

**Bold** = AS (Interviewer)

Normal text = Participant

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**In your practice would you have seen patients regularly on bisphosphonates?**

Yes

**And would that have been as the prescriber or would that have been initiated from secondary care**

Well, initially certainly when they were first starting to be used they were always secondary care initiated, and certainly in the more complex patients. Towards probably the last 4 to 5 years where the guidance changed. For example....it would have been usually if you had....I think someone over the age of 85 who had a fracture...then the guidance was to initiate bisphosphonate without going through the DEXA scans and all the rest.....certainly...In the majority of cases, certainly initially and actually even subsequently they were usually initiated by secondary care..

**By secondary care....and would that be both oral and IVs**

Yes certainly, yes. We came across oral and IVs. The majority of the patients would have been on oral preparations. Erm, but there were a small number where they were either intolerant to the oral preparations for whatever reason they were administered and I know at the point I retired there was one....they were bringing something in that was going to be able to be administered by specialist nurses in general practice. I think in a sort of shared care arrangement.....But that.....they were all going to be initiated within secondary care.

**Within secondary care.....with all shared care arrangement**

I think the GP involvement would largely have been in arranging for district nurses to actually give the drug.....I think first dose would be given in hospital and then for patient convenience, given at home. I don't quite know what the arrangement would have been...who actually would do the prescribing, whether it was going to be one of these homecare systems, where they deliver the drug at home or whether the GP would be asked to take on the prescribing. That was just sort of.....being mooted in a couple of patient when I left, but it hadn't actually been implemented in those patients. They were both very specialised...sort of ...complex patients.

**So the majority were oral**

Absolutely.....I think just a handful of patients that I could think of, who were on the IV preparation

**When you were prescribing bisphosphonates...errmm what sort of things were you aware of, or cautions of, is there anything you were errmm thinking about as you were prescribing that drug particularly.**

Errmm.....I think it was largely around, errmm the formulation.....which formulation would be suitable for the patient. Some patients preferred the weekly, but I did have one that preferred to actually take the daily one. It was around interaction with errmm you know times of prescriptions to avoid for example the problem with calcium at the same time. Also....trying to take into account especially elderly patient, concordance issues and the difficulty with the instruction. I knew them by heart.

### **Very specific instructions**

Very specific instructions, that had to be you know.....Issued to the patient to make sure that they were taken properly. And then later on with older patients who have got medication dispensed in dosette boxes and mediboxes etc. like that. The difficulty of having a spate one with a drug so...a lot of people.....to do with the practical.....practicalities of actually how they drug and the bisphosphonate and things rather than the intricacies of how it worked and all the rest of it.

**Great....Errmm....so was there any side effects particularly of bisphosphonates you were aware of in practice, or came across regularly.**

Errmm I think largely it was....side effects, intolerance, GI intolerance. Having to be aware of the potential for errmm oesophageal ulceration especially if the patient developed dyspepsia. I did have 2 patients that I became aware of osteonecrosis of the jaw.

**OK**

Once they had actually developed it.....They were both very complex patients, but they were.....the amount of morbidity involved with the ONJ in both of those patient was considerable....errmm and then later on towards the last 2-3 years of my practice was the discussion about the duration of therapy of bisphosphonate.

### **Bisphosphonate holidays?**

Holidays and things like that.... Certainly when I would have first started to use them, there was absolutely no discussion about the duration of therapy.

### **Lifelong**

That was the assumption at that time, it was lifelong therapy. Errmm and then errmm later on there was discussions about the atypical fractures....in the femur and then bisphosphonate holidays were being mooted and discussed.....Errmm....the major difficulty I encountered was the lack of errmm how should we say.....agreement, if you put it that way.....guidance.....There was a lot of discussion about bisphosphonate holidays. I have to say slightly vested interest as my mother had been taking for many years for osteoporosis. I was aware of that and also unable to get any agreed opinion as to how long bisphosphonates should be continued in a patient to give the maximum benefit. When you should consider the holiday, should you use something else instead.....how long was the holiday going to be for and that guidance at that point just was not there.....Errmm and when we reviewed our patient, we actually did an audit to review.....certainly of patients taking bisphosphonates, and then we ended up having to write to the bone clinic to say what is your advice? Those patients who they did see there didn't seem to be any sort of rationale that I could see, into why decisions were made and what those decisions were. It all seemed to be rather adhoc.

### **A lot of personal opinion?**

I think it was, certainly nothing written there and we are going to develop...we kept hearing developed guidelines would be developed but certainly at the time I had seen nothing relating to that. When I read the patient record of those that had been seen they were seen by the consultant at the clinic and of course that meant considerable waiting time.

### **Yes**

There was a specialist nurse...errmm there didn't seem to be consistency between them either, as to how they were making their decision, it was more like they had a feeling this was the right thing to do. Certainly there was nothing formal to ask in GP land.

### **As prescribers**

As prescribers to actually say, this is the guidance that I was aware of.

**OK, interesting. Going back to the two patients which you came across with ONJ errmm were you aware of ONJ before you came across these patients.**

I was aware of it, as one of the many ...you know...one of those that was in there.

### **On the list**

On the list, so I was aware of its potential as a complication and errmm so when one of the patients did develop, he had a persistent dental abscess, the alarm bell did start to ring.

### **Did he present to you?**

He presented to his dental practitioner. As I said he was a complex patient on long term steroids, for complex gout. Very severe, but only a man in his 40s and he after many years errmm as a smoker, drank excessively, diet was poor, a (location) man. After many years he developed an abscess and it didn't...he came for antibiotics. He was told in the end he must see a dentist. I think after about the third time of presenting he decided to go to his dentist and found it was rather more complex.

### **Did you have difficulty getting that patient to see his dentist?**

Yes, that patient was reluctant. I think basically he didn't like going to the dentist and my thinking he also had to pay. My perception is that this is a major barrier.

### **A barrier**

A phenomenal barrier.....Errmm you know I think the dental hygiene of an awful lot of my patients was you know...a cause for concern. And yet they couldn't afford or didn't perceive it was something they could afford to pay for. They weren't registered, we then had to refer them to a dental clinic within the surgery building, but it was only for complex.....you know....we couldn't really refer them up.

**OK, community dentistry...Really interesting. Errmm so I guess two patients in your career is not a lot of patients to have come across.**

But I remember them...because I said it caused significant morbidity to both of them.

**Were you aware of the risk factors for developing osteonecrosis of the jaw, other than the bisphosphonates?**

I was aware that poor dental hygiene and that would obviously, in combination with the bisphosphonate would be more of an issue. But I wasn't aware of anything specifically.

**OK, when you initiated bisphosphonates and you prescribe them....or during medication reviews, would you have counselled patients on adverse effects of bisphosphonates and not just osteonecrosis of the jaw... Other than the sort of dosing instructions**

Not particularly.....any...I don't think so. I think perhaps because in very few where they actually just taking bisphosphonates....bisphosphonates was one of a large list of other medications they were taking. Unless the patient...I think the one that would have been stressed would have been the dyspepsia.....I think...because of the awareness of the ulceration of the oesophagus, and I think somewhere way back in my career I saw someone who had you know oesophageal ulceration from bisphosphonate therapy. It's the sort of thing that once you see it....you then remember it. I suspect and thinking back now that probably....I was having had 2 patients with osteonecrosis of the jaw I did sort of mention to people when they started, subsequent to that.

**After you seen two patients?**

Until I had actually.....you know.....it's that sort of thing that how frequently does it happen?....when you have a list.

**Not sure on the prevalence? Lacking in awareness?**

Certainly, how common was it....certainly you know it is one of those thing were you get osteonecrosis of the jaw.....you get Osteonecrosis of the femoral head.....how significant is it....and I think again beginning when bisphosphonates were not being used so much.....it is always, its prevalence was going to be much less.....it came to be used more frequently than it was something we were going to be seeing. I think it would have been perhaps less...I don't know in the denture less older patient which is where we were using it in the majority of patients, with false tetchy it wasn't going to be a major issue. I think when it started being used in more complex patients, young people and when it was started being used.....almost prophylactically.....Patients who were taking steroids.

**Bone protection**

Bone protection became a major issue, with things like steroid use and it started being used in younger patients.

**More being prescribed....more**

I think it was in the bone protection side of it, rather than in the treatment of osteoporosis. Slightly different demographics

**OK, did you ever have patients discuss with you dental concerns who were taking bisphosphonates**

Apart from the guy who got the dental abscess....I am.....wasn't...I can't think of anyone particularly who came in and discussed.....certainly no one actually raised it as a particular concern.

**Going forward is.....would you think counselling on osteonecrosis of the jaw is relevant to prescribers. Should it be part of their.....**

Yes. I mean it's sort of can be such a potentially serious problem for patients that it's almost a sort of.....the.....I am not explain myself very well.....The two patient I saw were very complex patients, both of them had considerable morbidity, needing surgery and stabilisation, of the jaw etc.

One of them when they tried to fix one side of the jaw, and opened her mouth the other side.....it disintegrated.....She ended up with real problems. I think as I say.....it's that sort of awareness that makes you think twice about it. I know for example in renal transplant placements, pre transplant they don't go onto the list unless they have a dental check-up. It's part of the work up.

### **Yes**

Maybe everyone is a bit blasé about the potential for the problem.....Does it....this is a drug that you really need to have, but before we can prescribe it safely for you, you need to have a dental check-up. I don't know if that should come within you know.....who pays for that then? That becomes the difficulty

### **In an ideal world?**

I suppose you say to the patient, if it is an increasing problem it should be part of the checklist. As you wouldn't prescribe.....necessarily to a patient with active peptic ulceration. Then there is the argument for saying you wouldn't give a bisphosphonate without making sure the patient doesn't have dental problems either.....That's my perception of it...if you really want to do it properly and it's a problem. I certainly wouldn't prescribe a bisphosphonate to someone who recently had and endoscopy and found to have peptic ulcers. So.....if they had a dental check, then fine, I think the patient would have to make that choice.

### **If that patient refused the dental check, would you still prescribe?**

As long as they...well, up to the patient. If the patient said and I think patient need to be involved in these decisions. "I have heard what you say but I am prepared to accept the risk of what happens to my jaw if I don't have dental check". And the potential benefit of having a bisphosphonate is great, you weigh it up then there is an argument for saying the patient understands the consequences of not having a dental check and that they might develop osteonecrosis of the jaw.....Patient may say I am not having a dental check and I would rather not take the medicines....As long as it is an informed choice.

### **A lot about patient education**

Patient education....and it is engaging patients and also expecting the patient to be more involved.

### **Responsibility**

Taking responsibility and not just saying...what do you think....well have a dental check...I think that, in an ideal world what should be done.....but a lot of the time , certainly with older patients there is a bit of disenfranchise and we think it's a good idea.....here are some more tablet for you...so

### **Coming back to the barrier, we said about cost and patients not prepared. They have come to see you for free, prescribed meds for free and then asking them to go and pay**

That right, and I think I have to say I think it would be , perhaps different from the patients point of view if they have recently fallen and had a fracture.....they might be more inclined to go for the dental check, because they have had the fracture and can see the potential value having the bisphosphonate. I think doing that in a patient who you were using for bone protection.

### **Like primary prevention**

Yes, primary prevention.....I think it would be very difficult to sell it to a lot of patients on that basis, where a lot of them might say I won't take them....I won't have the dental check-up. I just won't take them.

### **We then have the risks of them not taking the bisphosphonate**

Exactly.....I think doctors and I include myself in this, are not well taught in explaining risk to patients, it's difficult and I think we don't really necessarily understand the risk for every medication and the benefits. To try and explain the risk to the patient and the potential benefit as opposed to the risks of osteonecrosis of the jaw.

### **Really a thing difficult to get right**

Difficult concept...if you are thinking of....you know.....some of the less articulate, less educated patients, for them to understand that. Then the feeling that you might then be denying them potentially...

### **Treatment**

Treatment which is actually going to be of benefit to them...yeah

### **OK, really Interesting.....Would you say that as....the prescriber, would you think that is it your sole responsibility or would you think there other HC professions. Pharmacists?**

I think pharmacists are far better... I mean I think....I think the initial prescriber wherever that is initiated it is that is the person who is making the decision

### **Yeah**

To start the drug, in that patient...and I think they should.....do the initial explaining.....The checks and that....but it is a lot of information for patients to take on.

### **OK**

Certainly in a busy hospital environment...and I have to say I think counselling about medication is far better done by the pharmacists....I think the other reason is perhaps.....when a patient sees a doctor they expect to be able to discuss all aspects of their lives and their care almost...you know...discuss the cat, the auntie....the uncle....the kids....whatever else, the social drugs etc.....When they see the pharmacist they know they are seeing the pharmacist about their medication.....I think it is much easier for the pharmacist to keep the patient focused on the drugs and the patient to stay focused on the drugs.

### **On the medication**

Rather than to be side tracked on other things...so I certainly think they benefit from the pharmacist, certainly if the patient is collecting prescriptions regularly, is that....therefore the prescription for the pharmacist to reinforce initial advice and the message.....I think that is really where I would see the pharmacist role being invaluable.

### **And to expand on that advice?**

Yes...absolutely...because you know.....advice changes.....errmm and concerns change...and benefits change...information about medication changes and I think that when they are having that discussion that that contact with the patient on a regular basis, I think that ideally placed to be able to do that...yep.....I certainly....and then within our practice and certainly in some of the community

pharmacies where they were actually undertaking some sort of medication reviews...I think that is the ideal time to be...

### **To be giving this message**

To be giving that....and if the patient is going to a regular pharmacist. If a new drug is initiated, that is the time to reinforce what the patients been told about the drug and you know to give them the message and I think more reinforcement and the more information the better.

**So, in terms of....sort of osteonecrosis of the jaw counselling, maybe by a pharmacist. If you are the GP who started the medication errmm you have reviewed the patient and then the pharmacist has brought up this issue of osteonecrosis of the jaw with this patient...would you like to see that patient referred back to yourself or would you like that patient to be**

I would be delighted if the pharmacist would refer that patient to the dentist....I think that because....I think the fewer steps in the patients journey...if you see what I mean...the better. Because what I am....going to do if the pharmacist has encountered this.....then the thing to do is to say to the patient to go to the dentist....because all I am going to do when I see the patient is say you need to go to the dentist....and the patient is going to perhaps then going sit there and say...you brought me in to tell me that.

### **It's another step**

It's another step and another....appointment...I think its if....if....you know...I think if the pharmacist says to me I have told the patient they need to see the dentist so perhaps the next time you see them you could reinforce that message and follow up...so you flag it up and say....look the pharmacist did say...or you could do it.....you can reinforce it in different ways.....we would certainly use our repeat prescription systems.....on the right side you know...as a reminder you need to see your dentist...have you seen your dentist.....and follow it up that way...errmm and sometimes even a phone call

### **Yes**

Have you been to your dentist yet...so you are reminding them.....I would be very happy in that situation for the pharmacist to?

### **At the point of the initial prescriptions.**

Any time at all, I have no problem as long as its pointed out to the patient at some time.....you know....and you can do it in a way that not going to cause issues...you have been given a lot of information...was it mentioned you ought to see your dentist and this is why.....I don't think that does any harm at all... they often...when the drug is initiated there is a lot of other stuff happening with the patient and they may not take on board all of these messages

**As the prescriber if....if the pharmacist is going to refer to the dentist, would you....where would you like to be brought back into that process.....would you like to be informed?**

I think...I think it would be...I mean...if we had proper shared records it wouldn't be an issue because the pharmacist could update the records accordingly...

### **Yeah**

But certainly we had....you know...our pharmacist could communicate with us through System One. Certainly some of the pharmacists could...not all of them... and you could even just send a message

saying....I advised this patient to go to the dentist.....so that it can be flagged up...as an alert on the front of the patient records....if this patient needs to be seen....has been checked....follow up that this patient has seen the dentist...I think that's only....I think it does two things....first of all so that we know they have been advised to do it and you can follow up....and we can keep raising it.....With the patient as a concern and reinforcing why it is important.

**In terms of information that you would like back from the dentist, would you like records of that as well...or**

I don't think a record....but I think if the patient is on them.....a note form the dentist to say I have seen Mr so and so has been for his check-up.....all is fine. Or I have concerns I think obviously if there was something negative that ....You know...there was a problem that you might have to reconsider the treatment....then I think.....I would expect the dentist to communicate that back.

**Back to you**

I think in patients on bisphosphonates....it wouldn't do any harm for the dentist to drop a note round and say.....in the same way as they do for the transplant patients when they have been to the dentist. If it's part of their initiation.....part of their protocol....their checklist....whatever you want to call it....before starting treatment or while they are on treatment....everyone is aware why it is important...I don't think it should be a problem for the dentist to....just say I have seen this and....it's not a problem to communicate that back so.....so you have got it in the....in the records, in the same way as if a pharmacist gives my patient....one of my patients a flu jab.

**Yes.....exactly**

I expect them to tell me that they have had something....as its part of their.....their care. So it's important.

**OK, errmm I have most of my questions really....I think if the patient went to their GP...as their dentist sort of thought no.....they are not fit for a bisphosphonate....would you....again would be comfortable for that dentist to say....hold on we are going to delay treatment until after we have remedied this or**

Yeah...it think if I am sending that patient to....unless there was some very pressing reason that the patient must have bisphosphonates then...in which case I think if it was a complex situation like that and I wasn't sure.....then there are always the specialists.....who I could ask for and say....this is the situation...what do you think I ought to do with this patient...but in that situation if the dentist had a real concern I would be holding off treatment until I had the expert option to say...no it withstanding what the dentist said, this patient needs a bisphosphonate and it ok to go ahead with it...as I say really potentially you are doing harm to the patient with that drug. I think in that situation you need to air on the side of caution.

**OK...last question ...so...I guess as a GP...when practicing do you feel you would have like to have had more information about bisphosphonate osteonecrosis of the jaw?**

I would like to have had more information about the potential serious...the potential morbidity....you know....I am aware it was there in among all the other lists of things...errmm but until I was....

**First had experience**

Yeah...you know. Osteonecrosis of the jaw...so what...really it was only when I saw it affect those two patients....it was like wow....I do think from what I have seen now an awareness of it.....things like that...I certainly seen cancer specialist and people like...referring patients for a dental ...

I think perhaps...perhaps...I think also because they may have encountered cases as well....which has then complicated the patients treatment as they have had to go get this problems sorted out...individual people have developed an awareness of it.

**Yes, it's been subject to a number of MHRA alerts over recent years, around dental check-up.**

I think it's there...part of the problem...I think is when you have a drug like a bisphosphonate which is complex...with its instruction on how to take it...and people are tied up in that.....and I think also that it is a thing of prioritising side effects as well and when you get osteonecrosis in among all the other lists of side effects...it's where that it.....in terms of.....you know.....how important is it...and something I think you know....almost a way of flagging up the really big side effects...the one I remember is the peptic ulceration as it was always flagged up as potentially lethal, perforating the oesophagus and the patient ending up really ill.

**Would you want to know.....in terms of prevalence or more, severity to the patient**

I think....I think prevalence is important to know...errmm it gives....it lets the patient know how common and frequently it can occur....and us as well off course.....I think in terms of severity because you can have a prevalent side effect that's not that series...you know if I take amoxicillin it makes me nauseated...that is fairly common but it isn't life threatening...it's not going to hopefully....apart from making me a bit sick not cause a major problem....there are two issues there...prevalence is useful to know but I think the severity of the side effect...you can say to a patient look its very rare...but if it happens you have got a big problem with it....because of what it can do...I don't know if that's explained it very well.

**No....No**

I think there are some side effects...like a patient on methotrexate who gets oral ulceration...yeah ok...lots of people might.....but in your situation it could be very serious...I think those are ones that we need to flag up as being very serious.

**OK, I have no more questions unless there is anything else you would like to discuss..**

No.no....that's fine