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The attitudes and perceptions of patients towards the multidisciplinary approach to the prevention of Medication Related Osteonecrosis of the Jaw (MRONJ). A qualitative study in England.

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The attitudes and perceptions of patients towards the multidisciplinary approach to the prevention of Medication Related Osteonecrosis of the Jaw (MRONJ). A qualitative study in England.

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ABSTRACT

Background: Medication related osteonecrosis of the jaw (MRONJ), is a rare adverse effect of anti-resorptive or anti-angiogenic drug therapy that can cause significant morbidity; commonly prescribed drugs such as bisphosphonates have been associated with MRONJ. A multidisciplinary approach promoting and prioritising preventative strategies to ensure patients are dentally fit prior to prescribing implicated medications is recommended. Current evidence suggests that patients have limited knowledge relating to MRONJ and that preventative strategies are rarely implemented.

Objective: To explore the impact of MRONJ on quality of life and to explore the attitudes and perceptions of patients towards the multidisciplinary approach to the prevention of the condition.

Design: Interpretivist methodology using qualitative semi-structured interviews.

Participants: 24 patients; 6 with MRONJ, 13 prescribed bisphosphonates, 5 with osteoporosis not currently prescribed any medication.

Setting: Primary care general medical practices and secondary care dental services in England

Methods: Using a Grounded Theory approach and integrating a process of constant comparison in the iterative enrichment of data, semi-structured interviews were undertaken, transcribed and analysed using Ritchie and Spencer's Framework Analysis. Salient themes were identified and related back to extant literature in the field.

Results: Five salient and inter-related themes emerged: (1) quality of life, indicating the physical, psychological and social impact of MRONJ; (2) limited knowledge, indicating limited awareness of the condition, risk factors and preventative strategies; (3) patient specific, referring to the complexity of patients, polypharmacy, prioritising aspects of care and personal responsibility; (4) inter-professional management, indicating a perceived organisational hierarchy, professional roles and responsibilities, articulation of risk and communication; (5) wider context, indicating demands on NHS resources, and barriers to dental care.

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Conclusions: MRONJ has a significant impact on quality of life yet appropriate preventative education is not apparent. Effective inter-professional patient education and prevention to mitigate against the risk of developing MRONJ is required.

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Strengths and limitations of this study

- Although MRONJ is not a common finding, affected patients experience significant morbidity, and management of this condition warrants further study to stimulate improve patient care.
- There is limited research into the impact of MRONJ on patients; this is the first qualitative study that has explored the impact of the condition on patient quality of life.
- A qualitative method yielded rich data through in-depth semi-structured interviews with three groups of patients (patients with a diagnosis of MRONJ, patients prescribed bisphosphonates and patients with a diagnosis of osteoporosis who are not currently prescribed medication). Constant comparison with concurrent data collection and analysis allowed further exploration and refining of emergent themes.
- The study was based around the *a priori* assumption of limited knowledge among patients in relation to MRONJ; patients were provided a patient information leaflet in advance, therefore exposing participants to the concepts before the interview

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Introduction:

Medication related osteonecrosis of the jaw (MRONJ) is defined as exposed bone, or bone that can be probed through an intraoral or extraoral fistula, in the maxillofacial region that has persisted for more than eight weeks in patients with a history of treatment with anti-resorptive or anti-angiogenic drugs, and where there has been no history of radiation therapy to the jaw or no obvious metastatic disease to the jaws.(1) The risks for MRONJ are hypothesised to be related to the unique nature of the blood supply and the anatomical structure, and function of the jaw bones.(2)

A number of drugs that are indicated for use in osteoporosis, Paget's disease or the treatment of cancer have been associated with MRONJ. These include both oral and intravenous bisphosphonates such as alendronic acid or zoledronate, receptor activator nuclear factor kappa-beta ligand (RANKL) inhibitors such as denosumab, and anti-angiogenic drugs such as bevacizumab, sunitinib and aflibercept.(3) In practice, the most commonly prescribed agents are oral bisphosphonates for the management of osteoporosis.

Risk factors for the development of MRONJ are thought to include the concomitant administration of corticosteroids with antiresorptive agents and a duration of therapy exceeding 4 years.(1)

The precise incidence and prevalence rates of MRONJ are difficult to quantify, with varying reports in the literature.(4-6) This is potentially attributable to a low incidence of reporting, the variance in diagnostic criteria and a percentage of mild self-resolving cases remaining undiagnosed. The estimated incidence of MRONJ in cancer patients treated with anti-resorptive or anti-angiogenic drugs is 1% and in osteoporosis patients treated with anti-resorptive drugs is 0.01-0.1%.(3)

MRONJ is clearly a rare adverse effect; however, the prescribing of the drugs associated with this condition has increased considerably over recent years. Alendronic acid is the most commonly prescribed bisphosphonate and statistical evaluation of prescribing in England reveals 6,738,288 individual dispensations of alendronic acid 70mg in 2016 compared with 2,841,358 in 2006.(7) This rise may be attributable to increases in the proportion of elderly people in the UK population, publication of guidance recommending the prescribing of

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bisphosphonates and the availability of generic products. The aging population in the UK is expected to result in a doubling of the number of osteoporotic fractures over the next 50 years.(8)

A systematic review of the diagnosis and management of osteonecrosis of the jaw identified the elimination or stabilisation of oral disease before initiating antiresorptive agents as a preventative strategy for MRONJ.(5) Before commencement of drugs associated with MRONJ, or as soon as possible thereafter, patients ought to be facilitated to be as dentally healthy as possible. The aim is to prioritise care that will reduce mucosal trauma or act prophylactically to help the avoidance of subsequent dental extractions or conditions which may further predispose the patient to oral surgery or dental procedures that impact on the osseous structures of the jaw.(3)

Clinical guidelines published by the Scottish Dental Clinical Effectiveness Programme (SDCEP) recommend that high risk oncology patients undergo a thorough dental assessment, with remedial dental treatment prior to initiation of drug therapy.(3) Guidance for prescribers and pharmacists also recommends that patients or their carers are advised that there is a risk of MRONJ but should ensure that they understand that the risk is small. Patients should be advised to make an appointment with their dentist to ensure they are dentally fit and inform their dentist that they will be taking the prescribed medication.(3)

Several prospective studies have identified that dental screening and preventative strategies reduce the risk of osteonecrosis of the jaw. A study by Dimopoulous (2008) found a statistically significant reduction in the incidence of MRONJ with the implementation of preventative measures and Vandone (2012) reported a 50% reduction in the incidence rate with screening and pre-treatment preventative dental care.(9-10)

A multidisciplinary approach to the prevention of MRONJ is recommended in the literature for the management of patients requiring bisphosphonate therapy,(3,11,12) incorporating both patient and health professional education of the risk of the development of MRONJ. (13)

Education of healthcare professionals and patients about MRONJ is indicated,(14) with specific emphasis on the provision of focused preventative measures and detailed oral hygiene instructions. (3,15)

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A qualitative study of general medical practitioners and pharmacists in North East England found that both professional groups had limited knowledge and awareness of MRONJ and due to the complex medical histories of patients, practitioners often overlooked the advice related to the risk and prevention of MRONJ. (16)

The limited knowledge identified amongst prescribers and pharmacists is likely to also result in poor patient awareness. Only 11.8% of GMPs and 9.7% of pharmacists advised patients to warn their dentist they were using bisphosphonates.(17)

A small scale quantitative study (n=55) found that the majority of patients acquired knowledge about the drug they were prescribed from the patient information leaflet (62%) with few patients (13%) receiving this information directly from their general practitioner (GP). When asked to identify side effects of bisphosphonate therapy, only 32% of patients receiving IV, and 17% of patients receiving oral, bisphosphonates were aware of the potential risk of developing osteonecrosis of the jaw. (18)

The aim of this study was to explore the impact of osteonecrosis of the jaw on patients with a diagnosis of the condition and to explore the attitudes and perceptions of patients towards the multidisciplinary approach to the prevention of MRONJ. Although a number of drugs are implicated in causing MRONJ, this study focused on the association between bisphosphonates and osteonecrosis of the jaw and the multidisciplinary approach to the prevention of this rare, yet serious, adverse effect.

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Aims and Objectives

1. To explore the impact of MRONJ on patients with a diagnosis of the condition
2. To explore the attitudes and perceptions of patients towards the roles of the pharmacist, general practitioner and dentist in the prevention of MRONJ
3. To explore the barriers and enablers to optimise risk prevention of MRONJ

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METHOD

Design:

A Grounded Theory approach was used throughout this research; grounded theory is defined as 'the discovery of theory from data systematically obtained from social research'.(19) A key component of this grounded theory approach is the concurrent collection and analysis of qualitative data with constant comparison between participants. Constant comparison was utilised as a means of enriching the data through iterative data collection and analysis; the emergence of themes during the process provided the opportunity for further exploration during subsequent data collection.(20)

An initial topic guide (Supplementary Document 1) was produced serving as a benchmark for semi-structured one-to-one interviews carried out at the participant's home, GP practice or dental clinic. The interviews were audio recorded and transcribed verbatim to help with qualitative analysis. Framework Analysis (Ritchie and Spencer, 2002) was used as a systematic approach to the analysis of the most salient themes emergent from the transcribed data.

Participants:

Participants were recruited with the assistance of three National Institute for Health Research Clinical Research Networks (NIHR CRNs); North East and North Cumbria, Yorkshire and Humber, and North Thames. Three distinct groups were recruited to the study, [1] patients prescribed bisphosphonates, [2] patients with a diagnosis of osteoporosis not currently undergoing drug treatment, [3] patients with a diagnosis of MRONJ.

An invitation letter (Supplementary Document 2-4) and participant information sheet (Supplementary Document 5-7) were posted to patients in group 1 and 2 by their general practitioner and a convenience sample of participants who responded to the invitation was recruited.

Patients in group 3 (diagnosis of MRONJ) were recruited through the Oral and Dental Speciality Group of the NIHR CRNs; two secondary care dental hospitals recruited participants by posting invitation letters and participant information sheets to eligible patients.

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Analysis:

Constant comparison allowed the enrichment of data and for new concepts to be explored through subsequent interviews and Ritchie and Spencer's Framework Analysis (2002),(21) allowed salient themes to be identified from the data. Framework analysis involves a five-stage process: familiarisation with the data; development of a thematic framework; indexing data; charting of the data and mapping of the data. Themes were reviewed until definitive concepts could be produced from the data.

Ethical review:

Ethical approval was obtained from the NHS North East – York Research Ethics Committee (REF: 17/NE/0033)

Patient Involvement:

The principal investigator met with a patient representative from the University of Sunderland Patient, Carer and Public Involvement Group to discuss the design and ethical implications of the study. This included the co-constructed design of the patient information sheet and the directions provided for patients requiring further advice or support following participation in the study.

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RESULTS

A total of 23 patients were included in this study (Table 1). In depth semi-structured interviews were carried out between May 2017 and March 2018 until no more new themes emerged. Interviews took place in patient's homes, at their general medical practice or at their secondary care dental clinic; 1 hour was designated for each interview.

Five salient inter-related themes emerged from the data: (1) quality of life; (2) limited knowledge; (3) patient specific factors; (4) interprofessional management; (5) wider context.

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1. Quality of life

Participants with a diagnosis of MRONJ highlighted the impact that the condition has had on their quality of life. Participants described experiencing a significant amount of pain with the condition, requiring the frequent use of analgesic medication.

> The big problem is all my lips are tender. When I touch them, it- it's just as though – I've never been hit in face, but- but I can imagine somebody hitting you in the face. I can imagine it feeling like that. And- and the tenderness, it never goes. It's always there. I touch it and I feel as though I don't want to touch it. (MRONJ-2)
>
> I've still got a pain. I mean, now I- I- I feel fine, but by the end of the day, by five o'clock tonight, I'll probably need two paracetamol. (MRONJ-1)

Participants identified challenges in relation to eating and drinking, and the associated social anxiety of eating awkwardly in public.

> When I'm drinking a drink or eating, I feel as though I'm- I've had anaesthetic at a dentist. I feel as though I'm dribbling. And I'm not. You know, if I go out with daughters for a meal, they are forever going – 'dad, you're not dribbling.' And I feel as though I am, cos it's like, cold s- I get cold sensations down here, just as though I'm dribbling. (MRONJ-2)
>
> Psychological and mental, yeah. If you're going out to a restaurant, then you have to be very careful. You don't want people to see that you are eating awkwardly. (MRONJ-5)

The psychological implications of a diagnosis of MRONJ were highlighted by participants; these were seen to take less of a priority for healthcare professionals but have a significant impact on the quality of patients' lives.

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> This is difficult, but mentally, it gives you some kind of anxiety because you- you- you know your bone is there- a little piece of bone on your left-hand side is there and then you think, maybe perhaps in the future, you need to have an operation. It's a big operation. (MRONJ 5)

All participants with a diagnosis of MRONJ were required to attend Secondary Care dental clinics for regular review and treatment. In some cases, patients had to regularly travel a considerable distance for ongoing management.

> I mean, I go every month at the moment, it's quite an- a big impact, I guess, in terms of appointments. Well, they- they have a look, see if it's got any worse, and then record it. They often have to send me for more x-rays. (MRONJ-2)

2. Limited knowledge

The concept of MRONJ was introduced in the participant information sheet and opened up for further discussion during the interview; participants without a diagnosis of MRONJ had minimal awareness of the associated risk.

> They didn't explain about- anything about any side-effects or anything about trouble with your teeth. (B-6)

Those patients with a diagnosis of MRONJ were aware of the condition and how this was related to their prescribed medication. All patients with MRONJ stated that they were unaware of this risk prior to commencing treatment with the bisphosphonate.

> I was given no information about that…Doctors don't tell you about the side-effects of drugs. (MRONJ-6)

It was clear from the discussions that the patients prescribed a bisphosphonate were uncertain about required duration of therapy; many patients had been prescribed the drugs for a number of years but were unclear on whether therapy should be continued indefinitely or for a set period of time.

> I reckon I've been taking it more than five years now. And it should- I've got a feeling it should've been reviewed after five years. (B-8)

Most patients reported that information relating to the risk and preventative strategies for MRONJ complications had not been discussed with the prescriber or pharmacist on initiation. Where patients had awareness of these issues, the information was typically gained from the patient information leaflet supplied with their medication.

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> Well, I usually read the little leaflet for any, you know, side-effects that they might have. (B-8)

Patients felt that although the internet can provide access to information, due to age, many people in this patient group have limited knowledge of, or access to, web-based information.

> You know, it's only since the internet that people able to look up on the actual – I mean, I- I'm not – I do use the internet, but not often or very well- I'm not on it every day cos I don't have it where I live. (MRONJ-6)

3. Patient specific factors

Most of the patients interviewed had a complex medical history. The age of participants and the presence of co-morbidities meant that osteoporosis was typically one of a number of ongoing medical conditions for which they were undergoing treatment; as a result, most patients were prescribed a number of medications.

> At one time, when I first came to hospital, I was on twenty- about twenty tablets a day, you know. Which is too much. (B-2)

Due to the complexity of patient's medical profiles and the associated polypharmacy considerations, it was identified that information is typically prioritised and that health care professionals only have limited time to provide information.

> They haven't got the time to go through everything with you. [chuckles] I think they have to pick out the key things. (B-1*)*

Participants also described the importance of taking responsibility for their own actions. If provided with information or management advice they perceived they ought to have ensured that this was acted on. Participants did stress that in order to take personal responsibility, they needed to be appropriately informed by the healthcare professional (s).

> It's your own responsibility. If you've been told about something properly, you know, it's then your responsibility too. You've got to look after yourself, you know. (B-2)

4. Interprofessional management

It became clear from the interviews that participants perceived there to be a clear organisational hierarchy in terms of the management of their condition. Participants felt that it was the responsibility of the prescribing clinician to provide information relating to the adverse effects of medication.

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> I think – and you needed that information, I think it should be the doctors telling you when- when he prescribes it, to say to- 'as a precaution, you should go to your dentist. (O-3)

Most participants placed trust in the professionals managing their care and perceived that prescribers would have already utilised professional judgement in relation to the possible risks and benefits of medication.

> I'm sure the doctor will use his own discretion, you know. That it is safe and appropriate. (B-2)

However, many participants identified that the risks and benefits of medication are not well articulated to patients, making it difficult to make informed decisions around their care.

> I think they should be able to provide the risks and the benefit and discuss with the patient what's probably be-best with them. I don't think this is done very well. (MRONJ-6)

Participants perceived pharmacists to have an important role in the reinforcement of advice given by prescribers and were receptive to receiving information from pharmacists relating to the administration and potential adverse effects of medication.

> Quite often, you know, you talk to your GP and you go away and you just forget- you forget something that they've said. So, having it reinforced a couple of times I think's a good idea. (B-8)

Pharmacists were seen as having specialised knowledge in relation to the adverse effects of medicines.

> I don't think doctors know a lot about the side-effect of the medication. For pharmacy, they should have more knowledge because they are specialised in medication. (MRONJ-5)

A number of patients had experienced a formal medication review by their pharmacist and appreciated the opportunity to discuss their medication and adverse effects.

> I feel as though the pharmacist that I go to, I could ask her anything and she would tell us. I have had a review with her, she's very, very helpful and knowledgeable about medication. (B-5)

Participants reported that dental practitioners routinely ask about changes to prescribed medicines during check-up and treatment appointments. Some participants identified that

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their dentist specifically ask about their prescribed bisphosphonate, but the interest in these drugs had not been explained to the participants.

> You've got to fill a- a form in every time with your medicines on. And funnily enough, alendronic acid is the one that I often forget and miss off. And they have asked us "are you still taking that?" (B-1)

Participants discussed the need for good communication between the professional groups to support the prevention of MRONJ. Participants were all happy for information to be shared between the professions and expected information regarding their treatment to be communicated effectively.

> If the doctor has recommended me to go, I would think there should be at least some liaison with the dentist and the doctors and that was on your medical records to say you're getting that check done. (O-3)

5. Wider context

Participants identified that there is an increasing demand on NHS resources and perceived that all healthcare professionals have a heavy workload. As such, they perceived that the implementation of preventative strategies could potentially place more demands on staff time and the already limited appointment schedules.

> Doctors are so over-stretched and – and – you only have a short time for the appointment to get the information. Sometimes you still wait forever to even get an appointment. (MRONJ-6)

Although most of the participants had a history of regular dental appointments, there was a strong feeling that many patients have a general reluctance to seek dental advice. Potential barriers such as a phobia towards dental treatment, a perceived lack of awareness of oral health and the financial implications of dental treatment were all identified by participants.

> Terrified. Uh-huh. Always have been. (B-5)

> You have to pay for the examination and then obviously, depending on the amount of work that you need, that can be quite expensive. And not everybody has that money. (B-6)

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DISCUSSION

Summary of main findings

It is apparent that osteonecrosis of the jaw has a significant effect on the quality of life of patients diagnosed with the condition. Patients described both the physical and psychological impact and challenges related to its ongoing management.

Patients prescribed bisphosphonates were confused about the intended duration of treatment with the drug; some patients were aware that the medication would only be prescribed for a set duration, whereas for others, this medication had already been prescribed for many years without any apparent review. Patients from all three groups had limited knowledge of the association between bisphosphonates and osteonecrosis of the jaw; and when patients possessed some knowledge, this typically came from the information leaflet supplied with medication or from the internet. However, given the demographics of this patient group, access to online information is potentially a challenge for some.

Many of the participants interviewed have complex medication histories and are prescribed multiple medications. Participants therefore described the need for prescribers to prioritise information related to their clinical management and in-patient education.

Participants described a perceived organisational hierarchy in relation to the management of their health; they expected prescribers to utilise professional judgment on the suitability of the medication for them, and to provide information related to the adverse effects of medications. Participants perceived that the pharmacist has an important role in reinforcing advice and were positive towards the pharmacist's role in providing information on medications and conducting medication reviews. Participants reported that their general dental practitioners were active in recording medication details and were also receptive to information being shared between medical and dental services. Key barriers in relation to the multidisciplinary prevention of MRONJ, such as the heavy demands on NHS resources, attitudes towards oral health, a reluctance to attend dental appointments, and the financial issues associated with dental care, were all identified by participants.

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Comparison with existing literature

Our previous qualitative study of general medical practitioners and pharmacists in England,(16) produced similar findings. The limited knowledge of both professional groups was mirrored in that of the patients interviewed during this study, and patients also perceived that practitioners prioritise information, and often overlook the advice related to the risk and prevention of MRONJ.

Masson (2009) identified that only 11.8% of GMPs and 9.7% of pharmacists advised patients to inform their dentist they were using a bisphosphonate.(17). The patients interviewed in this study also highlighted a lack of information from prescribers and pharmacists with most patients getting the information from the patient information leaflet. A small quantitative study (n=55) found that the majority of patients acquired knowledge about the drug they were prescribed from the patient information leaflets (62%), with few patients (13%) receiving this information from their GP. When asked to identify side effects of bisphosphonate therapy, only 32% of patients receiving IV, and 17% patients receiving oral, bisphosphonates were aware of the risk of developing osteonecrosis of the jaw.(18)

The literature supports preventative strategies due to the associated morbidity and challenges in treating osteonecrosis of the jaw,(1) but there is limited insight into how MRONJ affects quality of life. Although the significance of osteonecrosis of the jaw has been discussed in the literature, there are no qualitative studies that have explored the implication of osteonecrosis of the jaw on quality of life. A small quantitative study of 34 patients with MRONJ utilising the Oral Health Impact Profile (OHIP-14) found that the condition significantly ($p<0.001$) affects quality of life.(22) This study, along with the findings of this research, has highlighted the issues faced by patients and the ongoing physical and psychological distress associated with MRONJ.

Limitations

The study was based around the *a priori* assumption of limited knowledge among patients in relation to MRONJ; the concept of MRONJ was introduced during the patient information leaflet, therefore exposing participants to the concept before the interview.

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Participants were all located in England; this therefore may impact on the potential transferability/ecological validity of findings to other geographical locations or healthcare settings. For example, a variation in the access to dental services or the healthcare infrastructure in a particular location may influence the attitudes of patients.

This study has explored the attitudes and perception of patients prescribed bisphosphonates, focusing on those with a diagnosis of osteoporosis. Other medications are associated with MRONJ and in alternate indications such as cancer; patients in this group may have different attitudes towards risk and the findings of this study are not necessarily transferable to this patient group.

Future work and implications for clinical practice

Osteonecrosis of the jaw had a significant impact on the patients interviewed in this study. Although rare, the ongoing physical and psychological implications of MRONJ can have a significant impact on quality of life. As this condition can, in many cases, be prevented with appropriate oral health advice and preventative care, the importance of such measures should be stressed to all healthcare professionals managing this particular patient group.

Although published clinical guidelines recommend that patients should be referred for dental assessment and treatment prior to initiation of bisphosphonate therapy,(3) it is apparent this is not happening. The impact of this on dentists, and their perspective on how the professions can collaborate to improve patient care, would be important to consider before implementing any preventative strategies.

This study focused on the perceptions of patients prescribed bisphosphonates for osteoporosis. The literature is clear that the incidence of osteonecrosis is greater in patients prescribed intravenous bisphosphonates for the treatment of cancer; further work exploring the management of this patient group and any variation in the attitudes towards risk and ongoing management would substantially add to this body of literature.

Further work to explore the role of the pharmacist in the interprofessional team should be considered. Patients described the benefit of formal medication reviews with their pharmacist and a willingness to engage with pharmacy services to receive information related to the adverse effects of medication. The Medication Use Review (MUR) and New Medicine

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Services (NMS) are both Advanced Services within the NHS Community Pharmacy Contractual Framework in England. An MUR is a structured, adherence-centred polypharmacy review of patients prescribed multiple medicines and the NMS service provides support for patients with long-term conditions that have been newly prescribed a medicine. (23-24) However, the MUR and NMS service specification does not currently include bisphosphonates; the inclusion of this group of drugs could provide an opportunity for reinforcement of preventative advice during the initiation stages of treatment with bisphosphonates. A recent publication in *British Dental Journal* emphasised the potential benefits of interprofessional working between pharmacy and dental professionals;(25) further work to develop such services could be of particular benefit to this patient group.

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Conclusion

Medication related osteonecrosis of the jaw has a significant impact on patients' quality of life; however, patients demonstrated limited knowledge of the risk and of the preventative strategies recommended in the literature. Patients perceive prescribers to be responsible for educating them on the risks associated with medications; however, pharmacists can play a significant role in reinforcing information and providing advice to patients both newly prescribed medications and through formal medication reviews. Prescribing rates of bisphosphonates are increasing and a number of other medications prescribed for both osteoporosis and in the treatment of cancer have also been associated with osteonecrosis of the jaw. Therefore, the incidence of MRONJ is likely to increase; this may continue to be the case unless changes are made to current practice and appropriate patient education and preventative measures are introduced.

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Author Contributors: AS, SW, CH and PP designed the study. AS recruited the participants and carried out the study. AS identified the thematic framework and interpreted the data. AS, SW, PP and CH reviewed and refined the data. AS wrote the paper and all authors revised it. AS received training in qualitative research skills by the research team and through attendance at a Qualitative Research Methods in Health Course at University College London.

Data Sharing: Participant information sheets and invitation letters are included (Supplementary Files 2-7); no further data shared.

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Competing interests: None

Ethics approval: Ethical approval was obtained from the NHS North East – York Research Ethics Committee (REF: 17/NE/0033)

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The multidisciplinary approach to the prevention of bisphosphonate related osteonecrosis of the jaw (BRONJ). A Qualitative study into the attitudes and perceptions of patients (MAP-BRONJ)

Topic Guide

This study aims to explore the attitudes and perceptions of patients towards the multidisciplinary prevention of bisphosphonate related osteonecrosis of the jaw.

The following guide outlines the key areas for exploration during the interview.

Aims and objectives

To explore the attitudes and perceptions of patients towards the roles of the pharmacist, general practitioner and dentist in the prevention of Bisphosphonate Related Osteonecrosis of the Jaw (BRONJ).

To explore the barriers or enablers to optimising the risk prevention of BRONJ

To explore the attitudes and perceptions of patients about their broader priorities during counselling on medication

Introduction

Aim: To introduce the research and set the context for the proceeding discussion

- Introduce self: University of Sunderland, MAP-BRONJ study, why I am here
- Introduce the study: what it is about, who it is funded by
- Talk through key points
    - This will be a conversation where I will ask you questions
    - It will last between 30 and 60 minutes
    - There are no right or wrong answers
    - You don't have to answer all of the questions if you don't want to, just let me know that you want to move on
    - Participation is voluntary and participant can withdraw at any time
- Confidentiality/ anonymity
    - Transcripts will be anonymised
    - In report writing, any quotes won't be identified as being you
- The interview will be audio recorded
    - The recording will be kept secure, only accessed by the four researchers working on the project, and will be kept for 10 years as per policy
- I've brought the voucher for participation with me, so I'll give that to you after the interview
- This piece of paper is just to help me remember what questions I want to ask you, and I may make some brief notes during the interview to remind me to go back to something you said later on if that's ok
- Does the participant have any questions?

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CLINICAL PHARMACY ASSOCIATION

University of Sunderland

The multidisciplinary approach to the prevention of bisphosphonate related osteonecrosis of the jaw (BRONJ). A Qualitative study into the attitudes and perceptions of patients (MAP-BRONJ)

All Participants

Background of participant
Prompts: *age, employment, PMx, DHx, dental history, regular pharmacy, regular GP*

When you have been started on a new medicine, what do you want to know
Prompts: *priorities, side-effects, risks, indications, benefit, decision making process*

The role of the GP when starting new medicines
Prompts: *experiences, role, expectations*

The role of the pharmacist when starting new medicines
Prompts: *experiences, role, expectations, MUR/NMS*

Osteonecrosis of the jaw has been associated with bisphosphonate therapy. It can be difficult to treat and in many cases potentially preventable, the most recent guidelines recommend that healthcare professionals should work together to do this. Ideally patients should be dentally fit before starting these medicines and should have any dental work carried out before starting treatment and maintain good dental health while taking these drugs.

All Participants

The role of the GP in this team
Prompts: *role, responsibilities, expectations*

The role of the pharmacist in this team
Prompts: *role, responsibilities, expectations, MUR/NMS*

The role of the dentist in this team
Prompts: *experiences with dentists, role of the dentist, expectations*

The role of the patient in this team
Prompts: *roles and responsibilities, expectations*

The role of the multidisciplinary team
Prompts: *expectations, leadership, communication*

Any barriers or facilitators to this from happening
Prompts: *access to dentists, charges, fear, communication*

Would this influence (or have influenced) your decision to take this medicine
Prompts: *why, risk of not taking, balance risk*

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Patients with osteoporosis only

Tell me about your experiences of osteoporosis
Prompts: *symptoms, diagnosis, management*

Are you aware of the drugs that can be used to help patients with osteoporosis
Prompts: *Who told you, offered drugs?*

Patients prescribed bisphosphonates only

Tell me about your experiences of taking bisphosphonates
Prompts: *indication, history, administration, side-effects, efficacy*

Were you aware that this condition was a potential side-effect of one of your medicines
Prompts: *was this risk explained to you, who by, when*

Did you have a dental check-up prior to treatment
Prompts: *Was work carried out, advice given, was the dentist aware of the risk*

Do you maintain regular dental check-ups
Prompts: *Frequency, does the dentist know you're on a bisphosphonate,*

Patients with a diagnosis of BRONJ only

Tell me about your experiences of taking bisphosphonates
Prompts: *indication, history, administration, side-effects, efficacy*

Tell me about your diagnosis of osteonecrosis of the jaw
Prompts: *presentation, diagnosis, management, current management*

Tell me about how osteonecrosis of the jaw has affected your life
Prompts: *impact on daily activities, pain, discomfort, ongoing management, psychological impact*

Were you aware that this condition was a potential side-effect of one of your medicines
Prompts: *was this risk explained to you, who by*

Should you have been aware of this risk with this medicine
Prompts: *should you have been, would you still have taken this medicine, how/who should make you aware of this*

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The multidisciplinary approach to the prevention of bisphosphonate related osteonecrosis of the jaw (BRONJ). A Qualitative study into the attitudes and perceptions of patients (MAP-BRONJ)

Next steps

- Thank the participant
- Do they have any remaining questions about the research
- Reassurance around confidentiality and anonymity
- Would they like their GP to be informed about their participation in the interview
- Provide with gift voucher
- If not, would they like to be informed about the outcomes of the research, and if so method for doing this

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Invitation Letter for interviews – patients prescribed bisphosphonates

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DATE

TITLE FIRST SURNAME
ADDRESS LINE 1
ADDRESS LINE 2
POST CODE

Dear [TITLE] [FIRST NAME] [LAST NAME],

I WOULD LIKE TO ASK FOR YOUR HELP

Academics who are doing research at the University of Sunderland and Newcastle University have asked for my help to find patients to take part in a study. One of the medicines you take is what is called a bisphosphonate and they would really like to talk to you about it.

The research study being carried out is called MAP-BRONJ. This stands for 'The multidisciplinary approach to the prevention of bisphosphonate related osteonecrosis of the jaw. A qualitative study into the attitudes and perceptions of patients'.

Lots of people take bisphosphonates for a number of reasons, such as to help strengthen your bones. These medicines have been associated with a very rare side effect that can affect jawbones; however this condition is usually preventable with the right advice.

We would like to speak to patients to get a better understanding of how you think healthcare professionals should be working together to prevent side-effects such as this.

If you didn't know that one of your medicines could cause this side-effect and are worried, then please make an appointment with your usual doctor and they can give you the correct advice.

If you would like to take part in this study or want to know more about it, please read the information sheet which comes with this letter.

Kind regards,

[GP/Pharmacist]

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Invitation Letter for interviews – patients prescribed bisphosphonates

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I would like find out more about the **MAP-BRONJ** and I am happy for a member of the research team to contact me

Contact details *(Please enter your contact details below)*

Title: Mr/Mrs/Ms/Miss (*please delete as appropriate*)

Name: ____________________________________

Telephone contact number: ____________________________________

A convenient time to call is: Between ___________ and ______________

Please return this slip in the envelope provided. A member of research team will contact you on the contact number provided above.

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Invitation letter for interviews – patients with BRONJ

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Dear [TITLE] [FIRST NAME] [LAST NAME],

I WOULD LIKE TO ASK FOR YOUR HELP

Academics who are doing research at the University of Sunderland and Newcastle University have asked for my help to find patients to take part in a study. You have previously been diagnosed with a condition called osteonecrosis of the jaw and they would really like to talk to you about it.

The research study being carried out is called MAP-BRONJ. This stands for 'The multidisciplinary approach to the prevention of bisphosphonate related osteonecrosis of the jaw. A qualitative study into the attitudes and perceptions of patient'.

Osteonecrosis of the jaw is a rare side effect of a medicine called a bisphosphonate. We would like to speak to patients who have this condition to get a better understanding of how this has impacted on your life and to get your thoughts on how healthcare professionals can work together to prevent other patients from having this same problem.

If you have any worries about your condition then please make an appointment with your usual doctor and they can give you the correct advice.

If you would like to take part in this study or want to know more about it, please read the information sheet which comes with this letter.

Kind regards,

[Dentist/GP]

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Invitation letter for interviews – patients with BRONJ

I would like find out more about the **MAP-BRONJ** and I am happy for a member of the research team to contact me

Contact details *(Please enter your contact details below)*

Title: Mr/Mrs/Ms/Miss (*please delete as appropriate*)

Name: ______________________________________

Telephone contact number: ______________________________________

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Invitation letter for interviews – patients with osteoporosis

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DATE

TITLE FIRST SURNAME
ADDRESS LINE 1
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I WOULD LIKE TO ASK FOR YOUR HELP

Academics who are doing research at the University of Sunderland and Newcastle University have asked for my help to find patients to take part in a study. You have previously been diagnosed with a condition called osteoporosis that affects your bones and they would really like to talk to you about it.

The research study being carried out is called MAP-BRONJ. This stands for 'The multidisciplinary approach to the prevention of bisphosphonate related osteonecrosis of the jaw. A qualitative study into the attitudes and perceptions of patients'.

Lots of people have osteoporosis and sometime they need to take a medicine called a bisphosphonate to help strengthen your bones. You don't currently take one of these medicines, but sometimes if your osteoporosis gets worse then doctors might prescribe it for you. These medicines have been associated with a very rare side effect that can affect jawbones; however this condition is usually preventable with the right advice.

We would like to speak to patients to get a better understanding of how you think healthcare professionals should be working together to prevent side-effects such as this.

If you have any worries about your condition, then please make an appointment with your usual doctor and they can give you the correct advice.

If you would like to take part in this study or want to know more about it, please read the information sheet which comes with this letter.

Kind regards,

[GP/Pharmacist]

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Invitation letter for interviews – patients with osteoporosis

I would like find out more about the **MAP-BRONJ** and I am happy for a member of the research team to contact me

Contact details *(Please enter your contact details below)*

Title: Mr/Mrs/Ms/Miss (*please delete as appropriate*)

Name: ______________________________________

Telephone contact number: ______________________________________

A convenient time to call is: Between ___________ and ______________

Please return this slip in the envelope provided. A member of research team will contact you on the contact number provided above.

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MAP-BRONJ Information Sheet for patients prescribed bisphosphonates

The multidisciplinary approach to the prevention of bisphosphonate related osteonecrosis of the jaw (BRONJ). A Qualitative study into the attitudes and perceptions of patients (MAP-BRONJ) – IRAS 216783

Why is MAP-BRONJ being carried out?

A group of drugs called bisphosphonates are used to treat a number of conditions that affect bones, such as osteoporosis and certain cancers. Because we are living longer, more patients are being prescribed these drugs than ever before and a rare but important side effect, called osteonecrosis of the jaw, has been discovered.

This side effect causes problems with patient's jawbones, particularly if patients require a dental extraction. This condition can be difficult to treat and because of this healthcare professionals should try to prevent it from happening in the first place. In this study we are looking to find ways in which we can minimise this risk and how healthcare professionals can work better as a team to prevent it from occurring.

Why have I been invited to take part?

You have been asked to take part in this study as one of the medicines you take is associated with this rare side effect. Even though the condition we are studying is rare, we would like to talk to patients who are taking these drugs about how healthcare professionals can work as a team to prevent anyone from getting it.

If you would like more information about this side-effect, the study team can provide you with a leaflet on the condition and you can speak to your GP.

What would I have to do?

We would like your help with this study by asking you to talk to one of our team members for about an hour. We will audio record this conversation so that it is easier for us to make notes later about what was said. The interview can take place at your GP surgery, or we can come to your home to talk to you.

Will I be able to get my money back if I have to travel to take part?

Yes. We don't want taking part in the study to cost you anything. This means that we will give you the money for any bus fares or other travel costs which you have to pay to take part.

Will I get paid for taking part?

No. But we will be giving everyone who takes part a £10 gift voucher as a 'thank you' for taking part in our project.

What is the study for?

The information that we get from MAP-BRONJ will help us to know more about the expectations of patients and how healthcare professionals can work together. Potentially this

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could help the NHS and patients who use these medicines in the future.

Are there any risks to me from taking part?

We don't think there will be any risks to you from taking part in the study. It won't make any difference to the medicines or treatment that you are getting. If you require any further information about this side-effect or your treatment you should make an appointment to speak to your GP.

How will my information be kept confidential?

We won't use your name on anything we write. We might use some of your words in our reports, but we won't say that it was you who said it. The audio file will be sent to an external transcription service that has been approved by the University of Sunderland We will only keep your name and information about you in very safe places and the audio recordings will be destroyed once they have been transcribed and anonymised. If you are worried about that we can tell you more about it.

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Unless you tell us not to, we will let the person who prescribed your medicine know that you have helped us. We won't tell them what you've said, but by letting them know it means that you can ask them questions in the future and they will know that you've taken part.

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Who can I contact if I have questions about MAP-BRONJ?

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Once we have collected all of the information from the people who take part, we will want to let others know what we have found. This might be through writing articles for journals, magazines or newspapers. We also might tell people about it at conferences. We hope that by telling others what we've found out, we can give better support to people like you and prevent this side-effect from happening. Don't worry though, if we use some of your words

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we will use a code or a different name, so nobody will be know these words are yours. You will be asked if you wish to receive a copy of the final study report during the interview, the report can be emailed or posted to the contact details that you provide. It is anticipated this should be available within 6 months of the end of the study.

Who is doing MAP-BRONJ?

The research is being done by a research team at the University of Sunderland. The Chief Investigator for the project is Andrew Sturrock. His title is 'Senior Lecturer' and he is based in the Department of Pharmacy, Health and Wellbeing.

Who is paying for MAP-BRONJ?

The study is being supported by the UK Clinical Pharmacy Association and Pharmacy Research UK who have given us some money to carry out the study.

Have other patients and the public helped with MAP-BRONJ?

A patient representative from the University of Sunderland patient involvement group was involved in the initial design of this study.

Has anyone checked that MAP-BRONJ is okay to do?

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If you're concerned and want to talk to someone independent of the MAP-BRONJ team, you can contact the Chair of the University of Sunderland Research Ethics Committee, Dr Etta Evans, on etta.evans@sunderland.ac.uk or 0191 5152624.

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Once we have your form, someone from the MAP-BRONJ team will get in touch with you and let you know if we do need your help or not. If we do they will arrange the best time and place for you to meet and talk to us.

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MAP-BRONJ Information Sheet for Patients with a diagnosis of BRONJ

The multidisciplinary approach to the prevention of bisphosphonate related osteonecrosis of the jaw (BRONJ). A Qualitative study into the attitudes and perceptions of patients (MAP-BRONJ) – IRAS 216783

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A group of drugs called bisphosphonates are used to treat a number of conditions that affect bones, such as osteoporosis and certain cancers. Because we are living longer, more patients are being prescribed these drugs than ever before and a rare but important side effect, called osteonecrosis of the jaw, has been discovered.

This side effect causes problems with patient's jawbones, particularly if patients require a dental extraction. This condition can be difficult to treat and because of this healthcare professionals should try to prevent it from happening in the first place. In this study we are looking to find ways in which we can minimise this risk and how healthcare professionals can work better as a team to prevent it from occurring.

Why have I been invited to take part?

You have been asked to take part in this study as you have previously been diagnosed with osteonecrosis of the jaw. By speaking to patients like yourself, we can get a better understanding of the impact that this has had on you and how we can prevent it from happening to any other patients.

What would I have to do?

We would like your help with this study by asking you to talk to one of our team members for about an hour. We will audio record this conversation so that it is easier for us to make notes later about what was said. The interview can take place at your GP surgery, or we can come to your home to talk to you.

Will I be able to get my money back if I have to travel to take part?

Yes. We don't want taking part in the study to cost you anything. This means that we will give you the money for any bus fares or other travel costs which you have to pay to take part.

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MAP-BRONJ Information Sheet for Patients with a diagnosis of BRONJ

the end of the study.

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Who is paying for MAP-BRONJ?

The study is being supported by the UK Clinical Pharmacy Association and Pharmacy Research UK who have given us some money to carry out the study.

Have other patients and the public helped with MAP-BRONJ?

A patient representative from the University of Sunderland patient involvement group was involved in the initial design of this study.

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MAP-BRONJ Information Sheet for patients with osteoporosis

The multidisciplinary approach to the prevention of bisphosphonate related osteonecrosis of the jaw (BRONJ). A Qualitative study into the attitudes and perceptions of patients (MAP-BRONJ) IRAS 216783

Why is MAP-BRONJ being carried out?

A group of drugs called bisphosphonates are used to treat a number of conditions that affect bones, such as osteoporosis and certain cancers. Because we are living longer, more patients are being prescribed these drugs than ever before and a rare but important side effect, called osteonecrosis of the jaw, has been discovered.

This side effect causes problems with patient's jawbones, particularly if patients require a dental extraction. This condition can be difficult to treat and because of this healthcare professionals should try to prevent it from happening in the first place. In this study we are looking to find ways in which we can minimise this risk and how healthcare professionals can work better as a team to prevent it from occurring.

Why have I been invited to take part?

You have been asked to take part in this study as you have already been diagnosed with a condition that can affect your bones called osteoporosis. In some patients with this condition your doctor may prescribe you a medicine called a bisphosphonate in the future. This medicine can in some rare cases affect your jawbones and we would like to speak to you to get a better understanding of how healthcare professionals can work as a team to prevent anyone from getting it.

What would I have to do?

We would like your help with this study by asking you to talk to one of our team members for about an hour. We will audio record this conversation so that it is easier for us to make notes later about what was said. The interview can take place at your GP surgery, or we can come to your home to talk to you.

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Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:
Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

No. Item	Guide questions/description	Reported on Page #	Details
Domain 1: Research team and reflexivity			
Personal Characteristics			
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	22	Andrew Sturrock (AS)
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	1	AS has an MSc in Clinical Pharmacy
3. Occupation	What was their occupation at the time of the study?	1	Principal Lecturer – Master of Pharmacy Programme Leader
4. Gender	Was the researcher male or female?	1	Male
5. Experience and training	What experience or training did the researcher have?	1 + 22	AS received training in qualitative research skills by the research team and through attendance at a Qualitative Research Methods in Health Course at University College London..
Relationship with participants			
6. Relationship established	Was a relationship established prior to study commencement?	9	Invitation letter and participant information sheets were posted out prior to the study.
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Supplementary document 5-7	A participant information sheet was provided to all participants.
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	1+22	AS is a pharmacist. Interest in the research topic was developed due to teaching commitments on the MPharm programme at the University of Sunderland. The multidisciplinary team was assembled to reduce bias in the research process.
Domain 2: study design			
Theoretical framework			
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography,	9	A Grounded Theory approach, with constant comparison.

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	phenomenology, content analysis		
Participant selection			
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	9	A purposive and convenience sampling method were adopted
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	9	An invitation letter and information sheets was posted (Supplementary Documents 2-7)
12. Sample size	How many participants were in the study?	11	23 participants
13. Non-participation	How many people refused to participate or dropped out? Reasons?	9	No participants who responded to the invitation refused to participate or dropped out of the study.
Setting			
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	11	Data were collected at a time and place convenient to the interviewee; this was at their home, GP practice or dental clinic
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	9	Interviews were held on a one-to-one basis.
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	11	As displayed in table 1
Data collection			
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	9	Interview guide was developed and refined by the research team. Included as (Supplementary Document 1)
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	9	No repeat interviews were performed
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	9	Audio recording
20. Field notes	Were field notes made during and/or after the inter view or focus group?	9	No field notes were taken due to the verbatim transcribing
21. Duration	What was the duration of the interviews or focus group?	11	Up to 1 hour
22. Data saturation	Was data saturation discussed?	10	Data were analysed by AS, with transcripts and emerging themes cross-checked for interpretation and agreed amongst the research team. Constant comparison was utilised as a means of enriching the data through iterative data

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			collection and analysis
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	9	No
Domain 3: analysis and findings			
Data analysis			
24. Number of data coders	How many data coders coded the data?	22	AS identified the thematic framework and interpreted the data
25. Description of the coding tree	Did authors provide a description of the coding tree?	N/A	A description of the coding tree is not provided.
26. Derivation of themes	Were themes identified in advance or derived from the data?	10	Themes were derived from the data
27. Software	What software, if applicable, was used to manage the data?	N/A	
28. Participant checking	Did participants provide feedback on the findings?	9	No
Reporting			
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	12-16	Quotation are presented with clearly identifiable participant numbers
30. Data and findings consistent	Was there consistency between the data presented and the findings?	12-16	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	12-16	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	12-16	Yes

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BMJ Open

Patient Perceptions of and Attitudes towards Medication-Related Osteonecrosis of the Jaw (MRONJ). A qualitative study in England.

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Patient Perceptions of, and Attitudes towards, Medication-Related Osteonecrosis of the Jaw (MRONJ). A qualitative study in England.

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ABSTRACT

Objective: To explore the impact of medication-related osteonecrosis of the jaw (MRONJ) on quality of life and to explore the attitudes and perceptions of patients towards the multidisciplinary approach to the prevention of the condition.

Design: Interpretivist methodology using qualitative semi-structured interviews.

Setting: Primary care general medical practices and secondary care dental services in England.

Participants: 23 patients; 6 with MRONJ, 13 prescribed bisphosphonates, 4 with osteoporosis not currently prescribed any medication.

Results: Patients felt that MRONJ had a significant negative impact on their quality of life, and had poor knowledge of the preventive strategies recommended in the literature. Patients demonstrated positive attitudes towards a multidisciplinary approach to care; however, they perceived prescribers as having the key role in articulating risk. Four salient and inter-related themes emerged from the interviews: (1) perception of knowledge, indicating limited awareness of the condition, risk factors and preventive strategies; (2) quality of life, indicating the lived experiences of patients and the physical, psychological and social impact of MRONJ; (3) inter-professional management, indicating a perceived organisational hierarchy, professional roles and responsibilities, prioritising aspects of care, articulation of risk and communication; (4) wider context, indicating demands on NHS resources, and barriers to dental care.

Conclusions: MRONJ has a significant detrimental impact on quality of life, yet appropriate preventative education is not apparent. Effective inter-professional patient education and prevention to mitigate against the risk of developing MRONJ is required.

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Strengths and limitations of this study

- Although MRONJ is not a common finding, affected patients experience significant morbidity, and management of this condition warrants further study to improve patient care.
- There is limited research into the impact of MRONJ on patients; this is the first qualitative study that has explored the perceptions and consequent attitudes of patients and the resultant impact of the condition on quality of life.
- A qualitative method yielded rich data through in-depth semi-structured interviews with three groups of patients (patients with a diagnosis of MRONJ, patients prescribed bisphosphonates and patients with a diagnosis of osteoporosis who are not currently prescribed medication). Constant comparison with concurrent data collection and analysis allowed further exploration and refining of emergent themes.
- The study was based around an *a priori* assumption of limited knowledge among patients in relation to MRONJ; patients were provided a patient information leaflet in advance, therefore exposing participants to the concepts before the interview.

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Introduction:

Medication-related osteonecrosis of the jaw (MRONJ) is defined as exposed bone, or bone that can be probed through an intraoral or extraoral fistula, in the maxillofacial region that has persisted for more than eight weeks in patients with a history of treatment with anti-resorptive or anti-angiogenic drugs, and where there has been no history of radiation therapy to the jaw or no obvious metastatic disease to the jaws.(1) The risks for MRONJ are hypothesised to be related to the unique nature of the blood supply and the anatomical structure, and function of the jaw bones.(2-6)

A number of drugs that are indicated for use in osteoporosis, Paget's disease or the treatment of cancer have been associated with MRONJ. These include both oral and intravenous bisphosphonates such as alendronic acid or zoledronate, receptor activator of nuclear factor kappa-beta ligand (RANKL) inhibitors such as denosumab, and anti-angiogenic drugs such as bevacizumab, sunitinib and aflibercept.(7) In practice, the most commonly prescribed agents are oral bisphosphonates for the management of osteoporosis.

The major risk factor for the development of MRONJ is a dental extraction in a patient exposed to implicated medicines,(8) however duration of therapy with anti-resorptive drugs exceeding 4 years and concomitant administration of corticosteroids are also associated with an increased risk.(1) Exact incidence and prevalence rates of MRONJ are unclear, with varying reports in the literature.(4-6) The estimated incidence of MRONJ in cancer patients treated with anti-resorptive or anti-angiogenic drugs is 1% and in osteoporosis patients treated with anti-resorptive drugs is 0.01-0.1%.(7)

A systematic review of the diagnosis and management of osteonecrosis of the jaw identified the elimination or stabilisation of oral disease before initiating anti-resorptive agents as a preventative strategy for MRONJ.(9) Several prospective studies have identified that dental screening and preventive strategies reduce the risk of osteonecrosis of the jaw.(10-11) Before commencement of drugs associated with MRONJ, or as soon as possible thereafter, patients should be supported in becoming as dentally healthy as possible. This aim is to prioritise care that will reduce mucosal trauma and/or act prophylactically to help avoid subsequent dental extractions or conditions, which may further predispose the patient to surgical or dental procedures that further impact on the osseous structures of the jaw.(7)

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Clinical guidelines published by the Scottish Dental Clinical Effectiveness Programme (SDCEP) recommend that high risk oncology patients should undergo a thorough dental assessment, with necessary dental treatment prior to the initiation of drug therapy.(7) Guidance for prescribers and pharmacists also recommends that patients (and/or their carers) are advised that there is a risk of MRONJ, but should ensure that they understand that the risk is small. Patients should be advised to make an appointment with their dentist to ensure they are dentally fit and inform their dentist that they will be taking the prescribed medication.(7)

A multidisciplinary approach to the prevention of MRONJ is recommended in the literature; incorporating both patient and health professional education on the risk of the development of MRONJ, appropriate preventive measures and oral health instruction.(7,12-16) Our recent qualitative study of general medical practitioners (GMPs) and pharmacists in North East England found that both professional groups had limited knowledge and awareness of MRONJ and due to the complex medical histories of patients, practitioners often overlooked the advice related to the risk and prevention of MRONJ. (17)

The aim of this study was to explore the impact of osteonecrosis of the jaw on patients, and to explore the attitudes and perceptions of these patients towards the multidisciplinary approach to the prevention of MRONJ. Whilst several drugs are thought to contribute to the aetiology of MRONJ, this study focused specifically on the association between bisphosphonates and osteonecrosis of the jaw and the multidisciplinary approach to the prevention of this rare, yet serious, adverse effect.

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Aims

1. To explore the perceived impact of MRONJ on patients with a diagnosis of the condition
2. To explore the attitudes and perceptions of patients towards the roles of the pharmacist, GMP and dentist in the prevention of MRONJ
3. To explore the barriers and enablers to optimise risk prevention of MRONJ

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METHOD

Design:

A Grounded Theory approach was used throughout this research.(18) Constant comparison was utilised as a means of enriching the data through iterative data collection and analysis; the emergence of themes during the process provided the opportunity for further exploration during subsequent data collection.(19)

An initial topic guide (Supplementary Document 1) was developed by the principal investigator based on the published literature and the findings of our previous qualitative study.(17). The topic guide was reviewed and refined by the multidisciplinary research team and served as a benchmark for semi-structured one-to-one interviews carried out at the participant's home, general medical practice or dental clinic. The interviews were audio recorded and transcribed verbatim to aid qualitative analysis.

Participants:

Participants were recruited with the assistance of three National Institute for Health Research Clinical Research Networks (NIHR CRNs); North East and North Cumbria, Yorkshire and Humber, and North Thames. Three distinct groups were recruited to the study, [1] patients prescribed bisphosphonates, [2] patients with a diagnosis of osteoporosis not currently undergoing drug treatment, [3] patients with a diagnosis of MRONJ. An invitation letter (Supplementary Documents 2-4) and participant information sheet (Supplementary Documents 5-7) were posted to patients in group 1 and 2 by their GMP and a convenience sample of participants who responded to the invitation was implemented. Participants were assigned a participant number to ensure anonymity.

Patients in group 3 (diagnosis of MRONJ) were recruited through the Oral and Dental Speciality Group of the NIHR CRNs; two secondary care dental hospitals recruited participants by posting invitation letters and participant information sheets to eligible patients.

Analysis:

Constant comparison allowed for enrichment of data and for new concepts to be explored through subsequent interviews; Ritchie and Spencer's Framework Analysis (2002),(20)

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allowed salient themes to be identified from the data. Framework analysis involved a five-stage process: familiarisation with the data; development of a thematic framework; indexing data; charting of the data and mapping of the data. Themes were reviewed until definitive concepts could be produced from the data.

Ethical review:

Ethical approval was obtained from the NHS North East – York Research Ethics Committee (REF: 17/NE/0033)

Patient Involvement:

The principal investigator met with a patient representative from the University of Sunderland Patient, Carer and Public Involvement Group to discuss the design and ethical implications of the study. This included the co-constructed design of the patient information sheet, ensuring informed consent and finally information regarding the opportunity to access further advice or support following their participation in the study.

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RESULTS

23 patients were recruited to this study (Table 1). In-depth semi-structured interviews were carried out between May 2017 and March 2018 until no new themes emerged and current ones were exhausted. Interviews took place in patient's homes, at their general medical practice or at their secondary care dental clinic; 1 hour was designated for each interview.

Table 1. Participant Characteristics

Participant	Identifier	Diagnosis	Age range	Gender
1	MRONJ-1	Osteonecrosis due to bisphosphonate	50-59	Female
2	MRONJ-2	Osteonecrosis due to bisphosphonate	60-69	Male
3	MRONJ-3	Osteonecrosis due to bisphosphonate	50-59	Female
4	MRONJ-4	Osteonecrosis due to bisphosphonate	70-79	Female
5	MRONJ-5	Osteonecrosis due to bisphosphonate	60-69	Female
6	MRONJ-6	Osteonecrosis due to bisphosphonate	70-79	Female
7	B-1	Osteoporosis - prescribed bisphosphonate	60-69	Female
8	B-2	Osteoporosis - prescribed bisphosphonate	60-69	Male
9	B-3	Osteoporosis - prescribed bisphosphonate	60-69	Male
10	B-4	Osteoporosis - prescribed bisphosphonate	60-69	Female
11	B-5	Osteoporosis - prescribed bisphosphonate	60-69	Female
12	B-6	Osteoporosis - prescribed bisphosphonate	60-69	Female
13	B-7	Osteoporosis - prescribed bisphosphonate	60-69	Female
14	B-8	Osteoporosis - prescribed bisphosphonate	60-69	Male
15	B-9	Osteoporosis - prescribed bisphosphonate	50-59	Female
16	B-10	Osteoporosis - prescribed bisphosphonate	60-69	Female
17	B-11	Osteoporosis - prescribed bisphosphonate	70-79	Female
18	B-12	Osteoporosis - prescribed bisphosphonate	70-79	Female
19	B-13	Osteoporosis - prescribed bisphosphonate	70-79	Female
20	O-1	Osteoporosis - not prescribed bisphosphonate	60-69	Female
21	O-2	Osteoporosis - not prescribed bisphosphonate	70-79	Female
22	O-3	Osteoporosis - not prescribed bisphosphonate	70-79	Female
23	O-4	Osteoporosis - not prescribed bisphosphonate	80-89	Female

Four salient inter-related themes emerged from the data: (1) perceptions of knowledge; (2) quality of life; (3) interprofessional management; (4) wider context.

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1. Perceptions of knowledge

The concept of MRONJ was introduced in the participant information sheet and opened up for further discussion during the interview; participants without a diagnosis of MRONJ had minimal awareness of the associated risk.

> They didn't explain about- anything about any side-effects or anything about trouble with your teeth. (B-6)

Those patients with a diagnosis of MRONJ were aware of the condition and how this was related to their prescribed medication. All patients with MRONJ stated that they were unaware of this risk prior to commencing treatment with the bisphosphonate.

> I was given no information about that…Doctors don't tell you about the side-effects of drugs. (MRONJ-6)

Most patients reported that information relating to the risk and preventive strategies for MRONJ complications had not been discussed with the prescriber or pharmacist on initiation. Where patients had awareness of these issues, the information was typically gained from the patient information leaflet supplied with their medication.

> Well, I usually read the little leaflet for any, you know, side-effects that they might have. (B-8)

It was clear from the discussions that the patients prescribed a bisphosphonate were uncertain about required duration of therapy; many patients had been prescribed the drugs for a number of years but were unclear on whether therapy should be continued indefinitely or for a set period of time.

> I reckon I've been taking it more than five years now. And it should- I've got a feeling it should've been reviewed after five years. (B-8)

Patients felt that although the internet can provide access to information, due to age, many people in this patient group have limited knowledge of, or access to, web-based information.

> You know, it's only since the internet that people able to look up on the actual – I mean, I- I'm not – I do use the internet, but not often or very well- I'm not on it every day cos I don't have it where I live. (MRONJ-6)

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2. Quality of life

Most of the patients interviewed had a complex medical history. The age of participants and the presence of co-morbidities meant that osteoporosis was typically one of a number of ongoing medical conditions for which they were undergoing treatment; as a result, most patients were prescribed a number of medications.

> At one time, when I first came to hospital, I was on twenty- about twenty tablets a day, you know, which is too much. (B-2)

Participants with a diagnosis of MRONJ highlighted the impact that the condition has had on their quality of life. Participants described experiencing a significant amount of pain with the condition, requiring the frequent use of analgesic medication.

> The big problem is all my lips are tender. When I touch them, it- it's just as though – I've never been hit in face, but- but I can imagine somebody hitting you in the face. I can imagine it feeling like that. And- and the tenderness, it never goes. It's always there. I touch it and I feel as though I don't want to touch it. (MRONJ-2)

Participants identified challenges in relation to eating and drinking, and the associated social anxiety of eating awkwardly in public.

> Psychological and mental, yeah. If you're going out to a restaurant, then you have to be very careful. You don't want people to see that you are eating awkwardly. (MRONJ-5)

The psychological implications of a diagnosis of MRONJ were highlighted by participants; these were seen to take less of a priority for healthcare professionals but have a significant impact on the quality of patients' lives.

> This is difficult, but mentally, it gives you some kind of anxiety because you- you- you know your bone is there- a little piece of bone on your left-hand side is there (MRONJ 5)

All participants with a diagnosis of MRONJ were required to attend secondary care dental hospitals, where their condition was managed and regularly reviewed. In some cases, patients had to travel a considerable distance for treatment and were required to attend frequent appointments in secondary care.

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> I mean, I go every month at the moment, it's quite an- a big impact, I guess, in terms of appointments. Well, they- they have a look, see if it's got any worse, and then record it. They often have to send me for more x-rays. (MRONJ-2)

Participants with a diagnosis of MRONJ expressed concerns regarding the potential complications of the disease, the need for antibiotic treatment and for surgical intervention.

> I have had to have lots of antibiotics, it seems to keep getting infected. Hopefully they will keep working, but one time, they had to give me some extra strong antibiotics because the normal antibiotics didn't work (MRONJ-2)

> You think, maybe perhaps in the future, you need to have an operation. It's a big operation. (MRONJ-5).

3. Interprofessional management

It became clear from the interviews that participants perceived there to be a clear organisational hierarchy in terms of the management of their condition. Participants felt that it was the responsibility of the prescribing clinician to provide information relating to the adverse effects of medication.

> I think – and you needed that information, I think it should be the doctors telling you when- when he prescribes it, to say to- 'as a precaution, you should go to your dentist. (O-3)

Most participants placed trust in the professionals managing their care and perceived that prescribers would have already utilised professional judgement in relation to the possible risks and benefits of medication.

> I'm sure the doctor will use his own discretion, you know. That it is safe and appropriate. (B-2)

However, many participants identified that the risks and benefits of medication are not well articulated to patients, making it difficult to make informed decisions around their care.

> I think they should be able to provide the risks and the benefit and discuss with the patient what's probably be-best with them. I don't think this is done very well. (MRONJ-6)

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Due to the complexity of patient's medical profiles and the associated polypharmacy, it was identified that information is typically prioritised and that health care professionals only have limited time to provide information.

> They haven't got the time to go through everything with you. [chuckles] I think they have to pick out the key things. (B-1*)*

Participants perceived pharmacists to have an important role in the reinforcement of advice given by prescribers and were receptive to receiving information from pharmacists relating to the administration and potential adverse effects of medication.

> Quite often, you know, you talk to your GP and you go away and you just forget- you forget something that they've said. So, having it reinforced a couple of times I think's a good idea. (B-8)

Pharmacists were seen as having specialised knowledge in relation to the adverse effects of medicines; a number of patients had experienced a formal medication review by their pharmacist and appreciated the opportunity to discuss their medication and adverse effects.

> I feel as though the pharmacist that I go to, I could ask her anything and she would tell us. I have had a review with her, she's very, very helpful and knowledgeable about medication. (B-5)

Participants reported that dental practitioners routinely ask about changes to prescribed medicines during check-up and treatment appointments. Some participants identified that their dentist specifically ask about their prescribed bisphosphonate, but the interest in these drugs had not been explained to the participants.

> You've got to fill a- a form in every time with your medicines on. And funnily enough, alendronic acid is the one that I often forget and miss off. And they have asked us "are you still taking that?" (B-1)

Participants discussed the need for good communication between the professional groups to support the prevention of MRONJ. Participants were all happy for information to be shared between the professions and expected information regarding their treatment to be communicated effectively.

> If the doctor has recommended me to go, I would think there should be at least some liaison with the dentist and the doctors and that was on your medical records to say you're getting that check done. (O-3)

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Participants also described the importance of taking responsibility for their own actions. If provided with information or management advice they perceived they ought to have ensured that this was acted on. Participants did stress that in order to take personal responsibility, they needed to be appropriately informed by the healthcare professional (s).

> It's your own responsibility. If you've been told about something properly, you know, it's then your responsibility too. You've got to look after yourself, you know. (B-2)

4. Wider context

Participants identified that there is an increasing demand on NHS resources and perceived that all healthcare professionals have a heavy workload. As such, they felt that the implementation of preventive strategies could potentially place more demands on staff time and the already limited appointment schedules.

> Doctors are so over-stretched and – and – you only have a short time for the appointment to get the information. Sometimes you still wait forever to even get an appointment. (MRONJ-6)

Although most of the participants had a history of regular dental appointments, there was a strong feeling that many patients have a general reluctance to seek dental advice. Potential barriers such as a phobia of dental treatment, a perceived lack of awareness of oral health and the financial implications of dental treatment were all identified by participants.

> Terrified. Uh-huh. Always have been. (B-5)

> You have to pay for the examination and then obviously, depending on the amount of work that you need, that can be quite expensive. And not everybody has that money. (B-6)

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DISCUSSION

MRONJ is a serious condition that requires complex management, and current literature is indicative of the importance of preventive care interventions, due to the subsequent associated morbidity and challenges in treating osteonecrosis of the jaw(1). In this study, it was apparent that MRONJ has a significant effect on the quality of life experienced by patients who were interviewed. Previously, a study of 34 patients with MRONJ utilising the Oral Health Impact Profile (OHIP-14) questionnaire found that the condition significantly affects quality of life.(21) Whilst this provides tangible metrics regarding the significance of the condition for patients, it provides no specific information on what this means to people in their daily lives. The qualitative insight generated by our study has provided the first documented experiences of this particular patient group, highlighting the significant issues they face and the ongoing physical, psychological and social distress they associate with the condition.

As MRONJ can, in many cases, be prevented with appropriate oral health education and preventive care, the importance of such measures should be stressed to all healthcare professionals managing this particular patient group. It also leads us to consider how other allied health professionals may also incorporate the importance of this into their practice with patients and their carers and families. Masson (2009) identified that only 11.8% of GMPs and 9.7% of pharmacists advised patients to inform their dentist they were using a bisphosphonate.(22) Our previous qualitative study of GMPs and pharmacists in England also identified limited knowledge amongst these professional groups in relation to the risk and prevention of MRONJ.(17)

Patients from all three groups were generally unaware of the risks and preventive strategies, and the patients with MRONJ reported limited knowledge prior to diagnosis. A quantitative study (n=55) found that the majority of patients acquired knowledge about the drug they were prescribed from patient information leaflets (62%), with few patients (13%) receiving this information from their GMP. When asked to identify side effects of bisphosphonate therapy, only 32% of patients receiving IV, and 17% patients receiving oral, bisphosphonates were aware of the risk of developing osteonecrosis of the jaw.(23) When patients in our study possessed some knowledge, this typically came from the information leaflet supplied with medication or from the internet.

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Although published clinical guidelines recommend that patients should be referred for dental assessment and treatment prior to initiation of bisphosphonate therapy,(7) it is apparent this is not happening in practice. A lack of knowledge in relation to the risk and appropriate preventative strategies by prescribers is potentially exposing patients to a condition with significant quality of life implications and represents a key medication safety issue. An awareness of MRONJ amongst prescribers is key to ensuring that an appropriate risk assessment can be made relative to the prescribing of implicated medicines and the need for the effective education of patients on preventative strategies.

Patients prescribed bisphosphonates were confused about the intended duration of treatment with the drug; some patients were aware that the medication would only be prescribed for a set duration of time, whereas for others, this medication had already been prescribed for many years without any evident review.

Participants described a perceived organisational hierarchy in relation to the management of their health; they expected prescribers to utilise professional judgment on the suitability of the medication for them, and to provide information related to the adverse effects of medications. Many of the participants interviewed have complex medication histories, live with co-morbid conditions and as a consequence are simultaneously prescribed multiple medications. Participants therefore described the need for prescribers to prioritise information related to their clinical management and in-patient education in relation to their polypharmacy.

Participants perceived that the pharmacist has an important role in reinforcing advice and were positive in their regard of the pharmacist's role in providing information on medications and conducting medication reviews. Participants reported that their general dental practitioners were active in recording medication details and were also receptive to information being shared between medical and dental services. Key barriers in relation to the multidisciplinary prevention of MRONJ, such as heavy demands on NHS resources, attitudes towards oral health, a reluctance to attend dental appointments, and the financial issues associated with dental care, were all identified by participants.

This study has explored the attitudes and perception of patients prescribed bisphosphonates, focusing on those with a diagnosis of osteoporosis. The literature is clear that the incidence

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of osteonecrosis is greater in patients prescribed intravenous bisphosphonates for the treatment of cancer; further work exploring the management of this patient group and any variation in the attitudes towards risk and ongoing management would substantially add to this body of literature.

Patients have already demonstrated positive intentions to change oral health behaviours following pharmacy based oral health interventions;(24) further work to explore the role of the pharmacist in the interprofessional prevention of MRONJ should be considered. Patients in our study described the benefit of formal medication reviews with their pharmacist and a willingness to engage with pharmacy services to receive information related to the adverse effects of medication. The Medication Use Review (MUR) and New Medicine Services (NMS) are both Advanced Services within the NHS Community Pharmacy Contractual Framework in England. An MUR is a structured, adherence-centred polypharmacy review of patients prescribed multiple medicines and the NMS service provides support for patients with long-term conditions that have been newly prescribed a medicine. (25-26) However, the MUR and NMS service specification does not currently include bisphosphonates; the inclusion of this group of drugs could provide an opportunity for reinforcement of preventative advice during the initiation stages of treatment with bisphosphonates.

The perspective of dental practitioners on how the multidisciplinary team can collaborate to improve patient care, would be important to consider before implementing any preventative strategies. A recent publication in *British Dental Journal* emphasised the potential benefits of interprofessional working between pharmacy and dental professionals;(27) further work to develop such services could be of particular benefit to this patient group.

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Conclusion

MRONJ has a significant detrimental impact on patient quality of life; with significant physical, psychological and social implications. However, patients demonstrated limited knowledge of these risks and of the preventive strategies recommended for their avoidance, in the literature.

Patients perceive prescribers to be responsible for educating them on the risks associated with medications. The formal role of the pharmacist, however, can provide a significant opportunity to reinforce information and provide advice to patients regarding both newly prescribed medications and the evaluation of their other pre-existing pharmacological regimes, via formal medication reviews.

Increased focus on preventative dental care with the education of other healthcare professionals and patients on the importance of oral health and preventative strategies could potentially improve patient safety and prophylactically reduce the risk of the development of MRONJ in practice.

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Data Sharing: Participant information sheets and invitation letters are included (Supplementary Files 2-7); no further data shared.

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Competing interests: None

Ethics approval: Ethical approval was obtained from the NHS North East – York Research Ethics Committee (REF: 17/NE/0033)

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The multidisciplinary approach to the prevention of bisphosphonate related osteonecrosis of the jaw (BRONJ). A Qualitative study into the attitudes and perceptions of patients (MAP-BRONJ)

Topic Guide

This study aims to explore the attitudes and perceptions of patients towards the multidisciplinary prevention of bisphosphonate related osteonecrosis of the jaw.

The following guide outlines the key areas for exploration during the interview.

Aims and objectives
To explore the attitudes and perceptions of patients towards the roles of the pharmacist, general practitioner and dentist in the prevention of Bisphosphonate Related Osteonecrosis of the Jaw (BRONJ).

To explore the barriers or enablers to optimising the risk prevention of BRONJ

To explore the attitudes and perceptions of patients about their broader priorities during counselling on medication

Introduction
Aim: To introduce the research and set the context for the proceeding discussion

- Introduce self: University of Sunderland, MAP-BRONJ study, why I am here
- Introduce the study: what it is about, who it is funded by
- Talk through key points
  - This will be a conversation where I will ask you questions
  - It will last between 30 and 60 minutes
  - There are no right or wrong answers
  - You don't have to answer all of the questions if you don't want to, just let me know that you want to move on
  - Participation is voluntary and participant can withdraw at any time
- Confidentiality/ anonymity
  - Transcripts will be anonymised
  - In report writing, any quotes won't be identified as being you
- The interview will be audio recorded
  - The recording will be kept secure, only accessed by the four researchers working on the project, and will be kept for 10 years as per policy
- I've brought the voucher for participation with me, so I'll give that to you after the interview
- This piece of paper is just to help me remember what questions I want to ask you, and I may make some brief notes during the interview to remind me to go back to something you said later on if that's ok
- Does the participant have any questions?

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All Participants

Background of participant
Prompts: age, employment, PMx, DHx, dental history, regular pharmacy, regular GP

When you have been started on a new medicine, what do you want to know
Prompts: priorities, side-effects, risks, indications, benefit, decision making process

The role of the GP when starting new medicines
Prompts: experiences, role, expectations

The role of the pharmacist when starting new medicines
Prompts: experiences, role, expectations, MUR/NMS

Osteonecrosis of the jaw has been associated with bisphosphonate therapy. It can be difficult to treat and in many cases potentially preventable, the most recent guidelines recommend that healthcare professionals should work together to do this. Ideally patients should be dentally fit before starting these medicines and should have any dental work carried out before starting treatment and maintain good dental health while taking these drugs.

All Participants

The role of the GP in this team
Prompts: role, responsibilities, expectations

The role of the pharmacist in this team
Prompts: role, responsibilities, expectations, MUR/NMS

The role of the dentist in this team
Prompts: experiences with dentists, role of the dentist, expectations

The role of the patient in this team
Prompts: roles and responsibilities, expectations

The role of the multidisciplinary team
Prompts: expectations, leadership, communication

Any barriers or facilitators to this from happening
Prompts: access to dentists, charges, fear, communication

Would this influence (or have influenced) your decision to take this medicine
Prompts: why, risk of not taking, balance risk

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Patients with osteoporosis only

Tell me about your experiences of osteoporosis
Prompts: *symptoms, diagnosis, management*

Are you aware of the drugs that can be used to help patients with osteoporosis
Prompts: *Who told you, offered drugs?*

Patients prescribed bisphosphonates only

Tell me about your experiences of taking bisphosphonates
Prompts: *indication, history, administration, side-effects, efficacy*

Were you aware that this condition was a potential side-effect of one of your medicines
Prompts: *was this risk explained to you, who by, when*

Did you have a dental check-up prior to treatment
Prompts: *Was work carried out, advice given, was the dentist aware of the risk*

Do you maintain regular dental check-ups
Prompts: *Frequency, does the dentist know you're on a bisphosphonate,*

Patients with a diagnosis of BRONJ only

Tell me about your experiences of taking bisphosphonates
Prompts: *indication, history, administration, side-effects, efficacy*

Tell me about your diagnosis of osteonecrosis of the jaw
Prompts: *presentation, diagnosis, management, current management*

Tell me about how osteonecrosis of the jaw has affected your life
Prompts: *impact on daily activities, pain, discomfort, ongoing management, psychological impact*

Were you aware that this condition was a potential side-effect of one of your medicines
Prompts: *was this risk explained to you, who by*

Should you have been aware of this risk with this medicine
Prompts: *should you have been, would you still have taken this medicine, how/who should make you aware of this*

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Next steps

- Thank the participant
- Do they have any remaining questions about the research
- Reassurance around confidentiality and anonymity
- Would they like their GP to be informed about their participation in the interview
- Provide with gift voucher
- If not, would they like to be informed about the outcomes of the research, and if so method for doing this

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DATE

TITLE FIRST SURNAME
ADDRESS LINE 1
ADDRESS LINE 2
POST CODE

Dear [TITLE] [FIRST NAME] [LAST NAME],

I WOULD LIKE TO ASK FOR YOUR HELP

Academics who are doing research at the University of Sunderland and Newcastle University have asked for my help to find patients to take part in a study. One of the medicines you take is what is called a bisphosphonate and they would really like to talk to you about it.

The research study being carried out is called MAP-BRONJ. This stands for 'The multidisciplinary approach to the prevention of bisphosphonate related osteonecrosis of the jaw. A qualitative study into the attitudes and perceptions of patients'.

Lots of people take bisphosphonates for a number of reasons, such as to help strengthen your bones. These medicines have been associated with a very rare side effect that can affect jawbones; however this condition is usually preventable with the right advice.

We would like to speak to patients to get a better understanding of how you think healthcare professionals should be working together to prevent side-effects such as this.

If you didn't know that one of your medicines could cause this side-effect and are worried, then please make an appointment with your usual doctor and they can give you the correct advice.

If you would like to take part in this study or want to know more about it, please read the information sheet which comes with this letter.

Kind regards,

[GP/Pharmacist]

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I would like find out more about the **MAP-BRONJ** and I am happy for a member of the research team to contact me

Contact details *(Please enter your contact details below)*

Title: Mr/Mrs/Ms/Miss (*please delete as appropriate*)

Name: ____

Telephone contact number: ____

A convenient time to call is: Between ____________ and ________________

Please return this slip in the envelope provided. A member of research team will contact you on the contact number provided above.

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Invitation letter for interviews – patients with BRONJ

DATE

TITLE FIRST SURNAME
ADDRESS LINE 1
ADDRESS LINE 2
POST CODE

Dear [TITLE] [FIRST NAME] [LAST NAME],

I WOULD LIKE TO ASK FOR YOUR HELP

Academics who are doing research at the University of Sunderland and Newcastle University have asked for my help to find patients to take part in a study. You have previously been diagnosed with a condition called osteonecrosis of the jaw and they would really like to talk to you about it.

The research study being carried out is called MAP-BRONJ. This stands for 'The multidisciplinary approach to the prevention of bisphosphonate related osteonecrosis of the jaw. A qualitative study into the attitudes and perceptions of patient'.

Osteonecrosis of the jaw is a rare side effect of a medicine called a bisphosphonate. We would like to speak to patients who have this condition to get a better understanding of how this has impacted on your life and to get your thoughts on how healthcare professionals can work together to prevent other patients from having this same problem.

If you have any worries about your condition then please make an appointment with your usual doctor and they can give you the correct advice.

If you would like to take part in this study or want to know more about it, please read the information sheet which comes with this letter.

Kind regards,

[Dentist/GP]

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Invitation letter for interviews – patients with BRONJ

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I would like find out more about the **MAP-BRONJ** and I am happy for a member of the research team to contact me

Contact details *(Please enter your contact details below)*

Title: Mr/Mrs/Ms/Miss (*please delete as appropriate*)

Name: ______________________________

Telephone contact number: ______________________________

A convenient time to call is: Between ___________ and ______________

Please return this slip in the envelope provided. A member of research team will contact you on the contact number provided above.

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Invitation letter for interviews – patients with osteoporosis

DATE

TITLE FIRST SURNAME
ADDRESS LINE 1
ADDRESS LINE 2
POST CODE

Dear [TITLE] [FIRST NAME] [LAST NAME],

I WOULD LIKE TO ASK FOR YOUR HELP

Academics who are doing research at the University of Sunderland and Newcastle University have asked for my help to find patients to take part in a study. You have previously been diagnosed with a condition called osteoporosis that affects your bones and they would really like to talk to you about it.

The research study being carried out is called MAP-BRONJ. This stands for 'The multidisciplinary approach to the prevention of bisphosphonate related osteonecrosis of the jaw. A qualitative study into the attitudes and perceptions of patients'.

Lots of people have osteoporosis and sometime they need to take a medicine called a bisphosphonate to help strengthen your bones. You don't currently take one of these medicines, but sometimes if your osteoporosis gets worse then doctors might prescribe it for you. These medicines have been associated with a very rare side effect that can affect jawbones; however this condition is usually preventable with the right advice.

We would like to speak to patients to get a better understanding of how you think healthcare professionals should be working together to prevent side-effects such as this.

If you have any worries about your condition, then please make an appointment with your usual doctor and they can give you the correct advice.

If you would like to take part in this study or want to know more about it, please read the information sheet which comes with this letter.

Kind regards,

[GP/Pharmacist]

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Invitation letter for interviews – patients with osteoporosis

I would like find out more about the **MAP-BRONJ** and I am happy for a member of the research team to contact me

Contact details *(Please enter your contact details below)*

Title: Mr/Mrs/Ms/Miss (*please delete as appropriate*)

Name: ______________________________

Telephone contact number: ______________________________

A convenient time to call is: Between __________ and ____________

Please return this slip in the envelope provided. A member of research team will contact you on the contact number provided above.

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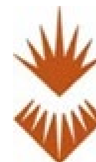
University of Sunderland

MAP-BRONJ Information Sheet for patients prescribed bisphosphonates

The multidisciplinary approach to the prevention of bisphosphonate related osteonecrosis of the jaw (BRONJ). A Qualitative study into the attitudes and perceptions of patients (MAP-BRONJ) – IRAS 216783

Why is MAP-BRONJ being carried out?

A group of drugs called bisphosphonates are used to treat a number of conditions that affect bones, such as osteoporosis and certain cancers. Because we are living longer, more patients are being prescribed these drugs than ever before and a rare but important side effect, called osteonecrosis of the jaw, has been discovered.

This side effect causes problems with patient's jawbones, particularly if patients require a dental extraction. This condition can be difficult to treat and because of this healthcare professionals should try to prevent it from happening in the first place. In this study we are looking to find ways in which we can minimise this risk and how healthcare professionals can work better as a team to prevent it from occurring.

Why have I been invited to take part?

You have been asked to take part in this study as one of the medicines you take is associated with this rare side effect. Even though the condition we are studying is rare, we would like to talk to patients who are taking these drugs about how healthcare professionals can work as a team to prevent anyone from getting it.

If you would like more information about this side-effect, the study team can provide you with a leaflet on the condition and you can speak to your GP.

What would I have to do?

We would like your help with this study by asking you to talk to one of our team members for about an hour. We will audio record this conversation so that it is easier for us to make notes later about what was said. The interview can take place at your GP surgery, or we can come to your home to talk to you.

Will I be able to get my money back if I have to travel to take part?

Yes. We don't want taking part in the study to cost you anything. This means that we will give you the money for any bus fares or other travel costs which you have to pay to take part.

Will I get paid for taking part?

No. But we will be giving everyone who takes part a £10 gift voucher as a 'thank you' for taking part in our project.

What is the study for?

The information that we get from MAP-BRONJ will help us to know more about the expectations of patients and how healthcare professionals can work together. Potentially this

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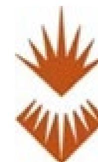

University of Sunderland

MAP-BRONJ Information Sheet for patients prescribed bisphosphonates

could help the NHS and patients who use these medicines in the future.

Are there any risks to me from taking part?

We don't think there will be any risks to you from taking part in the study. It won't make any difference to the medicines or treatment that you are getting. If you require any further information about this side-effect or your treatment you should make an appointment to speak to your GP.

How will my information be kept confidential?

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If you have any questions about your medicines, you should contact your doctor.

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Once we have collected all of the information from the people who take part, we will want to let others know what we have found. This might be through writing articles for journals, magazines or newspapers. We also might tell people about it at conferences. We hope that by telling others what we've found out, we can give better support to people like you and prevent this side-effect from happening. Don't worry though, if we use some of your words

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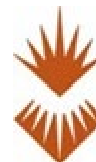

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MAP-BRONJ Information Sheet for patients prescribed bisphosphonates

we will use a code or a different name, so nobody will be know these words are yours. You will be asked if you wish to receive a copy of the final study report during the interview, the report can be emailed or posted to the contact details that you provide. It is anticipated this should be available within 6 months of the end of the study.

Who is doing MAP-BRONJ?

The research is being done by a research team at the University of Sunderland. The Chief Investigator for the project is Andrew Sturrock. His title is 'Senior Lecturer' and he is based in the Department of Pharmacy, Health and Wellbeing.

Who is paying for MAP-BRONJ?

The study is being supported by the UK Clinical Pharmacy Association and Pharmacy Research UK who have given us some money to carry out the study.

Have other patients and the public helped with MAP-BRONJ?

A patient representative from the University of Sunderland patient involvement group was involved in the initial design of this study.

Has anyone checked that MAP-BRONJ is okay to do?

MAP-BRONJ has been reviewed by an NHS Research Ethics Committee (IRAS ID 216783) and it has also been approved by the University of Sunderland Research Ethics Committee. They are happy that MAP-BRONJ is okay to be carried out by the team, and that no harm will come to you or them.

If you're concerned and want to talk to someone independent of the MAP-BRONJ team, you can contact the Chair of the University of Sunderland Research Ethics Committee, Dr Etta Evans, on etta.evans@sunderland.ac.uk or 0191 5152624.

What should I do if I want to take part?

If you don't have any questions and would like to take part, please can you fill in the contact information slip and send it to us. Please let us know the best way for us to get in touch with you. We don't know how many people will want to help us so we might find we have too many and we may not need to ask for your help.

Once we have your form, someone from the MAP-BRONJ team will get in touch with you and let you know if we do need your help or not. If we do they will arrange the best time and place for you to meet and talk to us.

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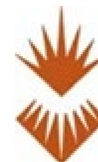

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MAP-BRONJ Information Sheet for Patients with a diagnosis of BRONJ

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Why is MAP-BRONJ being carried out?

A group of drugs called bisphosphonates are used to treat a number of conditions that affect bones, such as osteoporosis and certain cancers. Because we are living longer, more patients are being prescribed these drugs than ever before and a rare but important side effect, called osteonecrosis of the jaw, has been discovered.

This side effect causes problems with patient's jawbones, particularly if patients require a dental extraction. This condition can be difficult to treat and because of this healthcare professionals should try to prevent it from happening in the first place. In this study we are looking to find ways in which we can minimise this risk and how healthcare professionals can work better as a team to prevent it from occurring.

Why have I been invited to take part?

You have been asked to take part in this study as you have previously been diagnosed with osteonecrosis of the jaw. By speaking to patients like yourself, we can get a better understanding of the impact that this has had on you and how we can prevent it from happening to any other patients.

What would I have to do?

We would like your help with this study by asking you to talk to one of our team members for about an hour. We will audio record this conversation so that it is easier for us to make notes later about what was said. The interview can take place at your GP surgery, or we can come to your home to talk to you.

Will I be able to get my money back if I have to travel to take part?

Yes. We don't want taking part in the study to cost you anything. This means that we will give you the money for any bus fares or other travel costs which you have to pay to take part.

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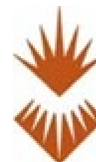
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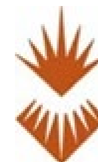

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MAP-BRONJ Information Sheet for Patients with a diagnosis of BRONJ

the end of the study.

Who is doing MAP-BRONJ?

The research is being done by a research team at the University of Sunderland. The Chief Investigator for the project is Andrew Sturrock. His title is 'Senior Lecturer' and he is based in the Department of Pharmacy, Health and Wellbeing.

Who is paying for MAP-BRONJ?

The study is being supported by the UK Clinical Pharmacy Association and Pharmacy Research UK who have given us some money to carry out the study.

Have other patients and the public helped with MAP-BRONJ?

A patient representative from the University of Sunderland patient involvement group was involved in the initial design of this study.

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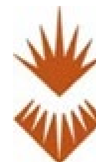
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MAP-BRONJ Information Sheet for patients with osteoporosis

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Why is MAP-BRONJ being carried out?

A group of drugs called bisphosphonates are used to treat a number of conditions that affect bones, such as osteoporosis and certain cancers. Because we are living longer, more patients are being prescribed these drugs than ever before and a rare but important side effect, called osteonecrosis of the jaw, has been discovered.

This side effect causes problems with patient's jawbones, particularly if patients require a dental extraction. This condition can be difficult to treat and because of this healthcare professionals should try to prevent it from happening in the first place. In this study we are looking to find ways in which we can minimise this risk and how healthcare professionals can work better as a team to prevent it from occurring.

Why have I been invited to take part?

You have been asked to take part in this study as you have already been diagnosed with a condition that can affect your bones called osteoporosis. In some patients with this condition your doctor may prescribe you a medicine called a bisphosphonate in the future. This medicine can in some rare cases affect your jawbones and we would like to speak to you to get a better understanding of how healthcare professionals can work as a team to prevent anyone from getting it.

What would I have to do?

We would like your help with this study by asking you to talk to one of our team members for about an hour. We will audio record this conversation so that it is easier for us to make notes later about what was said. The interview can take place at your GP surgery, or we can come to your home to talk to you.

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No. But we will be giving everyone who takes part a £10 gift voucher as a 'thank you' for taking part in our project.

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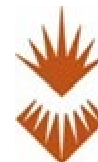
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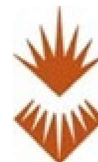

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MAP-BRONJ Information Sheet for patients with osteoporosis

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Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:
Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

No. Item	Guide questions/description	Reported on Page #	Details
Domain 1: Research team and reflexivity			
Personal Characteristics			
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	19	Andrew Sturrock (AS)
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	1	AS has an MSc in Clinical Pharmacy
3. Occupation	What was their occupation at the time of the study?	1	Principal Lecturer – Master of Pharmacy Programme Leader
4. Gender	Was the researcher male or female?	1	Male
5. Experience and training	What experience or training did the researcher have?	1 + 19	AS received training in qualitative research skills by the research team and through attendance at a Qualitative Research Methods in Health Course at University College London..
Relationship with participants			
6. Relationship established	Was a relationship established prior to study commencement?	7	Invitation letter and participant information sheets were posted out prior to the study.
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Supplementary document 5-7	A participant information sheet was provided to all participants.
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	1+19	AS is a pharmacist. Interest in the research topic was developed due to teaching commitments on the MPharm programme at the University of Sunderland. The multidisciplinary team was assembled to reduce bias in the research process.
Domain 2: study design			
Theoretical framework			
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	7	A Grounded Theory approach, with constant comparison.

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Participant selection			
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	7	A purposive and convenience sampling method were adopted
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	7	An invitation letter and information sheets was posted (Supplementary Documents 2-7)
12. Sample size	How many participants were in the study?	9	23 participants
13. Non-participation	How many people refused to participate or dropped out? Reasons?	9	No participants who responded to the invitation refused to participate or dropped out of the study.
Setting			
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	9	Data were collected at a time and place convenient to the interviewee; this was at their home, GP practice or dental clinic
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	9	Interviews were held on a one-to-one basis.
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	9	As displayed in table 1
Data collection			
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	7	Interview guide was developed and refined by the research team. Included as (Supplementary Document 1)
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	7	No repeat interviews were performed
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	7	Audio recording
20. Field notes	Were field notes made during and/or after the inter view or focus group?	7	No field notes were taken due to the verbatim transcribing
21. Duration	What was the duration of the interviews or focus group?	9	Up to 1 hour
22. Data saturation	Was data saturation discussed?	9	Data were analysed by AS, with transcripts and emerging themes cross-checked for interpretation and agreed amongst the research team. Constant comparison was utilised as a means of enriching the data through iterative data collection and analysis
23. Transcripts returned	Were transcripts returned to	7	No

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	participants for comment and/or correction?		
Domain 3: analysis and findings			
Data analysis			
24. Number of data coders	How many data coders coded the data?	19	AS identified the thematic framework and interpreted the data
25. Description of the coding tree	Did authors provide a description of the coding tree?	N/A	A description of the coding tree is not provided.
26. Derivation of themes	Were themes identified in advance or derived from the data?	7	Themes were derived from the data
27. Software	What software, if applicable, was used to manage the data?	N/A	
28. Participant checking	Did participants provide feedback on the findings?	7	No
Reporting			
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	10-14	Quotation are presented with clearly identifiable participant numbers
30. Data and findings consistent	Was there consistency between the data presented and the findings?	10-14	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	10-14	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	10-14	Yes

For peer review only