two antibiotic regimes. I haven't had the ability to sort of look at this in detail. It is not my work; but clearly it's done about my work.
MR. ASSAAD: I am not going to go any further with you, then, with respect to that question, then.
BY MR. ASSAAD:
Q. But you agree with me that the change in antibiotics does not add any sort of contamination to the sterile field; correct?

MR. GORDON: Object to the form of the question.
A. Yes. You wouldn't expect the antibiotic choice to contaminate the operative field.
BY MR. ASSAAD:
Q. There is nothing about changing the antibiotics that would increase the bacteria in the sterile field during the operation?
A. No.
Q. Now, based on your McGovern study, you agree that at the time, your opinion, based on the McGovern study, was that convection currents from the forced air warming device, the Bair Hugger here in this situation, had an effect on the unidirectional airflow in the operating room; correct?
A. Yes.
Q. And in fact, the correlation -- or the convection currents added particles or showed that there was air coming from underneath the operating room table into the surgical site; correct?
A. Yes.
Q. Did you see any bubbles going in the operating room, where the back table would be or the implant is, and the instruments?
A. I can't honestly recollect whether rogue bubbles would

have gone -- our back table would always be within the laminar flow. I don't know how things are done in the U.S. But -- I don't know. Probably --
Q. Is your back table close to the surgeon or -- or close to the scrub nurse or ...?
A. Yes. So everything is within this 2.4 meter squared canopy. We are pretty strict on that.
Q. So at the time, you didn't formulate an opinion on whether or not the disruption in the airflow caused by the Bair Hugger could contaminate the sterile instruments or the sterile implant?
A. So I can't confirm or refute that. It might be something to ask Paul McGovern who was in the room more frequently.
Q. What is a colony forming unit?
THE EXAMINER: A ...?
BY MR. ASSAAD:
Q. A colony forming unit, a CFU.
A. So this is -- yes, this essentially is a bacteria which goes on to cause an infection.
Q. So viable bacteria; correct?
A. Yes.
Q. Is there a correlation between particles and CFUs?
A. We certainly can't have any colony forming units without

any particles. We think that lots of particles are bacteria. In fact, there is, I think, published work on them, on how many particles will carry bacteria. I think it's in the region of 10 percent, but it's -- that's my recollection of the literature.
Q. Do you agree with me that airborne contaminants are the largest single contributor to infection; correct?
A. Yes, I think that's true. That's certainly what most orthopaedic surgeons would believe.
Q. And you would agree with me that a person would shed 1 billion skin cells daily?
A. That's what the literature says.
Q. That's what it would be --
A. Yes.
Q. And you just testified that 10 percent of those other particles would be carrying colony forming units; correct?
A. Correct. That is what the literature tells us.
Q. So as the colony forming units -- or the particles increase, it would be safe to assume that the amount of bacteria would increase?
A. Yes.
Q. So would you agree that the Bair Hugger, based on your research in the McGovern study and the Belani study,

increases particle counts?
THE EXAMINER: I don't think I want him to agree. I want him to answer whether that was a result of your research.
A. So there are several studies that show -- that compare forced air warming with conductive fabric warming. Many of these are on the table today. And yes, you will get more -- more contamination, if you like, from the sides if you are using forced air warming. I think there's numerous studies that show that.
BY MR. ASSAAD:
Q. And more contamination of particles would mean an increase of the bacteria in the surgical site; correct?
A. That's --
MR. GORDON: Object to form.
A. One would assume so.
BY MR. ASSAAD:
Q. Well, if 10 percent of the particles -- you just testified, if you increase the particles by five or six times, you would have five or six times more bacteria?
A. Correct. That's ...
MR. GORDON: Object to the form of the question.
BY MR. ASSAAD:

MICHAEL R. REED

Q. And would you agree with me that an increase of the bacteria in the surgical site would cause a greater chance of PJI by the susceptible host?
MR. GORDON: Object to the form of the question.
THE EXAMINER: What I really want to know is: was this as a result of the research they carried out, rather than -- when you ask him to agree with you, you are asking him in effect to express an personal opinion.
It is just rewording the question to say: did your studies show that ...
MR. ASSAAD: I would like to have back-ups, as a cross-examiner, of the document I am looking at.
BY MR. ASSAAD:
Q. Did any of your studies indicate that the increase in bacteria around the surgical site increases the likelihood of a peri-prosthetic joint infection by the susceptible host?
A. So what we have shown is an association with, you know, what we did for a period of time and then we changed, and then we had a change in our infection rates; with the caveats that we had changes to our practice. Apart from that, as we have detailed and as we have put in the paper.
Q. Besides -- and you have spent much time on the color

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graph and we will go over it a little bit, maybe go over it.
But is there anything in that graph or the changes in your practices that you could point to, that would cause increased particles into the surgical site, besides the forced air warming device?
THE EXAMINER: Is this the one you mean?
MR. ASSAAD: Yes.
A. No, there wouldn't be anything else that you would be suspicious of.
BY MR. ASSAAD:
Q. And going back to the other issue of the McGovern article that counsel has raised today.
Was the -- it was the xarelto issue with respect to changing the thrombo-prophylactics; correct? Do you recall doing a study which actually looked at the return to theater, in which you compared a low molecular weight heparin to xarelto and determined the infection rates?
A. Yes. So that was led by a colleague of mine, but I was part of the group. And the primary outcome measure was return to theater, not infection. But it didn't actually show a significant difference in infection rates, but ...
Q. Can you turn to tab 8?

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A. Tab 8, yes.
THE EXAMINER: Page?
MR. ASSAAD: Page Reed 84. Let's mark that as exhibit number 11.
THE EXAMINER: The page?
MR. ASSAAD: No, the entire article. Reed 84 to Reed 99.
(Exhibit Reed 11 marked for identification.)
BY MR. ASSAAD:
Q. Can you please describe this article? What are we looking at in exhibit 11?
A. Right. Well, I will certainly describe what we did and then if you give me a minute, I will describe what we found, because there is a lot of detail in here with the various types of complication.
Q. Just for the record, while we are looking at it, I am going to read the title, just so we have it clear for the ladies and gentlemen of the jury.
A. So this title -- this paper is entitled:
"Wound complications following rivaroxaban administration -- a multi-centre comparison with low molecular weight heparin for thromboprophylaxis in lower limb arthroplasty."
So in basic terms, this is people that are having a hip or a knee replacement and does -- does giving

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rivaroxaban or a low molecular weight result in more complications?
Q. Now, I need to confess to you. When I pulled up this document, it was in production by Nachtscheim; but actually yesterday, I actually found the published version which was published in the Journal of Bone & Joint Surgery in 2012; is that correct?
A. Yes, I think it was published in the American journal, the American Bone & Joint --
Q. I would offer you to look at the published version, if you would like, unless there is any objection by your counsel.
MR. HOLL-ALLEN: No.
THE EXAMINER: This is not the published version?
MR. ASSAAD: No, I found the published version.
A. Is it the same? I don't know.
BY MR. ASSAAD:
Q. I believe it is. It has the same numbers.
A. Thank you. Okay.
Q. Let's mark this as exhibit 12, please.
(Exhibit Reed 12 marked for identification.)
THE EXAMINER: Are the two first named authors from your trust?
A. They were at that time.

THE EXAMINER: They were at that time?
A. Yes. So this -- briefly, this is a paper where we asked other hospitals around the country that had changed similarly to us, to get in touch; and then we analyzed their data remotely to see what the complications had been.
BY MR. ASSAAD:
Q. And xarelto does not increase increased particles or bacteria to the surgical site; correct?
A. Correct.
Q. I would like you to refer to page 1556.
(Off the record remarks.)
Q. Now, Mr. Reed, you would agree with me that if someone has a peri-prosthetic joint infection, they would have to be returned to the operating room; correct?
A. Almost certainly. Very rarely not.
Q. Okay. So if you look at this document, you have wound complications using xarelto, as compared to a low molecular weight heparin. And then you have, two below it, return to surgery from infection. Do you see that?
A. Yes.
Q. And do you agree with me that if we are looking at PJIs, we should be looking at the differences between xarelto and the low molecular weight heparin for returning to

surgery for infection; correct?
A. Yes, correct. I just have the caveat that I don't know what timescale this looks at. But it is probably within 30 days, which would be a reasonable thing to look at.
(Off the record remarks.)
Q. So would you agree with me that the change from the low molecular weight heparin in the McGovern study to xarelto in the return had no effect; it was not a confounding factor with respect to the infection rates?
A. So based on this study of 12,000 patients, I would say there was no effect on return to surgery from infection.
Q. So would you agree with me that based on this study, that you are an author of, that looking at the date of the McGovern paper, that now we can exclude xarelto as a confounding factor for infection rates?
A. I think that's what this paper says.
THE EXAMINER: Because you nevertheless thought it appropriate to refer to the change in the McGovern paper.
A. Yes, because in our paper, there wasn't a significant difference in infection rates. But there was a signal; that was -- so that's why I put it in. It is safer to be upfront and fair about it.

BY MR. ASSAAD:
Q. And we had a discussion today about the unidirectional airflow in the operating rooms; correct?
A. Yes.
Q. And you believe that it prevents -- using unidirectional flow prevents peri-prosthetic joint infections?
A. Yes.
Q. Because it reduces the particles in the operating room; correct?
A. Yes.
Q. There is an argument that has been made with respect to critiquing your McGovern article, that laminar flow actually increases peri-prosthetic joint infections. Have you heard that argument before, regarding your article?
A. Yes.
Q. And you are of the opinion that, in fact, that needs to be looked at, because you think the forced air warming has an effect on the laminar unidirectional airflow; correct?
A. Yes. I think it may have an effect on that data.
Q. And actually you have written about that in the book chapter published in 2016; correct?
A. Yes, very likely.

Q. We have also discussed keeping patients warm during the preoperative and perioperative period; correct?
A. Yes.
Q. And you believe one or the other is fine; correct? Or I could have misunderstood you.
A. Well, it's not -- you haven't misunderstood me, but I think in terms of where the evidence is, I think that's possibly where the evidence is; one or the other is fine. But I would say the best practice now is to do both. And in fact, the NICE guidance draft, which has just come out, will be to do pre-warming and warming during surgery.
Q. But you agree that there's no evidence, scientific evidence, that indicates that keeping a patient warm during surgery and before surgery reduces peri-prosthetic joint infections?
A. So do -- okay. So there's definitely evidence that in colorectal surgery, that keeping people warm reduces their infection rate. And there is evidence from David Leaper's study, who you are going to meet, that pre-warming patients reduces infection rates in their clean surgery. But that is not during the operation. That is before.
I would say there isn't any evidence that doing

forced air warming during a joint replacement reduces the infection rates. I think that's the -- that's the purpose of the trial.

Q. And the colorectal study you are referring to is the study back in 1996, that I think that counsel was indicating in the 1996 New England Journal of Medicine?

A. It was in the New England Journal of Medicine, yes.

Q. Were you aware that the patients -- the controls were actually cooled in those cases?

A. I was aware of that and I think I put that in the Wood review article.

Q. Okay. Are you aware that Dr. Sessler and Dr. Kurz currently believe that that data would not withstand the current research guidelines today?

MR. GORDON: Object to the form of the question. Assumes facts not in evidence.

A. So their own study, do you mean?

BY MR. ASSAAD:

Q. Yes.

A. I wasn't aware of that.

Q. By the way, going back to the McGovern study, which is exhibit number 8. There is an odds ratio. What is the odds ratio of 3-point -- what does that mean, 3.8 odds ratio?

THE EXAMINER: Where do I find that?

MR. ASSAAD: Page number Reed 6.

A. It is the risk of something happening, essentially.

BY MR. ASSAAD:

Q. Would it be according -- could it be linked to the relative risk?

A. Yes.

THE EXAMINER: 15 ...

MR. ASSAAD: 42.

BY MR. ASSAAD:

Q. So based on your study in the McGovern, would it be fair to say that the relative risk of getting -- and based on the data, that the relative risk of getting a peri-prosthetic joint infection is 3.8 times greater using a Bair Hugger than using a conductive warming blanket, based on your study?

A. Based on that paper, yes.

THE EXAMINER: What was the figure you put to him?

MR. ASSAAD: 3.8.

BY MR. ASSAAD:

Q. Now, going forward to -- let me go back.

There came a time when you became part of the pilot study that -- it's called the "Reducing implant infection orthopaedics"; correct? The pilot study that

you were referring to?

A. The RIIO study, is it?

Q. The RIIO study, yes. The RIIO stands for "Reducing implant infection orthopaedics"; and that is under tab number 18. And let's make that exhibit 13.

(Exhibit Reed 13 marked for identification.)

Q. Have you seen this document before, this protocol?

A. Yes.

Q. And that is version 1.0, dated September 9, 2016; correct?

A. Yes. I have to say, I am not sure I have seen this version of the document, but I have seen -- I have seen the protocol.

Q. Do you know if there's more than one version?

A. Well, there will be several iterations. I know it is down as version 1.0, but it's probably -- you know, these things evolve over several weeks or months of discussion normally.

Q. Have you been part of authoring this pilot study?

A. I have certainly been involved in the -- in the conference calls about how it's designed.

Q. Were you aware that there was another 1.0 version dated July 5th, 2016?

A. Well, I am sure. I mean, generally there will be lots

of versions of them.

Q. If you go to exhibit number 4, binder 4. Not in mine. In the big gigantic binders over there.

A. Okay.

THE EXAMINER: Page?

MR. ASSAAD: Page 1609.

A. 1609, is it?

BY MR. ASSAAD:

Q. Yes.

A. Okay.

(Off the record remarks.)

Q. Have you seen this document before?

A. Well, I mean, I have definitely been involved in the evolution of this study.

Q. Were you involved in this project, the pilot study, prior to July 5th, 2016?

A. In terms of discussion about it, yes.

Q. Okay.

And at this time, the funder does not have 3M Healthcare as part of the funding. It has, like, three Xs there under "Funding" on page 1609; correct?

A. Yes, correct. It is just the Healthcare Infection Society.

Q. Do you know when 3M Healthcare decided to become

involved in this pilot study?
A. A little earlier than this; but I don't think they have signed contracts. I'm not aware they have signed contracts. So normally these things actually evolve over several months.
So were they discussing it in July? I think there probably was an expression of interest and an understanding that 3M may fund it, I believe.
Q. Do you know Dr. Mark Harper?
A. Yes.
Q. How do you know Dr. Mark Harper?
A. Well, we sit on the NICE guidance committee together. I run an infection prevention meeting in the North, which he spoke at about a month ago. So I have met him a few -- well, I would say three times.
Q. Do you know that he is on the 3M advisory panel, scientific advisory panel?
A. No, I didn't know that.
Q. Do you know he got paid by 3M?
MR. GORDON: Object to the form of the question.
A. No.
THE EXAMINER: What for?
BY MR. ASSAAD:
Q. For his consulting.

A. No. He may have been the link between 3M and the study, I suppose. He probably was.
Q. I take it the null hypothesis in this study is that there is no difference between forced air warming and resistive fabric warming; correct?
A. Yes.
Q. What is the hypothesis?
A. So we are just trying to tell if there is a difference between the two. And we will decide on numbers, based on the first 1,000 patients that we get in; it will give us a feel for the infection rates and then we will be aiming to show a difference or not between the two.
Q. But what is the working hypothesis, though? There has to be a working hypothesis. Is one better than the other?
A. I am not sure how the stats are structured, to be honest; whether it is an equivalent study or a superiority study.
Q. I think it is a superiority study. So it has to ...
A. Well, I imagine suggesting then that there is a difference, that forced air has a higher infection rate. But I can't remember the detail of that, I am afraid. Unfortunately it's not my study.
Q. What is your involvement in the study going to be?

A. So I have been involved in the design, if you like, of it; and I will be a recruiting center for it. Our trust will recruit patients, I think. That depends a little bit on whether my colleagues are willing to do it. But I mean, this is a study that I have been wanting to do for some time.
Q. Since you published the McGovern study; correct?
A. Since before that. 2009 is when I asked Scott Augustine to fund it. We didn't ask 3M at that point.
Q. And how much is the study going to cost, approximately, this patient study? Is there an estimate?
A. I think -- I have got the figure on my CV. So this is a pilot study, so it is not the whole study. But I think the -- I think 3M and the infection -- Healthcare Infection Society are putting in, was it 117,000 I saw on my CV?
Q. Yes. And are you getting compensated for your time involved in this study?
A. No.
Q. Do you have a contact at 3M that you are dealing with, regarding this study?
A. Regarding this study, no. I have got no involvement with 3M personally, with this study. I do have involvement with a different branch of 3M over my other

randomized trial that I am doing.
Q. Were you aware that other experts such as -- such as Dr. Sessler has also advised 3M over the years back?
MR. GORDON: Object to the form of the question.
BY MR. ASSAAD:
Q. If you go to page ...
Sorry.
(Off the record remarks.)
Q. Page Reed 172, 15 of 22 of the pilot. And this is the pilot study with your name on it; is that correct?
A. Yes.
Q. Okay.
If you look at the fourth line down, under "Warming method and temperature monitoring" under 8. It says:
"Both forced air warming and resistive fabric warming are established and licensed for use in the U.K. and are equally effective at preventing inadvertent perioperative hypothermia."
Did I read that correctly?
A. I can't see where you are reading it, but what you said --
Q. Under "Warming method" --
THE EXAMINER: Right down at the bottom of the page.
BY MR. ASSAAD:

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Q. The third line up from the bottom.
A. Yes. Yes.
"... are established and licensed for use in the U.K. and are equally effective at preventing inadvertent perioperative hypothermia."
Yes. I think that is a reasonable statement.
THE EXAMINER: So the primary function, they are equivalent.
A. In terms of warming, yes, I think that is a fair summary. I think even that is debated, but yes.
BY MR. ASSAAD:
Q. Mr. Reed, you stand by your studies; correct?
A. Yes.
Q. And even though Mr. Albrecht and Dr. Augustine were funding the studies involved, they did not influence the data or the results that you have concluded; correct?
A. Yes. So just to be clear, there was no funding for any of these studies apart from the very first one, which was the one actually that didn't show any difference. But yes, I do stand by them, yes.
MR. ASSAAD: All right. At this time, under the Federal Rules of Evidence, I am going to offer him as an expert and the stuff he has testified in, with respect to orthopaedic surgery, peri-prosthetic joint infections and the causation of peri-prosthetic joint infections.

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And after that, I have no further questions.
THE EXAMINER: I am sorry, you are going to have to say that again.
MR. ASSAAD: I am offering him as an expert in the testimony he has given to his studies, with respect to orthopaedic surgery, general causation on peri-prosthetic joint infections and general peri-prosthetic joint infections under the Federal Rules of Evidence.
THE EXAMINER: I don't know what you mean by "offering him as an expert". However, he is not here specifically under the terms of the U.K. order to give expert evidence, on the basis that both parties have their own experts in the United States.
Now, if you want to try and change this into something different in the U.S.A., that is a matter between the parties and the judge but I want to make it crystal clear that he has not been giving evidence today in this room as an expert. Okay?
Now, Mr. Gordon, it seems to me on the timescale, you have about 20 seconds left for re-examination.
MR. GORDON: I thought it was more like 40.
FURTHER EXAMINATION BY MR. GORDON:
Q. Mr. Reed, when counsel asked you about the McGovern studies showing an odds ratio of 3.8, and he asked you

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to agree with him, or whatever the exact words were, I can't remember. But essentially that using forced air warming was 3.8, and it increased the rate of infection 3.8 times over the other warming modality and you said "based on that paper".
Two questions.
First of all, why in the paper did you say:
"This study does not establish a causal basis for this association."
MR. ASSAAD: Objection to form.
THE EXAMINER: You may answer.
A. Because it doesn't. It doesn't establish causation, our paper. The -- yes, okay.
BY MR. GORDON:
Q. So what did you -- when you said "based on that paper", I mean, what was it that you were saying?
A. So as I said right at the start, right at the start of the proceedings, I said I wanted to mention something about that paper.
And -- in that we -- there was some very up to date data which I thought was in it. It does not actually change the material effect of the paper. You know, the conclusions are still the same.
But that final data that we got in, for some reason,

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did not get into the final paper. It might -- it did change the odds ratios very slightly. That's the reason that I mention it.
So it might not be 3.9. It was probably 3.8 or something like that. But I think it is somewhere in here. We could look it up.
Q. But regardless of whether it's 3.8 or 3.9 or ...
What does it mean that there is -- that the study does not establish a causal basis?
MR. ASSAAD: Objection. I think his time is up.
THE EXAMINER: I think I will allow you to answer this question and then that's it.
A. So what we have shown is association and not causation.
We made that pretty clear in the paper.
THE EXAMINER: Okay.
MR. GORDON: Thank you.
THE EXAMINER: Thank you very much.
MR. ASSAAD: Thank you.
THE EXAMINER: That concludes your examination, Mr. Reed. Thank you very much indeed.
THE VIDEOGRAPHER: This is the end of the deposition of Michael Reed. We are going off the record at 5:53.
(5:53 p.m.)
(Whereupon the deposition concluded.)

MICHAEL R. REED

CERTIFICATE OF DEPONENT

I, MICHAEL R. REED, hereby certify that I have read the foregoing pages, numbered 1 through 232, of my deposition of testimony taken in these proceedings on Sunday, December 4, 2016, and, with the exception of the changes listed on the next page and/or corrections, if any, find them to be a true and accurate transcription thereof.

Signed: .....
Name: MICHAEL R. REED
Date: .....

MICHAEL R. REED
CERTIFICATE OF COURT REPORTER

I, ROSE HELEN CLAIRE KAY, an Accredited LiveNote Reporter of London, England, hereby certify that the testimony of the witness MICHAEL R. REED in the foregoing transcript, numbered pages 1 through 232, taken on Sunday, December 4, 2016 was recorded by me in machine shorthand and was thereafter transcribed by me; and that the foregoing transcript is a true and accurate verbatim record of the said testimony.

I further certify that I am not a relative, employee, counsel or financially involved with any of the parties to the within cause, nor am I an employee or relative of any counsel for the parties, nor am I in any way interested in the outcome of the within cause.

Signed: .....
ROSE HELEN CLAIRE KAY
Dated: December 7, 2016

MICHAEL R. REED

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Deposition of MICHAEL R. REED

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