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General dental practitioners' perceptions of and attitudes towards, improving patient safety through a multidisciplinary approach to the prevention of Medication-Related Osteonecrosis of the Jaw (MRONJ). A qualitative study in the North East of England.

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General dental practitioners' perceptions of and attitudes towards, improving patient safety through a multidisciplinary approach to the prevention of Medication-Related Osteonecrosis of the Jaw (MRONJ). A qualitative study in the North East of England.

13 Sturrock A, Preshaw PM, Hayes C, Wilkes S

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15
16

Corresponding Author:

17
18 Andrew Sturrock MSc
19 Principal Lecturer – Master of Pharmacy Programme Leader
20 Faculty of Health Sciences and Wellbeing, The Sciences Complex, City Campus, Chester Road,
21 University of Sunderland, UK, SR1 3SD
22 Tel: 0191 515 2448
23 e-mail: andrew.sturrock@sunderland.ac.uk
24
25

26
27

Co-Authors:

28
29 Professor Philip M. Preshaw PhD
30 Professor of Periodontology
31 National University Centre for Oral Health, National University of Singapore, 11 Lower Kent
32 Ridge Road Singapore 119083
33 Tel +65-6772-8809
34 e-mail: philip.preshaw@nus.edu.sg
35
36

37
38 Dr Catherine Hayes PhD
39 Associate Professor of Health Professions Pedagogy & Visiting Professor of Higher Education
40 Faculty of Health Sciences and Wellbeing, The Sciences Complex, City Campus, Chester Road,
41 University of Sunderland, UK, SR1 3SD
42 Tel: 0191 515 2523
43 e-mail: catherine.hayes@sunderland.ac.uk
44
45

46
47 Professor Scott Wilkes PhD
48 Head, School of Medicine and Professor of General Practice and Primary Care
49 Faculty of Health Sciences and Wellbeing, The Sciences Complex, City Campus, Chester Road,
50 University of Sunderland, UK, SR1 3SD
51 Tel: 0191 515 2186
52 e-mail: scott.wilkes@sunderland.ac.uk
53
54

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ABSTRACT

Objective: To explore general dental practitioners' (GDPs') perceptions of and attitudes towards the risks of medication-related osteonecrosis of the jaw (MRONJ) and the current/potential multidisciplinary approach(es) to prevention of the condition.

Design: Interpretivist methodology using a Grounded Theory approach and Constant Comparative Analysis to undertake an iterative series of semi-structured interviews. Ritchie and Spencer's Framework Analysis facilitated the identification and prioritisation of salient themes.

Setting: Primary care general dental practices in the North East of England.

Participants: 15 GDPs

Results: GDPs are aware of the risk of MRONJ with commonly implicated medicines; however, they report limited collaboration between professional groups in person-centred avoidance of complications, which is a key requirement of the preventive advice recommended in extant literature. Four salient and inter-related themes emerged: (1) perception of knowledge; indicating the awareness of the risk, limited knowledge of implicated medications and experience of managing the condition; (2) risk; indicating the importance of accurate medication histories, the treatment of low risk patients in primary dental care, counselling of poorly informed patients, the fear of litigation, and perceived low priority of oral health in the context of general health and wellbeing; (3) access and isolation; referring to access to general medical records, professional isolation, and somewhat limited and challenging professional collaborative relationships; (4) interprofessional working; indicating oral health education of other professional groups, collaboration and communication, and a focus on preventive care.

Conclusions: Patients continue to be at risk of developing MRONJ due to limited preventive interventions and relatively disparate contexts of multidisciplinary team healthcare. Effective collaboration, education and access to shared medical records could potentially improve patient safety and reduce the potential risk of developing MRONJ.

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.
- This is the first qualitative study that has explored the attitudes and perceptions of general dental practitioners towards the multidisciplinary approach to preventing MRONJ.
- A qualitative method yielded rich data through in-depth semi-structured interviews with general dental practitioners; constant comparative analysis allowed further exploration and refining of emergent themes.
- The study was based around an *a priori* assumption of limited knowledge among general dental practitioners in relation to MRONJ; participants were provided a patient information leaflet in advance, therefore exposing participants to the concepts before the interview.

Introduction:

Bisphosphonates were first implicated in the pathogenesis of MRONJ in 2003;(1) however, other medications such as the anti-angiogenic drugs, bevacizumab, sunitinib and aflibercept, and the receptor activator of nuclear factor kappa-beta ligand (RANKL) inhibitor denosumab have subsequently also been associated with the condition.(2) 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 jaw.(3)

MRONJ is a rare complication; the estimated incidence 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%.(2) However, MRONJ is difficult to treat and can cause significant morbidity to patients; our previous qualitative study of patients diagnosed with MRONJ highlighted the significant quality of life implications, particularly the physical, psychological and social impacts associated with the condition.(4)

Prescribing rates of drugs associated with MRONJ have risen significantly in recent years and are expected to rise further. Prescribing of denosumab has increased in the UK with an estimated 24.4% rise in NHS expenditure on the drug between 2015/16 and 2016/17.(5) The introduction of intravenous bisphosphonates in the treatment of early breast cancer also approximates to a further 20,000 patients being prescribed bisphosphonates annually in the UK.(6)

Current clinical guidelines recommend that patients are to be in a state of optimal dental fitness, relative to their condition, specifically with the elimination or stabilisation of oral disease before commencement of MRONJ-implicated medications, or as soon as possible thereafter. A particular focus should be directed towards high risk oncology patients, including a thorough dental assessment and the prioritisation of care that reduces mucosal trauma or prophylactically reduces the risk of subsequent dental extractions.(2)

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3 A number of studies have described reductions in the incidence rates of MRONJ with the
4 execution of appropriate screening and preventive dental care.(7,8) However, a 2015 survey
5 (n=129) identified that more than 90% of general dental practitioners (GDPs) were unaware
6 of medications which are associated with MRONJ other than bisphosphonates and that 58%
7 of participants were not confident in performing an extraction in primary care on a patient
8 prescribed oral bisphosphonates.(9) The prevention of MRONJ should be promoted by the
9 multidisciplinary health care team with a collaborative approach to the education of patients
10 and promotion of high standards of oral hygiene and preventive measures.(2, 10-12)
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18 Our previous studies have identified limited awareness of MRONJ amongst patients, with little
19 promotion of appropriate preventive strategies from general medical practitioners and
20 pharmacists.(4,13) Both of these professional groups often overlooked the advice related to
21 the risk and prevention of MRONJ; the reasons for this were multifactorial, however a lack of
22 awareness of the condition, complexity of patient medical histories and prioritisation of other
23 information, were all potential barriers to optimal patient care.(4,13) In this study, we have
24 investigated the attitudes and perceptions of GDPs on the risks of MRONJ and approaches to
25 its prevention.
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Aims

- 1) To explore the attitudes towards, and perceptions of, GPs on the risks of MRONJ.
- 2) To explore the attitudes towards, and perceptions of, GPs on the multidisciplinary approach to the prevention of MRONJ.
- 3) To explore any perceived barriers or enablers to optimising the management of this patient group.

For peer review only

METHOD

Design:

The study adopted a Grounded Theory approach,(14) whereby Constant Comparative Analysis was utilised to enrich data through iterative cycles of data collection and analysis.(15) Individual semi-structured interviews were undertaken at the participants' places of work and up to 1 hour was designated for each interview conducted. An initial topic guide (Supplementary Document 1) was developed by the principal investigator based on the extant published literature to date and the findings of our previous qualitative study.(4,13) The topic guide was reviewed and refined by the multidisciplinary research team and served as a benchmark for the establishment of initial questions. However, flexibility in this process and the emergence of particular new themes facilitated further exploration during the interview and in subsequent data collection with other participants. The interviews were audio recorded and transcribed verbatim as an integral part of the qualitative analysis methods adopted.

Participants:

An invitation letter (Supplementary Document 2) and participant information sheet (Supplementary Document 3) were posted to GDPs and disseminated with the assistance of the Local Dental Professional Network. A convenience sample of participants who responded to the invitation was implemented initially, with snowball sampling adopted to successfully ensure further recruitment to the study.

Analysis:

Constant Comparative Analysis facilitated the enrichment of data and further exploration of emerging theoretical concepts in subsequent interviews. Ritchie and Spencer's Framework Analysis (2002) provided a systematic approach to data analysis and allowed the identification and prioritisation of salient themes from the data;(16) themes were reviewed by the principal investigator (AS) and the research team until definitive concepts became evident.

Ethical review:

Ethical approval was obtained from the University of Sunderland Research Ethics Committee (REF: 001169)

Patient Involvement:

A patient representative from the University of Sunderland Patient, Carer and Public Involvement Group was involved in co-constructed discussions around the practical implications of the design and ethical issues associated with this study.

For peer review only

RESULTS

A total of 15 GDPs participated in this study (Table 1). In-depth semi-structured interviews were carried out between May 2018 and September 2018 until theoretical emergence of the data was exhausted.

Table 1. Participant Characteristics

Participant	Identifier	No. Years' Graduation	Since	Gender
1	D1	5-9 years		Female
2	D2	<5 years		Male
3	D3	5-9 years		Female
4	D4	<5 years		Male
5	D5	> 20 years		Male
6	D6	<5 years		Female
7	D7	> 20 years		Male
8	D8	> 20 years		Male
9	D9	<5 years		Male
10	D10	5-9 years		Male
11	D11	5-9 years		Female
12	D12	<5 years		Female
13	D13	> 20 years		Female
14	D14	5-9 years		Female
15	D15	<5 years		Male

Four salient inter-related themes emerged from the data (1) perceived knowledge; (2) risk; (3) access and isolation; (4) interprofessional working

1. Perceived Knowledge

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2
3 The concept of MRONJ was introduced in the participant information sheet provided in
4 advance of the interview; however, all participants reported prior awareness of the risk of
5 osteonecrosis of the jaw posed by certain medications.
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9 Even though it's a low risk, as a dentist, maybe just I know that it – it's such a difficult
10 condition to manage and can't really be managed that well. (D1)
11
12

13 All participants were able to identify bisphosphonates as being associated with MRONJ; there
14 was limited knowledge of other implicated medications.
15
16

17
18 That's the only one (bisphosphonates) that I am really aware of. There's probably,
19 maybe, other ones, but I really wouldn't know what they are. (D4)
20
21

22 All participants had at least some (though minimal) experience of managing patients with
23 MRONJ; this was mostly gained during their undergraduate studies and participants had very
24 limited or no exposure to patients with MRONJ in their subsequent general practice.
25
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27
28 I've seen it as an undergraduate, but I have never seen it in practice. I think this
29 particular patient that I saw was quite disfigured by it and had been attending the
30 dental hospital for a long time. (D1)
31
32
33

34 Most of the participants were aware of guidelines for the prevention and management of
35 MRONJ. Although all participants practiced in England, the Scottish Dental Clinical
36 Effectiveness Programme Guideline was cited as a good source of information; (2) those
37 participants who had qualified most recently described being directed to these guidelines
38 during their undergraduate study.
39
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44 The guideline I usually tend to use for everything is the Scottish ones, SDCEP [Scottish
45 Dental Clinical Effectiveness Programme]. (D3)
46
47
48

49 **2. Risk**

50
51 Participants described the importance of taking accurate medication histories for each
52 patient; a particular focus was directed towards certain medications such as anticoagulants
53 and bisphosphonates.
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56
57 I'm looking out for any bisphosphonate really, and warfarin, any anticoagulants, they
58 are the main ones (D2)
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3 Participants were aware that the risk of MRONJ is small for patients who are taking oral
4 bisphosphonates and that intravenous formulations carry a higher risk. The risk of MRONJ
5 developing following a dental extraction in patients prescribed oral medications was deemed
6 to be small and this procedure was considered typically suitable for general practice. Patients
7 receiving intravenous medications associated with a cancer diagnosis were perceived to be at
8 higher risk and participants reported that they would typically refer these patients to
9 secondary care.
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17 The way I view it – if – if they are on IV or if they have had IV bisphosphonates recently,
18 then I would see it as high risk and I would probably refer to oral surgery. If they are
19 on long-term oral then I am not concerned and would do the extraction. (D10)
20
21
22

23 All participants reported that they discuss the risk with patients prior to carrying out
24 treatment; however, participants described the limited awareness of patients on the oral risks
25 associated with medications implicated in MRONJ. Typically, information regarding this was
26 introduced to the patient by the dentist prior to invasive procedures and had not been
27 introduced at the point of prescribing or dispensing the medication.
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33 The patients don't really have a clue to be honest, I think dentists are aware but I am
34 not sure anyone else even knows about it. (D10)
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36

37 It should come from the person prescribing I suppose, it's not me that is putting the
38 patient on these drugs, but it would be up to me to guide them through what's
39 appropriate for them once they are prescribed them. (D6)
40
41
42

43 Although there are guidelines that inform prevention, treatment planning and the
44 management of MRONJ, the fear of litigation following an extraction and subsequent
45 development of osteonecrosis was an emergent theme from the data.
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47
48

49 I don't think it's a big risk, at least not with orals [oral bisphosphonates], but I think
50 it's a litigation thing really, protecting yourself and making sure the patient is
51 informed, rather than it being a massive risk. (D9)
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55 Oral health was perceived to be low down the list of priorities for other healthcare
56 professionals, particularly amongst medical colleagues.
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1
2
3 I feel like whenever I have spoken to a GP about anything related to dentistry, they
4 are kind of very much of the opinion, “that’s your job and not mine, you know better
5 so sort it out”. (D14)
6
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9 A lot of the time they don’t think of oral health as – as being high up on that – on that
10 priority list. You know, they think about everything else, but the teeth and gums are
11 an afterthought. (D10)
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15 **3. Access and isolation**

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18 Participants described challenges in obtaining accurate medication histories from some
19 patients; the relative degree of time it takes when dentists are required to contact general
20 medical practitioners was seen as a significant barrier to improving patient care.
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23
24 I make sure I take medication histories for patients, but they don’t always know exactly
25 what they take. It’s sometimes hard to be sure the list they give you is accurate. (D15)
26
27

28 I think it’s sometimes very difficult to make contact, and like, if we try and phone them
29 and they phone us, obviously we’re all busy, we never have gaps at the same time, it can
30 be really time consuming. (D11)
31
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34
35 Access to Summary Care Records was described as a key opportunity to save clinical time and
36 ensure that dentists were fully aware of the patient’s current medical conditions and
37 medication history.
38
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41 It would be brilliant, if we could just see, even just an element of their records, even
42 just what drugs they were taking. That’s the main thing for us, it takes so long to get
43 the drug history out of a patient. (D13)
44
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48 Participants described the professional isolation that occurs in general dental practice. This
49 indicated isolation from other healthcare professionals and potentially from other dental
50 colleagues.
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52
53 I think with a lot of things with dentists really, that we are out of the loop, I just don’t
54 seem to have had much interaction with any other healthcare professionals. (D6)
55
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57
58 Participants described limited interprofessional relationships and communication with other
59 healthcare professionals in the existing organisational infrastructure. Typically,
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3 communication with general medical practitioners would be one way, difficult to initiate, and
4 only take place when needing to confirm complex medication histories.
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7 It's really just the difficulty getting in touch with them and the time that it takes, it's
8 quite hard to speak to the GP. (D3)
9
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11 I've never had a referral from the GP for anything (D2)
12
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14 Participants reported little collaboration with pharmacists, and some described a lack of
15 understanding of the pharmacist's role. Communication with pharmacists would typically be
16 to discuss issues around prescribing errors or with potential drug interactions; some
17 participants reported communication with pharmacists who run anticoagulant therapy
18 monitoring services.
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23 I personally don't really feel that I've got a good enough understanding of what an
24 actual pharmacist's job entails (D2)
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28 The only patients that I have really had any dialogue about with pharmacists are those
29 on warfarin. The pharmacist runs the anticoagulant monitoring service (D5)
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33 **4. Interprofessional working**

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35 A greater focus on oral health education in other healthcare professionals' training could
36 potentially develop a better collaboration between the professions of dentistry and general
37 medical practice and facilitate a greater understanding of the importance of oral health in
38 relation to the adverse effects of medication and the links between oral health and systemic
39 disease.
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44 I think the importance of oral health could be stressed more by other professions and
45 we could probably work better together really. You know, sometimes there are
46 medications that have side effects like with osteonecrosis and sometimes, there are,
47 there are benefits on other condition like diabetes with oral health. (D15)
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53 Participants described a willingness to engage with other healthcare professionals in order to
54 improve patient care. Greater collaboration, clear referral pathways and communication with
55 general medical practitioners and pharmacists would be well received.
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3 If there was a better multidisciplinary relationship, better communication, it would be
4 much better for us in terms of delivery of better patient care. (D2)
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7 Yeah definitely. Yeah, I'm more than happy if pharmacists could refer appropriate
8 patients, it's just about making sure that the patients know and getting them to see
9 me as soon as possible really. (D2)
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13 A greater focus on preventive care and the discussion of the oral health implications of
14 medications associated with MRONJ at the point of prescribing would improve care for this
15 patient group. This would allow dentists to implement preventive strategies before the
16 potential risk of MRONJ develops.
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21 If a patient is going to go on to alendronic acid or any of the bisphosphonates they
22 should be referred to be dentally screened first, because I don't think that happens at
23 all. It could really help to reduce the risk if we can do any work and explain things
24 properly to the patient first. (D8)
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DISCUSSION

In this research, we undertook semi-structured interviews to investigate the attitudes and perceptions of GPs on risks of MRONJ and approaches to its prevention. Although rare, MRONJ is associated with significant morbidity and can develop following common dental procedures such as tooth extractions. We therefore selected GPs as a key group of healthcare professionals who can play an important role in prevention strategies for MRONJ, to explore their knowledge in this area and learn from their prior experiences of multidisciplinary working. All participants reported being aware of the risk of MRONJ; however, it should be noted that this was introduced through the patient information leaflet given to participants as part of the consent process, therefore exposing participants to the concept before the interview. Although participants had minimal experience of managing patients with MRONJ, it was apparent that GPs are aware of the risks associated with bisphosphonate therapy and the importance of prioritising preventive care in this patient group. Our previous qualitative studies of general medical professionals, pharmacists and patients found that patients have poor awareness of the risk of MRONJ and that preventive strategies are rarely implemented at the point of prescribing implicated medicines.(4, 13) Participants in the current study have also reported similar experiences, as they often treat patients who are poorly informed about the associated risks of bisphosphonate use. All three studies suggest that patients are being poorly informed about the need for high standards of oral health and that preventive dental care is not being recommended. The multidisciplinary team appear to be working in relative isolation from one another, when prescribing and managing patients who have already been prescribed medications that are linked with the potential development of MRONJ.

Further education of dentists on specific medications, other than bisphosphonates, implicated in the pathogenesis of MRONJ is also required. The participants interviewed in our study had limited knowledge of other implicated medicines, with most participants only aware of the association with bisphosphonate therapy. These findings correspond with those of Tanna (2017) who identified that more than 90% of GPs were unaware of medications other than bisphosphonates which are associated with MRONJ.(9)

Participants were clear in the need to obtain accurate medical and medication histories from patients as part of routine care. Participants described their current practices and confidence

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3 in treating many patients prescribed the implicated medications in the context of primary
4 care; however, they would typically find that patients would be unaware of the risks
5 associated with them. It is clear that the recommendations in current guidelines are not
6 always followed and that education of prescribers and pharmacists on the risks of MRONJ is
7 required to ensure that patients are fully informed at the point of initiating pharmacological
8 therapy.
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15 The importance of counselling patients fully on the risks before treatment was highlighted by
16 participants who also referred to the potential risk of litigation from a poorly informed patient
17 or from patients who develop MRONJ following a dental procedure. Although not reported
18 by all, a fear of litigation was clearly a consideration for some participants. A survey by Tanna
19 (2017) of 129 GPs found that 21% identified a fear of litigation as a reason for not performing
20 an extraction in primary care.⁽⁹⁾ Participants in our study were, however, willing to perform
21 extractions on lower risk patients prescribed oral bisphosphonates in primary care; this
22 follows recommendations in current clinical guidelines, of which most participants were
23 aware. A 2014 paper highlighted that the legal implications of MRONJ are complex, however
24 legal liability and malpractice claims have been made.⁽¹⁷⁾ The authors identified the need for
25 dentists and other healthcare professionals to have an understanding in relation to
26 knowledge of MRONJ, provision of information to patients, prevention, diagnosis and
27 treatment.⁽¹⁷⁾
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39 Participants reported that GPs are often isolated contextually, situationally and
40 geographically from peers and other healthcare professionals; this was identified by
41 participants as a potential barrier to optimal care of this patient group. This is similar to the
42 findings of a previous qualitative study which explored the collaborative management of
43 patients with diabetes; the researchers identified an isolated knowledge base and a perceived
44 division between the medical and dental professions to negatively impact patient care.⁽¹⁸⁾
45 Professional isolation amongst dentists has also been reported in other studies; recent
46 research into the mental health and wellbeing of UK dentists by the British Dental Association
47 identified professional isolation as a contributing factor in mental illness and burnout
48 amongst dentists.⁽¹⁹⁾
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58 Summary Care Records (SCR) are an electronic summary of key clinical information, such as
59 medicines, allergies and adverse drug reactions that are created from GP medical records.
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3 More than 96% of the population in England currently have an SCR, which is accessible from
4 a variety of NHS service providers, including hospitals and community pharmacies; however,
5 general dental practitioners do not currently have access to SCRs.(20) Participants reported
6 challenges in taking accurate medication histories posed by the existing healthcare
7 infrastructure in which they operate, with access to patient's SCRs described as a potentially
8 useful opportunity to improve care and safeguard patient safety. Sharing medical records
9 with dental practices could save clinical time for dentists and reduce the risk to patients by
10 ensuring that GDPs have the required information to make informed decisions about
11 proposed dental health interventions. This could potentially benefit patients at risk of MRONJ
12 and directly contribute to the improvement of oral health-related outcomes and potentially
13 increase the opportunity for the safe(r) management of other patient groups.

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24 Mechanisms of reducing both perceived and actual professional isolation, improving
25 collaborative care and mechanisms of communication between professions should also be
26 reviewed. The House of Care model provides a framework for patient centred co-ordinated
27 care in the context of diabetes management,(21,22) this model relies of four key components;
28 [1] engaged and informed individuals; [2] professionals committed to partnerships; [3]
29 organisational and supporting processes; [4] system wide approaches to commissioning. The
30 integration of oral healthcare into the wider healthcare system following this model could
31 potentially address the issues identified in our research, optimise prevention of MRONJ and
32 also address other areas in which oral health impacts the overall health and wellbeing of
33 patients. Further research into how this model could be implemented, the development of
34 coordinated services and the integration of oral health into primary care settings could
35 potentially have significant benefits to patients.

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46 Participants perceived that oral health is low down the priority list of other (non-dental)
47 healthcare professionals. It is apparent that relationships between GDPs and other
48 professional groups are limited and that effective collaboration and communication could
49 significantly improve care of this patient group. A focus on the collective education of the
50 multidisciplinary team, highlighting the importance of preventive dental care and taking
51 opportunities to actively reinforce the need for good oral health to patients, could be a key
52 mechanism of facilitating and potentially reducing patients' risk of developing MRONJ.
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Conclusion

Participants identified awareness of the risk of MRONJ, but had limited knowledge of implicated medicines other than bisphosphonates. GPs place importance on the establishment of accurate medication histories from patients and ensure that patients are informed about the risk of developing MRONJ if invasive dental treatment is required.

Barriers to optimal patient care include a perception that oral health is a low priority area for other healthcare professionals, a feeling of professional isolation, limited interprofessional collaboration and a lack of access to medical records.

An increased focus on preventive dental care with education of other healthcare professionals on the importance of oral health, integration of oral health into collaborative care models, and access to medical records could potentially improve patient safety and reduce the risk of the development of MRONJ in practice.

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4

5
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7 carried out the study. AS identified the thematic framework and interpreted the data. AS, SW,
8 PP and CH reviewed and refined the data. AS wrote the paper and all authors revised it. AS
9 received training in qualitative research skills by the research team and through attendance
10 at a Qualitative Research Methods in Health Course at University College London.
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16 (Supplementary Documents 2 and 3); no further data shared.
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18

19
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22

23
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25

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CONFIDENTIAL



The multidisciplinary approach to the prevention of Medication-Related Osteonecrosis of the Jaw (MRONJ). A qualitative study into the attitudes and perceptions of general dental practitioners (MRONJ-GDP)

Topic Guide

This study aims to explore the attitudes and perceptions of general dental practitioners towards the multidisciplinary prevention of medication related osteonecrosis of the jaw.

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

Aims and objectives

- To explore the attitudes towards and perceptions of general dental practitioners, on the risks of medication-related osteonecrosis of the jaw.
- To explore the attitudes towards and perceptions of general dental practitioners on patient counselling and referral to a dental professional, by general medical practitioners and community pharmacists, for patients both newly started and established on medications associated with MRONJ
- To explore any perceived barriers or enablers to optimising the management of this patient group.

Introduction

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

- Introduce self: University of Sunderland, MRONJ-GDP study, why I am here
- Introduce the study: what it is about
- 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 2 years as per policy
- 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?



The multidisciplinary approach to the prevention of Medication-Related Osteonecrosis of the Jaw (MRONJ). A qualitative study into the attitudes and perceptions of general dental practitioners (MRONJ-GDP)

All Participants

Background of participant

Prompts: age, employment, experience, undergraduate training, postgraduate training

Are you aware of the risk of ONJ associated with certain medicines?

Prompts: which medicines, have you encountered patients with MRONJ, implications of this on patients, do you see this as an important issue in practice, risk factors

How do you approach the management of a patient prescribed a bisphosphonate or other MRONJ associated medicine

Prompts: med hx, counselling advice, referral, preventative work before initiation, ongoing management medical/legal implications

Are you aware of any guidance for general dental practitioners on the prevention and management of MRONJ?

Prompts: national/local guidelines, referral pathways

Patient knowledge of MRONJ risk?

Prompt: Have patients raised concerns regarding MRONJ risk, who/how informed of risk, influence on management

The role of the GP/prescriber when starting new medicines and as part of the multidisciplinary team

Prompts: experiences, roles, expectations

The role of the pharmacist when starting new medicines and as part of the multidisciplinary team

Prompts: experiences, role, expectations, MUR/NMS

The role of the dentist within this team?

Prompts: experiences, role, expectations

The role of the patient in this team

Prompts: roles and responsibilities, expectations

Communication or referral from prescribers/pharmacists?

Prompt: Has this happened, should it happen, could this improve prevention, barriers, facilitators

Any barriers or facilitators to improving prevention and management?

Prompts: access to dentists, charges, fear, risk of non-compliance, communication

Anything further to discuss?



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5 **The multidisciplinary approach to the prevention of Medication-Related**
6 **Osteonecrosis of the Jaw (MRONJ). A qualitative study into the attitudes**
7 **and perceptions of general dental practitioners (MRONJ-GDP)**
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13 **Next steps**

- 14 • Thank the participant
 - 15 • Do they have any remaining questions about the research
 - 16 • Reassurance around confidentiality and anonymity
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Mr Andrew Sturrock
School of Pharmacy and Pharmaceutical Sciences
Faculty of Health Sciences and Wellbeing
Sciences Complex
City Campus
Chester Road
University of Sunderland
SR1 3SD
Email: andrew.sturrock@sunderland.ac.uk
Tel: 01915152448

TITLE FIRST SURNAME
ADDRESS LINE 1
ADDRESS LINE 2
POST CODE

DATE

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

My name is Andrew Sturrock; I am a Principal Lecturer in Pharmacy Practice at the University of Sunderland. I am writing to you as an invitation to take part in a research project that I am running in conjunction with Scott Wilkes, Professor of General Practice and Primary Care.

Please find enclosed the participant information sheet, outlining the background to the study and what is required of participants.

Participation can be either in person at your practice or via a scheduled telephone appointment. If you would like to take part in the study please contact me via email or telephone at the above address or complete and return the response form in the prepaid envelope included with this letter.

Yours faithfully

Andrew Sturrock
Principal Lecturer– Pharmacy Practice



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

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

Title: _____ Dr/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.



MRONJ-GDP Participant Information Sheet

Study title:

The multidisciplinary approach to the prevention of Medication-Related Osteonecrosis of the Jaw (MRONJ). A qualitative study into the attitudes and perceptions of general dental practitioners. (MRONJ-GDP)

What is the purpose of this study?

- To explore the attitudes towards and perceptions of general dental practitioners, on the risks of medication-related osteonecrosis of the jaw.
- To explore the attitudes towards and perceptions of general dental practitioners on patient counselling and referral to a dental professional, by general medical practitioners and community pharmacists, for patients both newly started and established on medications associated with MRONJ
- To explore any perceived barriers or enablers to optimising the management of this patient group.

Who can take part?

General dental practitioners, registered with the General Dental Council.

Do I have to take part and can I change my mind?

Participation is entirely voluntary. If you change your mind about taking part in the study, you can withdraw at any point during the session without giving a reason and without penalty. Once the anonymised transcripts have been produced you will not be able to withdraw from the study. After the interview has been completed audio recording will be transcribed within 7 days.

What will happen to me if I take part?

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 in person or via telephone, at your practice, at the University of Sunderland, or we can come to your home to talk to you. The researcher will ask you a series of questions in relation to the study title and your experiences in practice, from which there are absolutely no right or wrong answers. Your answers may lead to further discussion around any point or topics raised.

What are the possible disadvantages and risks of taking part?

We don't think that there are any risks associated with taking part in this study.

What if something goes wrong?

If you change your mind about participation, please contact me by email to cancel your participation. If you feel unhappy about the conduct of the study, please contact me immediately or the Chairperson of the University of Sunderland Research Ethics Group,



MRONJ-GDP Participant Information Sheet

whose contact details are given below.

Will my taking part in this study be kept confidential?

Participation in this study will be kept confidential. No personally identifiable information will be included in any write up or publication; a non-identifiable participant code will be used against any quotes provided, the first participant will be given the code D1, the numerical value will change with each subsequent participant e.g. D2, D3 etc.

A list of participants and signed consent forms will be stored securely by the principle investigator for a period of up to 2 years. Audio recordings and transcripts will be stored securely by the principle investigator for a period of up to 6 years. Access will be restricted to the research team and persons authorised by the University for Quality Assurance purposes.

What will happen to the results of MAP-BRONJ?

If suitable, the results may be presented at academic conferences and/or written up for publication in peer reviewed academic journals. A summary of the results will be made available to participants if you choose to receive a copy.

Who is organising and funding the research?

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 'Principal Lecturer' and he is based in the School of Pharmacy and Pharmaceutical Sciences.

This project has received no external funding.

Who has reviewed the study?

The University of Sunderland Research Ethics Group has reviewed and approved the study.

Contact for further information:

Doctor John Fulton (Chair of the University of Sunderland Research Ethics Group, University of Sunderland) Email: john.fulton@sunderland.ac.uk Phone: 0191 515 2529

Who can I contact if I have questions about MRONJ-GDP?

If you have any questions, we would like you to get in touch with us. You can do this by telephoning us on 0191 5152448 or you can email us on andrew.sturrock@sunderland.ac.uk

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 **Response Form** 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 practitioners 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



MRONJ-GDP Participant Information Sheet

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.

Thank you for taking the time to read this information.

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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			
<i>Personal Characteristics</i>			
1. Interviewer/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..
<i>Relationship with participants</i>			
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 3	A participant information sheet was provided to all participants.
8. Interviewer characteristics	What characteristics were reported about the interviewer/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			
<i>Theoretical framework</i>			
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 comparative analysis.

<i>Participant selection</i>			
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	7	A convenience sampling and snowball 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 2-3)
12. Sample size	How many participants were in the study?	9	15 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.
<i>Setting</i>			
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	7	Data were collected at a time and place convenient to the interviewee; this was at their place of work.
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	7	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
<i>Data collection</i>			
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 interviews 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 interview 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?	7	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 comparative analysis was utilised as a means of enriching the data through iterative data collection and analysis
23. Transcripts returned	Were transcripts returned to	7	No

	participants for comment and/or correction?		
Domain 3: analysis and findings			
<i>Data analysis</i>			
24. Number of data coders	How many data coders coded the data?	19	AS identified the thematic framework and interpreted the data, which was reviewed and refined by the research team.
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
<i>Reporting</i>			
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	9-14	Quotation are presented with clearly identifiable participant numbers
30. Data and findings consistent	Was there consistency between the data presented and the findings?	9-14	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	9-14	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	9-14	Yes

BMJ Open

General dental practitioners' perceptions of and attitudes towards, improving patient safety through a multidisciplinary approach to the prevention of Medication-Related Osteonecrosis of the Jaw (MRONJ). A qualitative study in the North East of England.

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Complete List of Authors:	Sturrock, Andrew; University of Sunderland, School of Pharmacy Preshaw, Philip; National University of Singapore, National University Centre for Oral Health Hayes, Catherine; University of Sunderland, Faculty of Health Sciences and Wellbeing Wilkes, Scott; University of Sunderland, Faculty of Health Sciences and Wellbeing
Primary Subject Heading:	Dentistry and oral medicine
Secondary Subject Heading:	Communication, General practice / Family practice, Health services research, Qualitative research, Pharmacology and therapeutics
Keywords:	ORAL & MAXILLOFACIAL SURGERY, PRIMARY CARE, QUALITATIVE RESEARCH

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General dental practitioners' perceptions of and attitudes towards, improving patient safety through a multidisciplinary approach to the prevention of Medication-Related Osteonecrosis of the Jaw (MRONJ). A qualitative study in the North East of England.

13 Sturrock A, Preshaw PM, Hayes C, Wilkes S

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15
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Corresponding Author:

17
18 Andrew Sturrock MSc
19 Principal Lecturer – Master of Pharmacy Programme Leader
20 Faculty of Health Sciences and Wellbeing, The Sciences Complex, City Campus, Chester Road,
21 University of Sunderland, UK, SR1 3SD
22 Tel: 0191 515 2448
23 e-mail: andrew.sturrock@sunderland.ac.uk
24
25

26
27

Co-Authors:

28
29 Professor Philip M. Preshaw PhD
30 Professor of Periodontology
31 National University Centre for Oral Health, National University of Singapore, 11 Lower Kent
32 Ridge Road Singapore 119083
33 Tel +65-6772-8809
34 e-mail: philip.preshaw@nus.edu.sg
35
36

37
38 Dr Catherine Hayes PhD
39 Associate Professor of Health Professions Pedagogy & Visiting Professor of Higher Education
40 Faculty of Health Sciences and Wellbeing, The Sciences Complex, City Campus, Chester Road,
41 University of Sunderland, UK, SR1 3SD
42 Tel: 0191 515 2523
43 e-mail: catherine.hayes@sunderland.ac.uk
44
45

46
47 Professor Scott Wilkes PhD
48 Head, School of Medicine and Professor of General Practice and Primary Care
49 Faculty of Health Sciences and Wellbeing, The Sciences Complex, City Campus, Chester Road,
50 University of Sunderland, UK, SR1 3SD
51 Tel: 0191 515 2186
52 e-mail: scott.wilkes@sunderland.ac.uk
53
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55 **Keywords:** Medication-Related Osteonecrosis of the Jaw, Oral Health, Patient Safety,
56 Qualitative Research, Dentistry
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58 **Word Count:** 3654
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ABSTRACT

Objective: To explore general dental practitioners' (GDPs') perceptions of and attitudes towards the risks of medication-related osteonecrosis of the jaw (MRONJ) and the current/potential multidisciplinary approach(es) to prevention of the condition.

Design: Interpretivist methodology using a Grounded Theory approach and Constant Comparative Analysis to undertake an iterative series of semi-structured interviews. Ritchie and Spencer's Framework Analysis facilitated the identification and prioritisation of salient themes.

Setting: Primary care general dental practices in the North East of England.

Participants: 15 GDPs

Results: GDPs are aware of the risk of MRONJ with commonly implicated medicines; however, they report limited collaboration between professional groups in person-centred avoidance of complications, which is a key requirement of the preventive advice recommended in extant literature. Four salient and inter-related themes emerged: (1) perception of knowledge; indicating the awareness of the risk, limited knowledge of implicated medications and experience of managing the condition; (2) risk; indicating the importance of accurate medication histories, the treatment of low risk patients in primary dental care, counselling of poorly informed patients, the fear of litigation, and perceived low priority of oral health in the context of general health and wellbeing; (3) access and isolation; referring to access to general medical records, professional isolation, and somewhat limited and challenging professional collaborative relationships; (4) interprofessional working; indicating oral health education of other professional groups, collaboration and communication, and a focus on preventive care.

Conclusions: Patients continue to be at risk of developing MRONJ due to limited preventive interventions and relatively disparate contexts of multidisciplinary team healthcare. Effective collaboration, education and access to shared medical records could potentially improve patient safety and reduce the potential risk of developing MRONJ.

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.
- This is the first qualitative study that has explored the attitudes and perceptions of general dental practitioners towards the multidisciplinary approach to preventing MRONJ.
- A qualitative method yielded rich data through in-depth semi-structured interviews with general dental practitioners; constant comparative analysis allowed further exploration and refining of emergent themes.
- The study was based around an *a priori* assumption of limited knowledge among general dental practitioners in relation to MRONJ; participants were provided a patient information leaflet in advance, therefore exposing participants to the concepts before the interview.

Introduction:

Bisphosphonates were first implicated in the pathogenesis of MRONJ in 2003;(1) however, other medications such as the anti-angiogenic drugs, bevacizumab, sunitinib and aflibercept, and the receptor activator of nuclear factor kappa-beta ligand (RANKL) inhibitor denosumab have subsequently also been associated with the condition.(2) 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 jaw.(3)

MRONJ is a rare complication; the estimated incidence 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%.(2) However, MRONJ is difficult to treat and can cause significant morbidity to patients; our previous qualitative study of patients diagnosed with MRONJ highlighted the significant quality of life implications, particularly the physical, psychological and social impacts associated with the condition.(4)

Prescribing rates of drugs associated with MRONJ have risen significantly in recent years and are expected to rise further. Prescribing of denosumab has increased in the UK with an estimated 24.4% rise in NHS expenditure on the drug between 2015/16 and 2016/17.(5) The introduction of intravenous bisphosphonates in the treatment of early breast cancer also approximates to a further 20,000 patients being prescribed bisphosphonates annually in the UK.(6)

Current clinical guidelines recommend that patients are to be in a state of optimal dental fitness, relative to their condition, specifically with the elimination or stabilisation of oral disease before commencement of MRONJ-implicated medications, or as soon as possible thereafter. A particular focus should be directed towards high risk oncology patients, including a thorough dental assessment and the prioritisation of care that reduces mucosal trauma or prophylactically reduces the risk of subsequent dental extractions.(2)

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3 A number of studies have described reductions in the incidence rates of MRONJ with the
4 execution of appropriate screening and preventive dental care.(7,8) However, a 2015 survey
5 (n=129) identified that more than 90% of general dental practitioners (GDPs) were unaware
6 of medications which are associated with MRONJ other than bisphosphonates and that 58%
7 of participants were not confident in performing an extraction in primary care on a patient
8 prescribed oral bisphosphonates.(9) The prevention of MRONJ should be promoted by the
9 multidisciplinary health care team with a collaborative approach to the education of patients
10 and promotion of high standards of oral hygiene and preventive measures.(2, 10-12)
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18 Our previous studies have identified limited awareness of MRONJ amongst patients, with little
19 promotion of appropriate preventive strategies from general medical practitioners and
20 pharmacists.(4,13) Both of these professional groups often overlooked the advice related to
21 the risk and prevention of MRONJ; the reasons for this were multifactorial, however a lack of
22 awareness of the condition, complexity of patient medical histories and prioritisation of other
23 information, were all potential barriers to optimal patient care.(4,13) In this study, we have
24 investigated the attitudes and perceptions of GDPs on the risks of MRONJ and approaches to
25 its prevention.
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Aims

- 1) To explore the attitudes towards, and perceptions of, GPs on the risks of MRONJ.
- 2) To explore the attitudes towards, and perceptions of, GPs on the multidisciplinary approach to the prevention of MRONJ.
- 3) To explore any perceived barriers or enablers to optimising the management of this patient group.

For peer review only

METHOD

Design:

The study adopted a Grounded Theory approach,(14) whereby Constant Comparative Analysis was utilised to enrich data through iterative cycles of data collection and analysis.(15) Individual semi-structured interviews were undertaken at the participants' places of work and up to 1 hour was designated for each interview conducted. An initial topic guide (Supplementary Document 1) was developed by the principal investigator based on the extant published literature to date and the findings of our previous qualitative study.(4,13) The topic guide was reviewed and refined by the multidisciplinary research team and served as a benchmark for the establishment of initial questions. However, flexibility in this process and the emergence of particular new themes facilitated further exploration during the interview and in subsequent data collection with other participants. The interviews were audio recorded and transcribed verbatim as an integral part of the qualitative analysis methods adopted.

Participants:

An invitation letter (Supplementary Document 2) and participant information sheet (Supplementary Document 3) were posted to GDPs and disseminated with the assistance of the Local Dental Professional Network. A convenience sample of participants who responded to the invitation was implemented initially, with snowball sampling adopted to successfully ensure further recruitment to the study.

Analysis:

Constant Comparative Analysis facilitated the enrichment of data and further exploration of emerging theoretical concepts in subsequent interviews. Ritchie and Spencer's Framework Analysis (2002) provided a systematic approach to data analysis and allowed the identification and prioritisation of salient themes from the data;(16) themes were reviewed by the principal investigator (AS) and the research team until definitive concepts became evident.

Ethical review:

Ethical approval was obtained from the University of Sunderland Research Ethics Committee (REF: 001169)

Patient Involvement:

A patient representative from the University of Sunderland Patient, Carer and Public Involvement Group was involved in co-constructed discussions around the practical implications of the design and ethical issues associated with this study.

For peer review only

RESULTS

A total of 15 GDPs participated in this study (Table 1). In-depth semi-structured interviews were carried out between May 2018 and September 2018 until theoretical emergence of the data was exhausted.

Table 1. Participant Characteristics

Participant	Identifier	No. Years' Graduation	Since	Gender
1	D1	5-9 years		Female
2	D2	<5 years		Male
3	D3	5-9 years		Female
4	D4	<5 years		Male
5	D5	> 20 years		Male
6	D6	<5 years		Female
7	D7	> 20 years		Male
8	D8	> 20 years		Male
9	D9	<5 years		Male
10	D10	5-9 years		Male
11	D11	5-9 years		Female
12	D12	<5 years		Female
13	D13	> 20 years		Female
14	D14	5-9 years		Female
15	D15	<5 years		Male

Four salient inter-related themes emerged from the data (1) perceived knowledge; (2) risk; (3) access and isolation; (4) interprofessional working

1. Perceived Knowledge

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2
3 The concept of MRONJ was introduced in the participant information sheet provided in
4 advance of the interview; however, all participants reported prior awareness of the risk of
5 osteonecrosis of the jaw posed by certain medications.
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9 Even though it's a low risk, as a dentist, maybe just I know that it – it's such a difficult
10 condition to manage and can't really be managed that well. (D1)
11
12

13 All participants were able to identify bisphosphonates as being associated with MRONJ; there
14 was limited knowledge of other implicated medications.
15
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17
18 That's the only one (bisphosphonates) that I am really aware of. There's probably,
19 maybe, other ones, but I really wouldn't know what they are. (D4)
20
21

22 All participants had at least some (though minimal) experience of managing patients with
23 MRONJ; this was mostly gained during their undergraduate studies and participants had very
24 limited or no exposure to patients with MRONJ in their subsequent general practice.
25
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27
28 I've seen it as an undergraduate, but I have never seen it in practice. I think this
29 particular patient that I saw was quite disfigured by it and had been attending the
30 dental hospital for a long time. (D1)
31
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34 Most of the participants were aware of guidelines for the prevention and management of
35 MRONJ. Although all participants practiced in England, the Scottish Dental Clinical
36 Effectiveness Programme Guideline was cited as a good source of information; (2) those
37 participants who had qualified most recently described being directed to these guidelines
38 during their undergraduate study.
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44 The guideline I usually tend to use for everything is the Scottish ones, SDCEP [Scottish
45 Dental Clinical Effectiveness Programme]. (D3)
46
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49 **2. Risk**

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51 Participants described the importance of taking accurate medication histories for each
52 patient; a particular focus was directed towards certain medications such as anticoagulants
53 and bisphosphonates.
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57 I'm looking out for any bisphosphonate really, and warfarin, any anticoagulants, they
58 are the main ones (D2)
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2
3 Participants were aware that the risk of MRONJ is small for patients who are taking oral
4 bisphosphonates and that intravenous formulations carry a higher risk. The risk of MRONJ
5 developing following a dental extraction in patients prescribed oral medications was deemed
6 to be small and this procedure was considered typically suitable for general practice. Patients
7 receiving intravenous medications associated with a cancer diagnosis were perceived to be at
8 higher risk and participants reported that they would typically refer these patients to
9 secondary care.
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17 The way I view it – if – if they are on IV or if they have had IV bisphosphonates recently,
18 then I would see it as high risk and I would probably refer to oral surgery. If they are
19 on long-term oral then I am not concerned and would do the extraction. (D10)
20
21

22
23 All participants reported that they discuss the risk with patients prior to carrying out
24 treatment; however, participants described the limited awareness of patients on the oral risks
25 associated with medications implicated in MRONJ. Typically, information regarding this was
26 introduced to the patient by the dentist prior to invasive procedures and had not been
27 introduced at the point of prescribing or dispensing the medication.
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33 The patients don't really have a clue to be honest, I think dentists are aware but I am
34 not sure anyone else even knows about it. (D10)
35
36

37 It should come from the person prescribing I suppose, it's not me that is putting the
38 patient on these drugs, but it would be up to me to guide them through what's
39 appropriate for them once they are prescribed them. (D6)
40
41
42

43 Although there are guidelines that inform prevention, treatment planning and the
44 management of MRONJ, the fear of litigation following an extraction and subsequent
45 development of osteonecrosis was an emergent theme from the data.
46
47
48

49 I don't think it's a big risk, at least not with orals [oral bisphosphonates], but I think
50 it's a litigation thing really, protecting yourself and making sure the patient is
51 informed, rather than it being a massive risk. (D9)
52
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55 Oral health was perceived to be low down the list of priorities for other healthcare
56 professionals, particularly amongst medical colleagues.
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1
2
3 I feel like whenever I have spoken to a GP about anything related to dentistry, they
4 are kind of very much of the opinion, “that’s your job and not mine, you know better
5 so sort it out”. (D14)
6
7
8

9 A lot of the time they don’t think of oral health as – as being high up on that – on that
10 priority list. You know, they think about everything else, but the teeth and gums are
11 an afterthought. (D10)
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15 **3. Access and isolation**

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18 Participants described challenges in obtaining accurate medication histories from some
19 patients; the relative degree of time it takes when dentists are required to contact general
20 medical practitioners was seen as a significant barrier to improving patient care.
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23
24 I make sure I take medication histories for patients, but they don’t always know exactly
25 what they take. It’s sometimes hard to be sure the list they give you is accurate. (D15)
26
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28 I think it’s sometimes very difficult to make contact, and like, if we try and phone them
29 and they phone us, obviously we’re all busy, we never have gaps at the same time, it can
30 be really time consuming. (D11)
31
32
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34
35 Access to Summary Care Records was described as a key opportunity to save clinical time and
36 ensure that dentists were fully aware of the patient’s current medical conditions and
37 medication history.
38
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40
41 It would be brilliant, if we could just see, even just an element of their records, even
42 just what drugs they were taking. That’s the main thing for us, it takes so long to get
43 the drug history out of a patient. (D13)
44
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47
48 Participants described the professional isolation that occurs in general dental practice. This
49 indicated isolation from other healthcare professionals and potentially from other dental
50 colleagues.
51

52
53 I think with a lot of things with dentists really, that we are out of the loop, I just don’t
54 seem to have had much interaction with any other healthcare professionals. (D6)
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58 Participants described limited interprofessional relationships and communication with other
59 healthcare professionals in the existing organisational infrastructure. Typically,
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3 communication with general medical practitioners would be one way, difficult to initiate, and
4 only take place when needing to confirm complex medication histories.
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6

7 It's really just the difficulty getting in touch with them and the time that it takes, it's
8 quite hard to speak to the GP. (D3)
9
10

11 I've never had a referral from the GP for anything (D2)
12
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14 Participants reported little collaboration with pharmacists, and some described a lack of
15 understanding of the pharmacist's role. Communication with pharmacists would typically be
16 to discuss issues around prescribing errors or with potential drug interactions; some
17 participants reported communication with pharmacists who run anticoagulant therapy
18 monitoring services.
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23 I personally don't really feel that I've got a good enough understanding of what an
24 actual pharmacist's job entails (D2)
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28 The only patients that I have really had any dialogue about with pharmacists are those
29 on warfarin. The pharmacist runs the anticoagulant monitoring service (D5)
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33 **4. Interprofessional working**

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35 A greater focus on oral health education in other healthcare professionals' training could
36 potentially develop a better collaboration between the professions of dentistry and general
37 medical practice and facilitate a greater understanding of the importance of oral health in
38 relation to the adverse effects of medication and the links between oral health and systemic
39 disease.
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44 I think the importance of oral health could be stressed more by other professions and
45 we could probably work better together really. You know, sometimes there are
46 medications that have side effects like with osteonecrosis and sometimes, there are,
47 there are benefits on other condition like diabetes with oral health. (D15)
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53 Participants described a willingness to engage with other healthcare professionals in order to
54 improve patient care. Greater collaboration, clear referral pathways and communication with
55 general medical practitioners and pharmacists would be well received.
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3 If there was a better multidisciplinary relationship, better communication, it would be
4 much better for us in terms of delivery of better patient care. (D2)
5
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7 Yeah definitely. Yeah, I'm more than happy if pharmacists could refer appropriate
8 patients, it's just about making sure that the patients know and getting them to see
9 me as soon as possible really. (D2)
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13 A greater focus on preventive care and the discussion of the oral health implications of
14 medications associated with MRONJ at the point of prescribing would improve care for this
15 patient group. This would allow dentists to implement preventive strategies before the
16 potential risk of MRONJ develops.
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21 If a patient is going to go on to alendronic acid or any of the bisphosphonates they
22 should be referred to be dentally screened first, because I don't think that happens at
23 all. It could really help to reduce the risk if we can do any work and explain things
24 properly to the patient first. (D8)
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DISCUSSION

In this research, we undertook semi-structured interviews to investigate the attitudes and perceptions of GPs on risks of MRONJ and approaches to its prevention. Although rare, MRONJ is associated with significant morbidity and can develop following common dental procedures such as tooth extractions. We therefore selected GPs as a key group of healthcare professionals who can play an important role in prevention strategies for MRONJ, to explore their knowledge in this area and learn from their prior experiences of multidisciplinary working. All participants reported being aware of the risk of MRONJ; however, it should be noted that this was introduced through the patient information leaflet given to participants as part of the consent process, therefore exposing participants to the concept before the interview. Although participants had minimal experience of managing patients with MRONJ, it was apparent that GPs are aware of the risks associated with bisphosphonate therapy and the importance of prioritising preventive care in this patient group. Our previous qualitative studies of general medical professionals, pharmacists and patients found that patients have poor awareness of the risk of MRONJ and that preventive strategies are rarely implemented at the point of prescribing implicated medicines.(4, 13) Participants in the current study have also reported similar experiences, as they often treat patients who are poorly informed about the associated risks of bisphosphonate use. All three studies suggest that patients are being poorly informed about the need for high standards of oral health and that preventive dental care is not being recommended. The multidisciplinary team appear to be working in relative isolation from one another, when prescribing and managing patients who have already been prescribed medications that are linked with the potential development of MRONJ.

Further education of dentists on specific medications, other than bisphosphonates, implicated in the pathogenesis of MRONJ is also required. The participants interviewed in our study had limited knowledge of other implicated medicines, with most participants only aware of the association with bisphosphonate therapy. These findings correspond with those of Tanna (2017) who identified that more than 90% of GPs were unaware of medications other than bisphosphonates which are associated with MRONJ.(9)

Participants were clear in the need to obtain accurate medical and medication histories from patients as part of routine care. Participants described their current practices and confidence

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3 in treating many patients prescribed the implicated medications in the context of primary
4 care; however, they would typically find that patients would be unaware of the risks
5 associated with them. It is clear that the recommendations in current guidelines are not
6 always followed and that education of prescribers and pharmacists on the risks of MRONJ is
7 required to ensure that patients are fully informed at the point of initiating pharmacological
8 therapy.
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15 The importance of counselling patients fully on the risks before treatment was highlighted by
16 participants who also referred to the potential risk of litigation from a poorly informed patient
17 or from patients who develop MRONJ following a dental procedure. Although not reported
18 by all, a fear of litigation was clearly a consideration for some participants. A survey by Tanna
19 (2017) of 129 GPs found that 21% identified a fear of litigation as a reason for not performing
20 an extraction in primary care.⁽⁹⁾ Participants in our study were, however, willing to perform
21 extractions on lower risk patients prescribed oral bisphosphonates in primary care; this
22 follows recommendations in current clinical guidelines, of which most participants were
23 aware. A 2014 paper highlighted that the legal implications of MRONJ are complex, however
24 legal liability and malpractice claims have been made.⁽¹⁷⁾ The authors identified the need for
25 dentists and other healthcare professionals to have an understanding in relation to
26 knowledge of MRONJ, provision of information to patients, prevention, diagnosis and
27 treatment.⁽¹⁷⁾
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39 Participants reported that GPs are often isolated contextually, situationally and
40 geographically from peers and other healthcare professionals; this was identified by
41 participants as a potential barrier to optimal care of this patient group. This is similar to the
42 findings of a previous qualitative study which explored the collaborative management of
43 patients with diabetes; the researchers identified an isolated knowledge base and a perceived
44 division between the medical and dental professions to negatively impact patient care.⁽¹⁸⁾
45 Professional isolation amongst dentists has also been reported in other studies; recent
46 research into the mental health and wellbeing of UK dentists by the British Dental Association
47 identified professional isolation as a contributing factor in mental illness and burnout
48 amongst dentists.⁽¹⁹⁾
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58 Summary Care Records (SCR) are an electronic summary of key clinical information, such as
59 medicines, allergies and adverse drug reactions that are created from GP medical records.
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3 More than 96% of the population in England currently have an SCR, which is accessible from
4 a variety of NHS service providers, including hospitals and community pharmacies; however,
5 general dental practitioners do not currently have access to SCRs.(20) Participants reported
6 challenges in taking accurate medication histories posed by the existing healthcare
7 infrastructure in which they operate, with access to patient's SCRs described as a potentially
8 useful opportunity to improve care and safeguard patient safety. Sharing medical records
9 with dental practices could save clinical time for dentists and reduce the risk to patients by
10 ensuring that GDPs have the required information to make informed decisions about
11 proposed dental health interventions. This could potentially benefit patients at risk of MRONJ
12 and directly contribute to the improvement of oral health-related outcomes and potentially
13 increase the opportunity for the safe(r) management of other patient groups.

24 Mechanisms of reducing both perceived and actual professional isolation, improving
25 collaborative care and mechanisms of communication between professions should also be
26 reviewed. The House of Care model provides a framework for patient centred co-ordinated
27 care in the context of diabetes management,(21,22) this model relies of four key components;
28 [1] engaged and informed individuals; [2] professionals committed to partnerships; [3]
29 organisational and supporting processes; [4] system wide approaches to commissioning. The
30 integration of oral healthcare into the wider healthcare system following this model could
31 potentially address the issues identified in our research, optimise prevention of MRONJ and
32 also address other areas in which oral health impacts the overall health and wellbeing of
33 patients. Further research into how this model could be implemented, the development of
34 coordinated services and the integration of oral health into primary care settings could
35 potentially have significant benefits to patients.

46 Participants perceived that oral health is low down the priority list of other (non-dental)
47 healthcare professionals. It is apparent that relationships between GDPs and other
48 professional groups are limited and that effective collaboration and communication could
49 significantly improve care of this patient group. A focus on the collective education of the
50 multidisciplinary team, highlighting the importance of preventive dental care and taking
51 opportunities to actively reinforce the need for good oral health to patients, could be a key
52 mechanism of facilitating and potentially reducing patients' risk of developing MRONJ.
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Conclusion

Participants identified awareness of the risk of MRONJ, but had limited knowledge of implicated medicines other than bisphosphonates. GPs place importance on the establishment of accurate medication histories from patients and ensure that patients are informed about the risk of developing MRONJ if invasive dental treatment is required.

Barriers to optimal patient care include a perception that oral health is a low priority area for other healthcare professionals, a feeling of professional isolation, limited interprofessional collaboration and a lack of access to medical records.

An increased focus on preventive dental care with education of other healthcare professionals on the importance of oral health, integration of oral health into collaborative care models, and access to medical records could potentially improve patient safety and reduce the risk of the development of MRONJ in practice.

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4

5
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8 PP and CH reviewed and refined the data. AS wrote the paper and all authors revised it. AS
9 received training in qualitative research skills by the research team and through attendance
10 at a Qualitative Research Methods in Health Course at University College London.
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17
18

19
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22

23
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25

26
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For peer review only

CONFIDENTIAL



The multidisciplinary approach to the prevention of Medication-Related Osteonecrosis of the Jaw (MRONJ). A qualitative study into the attitudes and perceptions of general dental practitioners (MRONJ-GDP)

Topic Guide

This study aims to explore the attitudes and perceptions of general dental practitioners towards the multidisciplinary prevention of medication related osteonecrosis of the jaw.

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

Aims and objectives

- To explore the attitudes towards and perceptions of general dental practitioners, on the risks of medication-related osteonecrosis of the jaw.
- To explore the attitudes towards and perceptions of general dental practitioners on patient counselling and referral to a dental professional, by general medical practitioners and community pharmacists, for patients both newly started and established on medications associated with MRONJ
- To explore any perceived barriers or enablers to optimising the management of this patient group.

Introduction

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

- Introduce self: University of Sunderland, MRONJ-GDP study, why I am here
- Introduce the study: what it is about
- 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 2 years as per policy
- 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?



The multidisciplinary approach to the prevention of Medication-Related Osteonecrosis of the Jaw (MRONJ). A qualitative study into the attitudes and perceptions of general dental practitioners (MRONJ-GDP)

All Participants

Background of participant

Prompts: age, employment, experience, undergraduate training, postgraduate training

Are you aware of the risk of ONJ associated with certain medicines?

Prompts: which medicines, have you encountered patients with MRONJ, implications of this on patients, do you see this as an important issue in practice, risk factors

How do you approach the management of a patient prescribed a bisphosphonate or other MRONJ associated medicine

Prompts: med hx, counselling advice, referral, preventative work before initiation, ongoing management medical/legal implications

Are you aware of any guidance for general dental practitioners on the prevention and management of MRONJ?

Prompts: national/local guidelines, referral pathways

Patient knowledge of MRONJ risk?

Prompt: Have patients raised concerns regarding MRONJ risk, who/how informed of risk, influence on management

The role of the GP/prescriber when starting new medicines and as part of the multidisciplinary team

Prompts: experiences, roles, expectations

The role of the pharmacist when starting new medicines and as part of the multidisciplinary team

Prompts: experiences, role, expectations, MUR/NMS

The role of the dentist within this team?

Prompts: experiences, role, expectations

The role of the patient in this team

Prompts: roles and responsibilities, expectations

Communication or referral from prescribers/pharmacists?

Prompt: Has this happened, should it happen, could this improve prevention, barriers, facilitators

Any barriers or facilitators to improving prevention and management?

Prompts: access to dentists, charges, fear, risk of non-compliance, communication

Anything further to discuss?



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5 **The multidisciplinary approach to the prevention of Medication-Related**
6 **Osteonecrosis of the Jaw (MRONJ). A qualitative study into the attitudes**
7 **and perceptions of general dental practitioners (MRONJ-GDP)**
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13 **Next steps**

- 14 • Thank the participant
 - 15 • Do they have any remaining questions about the research
 - 16 • Reassurance around confidentiality and anonymity
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Mr Andrew Sturrock
School of Pharmacy and Pharmaceutical Sciences
Faculty of Health Sciences and Wellbeing
Sciences Complex
City Campus
Chester Road
University of Sunderland
SR1 3SD
Email: andrew.sturrock@sunderland.ac.uk
Tel: 01915152448

TITLE FIRST SURNAME
ADDRESS LINE 1
ADDRESS LINE 2
POST CODE

DATE

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

My name is Andrew Sturrock; I am a Principal Lecturer in Pharmacy Practice at the University of Sunderland. I am writing to you as an invitation to take part in a research project that I am running in conjunction with Scott Wilkes, Professor of General Practice and Primary Care.

Please find enclosed the participant information sheet, outlining the background to the study and what is required of participants.

Participation can be either in person at your practice or via a scheduled telephone appointment. If you would like to take part in the study please contact me via email or telephone at the above address or complete and return the response form in the prepaid envelope included with this letter.

Yours faithfully

Andrew Sturrock
Principal Lecturer– Pharmacy Practice



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

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

Title: _____ Dr/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.



MRONJ-GDP Participant Information Sheet

Study title:

The multidisciplinary approach to the prevention of Medication-Related Osteonecrosis of the Jaw (MRONJ). A qualitative study into the attitudes and perceptions of general dental practitioners. (MRONJ-GDP)

What is the purpose of this study?

- To explore the attitudes towards and perceptions of general dental practitioners, on the risks of medication-related osteonecrosis of the jaw.
- To explore the attitudes towards and perceptions of general dental practitioners on patient counselling and referral to a dental professional, by general medical practitioners and community pharmacists, for patients both newly started and established on medications associated with MRONJ
- To explore any perceived barriers or enablers to optimising the management of this patient group.

Who can take part?

General dental practitioners, registered with the General Dental Council.

Do I have to take part and can I change my mind?

Participation is entirely voluntary. If you change your mind about taking part in the study, you can withdraw at any point during the session without giving a reason and without penalty. Once the anonymised transcripts have been produced you will not be able to withdraw from the study. After the interview has been completed audio recording will be transcribed within 7 days.

What will happen to me if I take part?

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 in person or via telephone, at your practice, at the University of Sunderland, or we can come to your home to talk to you. The researcher will ask you a series of questions in relation to the study title and your experiences in practice, from which there are absolutely no right or wrong answers. Your answers may lead to further discussion around any point or topics raised.

What are the possible disadvantages and risks of taking part?

We don't think that there are any risks associated with taking part in this study.

What if something goes wrong?

If you change your mind about participation, please contact me by email to cancel your participation. If you feel unhappy about the conduct of the study, please contact me immediately or the Chairperson of the University of Sunderland Research Ethics Group,

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MRONJ-GDP Participant Information Sheet

whose contact details are given below.

Will my taking part in this study be kept confidential?

Participation in this study will be kept confidential. No personally identifiable information will be included in any write up or publication; a non-identifiable participant code will be used against any quotes provided, the first participant will be given the code D1, the numerical value will change with each subsequent participant e.g. D2, D3 etc.

A list of participants and signed consent forms will be stored securely by the principle investigator for a period of up to 2 years. Audio recordings and transcripts will be stored securely by the principle investigator for a period of up to 6 years. Access will be restricted to the research team and persons authorised by the University for Quality Assurance purposes.

What will happen to the results of MAP-BRONJ?

If suitable, the results may be presented at academic conferences and/or written up for publication in peer reviewed academic journals. A summary of the results will be made available to participants if you choose to receive a copy.

Who is organising and funding the research?

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 'Principal Lecturer' and he is based in the School of Pharmacy and Pharmaceutical Sciences.

This project has received no external funding.

Who has reviewed the study?

The University of Sunderland Research Ethics Group has reviewed and approved the study.

Contact for further information:

Doctor John Fulton (Chair of the University of Sunderland Research Ethics Group, University of Sunderland) Email: john.fulton@sunderland.ac.uk Phone: 0191 515 2529

Who can I contact if I have questions about MRONJ-GDP?

If you have any questions, we would like you to get in touch with us. You can do this by telephoning us on 0191 5152448 or you can email us on andrew.sturrock@sunderland.ac.uk

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 **Response Form** 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 practitioners 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

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MRONJ-GDP Participant Information Sheet

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.

Thank you for taking the time to read this information.

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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			
<i>Personal Characteristics</i>			
1. Interviewer/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..
<i>Relationship with participants</i>			
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 3	A participant information sheet was provided to all participants.
8. Interviewer characteristics	What characteristics were reported about the interviewer/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			
<i>Theoretical framework</i>			
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 comparative analysis.

<i>Participant selection</i>			
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	7	A convenience sampling and snowball 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 2-3)
12. Sample size	How many participants were in the study?	9	15 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.
<i>Setting</i>			
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	7	Data were collected at a time and place convenient to the interviewee; this was at their place of work.
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	7	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
<i>Data collection</i>			
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 interviews 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 interview 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?	7	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 comparative analysis was utilised as a means of enriching the data through iterative data collection and analysis
23. Transcripts returned	Were transcripts returned to	7	No

	participants for comment and/or correction?		
Domain 3: analysis and findings			
<i>Data analysis</i>			
24. Number of data coders	How many data coders coded the data?	19	AS identified the thematic framework and interpreted the data, which was reviewed and refined by the research team.
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
<i>Reporting</i>			
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	9-14	Quotation are presented with clearly identifiable participant numbers
30. Data and findings consistent	Was there consistency between the data presented and the findings?	9-14	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	9-14	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	9-14	Yes