THE ROLE OF THE PHARMACIST IN THE PROMOTION OF ORAL HEALTH AND THE INTERPROFESSIONAL PREVENTION OF MEDICATION-RELATED OSTEONECROSIS OF THE JAW (MRONJ)

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Abstract

Oral health conditions affect a significant proportion of the population, with many patients not engaging with dental services or prioritising oral healthcare. There is increasing evidence of associations between oral and general health, including a bidirectional link between type 2 diabetes and periodontal disease, and a number of prescribed medications also have oral health-related adverse effects. Medication-related osteonecrosis of the jaw (MRONJ) is an adverse effect of a range of medications used to treat osteoporosis and cancer. It has significant implications for patients and is challenging to treat, therefore the prioritisation of preventive measures through effective interprofessional collaboration is recommended for this patient group.

This thesis represents the cumulation of 5 individual peer reviewed publications that explore the role of the pharmacist in the promotion of oral health and in the prevention of MRONJ.

A grounded theory approach was adopted in this work, with a range of semi-structured interviews and focus groups undertaken with a total of 82 healthcare professionals and patients. Constant comparative analysis enabled the enrichment of data through an iterative process of data collection and analysis, with Ritchie and Spencer's framework analysis facilitating the identification and prioritisation of salient themes. In the final paper forming this thesis, a community pharmacy-based oral health intervention was developed and piloted on over 1,000 patients in County Durham.

Each of the studies has produced independent results and they are presented individually in this thesis. This is followed by the exploration of the work as a whole through the Rainbow Model of Integrated Care.

This work has highlighted that MRONJ has significant detrimental implications for quality of life, causing a range of significant physical, psychological and social complications. However, it has also shown that there is limited knowledge of the condition amongst healthcare professionals and patients, and that the recommended preventive care is not prioritised in practice. Dental professionals are isolated from other professional groups, with my research demonstrating that a lack of integration and collaboration between dental and general healthcare services limits the quality of patient care. An increased focus on preventive dental care and interprofessional education on oral health could help to reduce the risk of MRONJ and to improve both the oral and general health of the population.

This work has identified that pharmacists are able to play a greater role in the provision of oral healthcare and in preventing MRONJ. This research has identified that pharmacists are able to provide oral health interventions which are acceptable to patients and can result in positive intentions to change oral health behaviours. This includes engaging with patients who have a poor history of accessing dental services. I have added to the existing literature and provided evidence for commissioners and policy makers, demonstrating a key role for pharmacists in oral healthcare.

Lay summary

Many people in the UK have poor oral health, this includes problems with the mouth, teeth and gums. We also know that poor oral health can negatively affect a person's general health and wellbeing. A number of medications can also cause oral health problems. In many cases these can be quite mild, but some medications have very serious side effects. An example of this is called osteonecrosis of the jaw; this is a rare condition where the jaw bone does not heal after having a tooth taken out, causing a part of the jaw bone to die and become painful. Some medications which we use to treat certain cancers and bone conditions such as osteoporosis can cause this problem. This condition is, however, preventable, as patients should be educated on the importance of looking after their teeth when taking these medications and they should be seen by their dentist before starting the medication and again regularly whilst taking them.

However, we know that this preventive advice is not always provided by healthcare professionals and many patients do not know about the risk with these medications. In this research, a wide range of people (healthcare professionals and patients) have been interviewed to explore why this preventive advice is not being followed and how healthcare professionals could better work together to prevent this condition. I found that this condition has a very big impact on patients, causing pain, anxiety and problems such as eating and drinking in public. The patients reported that this causes a much bigger impact on their life than what we previously thought, which makes it more important than ever to prevent this condition from occurring. I found that most doctors and pharmacists did not know enough about this condition, which tells us we need to do more education on this topic to improve their knowledge and awareness. I also found that dentists and medical/pharmacy teams do not communicate well with each other and

that ways of improving team work and communication are needed to better help this patient group.

I also wanted to find out how pharmacists could generally improve the oral health of their patients. In this research, a community pharmacy-based oral health service was designed and over 1,000 patients were given information and practical demonstrations on how to look after their mouth, teeth and gums. This study found that many of these patients planned to change how they look after their mouth and teeth after they received the intervention and that pharmacies were a good place to receive information on oral health.

The work described above is a collection of 5 separate research papers which I have produced and published in academic journals. In this thesis I have presented all 5 of these papers and discussed how they together form a joined-up piece of research.

Acknowledgements

I would like to express my gratitude and sincere thanks to my supervisory team, Professor Scott Wilkes, Professor Catherine Hayes and Professor Philip Preshaw. I have benefited significantly from your individual knowledge, experience and continuous support. It has been a pleasure to publish with you all and we have become an effective team over the past 5 years. Any good research produces as many new questions as it does answers and I hope that we can continue to work together on many more projects in the future.

I would like to thank each of the 82 participants who gave up their time voluntarily to take part in interviews. This includes many patient participants, recruited with assistance from the NIHR North East and North Cumbria Clinical Research Network and from the University of Sunderland Patient Carer and Public Involvement group. Special thanks must go to the patient participants who suffer from medication-related osteonecrosis of the jaw. I hope I have captured the significance of the condition through my research and wish each of you the best with your ongoing treatment.

Many thanks to Pharmacy Research UK and the UK Clinical Pharmacy Association for funding part of this research and to my colleagues at the University of Sunderland for supporting my research and aspirations to complete my PhD. I would also like to thank my students at the University of Sunderland who continue to inspire me to develop engaging and impactful educational opportunities.

Finally, I would like to pay a special tribute to my family. My wife Deborah, daughter Grace, my parents Jeff and Kath, and sister Fiona. Many thanks for your unwavering support through the preparation of this thesis and in everything else that I do.

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Abbreviations

BDA	British Dental Association
BDJ	British Dental Journal
BMJ	British Medical Journal
BRONJ	Bisphosphonate-related Osteonecrosis of the Jaw
CRN	Clinical Research Network
EMA	European Medicines Agency
GP	General Practitioner (medical)
GDP	General Dental Practitioner
GPhC	General Pharmaceutical Council
HEE	Health Education England
IPE	Interprofessional Education
IV	Intravenous administration
MHRA	Medicines and Healthcare products Regulatory Agency
MRONJ	Medication-related Osteonecrosis of the Jaw
NHS	National Health Service
NIHR	National Institute for Health Research
NMS	New Medicines Service
NPT	Normalization Process Theory
NTF	National Teaching Fellow
PCN	Primary Care Network
PRUK	Pharmacy Research UK
RPS	Royal Pharmaceutical Society
REF	Research Excellence Framework
SDCEP	Scottish Dental Clinical Effectiveness Programme

SFHEA	Senior Fellow Higher Education Academy
UKCPA	United Kingdom Clinical Pharmacy Association

Professional Background

I am a registered pharmacist, with clinical experience across a wide range of pharmacy settings. I began my professional career in 2008 as a clinical pharmacist at Gateshead Health NHS Foundation Trust. During this time I gained experience rotating through a variety of different clinical specialities; these included medical admissions, general surgery, orthopaedics, elderly care, haematology, oncology, respiratory, cardiology, endocrinology, gastrointestinal medicine, and I provided anticoagulation monitoring services to satellite general practice (GP) clinics across Gateshead.

In 2010, I joined MD & AG Burdon, a small chain of independent community pharmacies in the North East of England. This was a joint post with Intelligent Prescribing Solutions; a company that provides medicines optimisation, prescribing support advice, and anticoagulant monitoring services to GP practices across the region. In this post I managed a busy community pharmacy and worked in several GP practices in both South Tyneside and County Durham.

In 2014, as part of my employment with MD & AG Burdon, the opportunity arose to work as an Academic Tutor in the School of Pharmacy at the University of Sunderland. In 2015 I was appointed to the full-time role of Senior Lecturer in Pharmacy Practice and Clinical Therapeutics, marking the start of my journey to become an independent researcher and the beginning of my PhD by Publication.

I was appointed to my current role as Principal Lecturer and the Programme Leader for the Master of Pharmacy (MPharm) course in 2017; with a cohort of approximately 700 students it is one the largest pharmacy programmes in the United Kingdom. In this role I am responsible for the strategic academic leadership and operational management of the MPharm programme; encompassing all aspects of teaching, learning, assessment

and student support, whilst upholding the requirements of our professional accrediting body, the General Pharmaceutical Council (GPhC).

Format and contents of the thesis

This thesis presents a body of published work comprising 5 first authored peer reviewed publications. Each of the papers forming this submission is presented independently, alongside a written narrative that acts to produce a cohesive body of work.

The thesis begins with an explanation of the contribution of each author to the published works and presents a range of associated publications and artefacts which are included in the appendices.

An introduction to the links between oral and systemic health and medication-related osteonecrosis of the jaw (MRONJ) is provided, and although literature reviews were performed as an integral part of the production of each individual paper, the introduction is followed by an overview of the key literature relevant to this work. The methodology chapter explores my positionality and the philosophical underpinnings of my research, explaining and justifying the methods adopted in each paper. The results section consists of each of the 5 published papers alongside a narrative synthesis of results explored collectively through the Rainbow Model of Integrated Care. The discussion presents a summary of key findings, a comparison of the work to the existing literature, critical exploration of the strengths and limitations of the work, recommendations for clinical practice and the future direction of study in this field. This is followed by a concise conclusion to the body of work.

The thesis concludes with chapters exploring the impact of my work on the education and training of pharmacists, and my reflections on my own research journey and the completion of a PhD by Published Works.

Published papers and contribution statements

Paper 1: Referred to in text as *(GP/pharmacist attitudes towards MRONJ)*

Sturrock, A., Preshaw, P., Hayes, C. and Wilkes, S. (2017). Attitudes and perceptions of GPs and community pharmacists towards their role in the prevention of bisphosphonate-related osteonecrosis of the jaw: a qualitative study in the North East of England. *BMJ Open*, 7(9), p.e016047 https://doi.org/10.1136/bmjopen-2017-016047

AS and SW designed the study. AS recruited the participants and carried out the study. AS identified the thematic framework and interpreted the data. AS, SW, PP and CH reviewed and refined the data. AS wrote the paper and all authors revised it.

Paper 2: Referred to in text as *(patient attitudes towards MRONJ)*

Sturrock, A., Preshaw, P., Hayes, C. and Wilkes, S. (2019). Perceptions and attitudes of patients towards medication-related osteonecrosis of the jaw (MRONJ): a qualitative study in England. *BMJ Open*, 9(3), p.e024376. https://doi.org/10.1136/bmjopen-2018-024376

AS, SW, CH and PMP designed the study. AS recruited the participants and carried out the study. AS identified the thematic framework and interpreted the data. AS, SW, PMP and CH designed the qualitative research methodology and reviewed and refined the data. AS wrote the paper and all authors revised it.

Paper 3: Referred to in text as *(dentist attitudes towards MRONJ)*

Sturrock, A., Preshaw, P., Hayes, C. and Wilkes, S. (2019). 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. *BMJ Open*, 9(6), p.e029951. https://doi.org/10.1136/bmjopen-2019-029951

AS, SW, CH and PMP designed the study. AS recruited the participants and carried out the study. AS identified the thematic framework and interpreted the data. AS, SW, PMP and CH reviewed and refined the data. AS wrote the paper and all authors revised it.

Paper 4: Referred to in text as *(lack of interprofessional working)*

Sturrock, A., Preshaw, P., Hayes, C. and Wilkes, S. (2020). 'We do not seem to engage with dentists': a qualitative study of primary healthcare staff and patients in the North East of England on the role of pharmacists in oral healthcare. *BMJ Open,* 0:e032261. https://doi.org/10.1136/bmjopen-2019-032261

AS, SW, CH and PP designed the study. AS recruited the participants and carried out the study. AS identified the thematic framework and interpreted the data. AS, SW, PP and CH reviewed and refined the data. AS wrote the paper and all authors revised it.

Paper 5: Referred to in text as *(oral health promotion in pharmacy)*

Sturrock, A., Cussons, H., Jones, C., Woodcock, C. and Bird, L. (2017). Oral health promotion in the community pharmacy: an evaluation of a pilot oral health promotion intervention. British Dental Journal, 223(7), pp.521-525. https://doi.org/10.1038/sj.bdj.2017.784

AS, CJ and CW designed the intervention; AS designed the evaluation; AS and HC analysed the patient evaluation data, performed the interviews and analysed the qualitative data; HC transcribed the qualitative data; AS prepared the manuscript which was reviewed by CJ, CW, HC and LB.

Associated publications and artefacts

Each of the studies which form this submission have led to a range of associated publications in peer reviewed academic journals and oral/poster presentations at professional conferences. This work is also supported by a range of artefacts, including press releases, editorial comments and various pieces of research documentation. Details of these publications and artefacts are presented in this section of the thesis, highlighting the links to the relevant appendix.

Publications

Appendix 1. Sturrock, A., Preshaw, P., Hayes, C. and Wilkes, S. (2020). The role of the pharmacist in the prevention of Medication-Related Osteonecrosis of the Jaw (MRONJ). *The Pharmaceutical Journal*. 303;7928 https://doi.org/10.1211/PJ.2019.20206623

Appendix 2. Sturrock, A. and Hayes, C. (2020). Designing and Implementing a Mixed-Methods Evaluation of a Community Pharmacy–Based Oral Health Intervention. *Sage Research Methods Cases.* https://dx.doi.org/10.4135/9781529717594

Appendix 3 . Sturrock, A. and Hayes, C. (2020). The Challenge of implementing a Grounded Theory approach in a Qualitative Study of GPs and Pharmacists in the Prevention of Bisphosphonate-related Osteonecrosis of the Jaw (BRONJ). *Sage Research Methods Cases*. https://dx.doi.org/10.4135/9781529709667

Appendix 4. Ferrie, L. and Sturrock, A. (2017). Interprofessional drug safety: enhancing collaborative knowledge exchange. *Medical Education.* 51:1176–1177. https://doi.org/10.1111/medu.13442

Oral/Poster Presentations

Sturrock, A., Preshaw, P., Hayes, C. and Wilkes, S. (2018). The Multidisciplinary Prevention of Medication-related Osteonecrosis of the Jaw (MRONJ). *National Osteoporosis Society Conference*, Birmingham. (Poster Presentation)

Sturrock, A., Preshaw, P., Hayes, C. and Wilkes, S. (2018). The Multidisciplinary Prevention of Medication-related Osteonecrosis of the Jaw (MRONJ). *Pharmacy Together Conference*, London. (Poster Presentation)

Sturrock, A., Preshaw, P., Hayes, C. and Wilkes, S. (2016). The multidisciplinary approach to Bisphosphonate-related Osteonecrosis of the Jaw. *Society for Academic Primary Care Northern Conference*, Windermere. (Oral Presentation)

Ferrie, L. and Sturrock, A. (2017). The last frontier. Interprofessional learning (IPL) events between dentistry and pharmacy. *37th SEF National Meeting with guest society@ the British Pharmacological Society*, Barcelona. (Oral Presentation)

Editorials, press releases and miscellaneous artefacts

Appendix 5. BDJ Research Insights – Thousands of new oral health educators Editorial piece from the Editor of the BDJ discussing the findings of *(oral health promotion in pharmacy)*.

Appendix 6. BDJ Research Insights – Other journals in brief

A selection of abstracts of clinically relevant papers from other journals discussing *(patient attitudes towards MRONJ)*.

Appendix 7. BDJ Author Q&A

A question and answer discussion related to the findings of *(oral health promotion in pharmacy)*.

Appendix 8. NIHR Letter

A letter congratulating the research team for recruiting to time and target for the NIHR portfolio study *(patient attitudes towards MRONJ)*.

Appendix 9. NIHR Certificate of Achievement

A certificate confirming successful recruitment to time and target for the NIHR portfolio study *(patient attitudes towards MRONJ)*.

Appendix 10. University of Sunderland Press Release

A press release discussing the findings of *(patient attitudes towards MRONJ)*.

Appendix 11. University of Sunderland Press Release

A press release discussing the findings of *(oral health promotion in pharmacy)*.

Appendix 12. BDJ Upfront

A news piece in the BDJ discussing the findings of *(oral health promotion in pharmacy)*.

Appendix 13. Pharmacy Research UK (PRUK) Press Release

A press release discussing the 2016 PRUK and UKCPA Clinical Pharmacy Research Grant for *(patient attitudes towards MRONJ)*.

Appendix 14. United Kingdom Clinical Pharmacy Association (UKCPA): In Practice Newsletter

A newsletter piece discussing *(patient attitudes towards MRONJ)*, which was funded by PRUK and UKCPA.

Appendix 15. Advance HE: National Teaching Fellow (NTF) Profile.

Chapter 1: Introduction

1.1 The links between oral and systemic health

Oral health conditions are thought to affect a significant proportion of the world's population, approximately 3.9 billion people worldwide and cost the National Health Service (NHS) in England £3.4 billion per year (Marcenes et al., 2013, NHS England, 2014). Dental treatment in the UK is provided through a combination of both NHS and private dental practices. The most recent statistics show that only 50.4% of the adult population in England were seen by an NHS dentist in the last 24 months (NHS Digital, 2019) and the most recent Adult Dental Health Survey (2009) stated that 23% of the UK population do not attend a dentist (O'Sullivan et al., 2011).

Oral health is, however, important for general health and wellbeing, and, for example, there is increasing evidence of a bidirectional relationship between periodontitis and some systemic conditions, most notably type 2 diabetes (Tonetti and Van Dyke, 2013, Chapple and Genco, 2013). Periodontitis affects approximately half of all adults in the UK (O'Sullivan et al., 2011); it is a chronic inflammatory disease that is caused by a persistent and dysregulated immune-inflammatory response to the presence of dysbiotic bacterial biofilm accumulation in the subgingival environment. It results in destruction of the supporting tissues surrounding the teeth, which is often painless, going unnoticed and untreated until reaching a more advanced stage, resulting in tooth mobility and early tooth loss (Bissett et al. 2013).

Poor glycaemic control in patients with type 2 diabetes is associated with elevated levels of systemic inflammatory markers, which increases inflammation in the tissues which surround the teeth. Patients with poorly controlled diabetes therefore have a

three-fold increased risk of developing periodontitis. In turn, the systemic inflammation associated with periodontal diseases is thought to also enhance the diabetic state and is associated with higher HbA1c levels and diabetes complications (Preshaw et al., 2011, Mealey and Oates, 2006, Preshaw and Bissett, 2019).

The importance of tight control of HbA1c is well established in the management of diabetes, with small reductions in HbA1c translating into improved patient outcomes for patients with type 2 diabetes; a 1% reduction in HbA1c has been associated with a 21% reduction in diabetes-related deaths, 14% reduction in myocardial infarctions and a 37% reduction in microvascular complications (Stratton et al., 2000). A Cochrane Systematic Review published in 2015 highlighted that randomised controlled trials have demonstrated that periodontal therapy is associated with a 3-4 mmol/mol (0.3-0.4%) reduction in HbA1c levels after 3 months (Simpson et al., 2015). This reduction is similar to that expected from the addition of second line diabetes medications (Bissett et al., 2013). There is also evidence of an association between atherosclerotic cardiovascular disease and poor oral health (Dietrich et al., 2017).

Cancer of the ‘mouth’ or oral cavity and ‘throat’ oropharyngeal cancer rank as the seventh most common cancers globally, with the highest incidence rates in males over the age of 60 years and patients living in deprived areas (International Agency for Research on Cancer, 2014, Purkayastha et al., 2016). Oral cancer is frequently preceded by a visually detectable pre-malignant condition (leukoplakia), therefore potentially making early detection through screening programmes feasible (Yusof et al., 2006). However, a recent study in Scotland found that in the majority of diagnosed oral cancer cases, patients had made no contact with a dentist in the 2

years preceding the diagnosis. This study concluded that the exploration of early detection strategies in alternative settings should be explored (Purkayastha et al., 2018). This potentially presents an opportunity for pharmacists to get involved with screening programmes and educational campaigns.

Many medications have the potential to impact negatively on a patient's oral health. Medication-related osteonecrosis of the jaw (MRONJ) is a rare, yet significant complication of anti-resorptive and anti-angiogenic drugs and is discussed further in Section 1.2 of this thesis. Other examples of medications impacting on oral health include: calcium channel blockers such as nifedipine, ciclosporin and phenytoin which are associated with drug-induced gingival overgrowth; inhaled corticosteroids with oropharyngeal adverse events, such as oral candidiasis; and medications with anticholinergic adverse effects resulting in xerostomia.

Oral health promotion has traditionally been the preserve of dental health professionals, but with the increasing recognition of the link between oral and general health, there is an increased importance in other health professionals promoting oral health. Wilson and Soni, the former presidents of the British Dental Association (BDA) and Royal Pharmaceutical Society (RPS), respectively, recently published an opinion piece in the *British Dental Journal*; emphasising the opportunities for pharmacy and dentistry to spearhead a new era of interprofessional healthcare (Wilson and Soni, 2016). The role of the pharmacist in the promotion of oral health and in the prevention of MRONJ is explored in this commentary and the individual papers which form this thesis.

1.2 Medication-related Osteonecrosis of the Jaw (MRONJ)

MRONJ is a complex phenomenon that has a significant negative impact on patients' quality of life; it is associated with a range of anti-resorptive and anti-angiogenic drugs. The official definition provided by the American Association of Oral and Maxillofacial Surgeons is as follows (Ruggiero et al., 2014):

> *"Exposed bone, or bone that can be probed through an intraoral or extraoral fistula, in the maxillofacial region that has persisted for more than eight weeks in patients with a history of treatment with anti-resorptive or anti-angiogenic drugs, and where there has been no history of radiation therapy to the jaw or no obvious metastatic disease to the jaws".*

The first case reports of osteonecrosis of the jaw date back to the early 2000s and linked bisphosphonate therapy to the presentation of the condition; this led to the initial definition of bisphosphonate-related osteonecrosis of the jaw (BRONJ) and the production of prescribing safety alerts by both the Medicines and Healthcare products Regulatory Agency (MHRA, 2009) and European Medicines Agency (EMA, 2009). The term BRONJ has subsequently been replaced with MRONJ due to the emergence of other implicated medications, as listed in (Table 1) below.

Table 1. Drugs with MHRA Safety Updates for MRONJ – as of April 2017

Drug Name	Trade name (s)	Indication
Bisphosphonates		
Alendronic acid	Binosto®	Osteoporosis
	Fosamax®	
	Fosavance®	
Sodium risedronate	Actonel®	Osteoporosis
	Actonel Combi®	Paget's Disease
Zolendronic acid	Aclasta®	Osteoporosis
	Zometa®	Paget's Disease
		Cancer
Ibandronic acid	Bondronat®	Osteoporosis
	Bonviva®	Cancer
	Iasibon®	
	Quodixor®	
Sodium pamidronate	Aredia®	Paget's Disease
		Bone pain
		Cancer
Sodium clodronate	Bonefoc®	Bone pain
	Clasteon®	Cancer
	Loron®	
RANKL Inhibitors		
Denosumab	Prolia®	Osteoporosis
	Xgeva®	Cancer
Anti-angiogenic drugs		
Bevacizumab	Avastin®	Cancer
Sunitinib	Sutent®	Cancer
Aflibercept	Zaltrap®	Cancer

Table adapted from SDCEP (SDCEP, 2017)

The pathogenesis of MRONJ is still not particularly well understood; it is likely multifactorial and thought to be related to the unique nature of the structure, function and blood supply of the jaw bones, and the microbiology of oral plaque biofilm (Otomo-Corgel, 2012). Both the mandible and maxilla have a high blood supply, which may result in an increased concentration of implicated medicines in the jaw. Remodelling also occurs at a much higher rate in alveolar bone (that part of the jaw bone which supports the teeth) than elsewhere in the body; this is likely due to the forces related to chewing and the presence of teeth, and therefore there is a higher uptake of implicated medications in the alveolar bone compared to elsewhere in the skeleton (Otomo-Corgel, 2012). Other proposed mechanisms of MRONJ development include the inhibition of angiogenesis, inflammation or infection, immune dysfunction, soft tissue toxicity and vitamin D deficiency (Ruggiero et al., 2014).

Invasive dentoalveolar surgery, such as a tooth extraction, in patients prescribed implicated medications is the major risk factor for the development of MRONJ; with a tooth extraction identified as a precipitating event in approximately 50-60% of patients with MRONJ (Ruggiero et al., 2014).

The diagnosis of MRONJ is complex and therefore requires specialist input; patients with suspected MRONJ lesions should be referred for general dental assessment and treatment interventions where necessary (SDCEP, 2017). However healthcare professionals should be aware of the key signs and symptoms of MRONJ in at-risk patients, these include: exposed necrotic bone in the oral cavity; pain; signs of infection, such as fistula, swelling, cellulitis and pus exudation; tingling and numbness / pins and needles (hypoesthesia or paraesthesia) in the chin or lower lip;

loosening of teeth (mobility); bad breath (halitosis) (Otto et al., 2018). Figure.1 shows the intra-oral appearance of a patient with MRONJ.

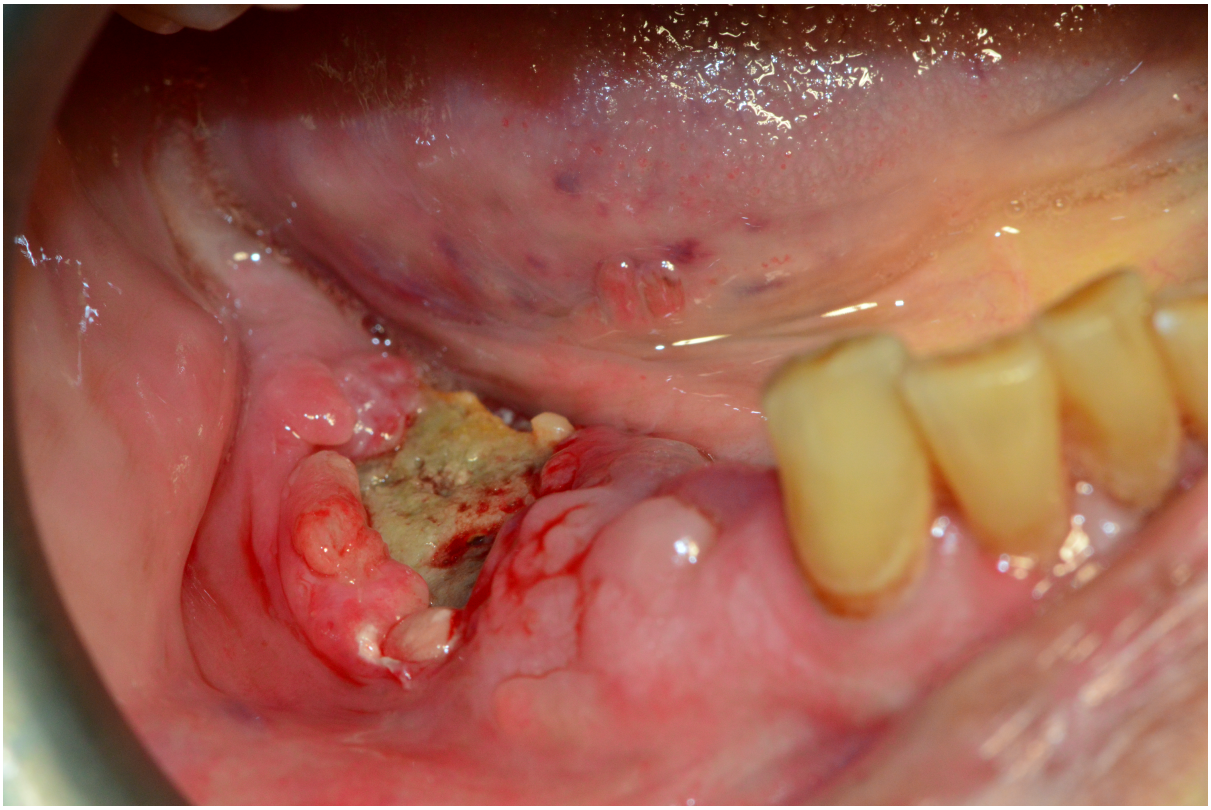

Figure.1 The intra-oral appearance of a patient with MRONJ.

Legend *Exposed necrotic bone is evident in the lower right region of the mandible, following extraction of the posterior teeth. Image courtesy of Dr F. Graziani and Dr Nisi*

The reported incidence rates of MRONJ vary in the published literature. The general consensus is that the incidence of MRONJ in osteoporosis patients treated with anti-resorptive drugs is 0.01-0.1%, with cancer patients treated with anti-resorptive or anti-angiogenic drugs at much greater risk, with an estimated incidence of 1% (SDCEP, 2017).

The management of MRONJ is challenging and the condition can cause significant morbidity; a small study of 34 patients with MRONJ utilised the Oral Health Impact Profile (OHIP-14) to find that the condition significantly affects patient's quality of life ($p<0.001$) (Miksad et al., 2011). Due to the significant morbidity associated with MRONJ and the limited treatment options available, the elimination or stabilisation of oral disease before initiating antiresorptive agents is recommended as a preventive strategy for MRONJ (SDCEP, 2017). Therefore, current clinical guidelines recommend that preventive measures are implemented with the elimination or stabilisation of oral diseases before the initiation of implicated medications. In particular, preventive measures should be prioritised in patients receiving treatment for cancer and with bone metastases. The aim is to prioritise care that will reduce mucosal trauma and/or act prophylactically to help avoid the need for future dental extractions or development of conditions which may result in a need for oral surgery or dental procedures that impact on the osseous structures of the jaw.

There is evidence to support the implementation of preventive strategies to reduce the risk of MRONJ. Vandone et al (2012) investigated the implementation of screening and pre-treatment preventive dental care in patients prescribed intravenous (IV) bisphosphonates for bone metastases from solid tumours. They reported a 50% reduction in the incidence rate with screening and pre-treatment; osteonecrosis of the jaw was observed in 5.5% of patients (n=11/200) not receiving preventive dental measures and 2.8% (n=6/211) in those receiving preventive dental care before and during treatment with bisphosphonates.

Dimopoulous et al (2009), reported a statistically significant reduction in the incidence of MRONJ amongst multiple myeloma patients prescribed zoledronic acid

following the implementation of preventive measures; the incidence rate before the implementation of preventive measures was 0.671/100 person-months and 0.230/100 person-months afterwards [IR ratio 2.92, P=0.029, 95% confidence interval 1.06-8.03].

Mucke et al., (2016) reported a statistically significant reduction in the incidence of MRONJ amongst prostate cancer patients treated with zolendronic acid; patients in group A were assigned to either standard treatment by the patient's general dental practitioner (GDP) and patients in group B were reviewed at 12 week intervals, receiving a dental assessment and any required treatment interventions before the administration of IV zolendronic acid. The incidence rate in group A was 0.073 cases/year, and there was a significant reduction ($p<0.001$) of 82% in the incidence rate reported in group B (0.0131 cases/year).

It is therefore important that patients are fully informed about the risk of MRONJ, the appropriate preventive strategies available, and patients are signposted to dental services, preferably before implicated medications are commenced. Current clinical guidelines recommend a multidisciplinary approach to the prevention of MRONJ; this clearly represents an opportunity for pharmacists, in all settings, to become involved with this patient group and provide both patient and healthcare professional education on the risk of the development of MRONJ and appropriate preventive measures.

Chapter 2: Literature Review

Literature reviews were performed as an integral part of each of the individual papers which contribute to this thesis. A comprehensive overview of the literature was required to establish the existing evidence base and the gaps in knowledge that my own research could address.

The purpose of this chapter is therefore to provide a summary of the key literature in relation to both the role of the pharmacist in the provision of oral health promotion and in the prevention of MRONJ.

2.1 The role of the pharmacist in the provision of oral health promotion

The role of the pharmacist in the provision of oral healthcare has been explored in the literature; the majority of these studies have been performed in the UK or Australia and New Zealand.

The existing literature has identified that patients routinely attend community pharmacies for advice in relation to oral health concerns; this evidence has been produced through several relatively small-scale survey-based studies. The study by Mauder and Landes (2005) is of particular relevance to my work. Their research surveyed community pharmacies located in the County Durham Dales Primary Care Trust; a geographical area similar to that in which my research has been undertaken. Their findings identified that patients were frequently visiting pharmacies for oral health advice, with 67.4% of pharmacies reporting more than 11 requests per week. This demonstrates that there is a potential pool of patients already engaging with pharmacies for oral health-related advice. A national survey in Australia, with a larger sample size of 644 pharmacists and 280 pharmacy assistants, explored oral health

service provision in community pharmacies; their participants also reported frequent consultations with patients requiring oral health advice. However, a survey of pharmacy counter assistants across parts of Northern England found that advice is usually only provided in response to patient requests as opposed to through health promotions activities (Steel and Wharton, 2011). This represents a key finding in relation to my research, as I have sought to focus the provision of oral health advice through the more proactive recruitment of potential patients (*oral health promotion in the pharmacy)* as opposed to reactive consultations in response to patient requests. This approach potentially facilitates engagement of a wider group of patients with oral health than the reactive provision of advice described previously in the existing literature.

The literature has shown that pharmacists and pharmacy support staff have demonstrated agreement that the provision of oral health advice is part of their role. The vast majority of both pharmacy counter assistant (89%) and pharmacists (99.4%) agreed that the provision of oral health education was part of their role (Steel and Wharton, 2011, Mann et all., 2015). Pharmacists have also expressed an interest in further expanding their current roles in relation to oral health, with 86% of participants keen to expand this role further in the future (Steel and Wharton, 2011).

Pharmacists have a clear role in providing advice to specific patient requests, however, targeted oral health interventions or specifically designed oral health promotion services have not been explored fully in the existing literature. In New Zealand, a large qualitative study identified both poor awareness of oral health and systemic health links, and a lack of additional provision of oral health advice to patients with cardiovascular disease and/or diabetes (Buxcey et al. 2012).

Missing from the literature is evidence to support how these activities should be delivered in practice and whether these services can positively influence patient's oral health behaviours. In particular, my study (oral health promotion in the pharmacy) will address this gap in the literature and provide evidence supporting the provision of proactive oral health promotion activities in a pharmacy setting.

There is also little evidence exploring the relationship between pharmacy and dental service providers, with integration between care settings being required to further develop roles and effective communication. The existing literature has identified poor collaborative relationships and a lack of communication between pharmacy and dental service providers (Hoang et al., 2019, Hajj et al., 2019). Although pharmacists reported awareness of the location of local dental practices, few had actually met each other and had no knowledge of opening times and emergency arrangements (Mauder and Landes, 2004). This is despite the vast majority of pharmacists expressing an interest in working collaboratively with other healthcare professionals in the local area (Freeman et al., 2017, Hoang et al., 2019). Across this whole body of work I have explored the attitudes and perceptions of a range of primary care staff and patients to delivering oral healthcare and integrating practices across professional boundaries; this is a particular focus of my paper (lack of interprofessional working). This addresses key gaps in the literature, providing evidence to support better integration of oral and general health services and barriers/facilitators to improving collaboration and patient care.

Pharmacists and pharmacy staff have reported confidence in managing common oral health problems (Mauder and Landes, 2004, Steel and Wharton, 2011), however, there is evidence of sub-optimal practices in the literature. A study utilising

a series of case vignettes identified that pharmacist's confidence was not associated with the provision of best oral health practice recommendations (Taing et al., 2019) and the presentation of simulated patients requesting mouth ulcer treatment demonstrated a lack of adherence to practice guidelines (Janse Van Rensburg, 2019).

Other studies have also identified a lack of knowledge/training in oral healthcare as a significant barrier to furthering the role of pharmacists in this field (Freeman et al., 2017, Hajj et al., 2019) with limited provision of oral health education as part of pharmacy training programmes (Gavaza et al., 2016, Hoang et al., 2019). In the study by Mauder and Landes (2004), 65% of participants were interested in further developing their knowledge through continued professional development (CPD) or educational programmes. However, there is no literature exploring the format of any additional education/training that is required to enable pharmacists to further oral health-related roles in practice. My work *(oral health promotion in the pharmacy)* provides a model for both an oral health promotion service and the training required for pharmacy staff to deliver such interventions. This training has subsequently been rolled out to pharmacy staff across the North of England, as discussed in Chapter 7 of this thesis.

It is apparent from the literature that pharmacists perceive the provision of oral health promotion to be part of their role. Pharmacists and pharmacy support staff require further education and training in this field to best support patients, however, the evidence base suggests that they are both well placed and willing to expand current provision.

2.2 The role of the pharmacist in the prevention of MRONJ

As highlighted above, pharmacists currently provide much of their oral health advice in response to specific patient requests (Steel and Wharton, 2011) with limited focus on the links between oral and systemic disease (Buxcey et al. 2012). There is a lack of published literature on the roles of pharmacists in relation to the oral health-related adverse effects of medication. Despite published clinical guidelines identifying a role for pharmacists in the prevention of MRONJ (SDCEP, 2017), there is a significant lack of quality evidence exploring both the knowledge of MRONJ amongst pharmacists and their current/potential role in the prevention of the condition.

What is clear, is that there is frequent contact between pharmacists and patients prescribed medications implicated in MRONJ. This is particularly the case for community pharmacists and patients prescribed oral bisphosphonates; with 77.4% of pharmacists seeing patients prescribed these medications each day (Masson et al. 2009). In comparison, in the same study only 35.3% of GPs and 3.4% of GDPs reported seeing patients prescribed these medications each day. In practice, the number of patients prescribed oral bisphosphonates has increased significantly since the publication of this study; in England, prescribing data show 6,007,071 individual supplies of alendronic acid 70mg in 2018, compared with 4,785,886 supplies in 2008 (NHS Digital, 2019). This is also the case for the prescribing of other MRONJ-implicated medications; for example, prescribing rates for denosumab are increasing rapidly with 52,210 individual supplies in England during 2018 compared with 43,063 in 2017 (NHS Digital, 2019). The frequency of contact with at-risk patients and the increasing use of medications implicated in MRONJ therefore represents a significant opportunity for pharmacists to engage with preventive advice.

The existing literature presents differing findings in relation to the awareness of MRONJ amongst pharmacists. The largest of these studies found that 84.6% of Australian pharmacists and 88.2% of GPs were able to identify MRONJ as a complication associated with bisphosphonate therapy (Raj et al., 2016). The only similar study in the UK produced very different findings, with only 11.8% of GPs and 9.7% of pharmacists able to specifically identify MRONJ as an adverse effect of bisphosphonate therapy (Masson et al., 2009); however, the generalisability of these findings is limited by the small response rate of the study, with only 31 pharmacist participants.

The recommendations in the MRONJ preventive guidelines include education of patients prescribed implicated medications on the associated oral health risks and referral for pre-treatment preventive dental care on initiation (SDCEP, 2017). Despite 100% of Australian pharmacists and 75.5% of GPs reporting that they advised patients to inform their dentist of their bisphosphonate prescription, more than 50% of GDPs reported ‘never’ or ‘rarely’ receiving referrals for pre-treatment dental care (Raj et al., 2016). Again, a small sample size of pharmacists (n=26) limits the reliability and generalisability of the results of this study, however a significantly larger number (n=283) GDPs did participate.

Although pharmacists have reported that they inform patients on the risk of MRONJ (Raj et al. 2016), a study undertaken in Germany found that this does not translate into patient awareness of the condition. Only 32% of patients prescribed IV bisphosphonates and 17% of patients prescribed oral products knew about the risk of developing MRONJ; only 13% of participants reported that they were informed of this risk by their GP. Where patients were aware of the association with MRONJ,

knowledge was typically acquired for most patients through the patient information leaflets supplied with the medication (Bauer et al., 2012). Of particular concern is the poor awareness of patients prescribed the higher risk intravenous preparations; there is a significantly higher incidence rate of MRONJ in this patient group, therefore guidelines recommend pre-treatment preventive dental care (SDCEP, 2017).

It is clear that there is a limited evidence base for the role of the pharmacist in MRONJ prevention; the studies reported in the published literature have typically adopted quantitative research methods and all have used patient or healthcare professional surveys. Significantly, these studies are limited by response rates and provide little insight into the underlying reasons or explanations of the findings. The literature does suggest that there is a lack of knowledge in relation to MRONJ amongst healthcare professionals and most importantly that patients prescribed implicated medications are not fully informed about the associated risks. My work has sought to explore the underlying attitudes and perceptions of pharmacists and GPs *(GP/pharmacist attitudes towards MRONJ),* GDPs *(dentist attitudes towards MRONJ)* and patients *(patient attitudes towards MRONJ)* towards the implementation of the recommended preventive care for this patient group. This adds to the literature providing evidence that explains the limited current provision of preventive care, identifies barriers and facilitators for improved integration of oral and general healthcare, and for improvements in patient safety for this patient group.

Chapter 3: Methodology and Positionality

3.1 Researcher background and philosophical assumptions

A discussion paper by (Bissell et al., 2002) highlighted that there *"is a tendency with pharmacy practice research to apply a research technique in order to get at the "truth" in the absence of a wider consideration of whether these techniques and the theoretical assumptions on which they were based are appropriate to the questions being asked".*

The purpose of this chapter is therefore to set out both my own personal position and the position of the work forming this thesis, against the theoretical and philosophical underpinnings that influence the research process.

Key to this research is the fact that I am a pharmacist and like all researchers hold a set of *a priori* beliefs; my embedded stance as a researcher brings together my personal and professional background, and my experiences in clinical practice. These could, perhaps, in the positivist paradigm, be seen as a source of bias, which could influence the outcome and credibility of the findings produced. However, my personal and professional experiences place me in a unique position to explore the role of the pharmacist in the provision of oral health; the interpretivist paradigm and the choice of qualitative methods employed in this research embrace this fact, acknowledging that the findings are co-constructed between the researched and the researcher.

It is my broad practice experience and my strong links to education that provide the foundations for my research. However, the oral health theme of this PhD was an obvious choice due to the relationship with my wife, Deborah, a GDP. This personal

relationship provides a unique foundation for the exploration of oral health, building upon my own professional and personal experiences. We have frequent conversations regarding prescribing in dentistry, the implications of prescribed medication on both dental and general health and wellbeing, and the limited dental education of non-dental healthcare professionals. As a result, exploration of the role of the pharmacist in the provision of oral healthcare became the focus of my work and the basis for the papers that form this submission.

Geographically, my work in clinical practice has been spread across the North East of England, a region in which there are areas of high deprivation and historically challenging healthcare needs. As a result, the oral health of many patients in the region is poor and this is something that I was aware of in my own practice. Many patients would attend my pharmacy seeking advice in relation to oral health problems and the number of patients not registered with GDPs or engaging with good oral hygiene behaviours was apparent.

During my own education I spent little time training with other healthcare professionals and no interprofessional learning opportunities were provided as part of my undergraduate training. The pharmacy profession is rapidly evolving, with pharmacists increasing providing more complex clinical care to patients, resulting in both increased clinical responsibility and accountability. In these roles pharmacists are required to work closely with the interprofessional team to provide optimum patient care and pharmacists are becoming established members of the team in general practice. Following a successful pilot, NHS England's General Practice Forward View (2016) committed to the investment of £112 million to further develop this role with the aim of providing an additional 1,500 clinical pharmacists to the

general practice workforce by 2020 (NHS England, 2016). Since I moved from clinical practice to an academic position, I have seen the benefits that interprofessional learning can bring for students, developing professional relationships, enhancing clinical knowledge and ultimately improving patient care. I was therefore motivated to explore opportunities to develop interprofessional collaboration at both an undergraduate level and in my research, in order to prepare my students for their future roles in clinical practice. This motivation, alongside my unique insight into oral healthcare and dental service provision led to the research forming this thesis.

Like most pharmacists I was educated to practice evidence-based medicine. Before embarking on my own research journey I was very much rooted in the traditional positivist biomedical paradigm, believing that extrinsic factors, variables and researchers themselves should be removed from the research process in order to categorically and statistically 'prove' a correlation or effect. The work forming this thesis takes a very different philosophical position, which will be explored in detail later in this chapter. However, it is important to acknowledge that I don't fundamentally disagree with this position. There is clearly an important place in the scientific and medical profession for objective research in the positivist paradigm. However, my perceptions of the social world in which medical services are actually delivered to patients, has changed through my work in clinical practice and exposure to differing standards and implementations of patient care across a range of healthcare settings.

The actual implementation of clinical services i.e. the provision of patient care through interaction with other human beings in the social world, is influenced by

many factors. Therefore, health services research, which is the field in which my work sits, leads to an altogether different approach to answering the questions posed by my research.

Four of the papers which form this submission follow the same methodological approach, however, due to the nature of the research question there are differences in (*oral health promotion in the pharmacy)*, which are expanded upon later in this chapter.

As my research questions developed, it became apparent that I was not looking to establish or categorically prove links between MRONJ and specific risk factors; this had already been answered, or was being examined by other researchers with a more suitable skill set than mine. However, it was apparent that the best practices and recommendations that have arisen from the scientific evidence were not being routinely implemented in clinical practice. This therefore leads to a very different approach and the limited works presented in the literature review chapter of this thesis clearly represent a relatively unexplored field of clinical practice. As such, the research process and research questions have been very much designed to illuminate what is happening in clinical practice, as opposed to testing a theory or a hypothesis against the data; this is therefore described as inductive discovery or inductive research.

This brings forward the principle of reflexivity, an important consideration in qualitative research. Reflexivity is the process of being self-aware and reflecting critically on the role of the researcher. Despite embracing my own role in the research process and the embedded stance which I bring, it should, however, at this point be noted that I have not undertaken this body of work in isolation. Each paper

has, under my leadership, been produced by a multidisciplinary research team that have worked closely to provide rigor in the research process and ensuring the reliability of findings. The exposure and collaboration within this team has had a significant contribution to my development as a researcher and my ability to conceptualise, design, implement and disseminate research findings has improved immeasurably as a result.

A researcher can be positioned against the various philosophical and theoretical components of the research process. Denzin and Lincoln (2018) describe this as a net; the figure below (Figure. 2) depicts my own position mapped against these intrinsically linked elements. Each of these elements will be considered in the remainder of this chapter and discussed in relation to both my professional and personal beliefs, and my research questions.

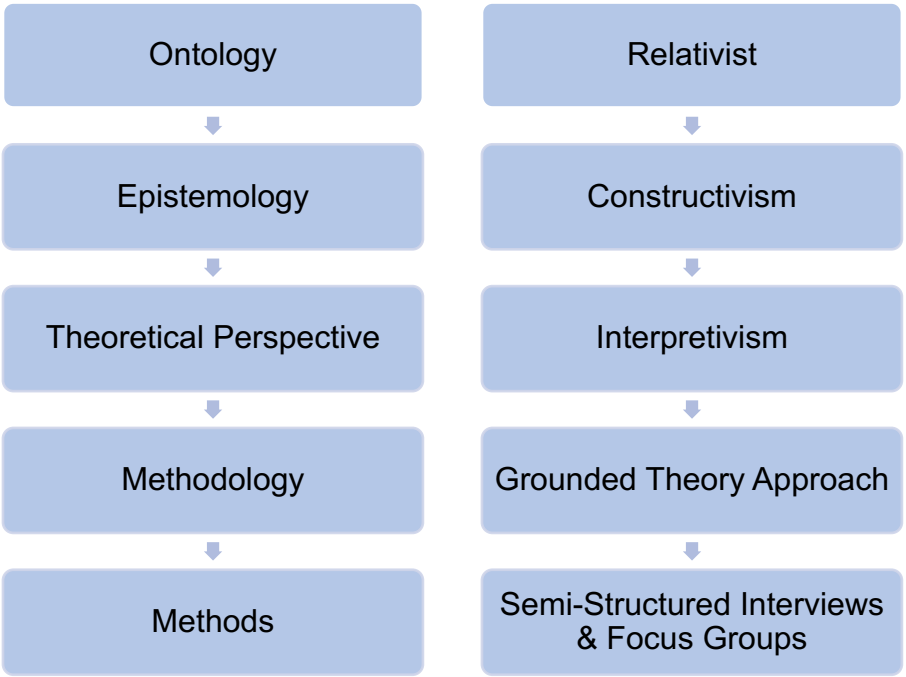

Figure.2 The philosophical and theoretical underpinning of my research

3.2 Ontology

Ontology is the study of *'being'* (Gray, 2018). Ontology is concerned with the nature of reality and what there is to know about the world (Ritchie et al., 2014).

My participants are all either healthcare professionals or patients. They are therefore human beings and not isolated entities interacting in the social world of clinical practice. It is my belief that they are influenced by their past experiences and their interactions in the social world, leading to my relativist ontological position. A relativist ontology asserts that no reality exists that is independent of our beliefs and understanding, and that the social world is influenced by context i.e. there is no shared social reality, only a series of different (individual) constructions (Ritchie et al,. 2014). The opposite ontological position is one of realism, a perspective in which reality exists independent of the human mind (Levers, 2013). The purpose of research from a relativist ontology is therefore to understand the subjective experience of reality and the multiple truths in which it holds (Levers, 2013).

3.3 Epistemology

Ontology and epistemology are fundamentally linked and tend to emerge together (Crotty, 2015). Whereas ontology provides an understanding of '*what is'*, epistemology is '*what it is to know'* (Crotty, 2015). It is concerned with the nature, validity and limits of enquiry and also how possible, if it is actually possible, to gain knowledge of the world (Hughes and Sharrock, 1997).

A researcher's epistemological view governs how the researcher understands the world and the relationship between them and what can be known. This informs the

theoretical perspective and ultimately the methodology and method adopted by the researcher.

I believe that the nature of the reality of healthcare practices can only be truly understood by those involved in either receiving or delivering such clinical services. My research therefore explores the role of the pharmacist in the multidisciplinary team and seeks to understand how their experiences and interactions in the social world influence and guide their practices. The academic literature has identified that MRONJ has a negative impact on patients' quality of life. However, what this impact is and how patient's quality of life is affected has not been established, therefore true understanding of this condition can only be gained from discussion with those people who have experienced it. The scientific evidence tells us that prevention is the best way to manage MRONJ, it guides the multidisciplinary team to implement preventive strategies and engage patients with their oral health. However, the format and actual delivery of this multidisciplinary prevention is contingent on human interaction, it is the interactions of patients, pharmacists and other healthcare professionals in the social world that dictates if/when/how such evidence is implemented and actioned in clinical practice.

My epistemological perspective is therefore described as constructivism. This perspective adopts the position that the social world is not bound by the laws and regularities that are explored in the natural sciences, therefore accepting that knowledge is produced by exploring and understanding the social world of the research participants, with meaning constructed between the researcher and participant (Ritchie et al., 2014).

Although the principles of epistemology are theoretical, they act to inform and justify the research methodology and therefore selection of an appropriate method. Figure 3 represents a simple diagrammatic representation of the relationship between epistemology, methodology and method.

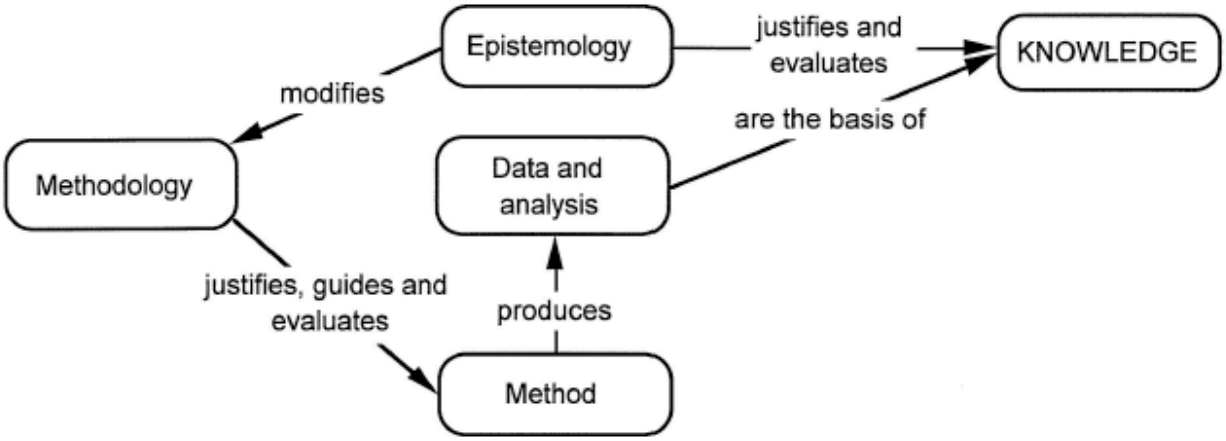

Figure.3 The relationship between epistemology, methodology and method (Carter and Little 2007)

3.4 Theoretical Perspective

A theoretical perspective is the philosophical stance which informs the methodology adopted by the researcher (Crotty, 2015). The interrelationship between my epistemological stance, theoretical perspective and resulting methodology is depicted diagrammatically in Figure 2. There are numerous theoretical perspectives, however both positivism and interpretivism are among the most influential and are routinely adopted by researchers (Gray, 2018). I have already explored my underlying ontological and epistemological position in this chapter and it is clear that

the nature of my research and the integral role in which I, as a researcher, play in this process leads us away from a positivist theoretical perspective. A positivist researcher would assume the position that traditional scientific methods can be adopted to objectively and systematically understand a phenomenon that can be measured in a world that is external to the researcher. My constructivist epistemology rejects this view of the social world and the theoretical perspective adopted in my research is described as interpretivism; an interpretivist theoretical perspective argues that knowledge is produced through the exploration and understanding of the social world of participants and is focussed on their meanings and interpretation. An interpretivist approach looks for culturally-derived and historically-situated interpretations of the social world (Crotty, 2015). This means that the methods used in the natural sciences are not appropriate, therefore leading to the adoption of a different methodology and consequently choice of method. (Bissel, 2002).

3.5 Methodology

The sparsity of published literature and exploration of the role of the pharmacist within the provision of oral health services and in the multidisciplinary prevention of MRONJ has already been discussed earlier in this thesis. This observation led to the formulation of my research question, and my own philosophical position highlighted in this chapter led to the adoption of a grounded theory methodological approach. Grounded theory seeks to explore and construct theories rather than apply existing theories; grounded theory is therefore a commonly adopted methodology when exploring a little known or under-researched field such as the one under investigation in my work.

Grounded theory is defined as '*a method of qualitative enquiry in which researchers develop inductive theoretical analyses from their collected data and subsequently gather further data to check their analyses. The purpose of grounded theory is theory construction, rather than description or application of existing theories'* (Charmaz and Bryant, 2011).

Grounded theory emerged as a methodology in the 1960s, spearheaded by Barney Glaser and Anselm Strauss, who worked together and developed the theory whilst exploring death and dying in hospitals in the United States. Their seminal publication in the late 1960s titled *The Discovery of Grounded Theory: Strategies for Qualitative Research* marked the first text in this field (Glaser & Strauss, 1967). Grounded theory has evolved since this initial publication with Glaser and Strauss diverging in their approaches to grounded theory; several prominent figures, such as Kathy Charmaz and Juliet Corbin, have also pushed the methodology in new directions.

Glaser's approach (Glaser, 1978) is most closely aligned to the original grounded theory methodology; Glaser's grounded theory is considered to fit with a positivist philosophical perspective and he positions the researcher as a distant observer that is independent of the data. The researcher can therefore work inductively to identify patterns and discover theories without bias (Singh and Estefan, 2018). This approach would also discourage researchers from engaging with extant literature; a process which can, in fact, be challenging when research funders require a thorough exploration and positioning of a research question against published literature.

Strauss and Corbin move grounded theory into the postpositivist perspective and provide a more structured approach to undertaking grounded theory research (Strauss and Corbin, 1998). Their approach acknowledges that although an

independent reality may exist, there are potentially multiple viewpoints of reality and whilst the researcher inevitably does impart a degree of subjectivity on the research process, it is possible to minimise this bias. Through a combination of both induction and deduction, emerging thoughts or more abstract ideas can therefore be tested against emerging data sets through the iterative and ongoing processes of data collection and analysis. (Singh and Estefan, 2018).

It is Kathy Charmaz's constructivist grounded theory that is most closely aligned with the approach adopted in my research (Charmaz, 2014). Charmaz takes a constructivist philosophical perspective, arguing that reality is dependent on both interpretation and human interaction. With constructivist grounded theory Charmaz presents the traditional strategies adopted in grounded theory as being flexible guidelines that can be used by researchers in their own way, as opposed to strict methodological rules. She therefore quite aptly describes grounded theory as *'a constellation of methods'* (Charmaz, 2014).

Charmaz's grounded theory embraces both the extant literature and my previously stated personal and professional experiences, this aligns with my epistemological position and acknowledges that research is a construction, and that I, as a researcher, am not a neutral observer or value-free expert. (Charmaz, 2014).

At this point, it is also important to acknowledge that many researchers do not follow the detailed processes of grounded theory in full, but utilise the grounded theory approach, embracing the '*constellation of methods'* highlighted in Charmaz's work. It is this approach which has been embraced in my work, with a grounded theory methodology adopted as a means of illuminating a little known area of practice.

Charmaz, however, sets out 5 actions which she considers provide evidence to support the use of grounded theory in a research study (Charmaz, 2014).

1. Conduct data collection and analysis simultaneously
2. Analyse actions and processes rather than themes and structure
3. Use comparative methods
4. Draw on data (e.g. narratives and descriptions) in service of developing new conceptual categories
5. Develop inductive abstract analytic categories through systematic data analysis

A key element of the grounded theory approach adopted in my work is the integration of an iterative and synergistic process of data collection and analysis; whereby initial data collection and analysis drives the focus of subsequent data collection and the exploration, and refinement of salient themes to further enrich data sets. Constant comparative analysis describes the process of continually comparing data to other data, i.e. within a transcript, between transcripts within the study and comparing data to other situations beyond the immediate research study (De Chesnay., 2014).

Other qualitative approaches were considered in the planning of this work. Another popular qualitative methodology is ethnography; in ethnographic research the '*researcher seeks to describe and interpret the shared learned patterns or values, behaviours, beliefs and language of a culture-sharing group*' (Creswell, 2007). Ethnographic research therefore typically requires participant observation and immersion in the daily lives of the participants. Given the busy nature of the

healthcare professional participants under investigation in my work and the differing professional roles studied, this approach was considered to not be suitable.

Phenomenological research focuses on describing the lived experiences of a group of participants with a shared phenomenon (Creswell, 2007). This approach could have, in hindsight, been adopted to explore the lived experiences of patients suffering from MRONJ in *(patient attitudes towards MRONJ)*; however, in this study I set out to explore patients' attitudes towards and perceptions of the multidisciplinary prevention of MRONJ. The grounded theory approach was able to identify a key theme of significantly impaired quality of life following interviews with affected patients. A more focused phenomenology-based study could have been used to explore this issue in more detail. However, the purpose of this study was to illuminate what was happening in clinical practice and to explore patients views on multidisciplinary MRONJ prevention. This was achieved by interviewing a wider range of patients, including those (1) with a diagnosis of MRONJ; (2) those prescribed implicated medications; (3) those with a diagnosis of osteoporosis not currently undergoing treatment. A grounded theory approach therefore was a better fit in order to explore the research question.

3.6 Data collection

Data collection was achieved through individual one-to-one semi-structured interviews and a focus group was also held with a group of patients in *(lack of interprofessional working)*; a total of 82 interviews have been performed across the studies which form this submission.

Interviews are commonly adopted by qualitative researchers and from my own perspective represented an obvious choice of method. An interesting observation at

this point was one of the questions raised by a member of the NHS Research Ethics Committee during the ethical review of the study forming *(patient attitudes towards MRONJ)* of this submission. I was asked how/if I was experienced enough to safely discuss complicated medical issues, such as MRONJ, with patients; of course, with my significant experience as a practicing pharmacist I am comfortable interviewing patients and discussing both complex and sensitive health-related issues on a one-to-one basis. This has been part of my professional role and not only am I comfortable discussing issues with patients, I am equally experienced in interacting with other healthcare professionals. This statement certainly appeased the ethics reviewer and thankfully led to the successful approval of the study.

Brinkman (2018) sets out the three main forms of interview; structured, unstructured and semi-structured. However, Brinkman argues that in reality, completely structured or completely unstructured interviews are not actually possible. Semi-structured interviews were used as they provide a loose structure through initial open-ended questions from which the interviewer and/or interviewee can diverge in order to pursue an idea or concept in more detail (Britten, 1995).

In reality this was facilitated through the production of initial topic guides. However, the grounded theory approach adopted in this study allowed for the refinement of topic guides for subsequent data collection and the semi-structured nature of the interviews facilitated the further exploration of emerging concepts that could not have been discovered through more rigid and structured interviews. The initial topic guides were designed following interrogation of extant literature in collaboration with the research team, a process which aligns closer to Charmaz's approach to grounded theory.

A focus group was held with a group of patients in *(lack of interprofessional working)*; focus groups allow the observation of group interaction in relation to the research topic and share many common features with less structured interviews. Focus groups are used to generate information on collective views and the meanings behind these views (Gill et al., 2008). In *(lack of interprofessional working)* one-to-one semi-structured interviews were initially performed with a range of primary care healthcare staff to explore the role of clinical pharmacists working in general practice in relation to the provision of oral healthcare. The purpose of holding a focus group was to further explore the key themes which emerged from interviews with the healthcare professional participants and to gather the collective views of the service users (patients) in a more open and discussion friendly format.

3.7 Data analysis

Each interview was audio recorded and transcribed verbatim. A number of the interviews were transcribed by me personally. However, the projects funded by PRUK *(patient attitudes towards MRONJ)* and the Universitiy of Sunderland's Individual Research Plan *(dentist attitudes towards MRONJ, lack of interprofessional working)* were transcribed by an independent transcription service using the financial resources that were awarded. Although transcription services can save the researcher a significant amount of time, I would now always encourage novice researchers to transcribe their own interviews, as this process provides an excellent opportunity for immersion in the data and contemplation of initial ideas.

The principles of constant comparative analysis discussed earlier in this chapter provided the basis for data analysis, with continued immersion in the data, ongoing comparisons between transcripts and enrichment of subsequent data sets.

The prioritisation of salient themes was achieved through the use of Ritchie and Spencer's framework analysis (2002). Framework analysis was developed in the UK, by the National Centre for Social Research and provides both a practical and systematic approach to the analysis of qualitative data. This approach to data analysis is not intrinsically aligned to any specific epistemological, philosophical or theoretical perspectives and provides a flexible tool that can be adapted to many qualitative approaches (Gale et al., 2013).

Framework analysis was adopted for my research as its principles provide a structured approach to the analysis of qualitative data (Ward et al., 2013). It is also a method that can be used to facilitate constant comparison analysis through the review of data (Gale et al., 2013). There is a five stage approach to the analysis of qualitative data through framework analysis as described in (Table 2) below.

Table 2. The five stages of Framework Analysis

Stage	Procedure
Familiarisation	Immersion in the raw qualitative data; achieved through the collection of data, listening to interview recordings and repetitive reading of transcripts to identify key ideas and notes.
Identification of a thematic framework	The key issues identified through familiarisation with the data form the basis of the thematic framework. This produced a detailed index of the data which can be labelled and further explored.
Indexing	The thematic framework is applied and all of the data are indexed against the codes. Facilitating the identification of data that correspond to a particular theme or code in the framework.
Charting	The indexed data are then arranged to form charts of key themes with data entries linked to individual participants
Mapping and interpretation	The charts produced from the data guide the comparison of identified themes. The comparisons are used to identify the salient themes and provide explanations and theories from the findings.

3.8 Piloting an intervention

It is clear from the existing literature (as discussed in chapter 2) that there is a clear lack of evidence to support how a community pharmacy-based oral health intervention might be best delivered in practice. Previous works identified in the

literature review section of this thesis had identified a role for pharmacists in this setting, but none had sought to implement and evaluate such a service.

In order to perform such a study and pilot a pharmacy-based oral health intervention collaboration with a range of stakeholders and gatekeepers was required. Therefore, I collaborated with the County Durham Public Health Team, Local Pharmaceutical Committee and the County Durham and Darlington Foundation Trust Oral Health Promotion Team.

The design and implementation of this service was therefore restricted by the financial support offered and needed to be workable in a practice setting. I decided that in order for an oral health service to be effectively and pragmatically workable in a community pharmacy, it would need to be brief, so that patients could be engaged while waiting for their prescriptions and it could be provided alongside existing pharmacy services. The design of this study is discussed further in the published paper *(oral health promotion in pharmacy)*; however, from a methodological perspective a more pragmatic mixed-methods approach was adopted. With a pragmatic approach, the researcher adopts the methods that best fits the specific research questions; therefore embracing the consideration that both quantitative and qualitative methods be complementary to one another and used to answer a research question or view the problem under investigation through a different lens. Mixed-methods research is defined as '*research in which the investigator collects and analyses data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or program of inquiry'* (Tashakkori and Creswell, 2007).

The qualitative evaluation of this study still fits with the methodology described earlier in this chapter, with semi-structured interviews forming the basis of the exploration of the pharmacy staff's attitudes towards, and perceptions of, the service. However, in this paper it was also important to gather information from the patients experiencing the intervention and it was apparent that it would not be possible or part of the remit of this study to follow up patients over a long-term period to assess any changes in their oral health. Therefore, a brief and anonymous evaluation questionnaire was designed to capture patients' perceived improvement in oral health, intention to change oral health behaviours and acceptability of oral health intervention in a community pharmacy setting.

3.9 Ethical Considerations

Each of the papers forming this submission have undergone ethical review by a range of both University and NHS Research Ethics Committees, details of which are provided in each of the papers.

The process of repeated ethical applications has been very time consuming. However, it has developed my ability as a researcher, and my experience of the NHS Integrated Research Application System and Health Research Authority approval processes have facilitated my ability to conceptualise, prepare appropriate documentation and undertake high quality and ethically sound research.

3.10 Synthesising the results against the conceptual framework

The findings from each of the studies forming this thesis are presented in the individual published papers and follow the methodological approach already discussed in this chapter. In the creation of this thesis a number of conceptual models were reviewed to assess their application to my work. These included Normalization Process Theory (NPT) (May and Finch, 2009) and Bronfenbrenner's Ecological Systems Theory (Bronfenbrenner, 1977). NPT is a sociological toolkit for understanding the implementation, embedding and integration of new interventions into practice. NPT was rejected as an approach, although on reflection it could have provided a different methodological approach if adopted at the outset of my work. Bronfenbrenner's theory was originally developed to explain human development, but has subsequently been adapted for health services research. Bronfenbrenner's work is based on the principle of micro, meso and macro systems and the interactions between individuals and these systems. The micro, meso and macro socio-institutional lens has been utilised previously in the literature in relation to collaborative health care models (Bourgeault and Mulvale, 2006, Nelson et al., 2014, Mulvale et al., 2016, Smith et al., 2019). Further exploration of this work identified the Rainbow Model of Integrated Care (Valentijn et al., 2013) as an appropriate framework that was applicable to my research.

For the purpose of this thesis, the results from each of my papers have been applied to the Rainbow Model of Integrated Care (Valentijn et al., 2013); the framework was designed to aid a better understanding of the concept of integrated care from a primary care perspective. This conceptual framework was therefore adopted to

explore the barriers and facilitators for integrating MRONJ prevention and oral health into the role of the pharmacist in this thesis.

Central to the framework is the co-ordination of concepts into three levels, or dimensions that capture the complexity and interdependent elements of collaborative healthcare. The Rainbow Model of Integrated Care, however, further develops this framework and encapsulates various forms of integration that are required for effective person-centred and population-focused healthcare.

Macro	*External structural, social and regulatory issues which are beyond the control of the individual or influence of individual organisations*
Meso	*Local community and institutional factors and influences*
Micro	*Day-to-day practices of individuals and their practice environments*

Person-focused healthcare is based around the premise that diseases are simultaneously medical, psychological and social problems, with care based on personal preferences, needs and values. Population-based healthcare indicates that services should be designed and delivered in line with the needs and characteristics of a defined population (Valentijn et al., 2013).

A key component of the Rainbow Model of Integrated Care at a macro level is system integration; this describes the structures, processes and techniques that are required to fit the needs of individual patients and populations across the continuum of patient care. System integration includes partnerships across traditional organisations and traditional professional boundaries to improve the quality and efficiency of the care system (Valentijn et al., 2013). Both vertical and horizontal integration are fundamental components of system integration. Vertical integration

includes strategies which link the various levels and degrees of specialised care across sectors; this includes integration of services from a primary care perspective, with both secondary and tertiary care settings. Horizontal integration takes a more holistic view and includes strategies which link similar levels of care across sectors, and acts to improve the health of individual patients and populations (Valentijn et al., 2013). (Figure 4) shows the vertical and horizontal components of system integration with both a person-focused and a population-based perspective.

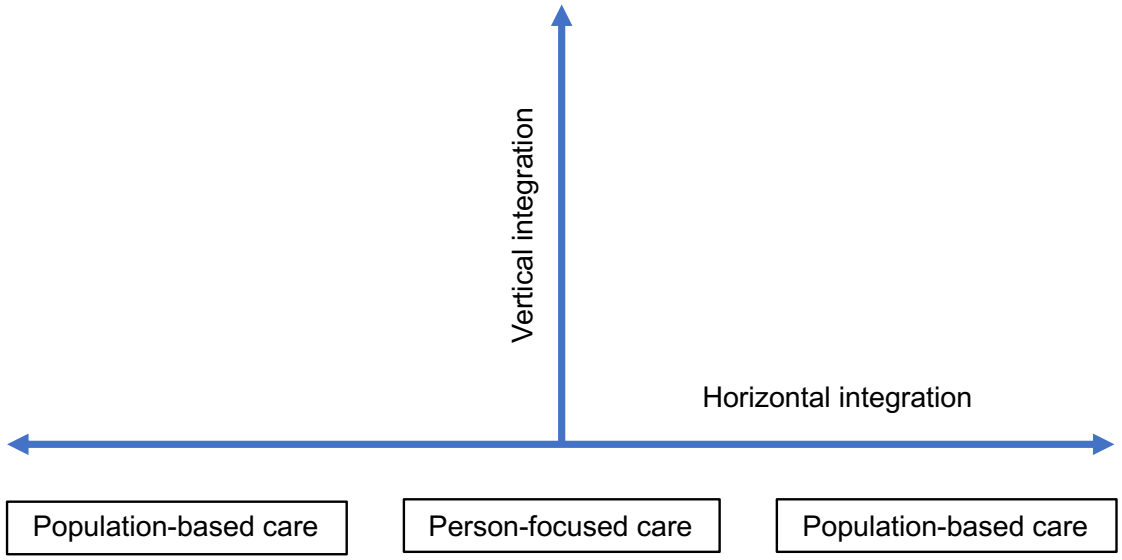

Figure.4 Vertical and horizontal integration

Valentijn et al., (2013) also describe and define a range of other forms of integration that are required for effective collaborative and integrated care at the meso and micro level. This includes both organisational and professional integration at a meso level and clinical integration at a micro level; each of these terms are defined below.

> Organisational integration is defined as *'Inter-organisational relationships (e.g. contracting, strategic alliances, knowledge networks, mergers) including*

common governance mechanisms to deliver comprehensive services to a defined patient population'.

Professional integration is defined as *'Inter-professional partnerships based on shared competencies, roles, responsibilities and accountability to deliver a comprehensive continuum of care to a defined population'*.

Clinical integration is defined as *'the coordination of person-focused care in a single process across time, place and discipline*'. This refers to the care of individual patients, co-ordinated across various professional institutional and sectorial boundaries within the healthcare system

Valentijn et al., (2013) also describe two further forms of integration that link the micro, meso and macro dimensions of the healthcare system, these are described as functional and normative integration.

Functional integration is described as the '*key support functions and activities (i.e., financial, management and information systems) structured around the primary process of service delivery, to coordinate and support accountability and decision making between organisations and professionals to add overall value to the system'.*

Normative integration is defined as *'the development and maintenance of a common frame of reference (i.e., shared mission, vision, values and culture) between organisations, professional groups and individuals*.

The Rainbow Model of Integrated Care was produced to conceptualise each of these components of integrated care (Figure 5). At the centre of the model is the individual patient, described through the concept of patient focused care and clinical

integration. At a meso level both professional and organisational integration emphasise a population-based approach and at a macro level system integration places the patient at the centre of the healthcare system, embracing the premise that what is best for the individuals within a defined population is also best for the population (Valentijn et al., 2013).

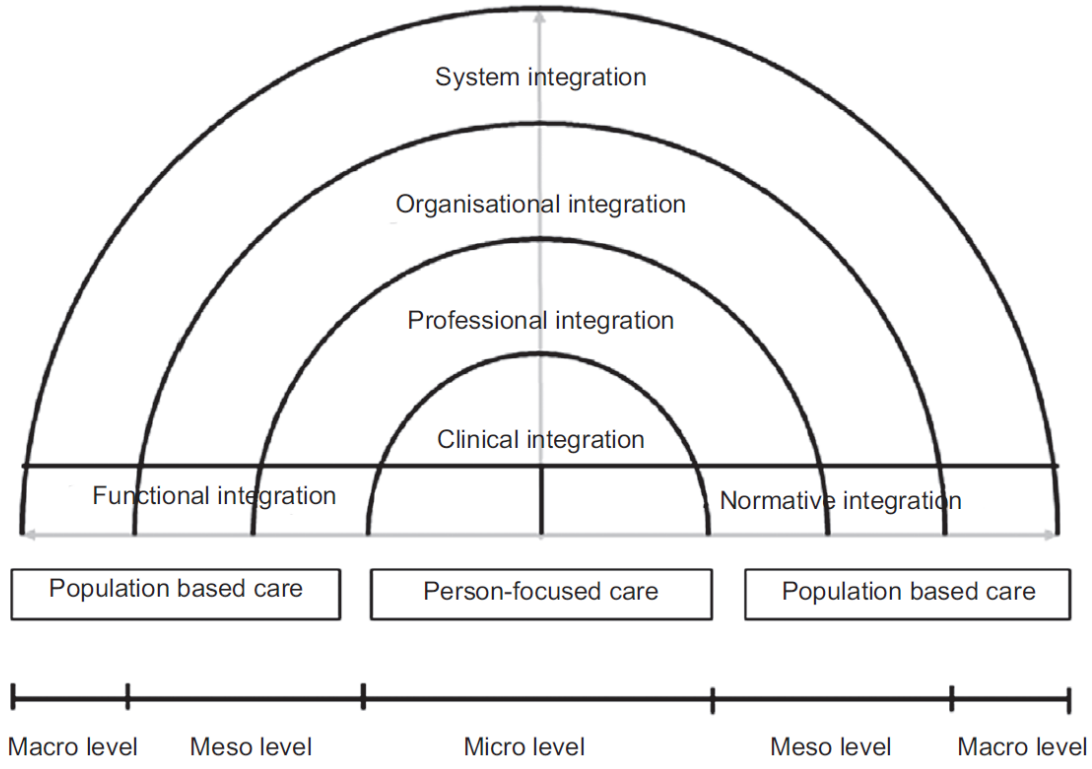

Figure. 5 Rainbow Model of Integrated Care (Valentijn et al., 2013).

Chapter 4: Results

In this chapter each of the published papers are presented that collectively form this thesis. Each paper represents a stand-alone publication, with independently presented results, discussions and conclusions.

The findings from across the whole body of work forming this submission have also been synthesised through the Rainbow Model of Integrated Care to explore the barriers and enablers for the integration of safe and effective MRONJ prevention and oral healthcare into the role of pharmacists.

4.1 Paper 1 (GP/pharmacist attitudes towards MRONJ

Sturrock, A., Preshaw, P., Hayes, C. and Wilkes, S. (2017). Attitudes and perceptions of GPs and community pharmacists towards their role in the prevention of bisphosphonate-related osteonecrosis of the jaw: a qualitative study in the North East of England. *BMJ Open*, 7(9), p.e016047 https://doi.org/10.1136/bmjopen-2017-016047

BMJ Open

Attitudes and perceptions of GPs and community pharmacists towards their role in the prevention of bisphosphonate-related osteonecrosis of the jaw: a qualitative study in the North East of England

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ABSTRACT

Background Bisphosphonate-related osteonecrosis of the jaw (BRONJ) is a rare, yet significant, adverse effect of bisphosphonate therapy. A multidisciplinary approach to the prevention of BRONJ is recommended due to the significant morbidity and difficulty treating the condition. Current evidence suggests that both general practitioners (GPs) and community pharmacists have limited knowledge relating to BRONJ and that preventative strategies are rarely implemented.

Objective To explore the attitudes and perceptions of GPs and community pharmacists on the risks and preventative strategies for the development of BRONJ.

Design Interpretivist methodological approach using qualitative semistructured interviews.

Participants 9 community pharmacists and 8 GPs.

Setting Primary Care in North East England and Cumbria, UK.

Methods Using a Grounded Theory methodology and integrating a process of constant comparison in the iterative enrichment of data sets, semistructured interviews were undertaken, transcribed and analysed using framework analysis. Salient themes were identified and related back to extant literature in the field.

Results Four salient and inter-related themes emerged: (1) uncertain knowledge, indicating limited exposure of respondents to BRONJ, and limited awareness of the implications of its diagnosis, risk factors and preventative strategies; (2) patient specific, referring to the complexity of patients, patient education and prioritising aspects of care; (3) wider context, indicating a lack of interdisciplinary communication and referral processes between professions, workload pressures, access and patient receptivity to dental services; and (4) professional, reflecting professional roles and responsibilities, authority and educational initiatives

Conclusions Effective communication or collaborative care between GPs and community pharmacists for the prevention of BRONJ is not apparent. Interventions to mitigate against the risk of developing BRONJ and clarity of GP and community pharmacy roles are required.

Strengths and limitations of this study

- Although bisphosphonate-related osteonecrosis of the jaw is not a common finding, affected patients experience significant morbidity, and management of this condition warrants further study to stimulate improved patient care.
- A qualitative approach yielded rich data through in-depth semistructured interviews with two groups of healthcare professionals (general practitioners and community pharmacists). Constant comparison with concurrent data collection and analysis allowed further exploration and refining of emerging themes.
- A study limitation was that, although consistent with the methodological approach, the sample size was relatively small. Furthermore, the study was conducted in the North East of England and Cumbria, which may impact on transferability of the findings to other settings.

INTRODUCTION

Bisphosphonates are a class of drugs used in a variety of therapeutic indications, such as osteoporosis, Paget's disease, hypercalcaemia of malignancy, osteolytic bone metastases and osteolytic lesions of multiple myeloma.[1] In practice, they are most commonly prescribed in the management of osteoporosis.

The prescribing of bisphosphonates has increased considerably over recent years. Statistical evaluation of prescribing in England reveals a rise of 122.6% in the number of individual prescription items dispensed between 2004 and 2014.[2] Alendronic acid is the most commonly prescribed bisphosphonate, with 7 391 000 individual dispensations in 2014.[2] This rise may be attributable to increases in the proportion of elderly people in the UK population, publication of guidance

recommending the prescribing of bisphosphonates and the availability of generic products. Risk for bisphosphonate-related osteonecrosis of the jaw (BRONJ) in people taking bisphosphonates is hypothesised to be related to the unique nature of the blood supply, structure and function of the jaw bones.[3] Case reports of BRONJ emerged in the early 2000s; it is now well documented in the literature,[4] and has been subject to a number of prescribing safety alerts in recent years.[3 5]

The actual incidence and prevalence rates of BRONJ are difficult to quantify, with varying reports in the literature. This is potentially attributable to a low incidence of reporting, the variance in diagnostic criteria and a percentage of mild self-resolving cases remaining undiagnosed. A nationwide study in the UK of patients presenting to departments of oral surgery, oral medicine, oral and maxillofacial surgery and dental hospitals identified 369 cases of BRONJ over a specified 2-year period. Oral bisphosphonates had been prescribed for 56% of the patients. Extrapolation of these data suggests that the incidence of BRONJ may be 8.2–12.8 cases/million of the population/year, which is equivalent to 508–793 patients/year in the UK.[6]

Ideally, optimal dental health should be established before patients commence bisphosphonate therapy.[7] This is to prioritise care that will subsequently reduce mucosal trauma or act prophylactically to aid in the avoidance of subsequent dental extractions or conditions which may further predispose the patient to oral surgery or dental procedures that impact on the osseous structures of the jaw.[8]

Several prospective studies have identified that dental screening and preventative strategies reduce the risk of osteonecrosis of the jaw. A study by Dimopoulous[9] found a statistically significant reduction in the incidence of BRONJ with the implementation of preventative measures and Vandone *et al*[10] reported a 50% reduction in the incidence rate with screening and pretreatment preventative dental care.[9 10] A multidisciplinary approach to the prevention of BRONJ is recommended in the literature for the management of patients requiring bisphosphonate therapy,[11 12] incorporating both patient and health professional education of the risk of the development of BRONJ.[5] Education of dentists, pharmacists, general practitioners (GPs) and patients about BRONJ is indicated,[13] with specific emphasis on the provision of focused preventative measures and detailed oral hygiene instructions.[14]

Available published evidence describing the attitudes of both GPs and pharmacists towards, and their perceptions of, their roles in preventive strategies for BRONJ is limited. A questionnaire survey of GPs (n=120) and pharmacists (n=60) in North Wales identified that although both sets of healthcare professionals have regular contact with patients who are prescribed bisphosphonates, they have limited knowledge of the dental implications associated with treatment. Both groups of professionals reported awareness of the side effects of bisphosphonates; however, only 11.8% of GPs and 9.7% of pharmacists specifically identified osteonecrosis as a potential unwanted effect of therapy.[15]

Furthermore, even when pharmacists and GPs report some knowledge of BRONJ, is it not clear how this awareness influences their clinical practice. The aim of this study was to explore the attitudes and perceptions of GPs and community pharmacists on the risks and preventative strategies for the development of BRONJ.

METHOD

Design

A Grounded Theory approach[16] with constant comparison was used throughout the research. Semistructured, one-to-one interviews were carried out by a single researcher (AS), at either the School of Pharmacy or the participant's workplace, depending on participant preference and availability. The interviews were audio-recorded and transcribed verbatim; field notes were not taken due to verbatim transcribing. Integrating a process of constant comparison,[17] an initial topic guide (see online supplementary 1) was produced and refined by the research team; this served as a benchmark of questioning, which was subsequently developed iteratively as data were progressively enriched.

Setting

Participants were recruited from a range of urban and rural primary care locations in the North East of England and Cumbria. GPs were recruited from both teaching and non-teaching practices and community pharmacists were recruited from independent (single or small-chain pharmacies) and multiple pharmacies (companies consisting of numerous pharmacy stores) (table 1).

Participants

Seventeen participants, nine community pharmacists and eight GPs were recruited to the study. An invitation letter and participant information sheet (see online supplementary file 2) were posted to GPs and community pharmacists. An initial convenience sample of participants who responded to the invitation was implemented with further recruitment achieved via snowball sampling. No participants who responded to the invitation refused to participate or dropped out of the study.

Analysis

Constant comparison allowed enrichment of data and for new concepts to guide subsequent interviews via the strategic development of each subsequent topic guide. Adoption of Ritchie and Spencer's framework analysis[18] allowed salient themes from the findings to be identified. Data were analysed by AS, using Microsoft Word 2010 and Microsoft Excel 2010, with transcripts and emerging themes cross-checked for interpretation and agreed among the research team until saturation occurred; transcripts were not returned to participants for comment

Table 1 Participant characteristics—pharmacists

Participant	Gender	Number of years since registration	Number of items dispensed per month	Practice location	Independent/multiple	Full/part-time
P1	Female	6–10	6000–8999	Suburban	Independent	Full-time
P2	Female	11–15	12 000+	Suburban	Multiple	Full-time
P3	Female	0–5	3000–5999	Suburban	Multiple	Full-time
P4	Female	21+	3000–5999	Urban	Independent	Part-time
P5	Female	0–5	6000–8999	Urban	Independent	Full-time
P6	Female	0–5	6000–8999	Urban	Independent	Full-time
P7	Male	6–10	6000–8999	Urban	Multiple	Full-time
P8	Female	16–20	6000–8999	Rural	Independent	Part-time
P9	Male	11–15	6000–8999	Semirural	Multiple	Full-time

P, pharmacist.

or feedback and repeat interviews were not performed. A sample transcript has been published alongside this paper (see online supplementary file 3). Framework analysis involved a five-stage process: (1) familiarisation with the data—interviews were transcribed by AS and key issues identified through immersion in the data; achieved via iterative cycles of reading and rereading of transcripts; (2) development of a thematic framework—the initial themes formed the basis of a thematic framework; (3) indexing data—data were indexed against the thematic framework; (4) charting—charts were produced of the data within the thematic framework; (5) mapping of the data—themes were reviewed until definitive concepts could be produced from the data.

Ethics

Ethical approval was obtained from the University of Sunderland (Reference PHW52).

RESULTS

Seventeen healthcare professionals were included in this study (tables 1 and 2). Interviews were carried out between January and October 2016; 1 hour was designated for each interview.

Four salient inter-related themes emerged: (1) uncertain knowledge—a lack of familiarity with the subject area, the prevalence and significance of BRONJ and limited exposure to the condition; (2) patient specific—complexity of patients, clinical priorities and patient education; (3) wider context—access/fear of dental services, interprofessional communication and clinical workload; (4) professional—perceived responsibilities, authority and interprofessional education.

Uncertain knowledge

All participants perceived themselves to have some degree of knowledge on the adverse effects that are associated with bisphosphonate therapy. The concept of BRONJ was introduced in the participant information sheet and opened up for discussion during the interview; participants actually had minimal knowledge on this topic but all were aware of the potential risk.

> 'I think it was probably sitting way at the back of my mind…it was probably in a lecture at some point.' (GP4)

Although poor dental health and the duration of therapy were frequently identified, all of the participants

Table 2 Participant characteristics—GPs

Participant	Gender	Number of years since registration	Practice size (patients)	Practice location	Teaching practice	Full/part-time
GP1	Female	21+	3000–5999	Urban	Non-teaching	Full-time
GP2	Male	16–20	12 000+	Urban	Teaching	Part-time
GP3	Male	21+	12 000+	Suburban	Teaching	Part-time
GP4	Male	11–15	9000–11 999	Semirural	Teaching	Full-time
GP5	Female	11–15	12 000+	Suburban	Teaching	Part-time
GP6	Female	16–20	3000–5999	Rural	Teaching	Part-time
GP7	Male	21+	9000–11 999	Semirural	Teaching	Full-time
GP8	Male	16–20	9000–11 999	Semirural	Teaching	Full-time

GP, general practitioner.

had limited awareness of the risk factors for the development of BRONJ.

> 'I am not aware of any, I imagine that significant dental problems would be associated with it, but I am not actually aware of any others.' (GP3)

Participants were uncertain on the prevalence of BRONJ and had limited knowledge on the significant morbidity associated with the condition.

> 'I have never seen it, so I presume it's not very common…I don't really know how serious it is when it does happen.' (P3)

One GP had first-hand experience of managing patients with BRONJ, and the significant morbidity that her patients had experienced influenced their attitude towards management of patients who are prescribed bisphosphonates. None of the other participants had been involved with the care of a patient with BRONJ.

> 'It's the sort of thing that once you see it, you then remember it. They were both very complex patients, but the amount of morbidity involved with the osteonecrosis of the jaw in both of those patients was considerable.' (GP1)

Patient specific

Patients prescribed bisphosphonates usually have a number of comorbidities. They are often elderly and are prescribed multiple medications, and their management can be complex. Indeed, this complexity requires that practitioners assign priorities in their care, relating to both the overall management of the patient and to more specific priorities related to bisphosphonates.

> 'They are lower down in the pecking order of things that we look at when we are supervising polypharmacy, when we are looking at chronic disease management.' (GP3)

All participants identified bisphosphonates as having very specific administration instructions and common side effects, such as gastrointestinal (GI) or oesophageal problems; these were the focus of consultations. However, participants were concerned about overloading patients with information and the risk of patients potentially refusing treatment.

> 'You try not to overload them with too much information because you know that sometimes they can't even take it on board at the best of times.' (P2)

Patient education was a key issue that emerged from the data; participants placed importance specifically on the education of patients in relation to administration instructions and common side effects of bisphosphonates. This would usually take the form of a set of predefined counselling points.

> 'I think when you have a drug like a bisphosphonate, which is complex with its instruction on how to take it and people are tied up in that.' (GP1)

Although some participants advised bisphosphonate patients to seek dental check-ups, most reported that many of their patients, in general, appeared to not appreciate the importance of achieving and maintaining good dental health through self-performed daily oral hygiene and regular dental check-ups. This was a common theme reported by participants in relation to patients' outlook on oral health issues as a whole and not just related to the specific preventative strategies for BRONJ. This was identified as a barrier in the management of this patient population and a focus for patient education.

> 'I would say that their oral hygiene was not particularly great. I think it's probably just not wanting to go to the dentist and fear of the dentist.' (P9)

Patients often tend to forget the initial advice given to them and reminders or continuous advices are necessary to enhance patient education. Teamwork highlights the importance of specific counselling and reinforces the advice that is given to patients.

> 'If a new drug is initiated, that is the time to reinforce what the patients been told about the drug and you know to give them the message. I think the more reinforcement and the more information the better.' (GP2)

Wider context

Both GPs and pharmacists identified that there is reluctance among certain patients to seek dental advice. A number of reasons were proposed for this, including the cost of dental treatment, a general lack of oral health awareness and patients with dental phobias.

> 'The processes of how you get people to take their dental health seriously are very difficult. The ones that pay for dentistry are likely to be the ones with good teeth, the others who get free treatment just don't access it.' (GP3)

Access to dentists was also felt to be an issue that both pharmacists and GPs had encountered, specifically the availability of dental services for patients and referral pathways between professions.

> 'Some people don't even have an NHS dentist. I am aware of where I work, there was a dentist upstairs, but it wasn't an NHS dentist. I think when you want to refer someone to another service you know it is going to be a little bit more problematic than just making an appointment with a GP for example.' (P2)

Participants all described a heavy workload and that in the small amount of time that they had with each patient, they would have to prioritise the information they gave to patients.

'In that 2 min that you have got to hand something out to somebody, you concentrate on the important things, such as how to take it, to get their concordance and compliance.' (P2)

A lack of communication between both GPs/pharmacists and dentists was identified as a major barrier. The absence of a formal referral process between pharmacists, GPs and the dental profession was highlighted throughout. This was felt to be an issue related to BRONJ and represented a wider problem in the management of oral health in primary care. In order to successfully manage the risk of BRONJ, it was clear from interviewees that communication between professionals is key.

'I think maybe there needs to be a little bit more communication involved with pharmacists. The triangle, pharmacist, dentist and prescriber.' (P2)

'Some sort of shared record keeping where you could enter into the system. You have done a review and these side effect were discussed with the patient, that would be brilliant. That would make it part of that clinical record, I'd know about it, the patient would know about it. I think that would work very well.' (GP7)

One of the key areas identified by all pharmacists and some of the GPs was the benefit of Medication Use Reviews (MURs) and the New Medicine Service (NMS) in community pharmacies. The MUR and NMS services are both advanced service within the National Health Service (NHS) Community Pharmacy Contractual Framework in England. An MUR is a structured, adherence-centred review of patients prescribed multiple medicines and the NMS service provides support for patients with long-term conditions that have been newly prescribed a medicine.[19 20]

These services provide pharmacies with both the time and structure to provide more detailed advice to patients on medications. Bisphosphonates are not currently specified in either service. Although it was felt that many drugs should be included, all participants identified that bisphosphonates should be included in these services due to their specific administration instructions and potential for side effects.

'I think during an MUR you certainly have more time to focus on the individual drugs and then it kind of triggers in your brain the more important things that you should be speaking to them about.' (P2)

Professional

GPs acknowledged their role as the prescriber and the need to counsel patients on the side effects of their medication. Both prescribers and pharmacists were in agreement that pharmacists are the experts on medications and they have a role to play in counselling patients on safe and effective use of medicines.

'I think counselling about medication is far better done by the pharmacists. I think the other reason is perhaps, when a patient sees a doctor they expect to be able to discuss all aspects of their lives and their care. When they see the pharmacist, they know they are seeing the pharmacist about their medication. I think it is much easier for the pharmacist to keep the patient focused on the drugs and the patient to stay focused on the drugs.' (GP1)

Although pharmacists acknowledged their role in counselling patients on medications, a number of them felt that if a patient needs to be dentally fit before commencing bisphosphonate therapy, then it would be the responsibility of the GP to arrange this. Although in many cases GPs would be responsible for initially prescribing bisphosphonates and their continued prescribing, it was commented that bisphosphonates can, at times, be initiated in secondary care. This was certainly the case for intravenous bisphosphonates with all GPs and pharmacists reporting little or no experience with prescribing or dispensing these products. As intravenous bisphosphonates are usually prescribed in secondary care, it was felt by some of the participants that this was a potential risk, as they can be missed on medication lists.

'Making sure that the dental check has been done and that they're healthy should actually be done before you prescribe medication, because if you prescribe a medicine without knowing that, then technically how do you know that it's going to be safe for the patient to take. I think my role as a pharmacist is certainly to promote that it's been done, and if it hasn't to take further steps with the patient.' (P7)

A number of participants also described limited education or training in relation to oral and dental health.

'We have no training in dental care. You know to brush your teeth and that's what you say to people. I think, I don't know, maybe we should have some more training.' (GP5)

'No not really, a little bit maybe in lectures at university but not with dentists, we have worked quite closely with the doctors but not with dentists.' (P1)

DISCUSSION

Summary of main findings

It is apparent that both sets of participants (GPs and pharmacists) had limited knowledge of BRONJ, in particular in relation to its prevalence and the morbidity associated with the condition. As BRONJ is relatively uncommon, the majority of participants also lacked first-hand experience of managing affected patients.

Due to the complexity of this patient group and bisphosphonates as a therapeutic class, interviewees assigned priorities in relation to clinical management and in patient education. Consultations would usually focus

on the specific administration requirements and more common GI-related adverse effects as opposed to the risk of developing BRONJ and the need for good oral and dental health.

Awareness of the issue was thought to be a key barrier to implementing preventative strategies in this patient group; however, wider issues in relation to the attitudes of patients towards oral health, a reluctance to attend the dentist and difficulties in accessing dental services were thought to be potential barriers for patients. The lack of communication between the professions was also cited as a key issue that needs to be addressed for the successful implementation of any future collaborative preventative strategies in this patient group, with the MUR and NMS pharmacy services identified as a potential facilitator.

Pharmacists and GPs reported good working relationships but interprofessional educational opportunities with dental colleagues appear to have been limited in scope or non-existent, and were cited as a potential enabler for improving multidisciplinary working.

Comparison with existing literature

Knowledge on the oral risks associated with bisphosphonate therapy has been reported to be limited.[15] All participants interviewed in this research reported being aware of the risk, although this was introduced before the interviews in the participant information leaflet.

Many of the participants would not routinely mention the risk of osteonecrosis of the jaw when prescribing bisphosphonates or when counselling patients about the medication. This is consistent with a small quantitative study that identified only 17% of patients prescribed oral bisphosphonates were aware of the risk of BRONJ, with the majority of these patients acquiring this knowledge from patient information leaflets and not from their GP.[21]

All participants reported reluctance among patients to attend dental appointments, with a significant proportion of their patients being either not registered with a dentist or not regular attendees. This is consistent with NHS dental statistics, which state that only 52% of the adult population has seen an NHS dentist within the previous 24 months.[22]

A number of clinical guidelines and patient safety alerts recommend that patients should be counselled on the risk of BRONJ and advised to seek a dental check-up prior to initiating bisphosphonate therapy.[5 8] Our data suggest that this does not appear to routinely happen. A recent study in Japan reported that 62% (n=629) of physicians did not request oral healthcare by a dentist before commencing bisphosphonate therapy and 72% of participants reported no cooperation between physicians and dentists. They concluded that a strategy for sharing information among physicians, dentists and patients is required to reduce the incidence of osteonecrosis of the jaw associated with osteoporosis treatment.[23] The population studied were all members of the Japan Osteoporosis Society; the nature of this sample and therefore interest in osteoporosis management of the participants could potentially explain the higher rates of dental referrals than reported in other studies.

The MUR and NMS were identified as potential facilitators in the prevention of BRONJ. Bisphosphonates are not directly specified in either of these services at present, although participants were in agreement that it would be beneficial for them to be included. The literature to support both services is mixed; a detailed review by the University of Nottingham found that the implementation of the NMS was constrained by the quality of the pharmacist's relationship with GPs. They found that poor communication between the professions and a lack of awareness or understanding by GPs about the service resulted in a lack of referrals; this is consistent with statements from some of the GPs in this study. Pharmacists also suggested that GPs were not interested in the NMS as it potentially encroached on professional boundaries and duplicated work undertaken by the GP.[24] In comparison, the GPs in this study, despite having limited knowledge of the service, were all supportive of its role and the reinforcement of important counselling points was thought to be a key responsibility of the pharmacist.

Pharmacists are subject to organisational pressures to meet targets around the MUR service which has been reported to result in their offering the service to patients who meet the minimum inclusion criteria and avoiding offering the service to more complex patients due to time pressures.[25] This potentially impacts the patient group under study as a clear theme that emerged from the data was the complexity and polypharmacy issues of patients taking bisphosphonates.

An ethnographic study utilising observations and patient interviews in two English community pharmacies found that patients generally were positive about the MUR, and patients tended to view the pharmacist as an expert on medicines. However, some participants felt wary of the pharmacist's involvement, considering that the pharmacists were deliberately or intentionally bypassing the GP. This study also found that there was little evidence to suggest that the professions were collaborating to identify patients who could benefit from the service.[25]

Limitations

The study was based around the a priori issue of limited knowledge among GPs and pharmacists in the prevention of BRONJ; the concept of BRONJ was introduced during the patient information leaflet, therefore exposing participants to the concept before the interview.

Participants were all located in the North East of England and Cumbria; this therefore may impact on the transferability of findings to other geographical locations or healthcare settings. For example, a variation in the access to dental services in a particular location may influence the practice of participants and patients.

Future work and implications for clinical practice

This study has highlighted a number of areas for future study. However, missing from this study and the

wider literature is the dental profession's insight into the interprofessional prevention of BRONJ. A recent publication in *British Dental Journal* highlighted the opportunities for interprofessional working between pharmacists and dentists; with a particular focus on chronic diseases, it was suggested that dental and pharmacy teams should take action to improve communication and devise schemes for collaborative working.[26] Published clinical guidelines recommend that patients should be referred for dental assessment and treatment prior to initiation on bisphosphonate therapy, but it is apparent this is not happening. The impact of this on dentists and their perspective on how the professions can collaborate to improve patient care would be important to consider before implementing any preventative strategies.

Raising awareness of the rare side effects of medicines is an important consideration when prescribing; explicitly pointing out rare side effects may create adherence problems and result in non-compliance with a potentially beneficial medicine which needs to be balanced against fully informing patients about the associated risks. Further research with patients to explore this issue would help guide practitioners and would be applicable to many other rare conditions and medicines.

The patient remains the central focus of the healthcare team, and therefore engaging patients in the management of their health is essential when introducing prevention strategies for BRONJ. Attitudes of patients towards the roles of the various team members and their priorities or expectations when being prescribed a new medicine will guide the development of such services.

CONCLUSION

Both GPs and pharmacists demonstrated relatively limited knowledge in relation to BRONJ and the preventative strategies recommended in the literature. Patients prescribed bisphosphonates often have complex medical histories, requiring practitioners to assign priorities in their management and, as such, the measures required to prevent the development of BRONJ can be overlooked.

Prescribing rates of bisphosphonates are increasing, with an ageing population and increasing emphasis on treating and preventing conditions such as osteoporosis. Therefore, the incidence of BRONJ is likely to increase; this may continue to be the case unless changes are made to current practice. Preventive measures should be implemented and further research performed to assess the effectiveness of such interventions.

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4.2 Paper 2 (patient attitudes towards MRONJ)

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BMJ Open

Perceptions and attitudes of patients towards medication-related osteonecrosis of the jaw (MRONJ): a qualitative study in England

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ABSTRACT

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

Design Interpretivist methodology using qualitative semistructured interviews.

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

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

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

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

Strengths and limitations of this study

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

INTRODUCTION

Medication-related osteonecrosis of the jaw (MRONJ) is defined as exposed bone, or bone that can be probed through an intraoral or extraoral fistula, in the maxillofacial region that has persisted for more than 8 weeks in patients with a history of treatment with antiresorptive or antiangiogenic drugs, and where there has been no history of radiation therapy to the jaw or no obvious metastatic disease to the jaws.[1] The risks for MRONJ are hypothesised to be related to the unique nature of the blood supply, and the anatomical structure and function of the jaw bones.[2–6]

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

agents are oral bisphosphonates for the management of osteoporosis.

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

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

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

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

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

Aims

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

METHODS

Design

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

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

Participants

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

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

Analysis

Constant comparison allowed for enrichment of data and for new concepts to be explored through subsequent interviews; Ritchie and Spencer's framework analysis (2002)[20] allowed salient themes to be identified from the data. Framework analysis involved a five-stage process: familiarisation with the data; development of a thematic

Table 1 Participant characteristics

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

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

framework; indexing data; charting of the data and mapping of the data. Themes were reviewed until definitive concepts could be produced from the data.

Patient involvement

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

RESULTS

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

Perceptions of knowledge

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

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

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

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

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

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

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

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

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

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

Quality of life

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

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

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

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

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

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

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

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

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

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

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

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

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

Interprofessional management

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Wider context

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

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

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

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

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

DISCUSSION

MRONJ is a serious condition that requires complex management, and current literature is indicative of the importance of preventive care interventions, due to the subsequent associated morbidity and challenges in treating osteonecrosis of the jaw.[1] In this study, it was apparent that MRONJ has a significant effect on the quality of life experienced by patients who were interviewed. Previously, a study of 34 patients with MRONJ utilising the Oral Health Impact Profile questionnaire-14 found that the condition significantly affects the quality of life.[21] While this provides tangible metrics regarding the significance of the condition of patients, it provides

no specific information on what this means to people in their daily lives. The qualitative insight generated by our study has provided the first documented experiences of this particular patient group, highlighting the significant issues they face and the ongoing physical, psychological and social distress they associate with the condition.

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

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

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

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

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

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

This study has explored the attitudes and perception of patients prescribed bisphosphonates, focusing on those with a diagnosis of osteoporosis. The literature is clear that the incidence of osteonecrosis is greater in patients prescribed intravenous bisphosphonates for the treatment of cancer; further work exploring the management of this patient group and any variation in the attitudes towards risk and ongoing management would substantially add to this body of literature.

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

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

CONCLUSION

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

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

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

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

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4.3 Paper 3 (dentist attitudes towards MRONJ*)*

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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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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 semistructured 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 well-being; (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 medication-related osteonecrosis of the jaw (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 (GDPs) towards the multidisciplinary approach to preventing MRONJ.
- ► A qualitative method yielded rich data through in-depth semistructured interviews with GDPs; constant comparative analysis allowed further exploration and refining of emergent themes.
- ► The study was based around an *a priori* assumption of limited knowledge among GDPs 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 medication-related osteonecrosis of the jaw (MRONJ) in 2003[1]; however, other medications such as the antiangiogenic drugs, bevacizumab, sunitinib and aflibercept, and the receptor activator of nuclear factor kappa-beta ligand 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 >8 weeks in patients with a history of treatment with antiresorptive or antiangiogenic 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 antiresorptive or antiangiogenic drugs is 1% and, in osteoporosis patients treated with antiresorptive 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 National Health Service (NHS)expenditure on the drug between 2015/2016 and 2016/2017.[5] The introduction of intravenous bisphosphonates in the treatment of early breast cancer also approximates to a further 20000 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]

A number of studies have described reductions in the incidence rates of MRONJ with the execution of appropriate screening and preventive dental care.[7 8] However, a 2015 survey (n=129) identified that >90% of general dental practitioners (GDPs) were unaware of medications which are associated with MRONJ other than bisphosphonates and that 58% of participants were not confident in performing an extraction in primary care on a patient prescribed oral bisphosphonates.[9] The prevention of MRONJ should be promoted by the multidisciplinary healthcare team with a collaborative approach to the education of patients and promotion of high standards of oral hygiene and preventive measures.[2 10–12]

Our previous studies have identified limited awareness of MRONJ among patients, with little promotion of appropriate preventive strategies from general medical practitioners and pharmacists.[4 13] Both of these professional groups often overlooked the advice related to the risk and prevention of MRONJ; the reasons for this were multifactorial; however, a lack of awareness of the condition, complexity of patient medical histories and prioritisation of other information, were all potential barriers to optimal patient care.[4 13] In this study, we have investigated the attitudes and perceptions of GDPs on the risks of MRONJ and approaches to its prevention.

Aims

1. To explore the attitudes towards, and perceptions of, GDPs on the risks of MRONJ.
2. To explore the attitudes towards, and perceptions of, GDPs 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.

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 semistructured interviews were undertaken at the participants' places of work and up to 1 hour was designated for each interview conducted. An initial topic guide (online 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 (online supplementary document 2) and participant information sheet (online 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[16] 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.

Patient and public involvement

A patient representative from the University of Sunderland Patient, Carer and Public Involvement Group was involved in coconstructed discussions around the

Table 1 Participant characteristics

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

practical implications of the design and ethical issues associated with this study.

RESULTS

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

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

Perceived knowledge

The concept of MRONJ was introduced in the participant information sheet provided in advance of the interview; however, all participants reported prior awareness of the risk of osteonecrosis of the jaw posed by certain medications.

> Even though it's a low risk, as a dentist, maybe just I know that it—it's such a difficult condition to manage and can't really be managed that well. (D1)

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

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

All participants had at least some (though minimal) experience of managing patients with MRONJ; this was mostly gained during their undergraduate studies and participants had very limited or no exposure to patients with MRONJ in their subsequent general practice.

> I've seen it as an undergraduate, but I have never seen it in practice. I think this particular patient that I saw was quite disfigured by it and had been attending the dental hospital for a long time. (D1)

Most of the participants were aware of guidelines for the prevention and management of MRONJ. Although all participants practiced in England, the Scottish Dental Clinical Effectiveness Programme (SDCEP) Guideline was cited as a good source of information[2]; those participants who had qualified most recently described being directed to these guidelines during their undergraduate study.

> The guideline I usually tend to use for everything is the Scottish ones, SDCEP . (D3)

Risk

Participants described the importance of taking accurate medication histories for each patient; a particular focus was directed towards certain medications such as anticoagulants and bisphosphonates.

> I'm looking out for any bisphosphonate really, and warfarin, any anticoagulants, they are the main ones. (D2)

Participants were aware that the risk of MRONJ is small for patients who are taking oral bisphosphonates and that intravenous formulations carry a higher risk. The risk of MRONJ developing following a dental extraction in patients prescribed oral medications was deemed to be small and this procedure was considered typically suitable for general practice. Patients receiving intravenous medications associated with a cancer diagnosis were perceived to be at higher risk and participants reported that they would typically refer these patients to secondary care.

> The way I view it—if—if they are on IV or if they have had IV bisphosphonates recently, then I would see it as high risk and I would probably refer to oral surgery. If they are on long-term oral then I am not concerned and would do the extraction. (D10)

All participants reported that they discuss the risk with patients prior to carrying out treatment; however, participants described the limited awareness of patients on the oral risks associated with medications implicated in MRONJ. Typically, information regarding this was introduced to the patient by the dentist prior to invasive procedures and had not been introduced at the point of prescribing or dispensing the medication.

> The patients don't really have a clue to be honest, I think dentists are aware but I am not sure anyone else even knows about it. (D10)
>
> It should come from the person prescribing I suppose, it's not me that is putting the patient on these drugs, but it would be up to me to guide them through what's appropriate for them once they are prescribed them. (D6)

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

> I don't think it's a big risk, at least not with orals [oral bisphosphonates], but I think it's a litigation thing really, protecting yourself and making sure the patient is informed, rather than it being a massive risk. (D9)

Oral health was perceived to be low down the list of priorities for other healthcare professionals, particularly among medical colleagues.

> I feel like whenever I have spoken to a GP about anything related to dentistry, they are kind of very much of the opinion, 'that's your job and not mine, you know better so sort it out'. (D14)

> A lot of the time they don't think of oral health as—as being high up on that—on that priority list. You know, they think about everything else, but the teeth and gums are an afterthought. (D10)

Access and isolation

Participants described challenges in obtaining accurate medication histories from some patients; the relative degree of time it takes when dentists are required to contact general medical practitioners was seen as a significant barrier to improving patient care.

> I make sure I take medication histories for patients, but they don't always know exactly what they take. It's sometimes hard to be sure the list they give you is accurate. (D15)

> I think it's sometimes very difficult to make contact, and like, if we try and phone them and they phone us, obviously we're all busy, we never have gaps at the same time, it can be really time consuming. (D11)

Access to summary care records (SCRs) was described as a key opportunity to save clinical time and ensure that dentists were fully aware of the patient's current medical conditions and medication history.

> It would be brilliant, if we could just see, even just an element of their records, even just what drugs they were taking. That's the main thing for us, it takes so long to get the drug history out of a patient. (D13)

Participants described the professional isolation that occurs in general dental practice. This indicated isolation from other healthcare professionals and potentially from other dental colleagues.

> I think with a lot of things with dentists really, that we are out of the loop, I just don't seem to have had much interaction with any other healthcare professionals. (D6)

Participants described limited interprofessional relationships and communication with other healthcare professionals in the existing organisational infrastructure. Typically, communication with general medical practitioners would be one way, difficult to initiate, and only take place when needing to confirm complex medication histories.

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

> I've never had a referral from the GP for anything. (D2)

Participants reported little collaboration with pharmacists, and some described a lack of understanding of the pharmacist's role. Communication with pharmacists would typically be to discuss issues around prescribing errors or with potential drug interactions; some participants reported communication with pharmacists who run anticoagulant therapy monitoring services.

> I personally don't really feel that I've got a good enough understanding of what an actual pharmacist's job entails. (D2)

> The only patients that I have really had any dialogue about with pharmacists are those on warfarin. The pharmacist runs the anticoagulant monitoring service. (D5)

Interprofessional working

A greater focus on oral health education in other healthcare professionals' training could potentially develop a better collaboration between the professions of dentistry and general medical practice and facilitate a greater understanding of the importance of oral health in relation to the adverse effects of medication and the links between oral health and systemic disease.

> I think the importance of oral health could be stressed more by other professions and we could probably work better together really. You know, sometimes there are medications that have side effects like with osteonecrosis and sometimes, there are, there are benefits on other condition like diabetes with oral health. (D15)

Participants described a willingness to engage with other healthcare professionals in order to improve patient care. Greater collaboration, clear referral pathways and communication with general medical practitioners and pharmacists would be well received.

> If there was a better multidisciplinary relationship, better communication, it would be much better for us in terms of delivery of better patient care. (D2)

> Yeah definitely. Yeah, I'm more than happy if pharmacists could refer appropriate patients, it's just about making sure that the patients know and getting them to see me as soon as possible really. (D2)

A greater focus on preventive care and the discussion of the oral health implications of medications associated

with MRONJ at the point of prescribing would improve care for this patient group. This would allow dentists to implement preventive strategies before the potential risk of MRONJ develops.

> If a patient is going to go on to alendronic acid or any of the bisphosphonates they should be referred to be dentally screened first, because I don't think that happens at all. It could really help to reduce the risk if we can do any work and explain things properly to the patient first. (D8)

DISCUSSION

In this research, we undertook semistructured interviews to investigate the attitudes and perceptions of GDPs 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 GDPs 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 GDPs 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[9] who identified that more than 90% of GDPs 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 in treating many patients prescribed the implicated medications in the context of primary care; however, they would typically find that patients would be unaware of the risks associated with them. It is clear that the recommendations in current guidelines are not always followed and that education of prescribers and pharmacists on the risks of MRONJ is required to ensure that patients are fully informed at the point of initiating pharmacological therapy.

The importance of counselling patients fully on the risks before treatment was highlighted by participants who also referred to the potential risk of litigation from a poorly informed patient or from patients who develop MRONJ following a dental procedure. Although not reported by all, a fear of litigation was clearly a consideration for some participants. A survey by Tanna[9] of 129 GDPs found that 21% identified a fear of litigation as a reason for not performing an extraction in primary care.[9] Participants in our study were, however, willing to perform extractions on lower risk patients prescribed oral bisphosphonates in primary care; this follows recommendations in current clinical guidelines, of which most participants were aware. A 2014 paper highlighted that the legal implications of MRONJ are complex; however, legal liability and malpractice claims have been made.[17] The authors identified the need for dentists and other healthcare professionals to have an understanding in relation to knowledge of MRONJ, provision of information to patients, prevention, diagnosis and treatment.[17]

Participants reported that GDPs are often isolated contextually, situationally and geographically from peers and other healthcare professionals; this was identified by participants as a potential barrier to optimal care of this patient group. This is similar to the findings of a previous qualitative study which explored the collaborative management of patients with diabetes; the researchers identified an isolated knowledge base and a perceived division between the medical and dental professions to negatively impact patient care.[18] Professional isolation among dentists has also been reported in other studies; recent research into the mental health and well-being of UK dentists by the British Dental Association identified professional isolation as a contributing factor in mental illness and burnout among dentists.[19]

SCRs are an electronic summary of key clinical information, such as medicines, allergies and adverse drug reactions that are created from GP medical records. More than 96% of the population in England currently have an SCR, which is accessible from a variety of NHS service providers, including hospitals and community pharmacies; however, GDPs do not currently have access to SCRs.[20] Participants reported challenges in taking accurate medication histories posed by the existing healthcare infrastructure in which they operate, with access to patient's SCRs described as a potentially useful opportunity to improve care and safeguard

patient safety. Sharing medical records with dental practices could save clinical time for dentists and reduce the risk to patients by ensuring that GDPs have the required information to make informed decisions about proposed dental health interventions. This could potentially benefit patients at risk of MRONJ and directly contribute to the improvement of oral health-related outcomes and potentially increase the opportunity for the safe(r) management of other patient groups.

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

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

CONCLUSION

Participants identified awareness of the risk of MRONJ, but had limited knowledge of implicated medicines other than bisphosphonates. GDPs 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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4.4 Paper 4 (lack of interprofessional working)

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BMJ Open

'We do not seem to engage with dentists': a qualitative study of primary healthcare staff and patients in the North East of England on the role of pharmacists in oral healthcare

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ABSTRACT

Objective To explore the attitudes towards, and perceptions of, primary care healthcare staff and patients, regarding the role of clinical pharmacists in the provision of oral health advice and collaboration with dentists in general practice.

Design Interpretivist methodology using qualitative semi-structured interviews and focus groups.

Participants 22 participants; 10 pharmacists; 3 general practitioners; 2 nurses; 1 practice manager; 6 patients.

Setting Primary care general medical practices in the North East of England and the University of Sunderland Patient Carer and Public Involvement group.

Methods One-to-one semi-structured interviews were performed with primary care healthcare staff. An iterative approach using constant comparative analysis facilitated the ongoing enrichment of data; salient themes were identified using Framework Analysis and related back to extant literature. A focus group was held with patients to further explore key themes.

Results Four salient and inter-related themes emerged: enhanced clinical roles; indicating rapidly changing roles of pharmacists working in general practice, increased responsibility and accountability of pharmacist prescribers and the delivery of advanced clinical services; limited knowledge; indicating basic understanding of appropriate oral health advice, but limited insight and provision of advice to patients with regards to links with systemic diseases and medication; geographical/situational isolation of the dental team; indicating the disparate contexts and challenges of multidisciplinary working in oral health, and patients' attitudes towards dental care; integration of oral health advice; indicating the potential of pharmacists to integrate oral health advice into current roles and to target specific patient groups in practice.

Conclusions The lack of integration between oral and general healthcare services potentially impacts negatively on patient care, requiring further interprofessional oral health education. The developing role of the pharmacist in general practice represents an opportunity to integrate oral health advice and/or interventions into the management of patients in this setting.

Strengths and limitations of this study

- ► There is limited research into the role of pharmacists in this setting; this is the first qualitative study that has explored the role of pharmacists as part of the general practice team in relation to oral healthcare.
- ► A wide range of general practice healthcare professionals and patients participated in this study; however, a limitation is that no general dental practitioners were interviewed.
- ► Semistructured interviews provided rich qualitative data and an iterative process of concurrent data collection and constant comparative analysis facilitated the simultaneous exploration, refinement and enrichment of key themes.

INTRODUCTION

Oral health conditions are thought to affect a significant proportion of the world's population, approximately 3.9 billion people worldwide and cost the National Health Service (NHS) in England £3.4 billion per year.[1 2] The most recent Adult Dental Health Survey (2009) stated that 23% of the UK population do not attend a dentist.[3] Oral health is important for general health and well-being, and there is increasing evidence that has linked periodontitis to a number of diseases, such as cardiovascular disease and diabetes.[4 5]

Wilson and Soni's recent opinion piece in the *British Dental Journal* highlighted the potential for a collaborative approach between pharmacy and dentistry in the management of chronic diseases, such as diabetes and the potential capacity for pharmacists to encourage hard-to-reach individuals to become dental attenders.[6] In the UK, dental treatment is available privately or provided as part of the NHS. However, even under NHS arrangements, the majority of patients pay a contribution towards the cost of

their care, and currently care is charged into one of three bands (band 1 £22.70; band 2 £62.10; band 3 £269.30) depending on the extent and complexity of treatment that is needed.[7]

Approximately half of the adults in the UK are affected by some level of periodontitis; a chronic inflammatory disease caused by bacterial infection of the supporting tissues surrounding the teeth.[3] This condition is usually painless and often goes unnoticed and untreated until it reaches an advanced stage.[8] The Cochrane Collaboration published a review in 2015, highlighting that randomised controlled trials have demonstrated that periodontal therapy is associated with a 3–4 mmol/mol (0.3%–0.4%) reduction in HbA1c levels after 3 months[9]; this is a clinical impact equivalent to adding a second drug to a pharmacological regimen.[10] There is evidence that even a modest reduction in HbA1c is associated with improving outcomes for patients with type 2 diabetes; a 1% reduction in HbA1c has been associated with a 21% reduction in diabetes-related death, 14% reduction in myocardial infarctions and 37% reduction in microvascular complications.[11] There is clear evidence of a bidirectional relationship between periodontitis and diabetes; poorly controlled diabetes increases the risk of periodontitis 2–3 times, and in turn periodontitis is associated with higher HbA1c levels and worse diabetes complications.[12 13] There is also evidence of an association between atherosclerotic cardiovascular disease and poor oral health.[14]

A number of medications can negatively impact oral health, representing a significant opportunity for pharmacists to provide advice in relation to the prevention and management of these issues. For example, polypharmacy and a high anticholinergic burden are associated with the development of xerostomia and inhaled corticosteroids with oropharyngeal adverse events, such as oral candidiasis.[15 16] Calcium channel blockers such as nifedipine, ciclosporin and phenytoin are all associated with development of drug-induced gingival overgrowth.[17] Medication-related osteonecrosis of the jaw (MRONJ) is a rare, yet significant complication of antiresorptive and antiangiogenic drugs used in the treatment of osteoporosis and cancer.[18] MRONJ is difficult to treat and significantly impacts on patient's quality of life[19]; therefore a multidisciplinary approach to prevention is usually recommended.[18]

Evidence suggests that pharmacists working in a community pharmacy setting see the provision of oral health promotion to be part of their professional role. An oral health promotion intervention in the North East of England demonstrated patient's acceptance to the pharmacist's intervention and a positive intention to change oral health habits.[20] To the authors' knowledge, no studies have explored the utilisation of pharmacists working in general practice to provide patients with oral health advice; however, a systematic review of pharmacists working in general practice found favourable results in various areas of chronic disease management and the optimal use of medicines.[21]

Following a successful pilot, NHS England's General Practice Forward view (2016) committed to the investment of £112 million to further develop this role with the aim of providing an additional 1,500 clinical pharmacists to the general practice workforce by 2020.[22] The Primary Care Pharmacy Association's Clinical Pharmacist in General Practice Job Description sets out the duties and areas of responsibility for pharmacists in this setting in the UK[23]; this includes managing long-term conditions, performing medication reviews, implementing medication safety guidance, supporting public health campaigns and signposting to appropriate healthcare professionals.

Each of these areas represents an opportunity for the provision of oral healthcare by clinical pharmacists. Potential oral health-related roles could include the provision of oral hygiene advice and the recommendation of appropriate products, which could be targeted to high risk patient groups or those in which the benefits of improved oral hygiene can impact on systemic health, for example, diabetes. Pharmacists could play an important role in the prevention or management of the oral health-related adverse drug effects outlined above; this includes the prevention of MRONJ through signposting and formal dental referrals, the prescribing of saliva substitutes or high fluoride toothpastes, deprescribing medications implicated with xerostomia and screening patients for oral cancer. The role of clinical pharmacists in the provision of oral health advice and collaboration with dentists in general practice is explored in our study.

Aims

1. To explore the attitudes towards and perceptions of primary care healthcare staff and patients, regarding the role of the clinical pharmacist in providing oral health advice in a general practice setting.
2. To explore any potential barriers and/or facilitators in using pharmacists in general practice to improve the interprofessional management of oral health.

METHOD

Design

An interpretive approach was adopted throughout this research; an initial topic guide (online supplementary file 1) was produced serving as a benchmark for semi-structured one-to-one interviews with healthcare professionals, which were audio recorded and transcribed verbatim. Constant comparative analysis, facilitated the concurrent and iterative process of data collection and analysis.[24] This process provided the opportunity for the further exploration of emergent themes through subsequent data collection. Ritchie and Spencer's Framework Analysis facilitated the process of constant comparative analysis and provided a systematic approach to the identification and analysis of salient themes.[25] Framework Analysis involved a five-stage process[1]: familiarisation with the data—achieved via iterative cycles of listening to and rereading of transcripts[2]; development of a thematic

framework—the initial themes formed the basis of a thematic framework[3]; indexing data—data were indexed against the thematic framework[4]; charting—charts were produced of the data within the framework[5]; mapping of the data—themes were reviewed until definitive concepts were produced. A focus group was held with patients to explore key themes; a topic guide (online supplementary file 2) was produced following the collection and analysis of data from healthcare professionals.

Participants

General practice healthcare professionals were recruited from 12 practices across the North East of England. Four distinct professional groups were recruited to the study: (1) pharmacists working in general practice; (2) general practitioners; (3) general practice administrative staff; (4) general practice nurses.

An invitation letter (online supplementary file 3) and participant information sheet (online supplementary file 4) were posted to medical practices in the region; an initial convenience sample of participants who responded to the invitation was implemented with further recruitment facilitated via snowball sampling.

Patient participants were recruited from the University of Sunderland Patient Carer and Public Involvement (PCPI) group; participant information sheets were emailed to PCPI representatives and those that responded to the invitation participated in a focus group.

Analysis

Constant comparative analysis facilitated the identification and further exploration of salient themes through an iterative process of data collection and analysis. Ritchie and Spencer's Framework Analysis (2002),[25] provided a systematic five-stage approach to data analysis; familiarisation with the data; development of a thematic framework; indexing data; charting of the data and mapping of the data. Themes were reviewed by the research team until definitive concepts could be produced from the data.

Patient involvement

The principal investigator met with a patient representative from the University of Sunderland PCPI group to discuss the initial design and ethical implications of the study. Following the collection and analysis of data from healthcare professionals, a focus group was held with six patients; the focus group facilitated the refinement of emerging concepts and the coconstruction of overarching themes.

RESULTS

22 participants were recruited to this study (tables 1 and 2). In-depth semistructured interviews were carried out between October 2018 and April 2019 until no new themes emerged and extant ones were exhausted. Interviews took place at participants' places of work or at the University of Sunderland, with two interviews performed via telephone for logistical reasons; 1 hour was designated for each interview. Six patients participated in a focus group, lasting 1 hour, held in April 2019 at the University of Sunderland.

Four salient inter-related themes emerged from the data and a coding tree was produced (online supplementary file 5): (1) enhanced clinical roles; (2) limited knowledge; (3) geographical/situational isolation of the dental team; (4) integration of oral health advice.

Table 1 Healthcare professional participant characteristics

Participant	Identifier	Role	Years' experience (N)	Gender
1	Ph1	Pharmacist	5–9	Female
2	Ph2	Pharmacist	10–14	Male
3	Ph3	Pharmacist	<5	Female
4	Ph4	Pharmacist	>20	Female
5	Ph5	Pharmacist	10–14	Female
6	Ph6	Pharmacist	5–9	Male
7	Ph7	Pharmacist	10–14	Female
8	Ph8	Pharmacist	10–14	Male
9	Ph9	Pharmacist	<5	Female
10	Ph10	Pharmacist	15–19	Female
11	PM1	Practice manager	>20	Female
12	GP1	General practitioner	15–19	Female
13	GP2	General practitioner	<5	Male
14	GP3	General practitioner	>20	Male
15	N1	Nurse	15–19	Female
16	N2	Nurse	>20	Female

Table 2 Patient participant characteristics

Participant	Identifier	Role	Age (years)	Gender
1	Pt1	Patient	50–59	Female
2	Pt2	Patient	60–69	Male
3	Pt3	Patient	50–59	Female
4	Pt4	Patient	60–69	Male
5	Pt5	Patient	40–49	Female
6	Pt6	Patient	60–69	Female

Enhanced clinical roles

Participants highlighted the accessibility of pharmacists as part of the general practice team, providing a complementary skill set to existing staff that enhances the provision of services provided at practices.

> I'm directly contactable face-to-face by prescribers, GPs, nurse practitioners, nurses, admin team, everything. They can just come directly into my office and ask me for information. So, I'm probably more likely to be utilised clinically. In community pharmacy, you obviously have other responsibilities as well and the pharmacist also takes on the role of the manager. (Ph1)

Participants identified that general practice is a rapidly evolving role for pharmacists, who are increasingly involved with, and leading, more advanced, patient facing clinical services. These services require an enhanced level of clinical knowledge compared with more traditional pharmacy roles, with pharmacists increasingly inputting more into the clinical management of patients in this setting.

> Our roles in the surgeries are evolving and perhaps new to some, but I found it on the whole to be very very positive and that the other staff have been accepting. (Ph8)

Many of the pharmacist participants described providing a higher level of clinical service facilitated through obtaining postgraduate prescribing qualifications resulting in a greater degree of clinical responsibility and accountability.

> I'm in quite an advanced clinical role now. So I do a lot of diagnostics and treating myself. I'm a prolific prescriber. (Ph7)

Participants perceived the management of chronic long-term conditions, with a specific focus on optimising therapy and the provision of detailed, clinically focused medication reviews to be a key role for pharmacists in this setting.

> I would see patients for medication reviews, particularly the complex ones, the ones with polypharmacy in particular come to me. It would be about making sure they are on the right regimens, making sure they haven't got any adverse effects and maybe stopping drugs if no longer appropriate. (Ph4)

The management of high-risk medications and the reconciliation of medication provided on discharge or from a specialist setting was seen as an important part of the pharmacist's role. The services provided are integrated into the existing practice infrastructure and the access of pharmacists in this setting to full clinical records facilitates a higher degree of clinical input. Through working in this setting pharmacists can also clearly communicate with the rest of the practice team; this includes following up on monitoring requirements, liaising with community pharmacies and updating medical records to accurately reflect patient's current medication.

> Some of my work is quite administrative, so dealing with queries, issues from community pharmacies, discharge prescriptions or hospital letters, things like that. Making sure that patient's medication lists are correct, particularly with medicines started on discharge or in outpatients, you know, ones with shared care agreements or high-risk drugs. (Ph3)

The provision of lifestyle and preventive advice was seen as a key role for pharmacists, complementing work done by practice nurses; this would typically include signposting patients and formal interprofessional referral where required.

> There is an increasing amount of work for GPs, and I think the lifestyle issues seem to get shifted down the line as to what we are able to focus on, it's often not what the patient presents with. I think both pharmacists and nurses are good at doing that, it is about prioritising in that short time you have. (GP1)

Some of the patients had experience of having appointments with pharmacists in general practice. Those who had reported favourable experiences were positive towards the benefits for their care; with a particular focus on reviewing medications and reducing the known side-effects of prescribed medicines.

> She (pharmacist) rang up to discuss the medication because they were changing my insulin. So, she was on about ten minutes going through everything that I was on to make sure I was happy, everything was balanced, no side-effects and she decided to change a couple of things that I'd been on for a number of years. She was really helpful and it's definitely better now. (Pt1)

Some patients had not experienced services provided by pharmacists in this role; a number of participants perceived that the benefit of pharmacists resulted from the accessible locations and opening hours of community pharmacies and were concerned that the pharmacist in general practice would become another healthcare professional with whom making appointments was challenging.

This was a common experience of patients when trying to make appointments with general practice staff.

> You could get a doctor's appointment more easily when we were young. But I think people tend to just to pop in a pharmacy, I think there's more information in the pharmacy now, there is no wait for appointments and they are open all the time. (Pt3)

> If you have to wait to get an appointment with the pharmacist at the doctor's surgery, you may as well just see the doctor or whatever else, the point of a pharmacist to me is that it's, like, around the corner and it's easy. (Pt6)

Limited knowledge

All healthcare professional participants reported limited knowledge of basic oral health advice and would try to signpost patients to dental services where possible, but perceived that they were able to manage common conditions, such as a mouth ulcer, and provide basic oral hygiene advice.

> You will get people presenting to surgery with queries around the mouth generally. Perhaps unexplained problems. It might be anything from halitosis, to soreness, to ulcers, to even presenting with dental abscess because they'd rather come to us than go to a dentist. We try to signpost them to a dentist, but we can deal with some of the minor issues. (N1)

The primary care staff participants described the presentation of patients in general practice with dental problems, such as dental pain and likely infections. Participants described limited knowledge in the assessment and management of dental infections; GPs would typically signpost these patients to a dentist, but did report a perceived duty of care to help this patient group if the patient was unable/unwilling to attend a dental appointment.

> Even if a GP thinks, 'actually, I think it's an abscess' he or she's got a duty of care to treat that infection and not to leave it, even if we don't know a great deal about more complex dental issues. Especially when they say they don't have a dentist. (Ph10)

Participants had limited knowledge of the links between oral and systemic health; with oral health advice not usually forming part of discussions with patients in high risk groups, such as those with diabetes and with multidisciplinary diabetes teams not including dental professionals.

> I haven't really heard of links between the two. I see lots of patients with diabetes and it is definitely not something that I would tell patients about. (Ph5)

Although not a direct focus of interventions, pharmacists described a key role in the deprescribing of medications in patients with a high anticholinergic burden. These patients would typically have symptoms of a dry mouth and this would be used by some as an incentive to stop or reduce implicated medicines.

> I look to stop some medicines during medication or falls reviews, medicines that have antimuscarinic side-effects, so like those for urinary incontinence or tricyclic antidepressants that cause, like a drying effect, and patients experience dry mouth. (Ph1)

The pharmacists were aware of MRONJ, mainly due to historic Medicines and Healthcare products Regulatory Agency safety alerts. The actioning of these alerts was described as a key role of the practice pharmacist; participants reported that following safety alerts patients were identified and provided signposting advice, however, pharmacist and GP participants acknowledged that these alerts are often forgotten or lose focus and need to become longer term initiatives, not isolated alerts.

> I remember a couple of years ago, there was an alert and where we set it up so that all new patients going on a bisphosphonate got told to have a dental check-up before they went on. Now, I don't know—I haven't seen anything around that lately and I've got a feeling that might have lapsed a bit. Or at least I'm not aware of it happening. (Ph4)

The patient participants identified that their knowledge in relation to oral health had almost exclusively come from their dentist or their parents as a child. None of the participants described receiving any oral health advice from other healthcare professionals.

> I think it would be from my mum and dad and then the dentist. I don't think anyone else has ever talked about oral health with me, maybe the school nurse a long time ago. (Pt5)

All participants described a need and willingness to receive further education and training on oral health; this was perceived as a deficit in both undergraduate training in post-registration continuing professional development.

> I think it would be useful to have more training—directed at general practice. I think most of us know the basics, but not really much depth, especially around how oral health and just general health and wellbeing are related. (Ph3)

Geographical/situational isolation of the dental team

General practice staff reported limited collaboration with dental colleagues in primary care, with no formal referral pathways between medical and dental services and a lack of communication between the professional groups. These were all seen as significant barriers to providing high quality and safe oral healthcare to patients.

> I would say there is anonymity really. If you compare it with, for example, local opticians where we have frequent interactions, albeit by paper, we don't really

get any, sort of, direct contact. Not that I can recall. (GP3)

We don't seem to engage with dentists. In fact, the only time that I ever had a proper conversation with a dentist was when I worked in community pharmacy and that would have been over an incorrect prescription or an out of stock item. And I just think, you know, there is a lot of cross-conversations that we could have. (Ph10)

There were concerns about the lack of information shared between primary medical and dental services and the impact that this has on patient safety; with dentists not having access to patient's Summary Care Records (SCRs) and general practice staff not receiving information about the care or interventions provided in a dental setting. This included a lack of information on medication prescribed by dentists.

We would never know if the dentists had prescribed any antibiotics or anything for a patient. Yet, if anyone else in the primary healthcare team prescribes anything for our patients, we know. We would get either a letter or a fax summary, something sent over to say this is what's happened in this patient. (Ph7)

Both patients and the healthcare professionals described their own and their patient's reluctance to engage fully with dental services; barriers include the cost of both preventive and remedial dental work, dental phobias and a lack of education on the benefits of good oral health.

The area I am in is very deprived and actually, I would say that the majority don't ever visit the dentist, I think they just don't see it as important and loads of them just don't have the money, and fear, loads of people hate seeing a dentist unless it's absolutely necessary. (Ph5)

The patients also reported a perceived segregation between the dental and medical professions, with historic stereotyping contributing to their formative understanding of each role. This was described as a barrier in engaging with oral healthcare outside of a dental setting, as historically this is not an environment that patients associate with dental care provision.

I think it's just the way society has brought us up in that the there are two defining people, dentists and doctors. Anything to do with dentists, you go to the dentist. Anything about your health you go to the doctors. They have always been seen as separate. (Pt6)

Integration of oral health advice

Pharmacists working in general practice have better access to patient medical records than their community pharmacy colleagues and are therefore well placed to identify patients who may be suitable for targeted interventions. For example, the practice diabetes register or those patients prescribed medications with oral health-related adverse effects, such as bisphosphonates, could be easily identified and invited for review by the pharmacist.

In GP practices, people are coded appropriately, as smokers, or based on specific conditions, or you could look at medications that are associated with oral complications and target those people. It is easy enough to identify potential higher risk patients. (Ph1)

Participants described the role of the pharmacist in optimising medication regimens and their specific focus on providing input into patient care through chronic disease management clinics and medication reviews. All participants agreed that the provision of appropriate lifestyle advice should form a key element of these consultations.

Generally, I think pharmacists can focus on medicines and do a really good job getting those right, but with the, let's call it, soft interventions, lifestyle advice etc., they seem to work better when they're repeated by various people. (GP3)

Participants reported that consultations with the pharmacist are typically less time pressured than GP appointments; with most pharmacist participants not routinely involved in providing acute care. This time could facilitate the provision of more detailed consultations, representing an opportunity to incorporate oral health advice into current practices.

My clinics could easily be timetabled for 20 min instead of 10, and as I don't really see acute patients or have the same time pressures as some of the GPs or practice nurses. I can talk longer and to go into more detail about things, there is scope to take more time and really reinforce the key messages. (Ph2)

I don't see any reason why you can't promote oral hygiene at a doctor's practice, you can promote it, give people the information so they are properly informed. Then it is up to them. (Pt2)

The incorporation of basic oral health advice can be integrated into the current role of the pharmacist; however, participants reported a need for more direction from professional bodies or the commissioners of local or national services to provide more complex interventions and to improve interprofessional collaboration with dental professionals.

There is loads that we could do and as a practice we could just do it to give a better quality of care, but if it is a paid service or linked to certain targets etc then there may be more incentive to focus on it. (Ph2)

DISCUSSION

Our research has highlighted the disparate contexts of provision of oral and general healthcare in the North East of England. This is further hindered by a lack of

communication between medical and dental service providers, a lack of clear referral pathways and no shared access to medical records. All of these are significant barriers to the provision of high quality and safe oral healthcare. Further consideration and action are therefore needed at the level of policy and practice if patient safety and quality care in an oral health context are to be implemented and sustained in a non-dental setting.

The evolving role of the clinical pharmacist in general practice is facilitating the provision of additional clinical services and is improving patient care.[21 26] The provision of oral healthcare by pharmacists in general practice is limited at present, but this role represents an opportunity to target at risk patients and incorporate appropriate advice into current services.

The limited knowledge of oral health reported by our participants is similar to findings published in the literature.[27] In particular, our findings in relation to the limited knowledge of general practice staff of the bidirectional relationship between periodontitis and diabetes match those by Bissett *et al*.[8] Their study did not specifically include pharmacists and the subsequent enhancement of the clinical pharmacist in general practice role discussed in our study represents an unexplored opportunity to improve medical and dental collaboration.

Previous studies have identified a role for pharmacists working in a community pharmacy setting to provide oral health advice to patients.[20 28–31] Our study has explored the expanding role of the pharmacist in the general practice setting; this has received significant funding from the NHS and forms a key component of NHS England's General Practice Forward View (2016).[21] Further exploration of the potential roles of pharmacists in this setting is required to establish the impact made on patient care.

Further consideration needs to be made by both clinicians and policymakers to better integrate oral health into holistic healthcare provision. Research by Bissett *et al* identified that dentists tend not to contact GPs regarding the management of patients with diabetes, and when they do so, they typically communicate through the patient, as opposed to through formal referral channels.[32] Participants in our study reported little collaboration between general practice and dentists, with a lack of formal referral pathways and the limited sharing of patient information. A lack of shared information between medical and dental services was identified by participants in our study as a risk to patient safety. More than 96% of the population of England have a SCR that can be accessed from a variety of NHS service providers; however, NHS dental practices do not currently have access to SCRs.[33] This represents a barrier to optimal patient care, but also potentially results in a risk to patient safety; dentists are currently reliant on patients to be able to provide accurate medication histories and general practice staff are potentially unaware of medication prescribed by dentists. Access to medical records in dental practices could improve collaboration,[34] facilitate a reduction in patient safety concerns that arise as a result of incomplete or inaccurate information. For example, accurate medication histories could reduce the risk of dentists and doctors inadvertently prescribing medication that negatively interacts with existing therapy or missing dentally important drugs such as bisphosphonates and could encourage better communication between settings. Participants in our study described a key role for pharmacists in general practice in relation to the reconciliation of medicines and the maintenance of accurate medication histories; this represents an opportunity to ensure the flow of correct information between care settings and could be utilised if records were shared between medical and dental service providers.

Participants described the presentation of patients in general practice with oral health complaints; this was perceived to be due to issues with patients accessing dental services, the cost of dental treatment in the UK and patients' phobias of dentists. The healthcare professional participants reported some knowledge in relation to basic oral health advice, however, there is a clear need for further education of non-dental health professionals to address the limited knowledge of the associated links between oral health and systemic diseases.

This is the first study that has explored the role of the pharmacist in general practice in relation to the provision of oral health advice, but these findings are consistent with those in the literature in relation to community pharmacists and other healthcare professionals.[8 20] There is also a need for further interprofessional education between the professional groups, as identified our previous qualitative studies and in research outside of the UK.[35] This could act to improve collaboration, reduce the perceived isolation of dental services and optimise patient care.

Pharmacists are now providing more complex clinical services in general practice, representing an opportunity to enhance service provision, taking both increased responsibility and accountability; this represents an opportunity to facilitate the provision of oral health advice by this professional group and optimise patient care.

Our study has shown that pharmacists in general practice represent a new avenue for the provision of oral healthcare. Further enhancement of this role could improve the quality and safety of oral healthcare through effective collaboration between pharmacists, other members of the primary care health team and the dental profession. Professional bodies and the commissioners of healthcare services at both a local and national level should consider using pharmacists in general practice to provide oral health-related advice and/or interventions. Further research to explore the potential for this group to impact on patient care is needed; however, the integration of this could potentially have significant benefits for patients.

CONCLUSION

Our findings suggest that clinical pharmacists working in general practice are not currently providing optimum

care in relation to oral health, with limited incorporation of oral health issues into current clinical practices. However, the disparate contexts of oral and general healthcare services, and a lack of clear referral pathways, are a significant barrier for the provision of high quality and safe oral healthcare in a primary care setting. The limited dental input into the multidisciplinary primary care team, a lack of communication and the absence of access to medical records by relevant primary care health professionals are potentially impacting on capacity to provide optimal patient care.

Further education in relation to oral health is required and could enable improved oral healthcare in this setting; the established links between periodontitis and diabetes, and the association of specific medicines with oral health-related adverse drug reactions represent a key focus for pharmacists who are becoming increasingly responsible and accountable for patient care in general practice.

The role of the clinical pharmacist working in general practice is rapidly developing and growth of this professional group is part of the NHS General Practice Forward View[22]; this represents an opportunity to integrate oral health advice into the management of patients in this setting. Further work to explore the benefit and impact of providing oral healthcare by this professional group in general practice ought to be explored.

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4.5 Paper 5 (oral health promotion in pharmacy)

Sturrock, A., Cussons, H., Jones, C., Woodcock, C. and Bird, L. (2017). Oral health promotion in the community pharmacy: an evaluation of a pilot oral health promotion intervention. British Dental Journal, 223(7), pp.521-525. https://doi.org/10.1038/sj.bdj.2017.784

4.6 Macro (system integration)

At a macro level, a number of key barriers and enablers exist for the integration of oral healthcare and MRONJ prevention into the role of pharmacists in a primary care setting.

4.6.1 NHS policy and dental care services

Dental care services in the UK currently place limited emphasise on preventive dental care, with healthcare professionals and patients describing dental work to generally be remedial as opposed to being preventive. This is of particular importance with the prevention of MRONJ, where good oral hygiene and preventive dental treatment can significantly reduce the risk of patients developing the condition. There needs to be a greater focus on engaging patients and other healthcare professionals with oral health promotion and preventive care; this relates to the education of patients and to the structure and funding of dental services. Patients in England currently pay for dental check-ups on the NHS; this was described as a significant barrier by both patients and healthcare professionals in getting some elements of the population to engage fully with dental care. Supportive and prevention-based oral health policies could facilitate better engagement of both patients and healthcare professionals in oral healthcare.

4.6.2 Professional body representation

Professional bodies provide strategic direction in terms of the scope of practice and championing the role of specific professional groups; for example, the Primary Care Pharmacist Association provides guidance on the potential roles and responsibilities of pharmacists working in general practice. Oral health does not specifically feature

in this guideline, although is clearly associated with the safe prescribing, health promotion and chronic disease management elements of pharmacists' roles. Professional bodies have a significant role in ensuring the education and training of future healthcare professionals, and for example, can mandate the inclusion of oral health education in accredited programmes. Joined up and collaborative working between various professional bodies could demonstrate a committed and multidisciplinary approach to the integration of oral and general health and wellbeing.

4.6.3 Education of patients and preconceptions

Oral health education is typically only provided in a dental setting. This strengthens the silo attitudes towards dental and medical services, acting as a barrier for full integration of dental and general health and wellbeing. A common theme from all of the studies forming this submission is the phobia of dental treatments reported by many patients. A move to preventive dental care to reduce the need for invasive dental treatment could help to engage more patients with oral healthcare. There is also a need for patient education on the roles of the healthcare team; patient participants recognise pharmacists as good sources of healthcare information, but there has historically been limited engagement with oral health as part of their role. The patients interviewed in this work described growing up with healthcare professionals undertaking stereotyped traditional roles, with little dental education forming part of any contact with professionals other than dentists. In order to fully engage the public with oral health, the isolation of dental care from general health and wellbeing services needs to be addressed, integrating it into the multidisciplinary team and challenging society's preconceptions of dental care. The positive response of patients towards the intervention piloted in *(oral health promotion in pharmacy)*

found that only 3.3% (n=35) of patients receiving the intervention reported that a pharmacy was not an appropriate place to receive advice about their teeth, demonstrating the acceptability of patients to pharmacy's increased role in the provision of oral healthcare.

4.7 Meso (organisational/professional integration)

At a meso level there are a number of barriers to both organisational and professional integration that impact on the quality and safety of population-based oral healthcare.

4.7.1 Isolation

All professional groups interviewed in this work cited poor working relationships between dental and medical services, and isolated practices, both at an individual clinical level and at a meso (organisational/professional level). This includes both situational and geographical isolation, which is further enhanced through limited referral pathways between the settings and minimal interprofessional education. The lack of locally commissioned collaborative services represents a barrier; however when oral health teams and pharmacy collaborate *(oral health promotion in pharmacy),* positive contributions to both population and individual patient health can be achieved. This requires closer networking between the professional groups to meet the needs of local populations.

4.7.2 Communication and collaboration

A significant challenge for the integration of oral and general medical care is the limited communication and collaboration between care settings. Pharmacy and medical participants reported good lines of communication between their respective

services, with pharmacists increasingly contributing to more advanced clinical services in both community and general practice settings. This was facilitated through close joined up interprofessional education, formal referral pathways and shared access to either full medical records (in the case of general practice pharmacists) or Summary Care Records. These lines of communication and collaboration between dental services and pharmacy/medical services in primary care do not exist, posing a significant barrier for the integration of oral healthcare across care settings.

4.7.3 Local population needs

As a meso level there are local population issues/demands that impact on the provision of services in the area. In *(oral health promotion in pharmacy)* a pharmacy-based oral health intervention was piloted in parts of County Durham with a high degree of deprivation. Participants reported that in the North East of England, large proportions of the population place a low emphasis on the importance of oral health; with this study identifying that 20.2% (n=216) of patients had not visited their dentist in the previous 2 years. This represents an opportunity for pharmacy to engage with patients that are poor dental attenders and the service that was delivered resulted in 66% (n=701) patients reporting a positive intention to ‘definitely’ change oral health behaviours following the intervention. Many participants did, however, report significant issues in relation to their workloads, both at an individual and institutional level. Therefore, the addition of new services and expansion of roles needs to be considered in relation to the wider demands on staff time and capacity.

4.7.4 Education of healthcare professionals

Pharmacy professionals had a good understanding of their current/potential role in oral healthcare. However dental participants in particular had a limited understanding of what the pharmacist's role involved, over and above the traditional sale and supply of medication from a community pharmacy. A fundamental consideration in relation to the provision of safe and effective oral healthcare is the limited interprofessional education on oral health. Participants reported limited interprofessional training with dentists, resulting in poor understanding of the other professionals' roles, responsibilities and each other's potential to improve patient care. As a result, the scope of oral healthcare and the competence of individual non-dental professionals in the provision of oral health advice and/or more specific targeted interventions is limited. Interprofessional oral health education needs to be part of training programmes to develop both subject knowledge and more effective interprofessional collaborations.

4.7.5 Practitioner's competence and capability

Although not specific to oral health-related conditions, there is clearly an advancing role for pharmacists in the delivery of clinical interventions in primary care. Many of the pharmacists, particularly those working in a general practice setting, were either working towards or already acting as independent prescribers. The varying clinical capability of pharmacists represents differences in the clinical responsibility and accountability in this professional group, and therefore the limitations on the care individuals provide at a micro/clinical level. The roles of individual staff and their potential to engage in oral healthcare could potentially be enhanced through upskilling the pharmacy workforce and through further education.

This enhanced role represents an opportunity for pharmacists, who are the medication experts in the multidisciplinary team, to take greater responsibility for safe and effective medication use; this aligns with the safe prescribing and monitoring of MRONJ-implicated medicines and greater involvement with conditions such as type 2 diabetes as part of chronic disease management.

4.7.6 Perceived hierarchy

Despite the increased responsibility and accountability of pharmacy professionals identified above, there remains a perceived hierarchy from both professionals and patients, in terms of roles and responsibilities. Pharmacists would typically report referring patients for further investigation with dental and medical issues to either the GDP or GP respectively. Although clearly an appropriate safety net, pharmacists identified that they could contribute more and in many cases are the right professional group to manage simple oral health issues.

4.8 Micro (practice integration)

4.8.1 Individual clinical competencies

The limited interprofessional education on oral health translates at a micro level to a lack of competency in providing oral health services. Knowledge of oral health issues varied between participants, although most had a workable understanding of basic oral health promotion advice. Participants identified that a pharmacists' role includes the promotion of healthy lifestyles, the provision of preventive advice and the safe use of medication. However, there were clear gaps in the knowledge of appropriate preventive strategies for MRONJ and in the wider associations of oral health with general health and wellbeing. Although very few participants had encountered a

patient with MRONJ, the significant quality of life implications associated with the condition resulted in these practitioners being more vigilant towards the prevention of the condition and the education of patients at risk of its development.

4.8.2 Professional relationships

The relationships between pharmacists and both their patients and other healthcare professionals directly influences their individual practices. Both pharmacists and patients reported good reciprocal relationships, with patients highlighting the ease of access and approachability of pharmacists, making them a valued source of health advice. Patient participants generally displayed a positive attitude towards the widening role of pharmacists and in integration of pharmacists into the general practice team. There were, however, some concerns regarding the accessibility of pharmacists in this setting, as a strength of the traditional community pharmacist is both their convenient location and accessible working hours.

4.8.3 Isolated working patterns

A key finding was the perceived isolation of the dental team from other primary care health service providers *(dentist attitudes towards MRONJ* and *lack of interprofessional working).* Although this is clearly an issue at a meso and macro level as described above, it also results in challenges for the management of individual patients and for individual practitioners. Participants across the studies reported poor collaborative care between medical and dental services, with limited interprofessional relationships and a distinct lack of formal referral pathways. As a result, referrals to dental teams are typically informal and revolve around the principles of signposting patients to services, with little or no further follow up. The contextual, situational and geographical isolation of dental professionals reported at

an individual level impacts on many aspects of patient care; in particular for dentists, obtaining accurate medication histories from patients and in engaging with high quality collaborative patient care is a challenge.

4.8.4 Individual patient needs

Although wider policies and practices at a meso or macro level can impact on individual patient care, it was apparent from the interviews with both patients and with healthcare professionals that there are significant variations in individual patient needs and complexities. Consequently, healthcare practitioners often have to prioritise the management of certain conditions and/or the information that is provided to patients. In many cases where patients have multiple co-morbidities, oral health was seen as having a lower priority and therefore was neglected in preference for matters deemed to be more clinically relevant to individuals by clinicians. Although MRONJ is rare, it was apparent from the findings in *(patient attitudes towards MRONJ)* that the condition can have significant negative effects on patients' quality of life. The qualitative interviews with patients highlighted the extent of the physical, psychological and social implications of the conditions that impact significantly on individual patients. This includes experiencing pain associated with MRONJ and the regular need for analgesic medication, the requirement to attend regular appointments with medical/dental professionals, concerns about potential complications and surgical management, and social anxieties linked to eating and drinking in public. Although MRONJ is rare, the current lack of focus on preventive strategies at a population-based level are putting individual patients at risk. Greater focus on preventive care across this patient group could facilitate a reduction in the incidence of MRONJ.

4.9 Functional and normative integration

A significant barrier to effective collaborative oral healthcare is the current lack of access to shared medical records. Pharmacists have access to Summary Care Records, but currently GDPs have no access to either full or Summary Care Records. This was described by participants as a significant challenge that potentially impacts negatively on patient safety *(dentist attitudes towards MRONJ)*. The safe prevention of MRONJ requires dental practitioners to be fully informed about a patient's medication history and access to this information could improve patient safety, facilitating the implementation of MRONJ prevention guidelines. Dentists currently rely on patients to provide medication histories or need to contact general medical practices directly to obtain the information, which is a time-consuming and inefficient process. The access to shared records can also be an issue from the perspective of medical/pharmacy professionals, as they have no record of what dental treatment has been performed or which medication has been prescribed by GDPs.

There is also a distinct lack of formalised referral pathways between dental and medical care settings, with participants reporting that referrals were typically informal and generally based on simply signposting patients. As a result, there is no follow up of patients requiring referral, no records that referrals have taken place and minimal communication between care settings. This poses a significant challenge in the implementation of MRONJ prevention strategies, which require referrals from prescribers to dentists on prescribing of implicated medications and, in turn, assurance that patients are dentally fit to receive these medications before initiation. Formalised referral pathways, with shared medical records could facilitate the

implementation of these recommendation and reduce the incidence of MRONJ in at-risk patients.

The lack of collaboration between the professional groups and the limited focus on oral health prevention is a barrier to effective oral healthcare. Oral health was seen by some participants as being the responsibility of dentists, with other healthcare professionals and patients not being aware of, or engaging with, the links between dental and general health. Education of both healthcare professionals and patients on the links to general health and wellbeing could strengthen the relationship between oral and general healthcare. Getting all professional groups to engage with the links between oral and general health could facilitate the development of a shared mission and provide tangible benefits for both individual patients and the population. This requires effective integration across micro, meso and macro levels of patient care facilitated through education, supportive healthcare policies and better lines of communication. The isolation of dental services represents a significant barrier at all levels; for individuals, locally organised meeting and educational opportunities that include all the professional groups could help individuals to form better working relationships with their peers in their local communities.

Chapter 5: Discussion

5.1 Summary of key findings and comparison to the existing literature

Each of the papers forming this submission have produced independent results; the coherence of the work as a whole and the exploration through the Rainbow Model of Integrated Care has identified a number of key findings that further develop the existing literature in this field.

On an individual, clinical level, the significant negative impact of MRONJ on quality of life has been illuminated through my research. Despite MRONJ being a rare phenomenon, the impact that this condition has on the individual patients interviewed in my research was apparent (*patient attitudes to MRONJ*) and is a key message that needs to be taken from this research. MRONJ affects patients physically, through ongoing pain that requires regular analgesic medication and repeated infections requiring antibiotic therapy. There are also significant psychological and social implications for patients; concerns over the need for extensive surgical interventions, the requirements for regular dental appointments and challenges in relation to eating and drinking in public were described by participants. Although the majority of healthcare professional participants had not encountered a patient with MRONJ in practice, those who had clearly understood the implications of the condition and reported changing their practices to incorporate preventive advice due to the impact they had observed in their patients.

The impact of MRONJ on quality of life has been explored previously in the literature and by research forming the PhD of the applicant for this Advanced Fellowship Award. The qualitative methodology adopted in my work provided insight through in-depth interviews with patients suffering from MRONJ, capturing the significant

negative impact of the condition and highlighting the ongoing challenges, and the physical, psychological and social distress that results from MRONJ. This study, however, focused on patients who were prescribed implicated medications for osteoporosis, and did not explore QoL in patients with a concurrent cancer. Cancer patients represent the highest risk group in terms of MRONJ development and the interrelationship between cancer and MRONJ has not been explored.

A small-scale study of 34 participants using the Oral Health Impact Profile-14 questionnaire, concluded that MRONJ does negatively impact on quality of life (Miksad et al., 2011). This study was able to quantify the significance of the condition, but provided no insight into the specific effects that MRONJ has on patients in their daily lives. The published clinical guidelines make it clear that MRONJ is difficult to treat, hence the recommendation of preventive strategies (SDCEP, 2017); the significant impact of the condition identified through my work strengthens the messages in these guidelines and reinforces the need for prioritisation of preventive care.

A key finding across this body of work is the poor knowledge of oral health amongst pharmacists, GPs and patients; this was particularly apparent in relation to the implementation of MRONJ prevention and with the links between oral and general health. This lack of knowledge adds to the existing literature, in which there are examples of studies demonstrating poor knowledge in this field. A small questionnaire-based study in North Wales found that only 11.8% of GPs and 9.7% or pharmacists were able to specifically identify osteonecrosis of the jaw as an adverse effect of bisphosphonate therapy (Masson et al., 2009). The pharmacist and GP participants in my work were all aware of osteonecrosis of the jaw associated with

bisphosphonate therapy; this finding correlates more closely with the work of Raj et al. (2016), who, again through a survey based study, found that 88.2% of GPs and 84.6% of pharmacists were able to identify osteonecrosis of the jaw as a complication of bisphosphonate therapy. However, it should be noted that in my work an essential component of gaining informed consent required the provision of a participant information leaflet in advance of participation; this potentially exposed participants to the study concepts prior to the interviews.

Participants from across all professional groups had limited knowledge of other medicines implicated in MRONJ; most were only aware of the association with bisphosphonate therapy. This lack of knowledge corresponds with a study by Tanna et al., (2017) who found that more than 90% of GDPs were unaware of medications other than bisphosphonates which are associated with MRONJ. This represents a significant risk to patient safety, particularly given the increased prescribing rates of these medications and that many of these are initiated and often supplied exclusively in a hospital setting. As a result, many primary care practitioners are potentially unaware of a patient's full medication list, compromising patient safety for this patient group.

My research has also highlighted that the preventive strategies recommended in published clinical guidelines are not being routinely followed in practice. This poses a question regarding the potential legal liability of the healthcare team if the recommended preventive care and associated patient education are not prioritised. An article in the *British Dental Journal* highlighted the potential legal implications and identified that malpractice claims have been made in relation to MRONJ (Russo et al., 2014).

There is an awareness of the risk associated with some of the medications as described above, but this knowledge does not translate into the provision of optimal patient care. This represents a significant patient safety issue and places patients at risk of developing MRONJ. Raj et al., (2016) found that the majority of GPs did not advise pre-treatment dental care; this corresponds with the findings of my work, in which both patients and healthcare professionals reported little engagement with the recommended preventive advice in clinical guidelines and education of patients on the risk of MRONJ. The lack of knowledge amongst patient participants was evident in my work (*patient attitudes to MRONJ)*; a result of a lack of education by healthcare professionals on the risks and enforcement of preventive advice. This is similar to a study in Germany which reported that only 32% of patients who were prescribed IV and 17% of patients who were prescribed oral bisphosphonates knew about the risk of developing osteonecrosis of the jaw (Bauer et al., 2012).

The lack of knowledge of oral health goes further than MRONJ prevention. Non-dental participants reported a reasonable working knowledge of basic oral health issues, a finding similar to previous work in the North East of England (Mauder and Landes, 2004), but there was an apparent lack of knowledge of the crossover with general health and wellbeing. This supports findings from similar research in New Zealand, in which pharmacists did not provide any additional advice to patients with diabetes or cardiovascular disease (Buxcey et al. 2012). Although pharmacists were not included, a qualitative study exploring the collaborative management of patients with type 2 diabetes in the North East of England also identified that an isolated knowledge base and a perceived segregation between medical and dental professions were negatively impacting on patient care (Bissett et al., 2013). The need for further oral health education is not a finding unique to pharmacists working

in the UK; studies in Australia and New Zealand have produced similar findings, concluding that there was a need for further education and training of pharmacy staff to enhance their role in practice. (Freeman et al., 2017, Janse Van Rensburg et., 2019, Taing et al., 2019).

The lack of interprofessional education in oral health is a significant barrier to optimal patient care. This translates at a micro level to a lack of competence amongst individual practitioners in delivering oral healthcare, with patients therefore not always fully informed about the risk of MRONJ. At a professional and organisational level, the lack of interprofessional education results in poor understanding of each professional's role and the segregated approaches to patient care evident in my research. At a macro, or system level, greater focus on preventive oral health policies and education of both patients and healthcare professionals could facilitate better collaboration in practice. The development of Primary Care Networks (PCNs) as part of the NHS Long Term Plan potentially represent a means of improving collaboration between organisations. Work to incorporate dental services into PCNs is needed to explore the potential benefits of improved organisational integration on collaborative care at a population level.

I have demonstrated that pharmacists can provide basic oral health interventions *(oral health promotion in pharmacy).* Pharmacists were able to provide oral health advice to a large number of patients, including those whom reported minimal prior engagement with dental services, producing positive intentions to change oral health behaviours. In my study, pharmacists were able to proactively recruit patients to receive oral health interventions; this is a significant development in the evidence base, as studies to date have found that oral health advice is currently only provided

in repose to patient requests (Steel and Wharton, 2011). The expansion of pharmacist roles to incorporate oral healthcare could facilitate an improvement in oral health in at-risk patient groups. The model designed and piloted in my work in County Durham could be transferable to other geographical settings and potentially represents a novel means of addressing oral health inequalities in populations that include poor dental attenders and those with high oral health needs.

The contextual, situational and geographical isolation of dental teams is a barrier to optimal patient care. This is further enhanced by a lack of supportive and functionally integrative systems; such as no dental access to patient's clinical information through full medical or Summary Care Records. Isolation of dental professionals has been identified previously as a significant issue in practice; work by the British Dental Association identified professional isolation as a contributing factor to mental illness and burnout amongst dentists (Larbie et al., 2017). The isolated knowledge base and perceived divisions between the medical and dental professions was also identified in research exploring the collaborative management of diabetes (Bissett et., 2013). Work to develop interprofessional relationships could therefore result in higher quality patient care and less isolation of dental services from general healthcare. Good personal relationships between practitioners has been identified in previous qualitative work as contributing to positive experiences of cooperation and collaboration (Holzinger et al., 2016).

In my work it is apparent that this isolation is preventing effective collaborative care and with MRONJ it is essential that dentists are aware that patients are prescribed implicated medications. This isolation and lack of integration represents a patient safety issue, as dentists are performing invasive dental treatment and prescribing

medications in situations where they are potentially unaware of patient's medical and medication information. Currently, dentists rely almost exclusively on patients to provide medical histories, posing a risk to patient safety. A study of 258 osteoporosis patients produced findings that highlight the perceived lack of awareness of dentists about patients' medical conditions; 46.5% of patients estimated that their dentist was unaware of their diagnosis of osteoporosis (Rotman-Pikielny et al., 2019). It was also apparent that there is limited communication between medical and dental services, with participants reporting a lack of formal referral pathways. This is similar to another study exploring interprofessional collaboration in diabetes, which found that dentists tend not to contact GPs regarding the management of patients with diabetes and when they do so it is typically through the patient, as opposed to through formal referral channels (Bissett et al., 2019).

Both the healthcare professionals and patients interviewed in my research identified a potential role for pharmacists in oral healthcare and the prevention of MRONJ. The increased responsibility and accountability of this professional group, particularly in those with independent prescribing qualifications undertaking expanded clinical roles represents a potentially unexplored approach to facilitating an increase in the adoption of MRONJ preventive care.

The acceptability of patients towards pharmacies playing a role in the provision of oral healthcare represents a key finding of my work. Previous literature had identified that pharmacist and pharmacy support staff perceived oral health as part of their professional role (Steel and Wharton, 2011, Mann et al., 2015), but little work had been done to explore this from a patient's perspective. The intervention trialled in *(oral health promotion in pharmacy)* demonstrated that a pharmacy is an appropriate

place for patients to receive oral health advice, providing evidence for commissioners to consider utilising pharmacies to reach patients that do not engage with regular dental services.

5.2 Strengths and limitations

This thesis is the cumulation of 5 individual papers; the synthesis of the results around a cohesive theme provides both strength and depth to the research that is not possible when viewing each paper in isolation. Across this whole body of work I have interviewed a total of 82 individuals, including 59 healthcare professionals and 23 patient participants. This represents a significant piece of in-depth qualitative research and collectively this work as a whole strengthens the findings of each individual study.

Each of the papers has gone through a rigorous ethical and subsequent peer review process prior to publication. Each paper was improved through this process and each has been published in a well-regarded academic journal. The papers published in *BMJ Open* are Open Access, with readers able to view peer review comments, supplementary files and research checklist in full. This improves the transparency of the work and demonstrates that the research has been performed to a high standard that is fit for academic publication. The process of preparing my work for publication and responding to peer review comments has also acted to significantly develop my own skills as an independent researcher. This has given me the ability and confidence required to conceptualise, design, undertake and disseminate high quality research. This will enable me to progress as a researcher and enhance the quality of my future work following the completion of my PhD.

Much of this work has been performed in the North East of England, with the exception of the MRONJ patients that were recruited to *(patient attitudes towards MRONJ)* from Sheffield and London. The North East is a region with traditionally poor oral health and challenging socio-economic demographics. The qualitative work performed in this research does not seek to generalise findings, but rather produce transferable findings that can be considered in the context of similar locations and/or settings. Therefore, the application of this work to other regions with differing demographics, or to other settings with differing dental and/or medical care service models may not be possible. The methodological approach adopted strengthens the existing literature, which is currently predominated with relatively small-scale quantitative studies. The qualitative approach has illuminated the underlying attitudes and perceptions of participants in a way not possible through the methods adopted in the existing literature.

The analysis of the cohesive body of work through the Rainbow Model of Integrated Care has identified a number of barriers and enablers for the integration of oral health and MRONJ prevention into pharmacists' roles. These provide evidence and recommendations that are relevant to both clinicians and policy makers and could be utilised to further this research and area of practice.

My work has built on the extant literature; significantly, the findings in relation to the quality of life implications of MRONJ provide evidence that did not previously exist. Research and published clinical guidelines make reference to the quality of life implications of MRONJ, but there has been little exploration beyond this point. My work has added to the evidence base, demonstrating the significance of MRONJ and the extent of the physical, psychological and social issues faced by this patient

group. This evidence acts to further support the recommendations for the prioritisation of preventive care and the education of both healthcare professionals and patients.

My work has progressed the evidence base by moving beyond '*what could pharmacy do'* to improve oral healthcare and has explored what a pharmacy-based intervention can actually look like in practice. The service designed and evaluated in *(oral health promotion in pharmacy)* acts as a model that can be replicated and transferred to other locations. This work has also resulted in a significant drive across the North of England to improve the education of pharmacy professionals and students; this is discussed further in Chapter 7.

5.3 Implications for clinicians and policy makers

At an individual level, clinicians need to be aware of the links between oral and general health, and of the potential implications of prescribed medication on the oral cavity. The significant quality of life implications of MRONJ highlighted in this research represent a key finding and further develop the evidence base that supports the preventive recommendations provided in clinical guidelines. The introduction of interprofessional education in oral health could facilitate an improved working knowledge that translates into increased implementation of preventive advice with medicines associated with MRONJ and the provision of oral health advice to at-risk patients.

At an organisational and professional level, greater consideration should be given to the incorporation of oral health into locally commissioned services, designed to meet local population needs. Services which require closer collaboration between the dental and medical professions could facilitate a reduction in isolated practices and

facilitators for functional integration, such as shared medical records and formal referral pathways, could improve lines of communication. Interprofessional education could not only improve oral health knowledge, but it could also improve understanding of professional roles, breaking down perceived hierarchies and historically stereotyped roles.

The House of Care model provides a framework for patient-centred co-ordinated care in the context of diabetes management (Year of Care, 2011), with diabetes representing a key example of patient care requiring the co-ordination of multiple healthcare professionals. The House of Care model consists of four key constructs: (1) engaged and informed individuals, (2) professionals committed to partnerships, (3) organisational and supporting processes and (4) system wide approaches to commissioning. The evidence from my research has clearly shown that dentists are isolated and poorly integrated into the multidisciplinary team. However, the integration of oral healthcare into the wider healthcare system following this model could potentially address the issues identified in my research. This could aid the optimisation of MRONJ prevention and could also address other areas in which oral health impacts the overall health and well-being of patients.

My work has demonstrated that pharmacists are willing to expand their professional role to include oral healthcare, a role for which patients have also demonstrated an acceptance towards and one which has produced positive intentions to change oral health behaviours. Commissioners should consider pharmacists as a potential avenue for engaging with historically hard-to-reach patient groups and those who are at high risk of both oral and general health complications. This could be facilitated through upskilling pharmacists; this includes the provision of promoting oral health

promotion, targeted intervention in high risk population groups, for example as part of type 2 diabetes chronic disease management clinics, and in relation to oral adverse effects of medications. This includes continuing to train pharmacists as independent prescribers in both community and general practice settings, the provision of oral health-related CPD and integration of oral health into the initial education and training of pharmacists.

The success of *(oral health promotion in pharmacy)* has resulted in Health Education England (HEE) rolling out oral health CPD sessions for pharmacists across the North of England. At the time of submission of this thesis, 346 pharmacy staff have received this training. The success of *(oral health promotion in pharmacy)* resulted in a change in health policy at Durham County Council. In 2018-19 oral health became a local target for all 109 Healthy Living Pharmacies in the county, meaning that in order to receive NHS quality payments, pharmacies must actively support their patients' oral health, engaging in health promotion activities. This is an excellent example of how health policies can be focused to meet the oral health needs of a local population.

There is a significant need at a system level to change the oral health attitudes and behaviours of the population. This could be facilitated through an NHS dental service that is focused on prevention and through education of the general public on the benefits of good oral health care, specifically related to general health and wellbeing. Collaborations between professional bodies and patient groups could act to champion and role model optimal practice and encourage integration of care.

5.4 Unanswered questions and future work

This body of work has presented as many questions requiring further research as it has answers. This, however, represents a significant opportunity for myself to progress as an independent researcher alongside continuing the effective collaborative relationships that have been successful in achieving quality outputs to date. I intend to seek funding as the principal investigator from organisations such as the NIHR to further pursue a number of these themes on completion of my PhD.

My work has shown that pharmacists can play a role in the provision of oral healthcare and although in *(oral health promotion in pharmacy)* patients self-reported positive intentions to change behaviours it was not feasible to establish if this resulted in any long term or clinically significant improvements in oral or general health. Further work to explore these benefits is required and this could, in particular, take an increasing focus on targeting those patients at highest risk, or those whom would benefit the most. A clear example of this would be type 2 diabetes, whereby improved oral health of patients has already demonstrated the potential to improve diabetic control; pharmacists could work specifically to identify and target this group of patients. There are also potentially opportunities for pharmacists to engage with oral cancer screening services; work published recently has identified that many oral cancer patients have not engaged with dental services in the 2 years preceding diagnosis (Purkayastha et al., 2018). This potentially presenting an opportunity for pharmacists to get involved with screening programmes and educational campaigns, especially integrated into existing services such as smoking cessation and medication reviews. At the time of submitting this thesis, I am working on a research

proposal with the view to seek funding to investigate the potential role for pharmacists in the early detection of oral cancer.

There is a clear need for further work to optimise the prevention of MRONJ. My research has, alongside existing published literature, highlighted that the preventive strategies and the patient education recommended in clinical guidelines are not followed routinely in practice. Clearly, much of this is attributable to a lack of education and it is important to signpost practitioners to these guidelines. However, there needs to be further work to develop more effective lines of communication, referral pathways and collaborative care of this group. Current practices are putting patient safety at risk and with the increased prescribing of implicated medicines, MRONJ could become more prevalent in clinical practice.

Current pharmacy services, such as the New Medicines Service (NMS) could be adapted to include bisphosphonates; the NMS is part of NHS Community Pharmacy Contractual Framework in England and the service provides support for patients with long-term conditions that have been newly prescribed a medicine. The economic evaluation of the service identified the NMS to be a cost-effective intervention that improves adherence to medications and that the service had the potential to be expanded to other areas and to other health systems (Elliott et al., 2017). The NMS service specification does not currently include bisphosphonates, however further work to explore the benefits of this could provide a means of facilitating patient education and referrals to dental services by pharmacists at the point of treatment initiation.

A key enabler to improving patient safety in general dental practices would be access to Summary Care Records. Further work is needed to explore the

implementation of this in dental practices and to establish the benefits that access to this information provides.

A common theme in this thesis is the need for more effective oral health and interprofessional education. There are a variety of ongoing initiatives, including those introduced as part of my work (Chapter 7), however further evidence is required to establish the effectiveness of these educational interventions and any resulting changes in practice. A more joined up approach to system integration facilitated through professional bodies and healthcare policy could enable higher quality and widespread educational developments.

Chapter 6: Conclusion

MRONJ represents an ongoing challenge in clinical practice, with patients prescribed implicated medications continuing to be at risk of developing the condition. My work has demonstrated limited awareness of MRONJ amongst both healthcare professionals and patients; therefore, the recommended preventive dental care and the reinforcement of good oral hygiene for this patient group is not prioritised in practice. The impact of this is significant and my research has added to the evidence base highlighting the considerable quality of life implications associated with MRONJ. Patients with MRONJ have described a range of physical, psychological, and social issues, that impact negatively on their lives, strengthening the need for the prioritisation of preventive dental care.

Multidisciplinary working in oral health is limited, with my work identifying poor communication, a lack of referral pathways, and no access to shared medical records. The isolation of the dental team from other healthcare professionals reinforces the historically stereotyped and segregated roles that patients associate with each professional group. The limited focus on oral health by pharmacists and GPs is a result of poor knowledge of oral health issues; particularly on the links between oral and systemic health in conditions such as diabetes.

The rapidly developing role of the clinical pharmacist in general practice represents an opportunity to integrate oral health advice into the management of patients in this setting. Pharmacists in this setting are taking more clinical responsibility and therefore becoming increasingly accountability for safe patient care. My work has identified key roles for pharmacists in the prescribing of medications, maintenance of medication histories and the transfer of information between care settings; this

represents an opportunity for pharmacists to engage with oral healthcare and the prevention of MRONJ.

A greater emphasis on preventive dental care at both a policy and practice level are required, alongside the need for interprofessional education on oral health. Interprofessional education could act to improve knowledge at an individual clinical level, as well as developing effective collaborative relationships that cross professional boundaries.

Although current practices do not facilitate optimum patient care, my work has identified that pharmacists are able to play a greater role in the provision of oral healthcare. I have demonstrated that pharmacists in a community setting can engage patients with a poor history of accessing dental services and can provide simple oral health interventions that result in positive intentions to change oral health behaviours. This service represents a model that could be adopted and transferred to similar settings to address local population needs and oral health inequalities.

Further work to optimise the prevention of MRONJ is required, exploring collaboration across different professional groups, the sharing of patient information and improved referral pathways. There is also significant scope to further develop the role of the pharmacist in oral healthcare. This includes research that explores utilising pharmacists to target patient groups at highest risk of oral health issues, for example type 2 diabetes. Pharmacists also have the potential to engage with oral cancer screening services and to continue promoting good oral hygiene behaviours to the wider population.

Chapter 7: Translating my research into pharmacy education

My research into the role of pharmacy in the provision of oral health inspired me to explore opportunities to collaborate with dental colleagues from the University of Newcastle to address the limited interprofessional collaboration between the professional groups highlighted in this submission.

I worked with colleagues at the University of Newcastle to conceptualise and introduce an interprofessional education (IPE) initiative for both undergraduate pharmacy and dental students with two main aims; (1) to develop an understanding of the roles of each professional group; (2) to support the development of knowledge in relation to key patient safety issues encountered in practice. A case-based approach was initially piloted, with students working in small interprofessional groups to explore cases that contextualised course material and prior learning. The IPE initiative has been iteratively developed based on feedback from students and facilitators; this has included simple adjustments to the student group size, timings of the sessions and background of staff delivering the sessions. The student response to this has been overwhelmingly positive; 95% of students reported that they were motivated to learn about the subject and 89% agreed that they now understood how to work collaboratively. Poor understanding of professional roles was identified as a barrier to effective collaborative care in my research and the IPE has been developed over each iteration to place a greater focus on developing relationships between the professions over academic content. It is now a highly valued permanent fixture in the curriculum at both institutions, has been delivered to over 700 students and sets the foundations for collaboration before students enter clinical practice.

This pedagogic work has resulted in the publications and conference presentations listed below.

Ferrie, L. and Sturrock, A. (2017). Interprofessional drug safety: enhancing collaborative knowledge exchange. *Medical Education.* 51:1176–1177. https://doi.org/10.1111/medu.13442

Ferrie, L. and Sturrock, A. (2017). The last frontier. Interprofessional learning (IPL) events between dentistry and pharmacy. *37th SEF National Meeting with guest society@ the British Pharmacological Society*, Barcelona. (Oral Presentation)

The oral health intervention service in community pharmacies, as described in *(oral health promotion in pharmacy)* of this submission was incredibly successful and the publication has generated interest across the pharmacy and dental professions. The role of pharmacists as oral health educators has subsequently been highlighted by the editor of the *British Dental Journal* (Appendix 5).

A key impact of my work is the increased focus on oral health education across the region. The impact of my work has demonstrated that the concept of pharmacists providing oral health advice could be replicated on a wider scale with appropriate education and training. The training provided for participating pharmacies in this project has subsequently been rolled out across the North of England, with training sessions provided by the HEE Dental Team for pharmacists, and pharmacy support staff; to date 346 pharmacy staff have received this training as an accredited CPD session.

I have also worked with the team to provide training for Health and Social Care staff on the impact of medications on oral health. This has also included educating these staff on the role that pharmacists can play in managing the oral health of patients in a care setting and encouraging interprofessional collaboration.

I have worked with the HEE Dental Team to embed this oral health training into the undergraduate pharmacy programme at the University of Sunderland; following the teaching sessions 92% of students agreed that the provision of oral health advice is part of their role, strengthening links between undergraduate education and clinical practice. To date over 300 pharmacy students have completed this training. This has created a unique link that showcases the reach of my work, impact on patients in practice, professional development of pharmacy staff, and adding value to the undergraduate pharmacy programme. The collaborative opportunities between the professions and my research have been highlighted by the Editor-in-Chief of the *British Dental Journal*.

> *Pharmacists can be such a valuable potential source of patient education and could potentially be helped to develop into a more recognised resource of community information on oral health. (Editor-in-Chief, British Dental Journal)*

The development of research informed teaching and the introduction of novel interprofessional opportunities in the provision of oral health education, has alongside other pedagogic work, led to professional recognition on a national scale. I became a Senior Fellow of the Higher Education Academy (SFHEA) in February 2019 and in August 2019 I was awarded a prestigious Advance HE National Teaching Fellowship (NTF). My NTF was awarded for my work developing interprofessional education in oral health, the alignment of my pedagogic work with

my research, and for the use of simulation-based teaching and interprofessional mental health education. The works presented in this thesis have therefore helped to facilitate the development of my career, both in relation to research and to teaching and learning. These are both elements which I plan to pursue further in my career. My PhD will act as a springboard to exploring further research opportunities as a principal investigator and as a PhD supervisor, and the development of high-quality teaching and learning initiatives that champion the importance of oral health and collaborate education.

Chapter 8: Reflections on my research journey and a PhD by publication

I entered academia from clinical practice with limited experience of research, but a desire to develop professionally and progress to become one of the country's leading clinical academic pharmacists. Following my appointment as a Senior Lecturer I was fortunate to be mentored by my PhD Supervisor Professor Scott Wilkes; a Professor of General Practice and Primary Care and now the Head of the University of Sunderland School of Medicine. Professor Wilkes provided an overview of the various routes towards obtaining a PhD, and a PhD by Publication fitted well alongside my teaching commitments and my desire to develop a portfolio of peer reviewed publications.

I was also appointed as a Clinical Research Pharmacist (0.2 WTE for 12 months) at Coquet Medical Group under the supervision and management of Professor Wilkes. In this role I set up and recruited patients from the practice into NIHR Portfolio studies; this experience gave me exposure to high quality clinical research and served as an excellent learning and development opportunity.

The University of Sunderland funded my attendance at a Qualitative Research Methods course at University College London; this is a learning experience that has benefited me significantly in the conceptualisation, delivery and dissemination of the papers forming this submission.

In 2016 I received the Pharmacy Research UK (PRUK) and United Kingdom Clinical Pharmacy Association (UKCPA) Clinical Research Award, to undertake the research project that forms *(patient attitudes towards MRONJ)* of this submission. This funding facilitated the adoption of my research onto the NIHR Portfolio, providing Clinical Research Network (CRN) support to recruit patients with MRONJ from across

England. The experience gained through undertaking an NIHR Portfolio study has been invaluable and I aim to utilise this in the future as I seek research grant income and NIHR support to further my work at post-doctorate level.

Even though I prospectively set out to achieve a PhD by Publication, it has not been without its challenges. The individual research projects that form this submission have all required individual research ethics and governance approvals; a significant amount of work and a time-consuming process. However, I believe that my development as a researcher and each of my studies has benefited from this process and I am confident in my ability to conceptualise, prepare the documentation and undertake high quality, ethically sound research that is fit for peer reviewed publication.

I have performed a total of 82 qualitative interviews across the papers that form this submission, interviewing 59 healthcare professionals and 23 patients. Recruitment of participants has perhaps been the most difficult part of my research journey to date. All participants have given their time voluntarily and recruiting busy healthcare professionals has been a time consuming and challenging process; I am grateful to all those who have taken part and given their time to contribute to this work. Patient recruitment in *(patient attitudes towards MRONJ)* was particularly challenging due to the rare nature of MRONJ; I travelled to both London and Sheffield to recruit participants for this study and I am again grateful to the NIHR CRNs who facilitated this process.

I have developed significantly along this journey and I am a very different pharmacist to the one that was appointed as a Senior Lecturer in 2015. Each of my papers has been subject to rigorous peer review prior to publication, and again I believe that my

research and my approach to future work has benefited from this process considerably.

On submission of my thesis I have developed a reputation for delivery high quality clinical research that has benefited my own professional development and the University of Sunderland. The papers forming this submission will also be submitted by the institution to the Research Excellence Framework (REF) 2021; provisional feedback has indicated that the papers meet the REF 3* Quality Standard i.e. 'internationally excellent in terms of originality, significance and rigour but which falls short of the highest standards of excellence'. At the time of submission of this thesis I am also preparing a REF Impact Case Study; this is focused on the impact of *(oral health promotion in pharmacy)* on a large number of patients both through the study and subsequently in practice, and the changes to oral health education and training which is now provided across the region. The successful production of high quality research has also furthered my progression and access to support at the institution; I am grateful to the research time allocated, article processing charge fees and research costs provided by Sunderland University's Individual Research Plan allocation.

I am proud to have transitioned from an inexperienced researcher into a clinical academic pharmacist through the completion of my PhD and look forward to exploring future opportunities to lead independent research projects and continue the excellent collaborative relationships with my supervisory team. I fundamentally believe that the pharmacy profession will benefit from a greater focus on the development of clinical academic pharmacists, embracing research as a key element of the pharmacist's role. I have already taken on responsibilities supervising

postgraduate students undertaking a range of pharmacy practice-based MSc projects, a number of which I have supported to receive external funding to support their work. I intend to further my involvement at a postgraduate level through the supervision of other PhD candidates in the near future and hope to initially act as a co-supervisor with my own PhD supervisory team as I gain experience at this level.

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Appendices

Appendix 1

Sturrock, A., Preshaw, P., Hayes, C. and Wilkes, S. (2020). The role of the pharmacist in the prevention of Medication-Related Osteonecrosis of the Jaw (MRONJ). *The Pharmaceutical Journal*. 303;7928 https://doi.org/10.1211/PJ.2019.20206623

Appendix 2

Sturrock, A. and Hayes, C. (2020). Designing and Implementing a Mixed-Methods Evaluation of a Community Pharmacy–Based Oral Health Intervention. *Sage Research Methods Cases.* https://dx.doi.org/10.4135/9781529717594

Appendix 3

Sturrock, A. and Hayes, C. (2020). The Challenge of implementing a Grounded Theory approach in a Qualitative Study of GPs and Pharmacists in the Prevention of Bisphosphonate Related Osteonecrosis of the Jaw (BRONJ). *Sage Research Methods Cases*. https://dx.doi.org/10.4135/9781529709667

Appendix 4

Ferrie, L. and **Sturrock, A.** (2017). Interprofessional drug safety: enhancing collaborative knowledge exchange. *Medical Education.* 51:1176–1177. https://doi.org/10.1111/medu.13442

Appendix 5

RESEARCH INSIGHTS

Thousands of new oral health educators

Oral health promotion in the community pharmacy: an evaluation of a pilot oral health promotion intervention
Br Dent J 2017; **223:** 521-525; http://dx.doi.org/10.1038/sj.bdj.2017.784

How amazing would it be if we had thousands of new oral health educators on whom to rely? Would they be able to motivate improved oral health, lower caries levels, improve periodontal health and prompt more frequent dental attendance? All sounds too good to be true? Think again, since it seems that community pharmacists are not only hovering in the background they are actively promoting oral health on a daily and regular basis, and as part of their NHS contracts.

This paper, in reporting an initiative in deprived areas of County Durham last autumn, highlights how interdisciplinary collaboration can be of great potential benefit to society in general and dental patients, actual and potential, in particular. For me, one of the key elements of this paper is the fact that people visited and asked questions of their pharmacists precisely because they are not dentists. That may seem so counterintuitive that it is nonsense and yet with careful thought it makes complete sense. Oftentimes people are wary of asking questions of 'an expert' for a variety of reasons. They may not have access – apparently 90% of the UK population has a community pharmacist 20 or fewer minutes away; they may not want to 'bother' an expert (the dentist) as it seems a small matter, or because the expert is always so very busy – the pharmacist may be rather more approachable in these contexts.

Also, we do have to remember, however reluctantly, that not everybody likes visiting us! It was a point of view often given in the days before clinical dental technicians could legally practice. Patients who attended the then 'denturists' argued that it was a dentist who had extracted all their teeth and given them the dentures that now didn't fit properly, so what was the point of going back? They attended specifically because the expert was not a dentist.

With these factors in mind it is less surprising that pharmacists can be such a valuable potential source of patient education and could potentially be helped to develop into a more recognised resource of community information on oral health. What adds further positive hope is that in another survey, quoted in this paper, a questionnaire of 354 London pharmacies found that 99.4% of participants recognised oral health promotion as part of their role and 72.5% of participants were willing to incorporate this into their NHS contract. Almost all of us in the UK have one in easy reach – shall we talk to them?

By Stephen Hancocks

RESEARCH INSIGHTS

Other journals in brief

A selection of abstracts of clinically relevant papers from other journals.
The abstracts on this page have been chosen and edited by Reena Wadia

MRONJ unrelated to bisphosphonates and denosumab

King R, Tanna N, Patel V. Medication-related osteonecrosis of the jaw unrelated to bisphosphonates and denosumab-a review. *Oral Surg Oral Med Oral Pathol Oral Radiol* 2019; **127:** 289–299.

A wide range of medications classified as tyrosine kinase inhibitors, monoclonal antibodies, mammalian target of rapamycin inhibitors, radiopharmaceuticals, selective oestrogen receptor modulators, and immunosuppressants have also been found to be implicated in MRONJ.
The link between medication-related osteonecrosis of the jaw (MRONJ) and bone modulating drugs, such as bisphosphonates and denosumab is well established. The development of novel medications used in the treatment of cancer, as well as autoimmune and bone conditions has led to further cases of MRONJ being reported. However, in addition to this group of medications, increasing numbers of new agents in cancer therapy, such as antiangiogenic agents, have also been implicated in the development of MRONJ. The authors mention that as these newer agents with similar mechanisms are routinely used, the numbers of reported cases will likely rise. A wide range of medications classified as tyrosine kinase inhibitors, monoclonal antibodies, mammalian target of rapamycin inhibitors, radiopharmaceuticals, selective oestrogen receptor modulators, and immunosuppressants have been found to be implicated in MRONJ. The authors emphasised the importance of oral health care providers being aware of these new medications.

DOI: 10.1038/s41415-019-0369-5

Biomarkers and MRONJ

Moraschini V, de Almeida D C F, Figueredo C M, Calasans-Maia M D. Association between biomarkers and medication-related osteonecrosis of the jaws: a systematic review. *Oral Surg Oral Med Oral Pathol Oral Radiol* 2019; pii: S2212-4403(19)30147-6. DOI: 10.1016/j.oooo.2019.02.014. [Epub ahead of print].

Although many biomarkers have been associated with MRONJ, there is scarce clinical evidence supporting the use of these biomarkers for the diagnosis and prognosis of MRONJ.
This systematic review assessed the role of human biomarkers in the diagnosis or prognostication of medication-related osteonecrosis of the jaws (MRONJ). Eligibility criteria included randomised and non-randomised clinical trials, prospective or retrospective cohorts, case controls, and case series. The search and selection process yielded 19 studies (two case series, six case-control studies, nine prospective cohort studies, and two retrospective studies) published between 2008 and 2018. Twenty-four biomarkers collected from serum, saliva, and urine were included. Eleven biomarkers were possibly related to MRONJ; however, no consensus was observed in the literature with regard to the sensitivity and clinical effectiveness of these biomarkers.

DOI: 10.1038/s41415-019-0378-4

Patient perceptions of MRONJ

Sturrock A, Preshaw P, Hayes C, Wilkes S. Perceptions and attitudes of patients towards medication-related osteonecrosis of the jaw (MRONJ): a qualitative study in England. *BMJ Open* 2019; **9:** e024376. DOI: 10.1136/bmjopen-2018-024376.

MRONJ has a significant detrimental impact on quality of life, yet appropriate preventative education is not apparent. Effective inter-professional patient education and prevention to mitigate against the risk of developing MRONJ is required.
This study explored the impact of medication-related osteonecrosis of the jaw (MRONJ) on quality of life and considered the perceptions of patients towards a multidisciplinary approach. Twenty-three patients in primary care general medical practices and secondary care dental services in England were interviewed using qualitative semi-structured interviews. Of those interviewed, six had MRONJ, 13 were taking prescribed bisphosphonates, four had osteoporosis but were not currently taking any medication. Patients felt that MRONJ had a significant negative impact on their quality of life including physical, psychological and social impacts. There was also poor knowledge of the recommended preventive strategies. Patients demonstrated positive attitudes towards a multidisciplinary approach to care; but perceived prescribers as having the key role in articulating risk.

DOI: 10.1038/s41415-019-0376-6

Awareness of MRONJ amongst dentists

Al-Samman A A, Al-Ani R S. A cross-sectional survey on medication-related osteonecrosis of the jaws' knowledge and awareness in a sample of dental society. *J Craniomaxillofac Surg* 2019; pii: S1010-5182(18)30754-6. DOI: 10.1016/j.jcms.2019.02.006. [Epub ahead of print].

There is a need to strengthen MRONJ awareness and knowledge amongst general dentists and dental specialists to identify 'at risk' patients for appropriate advice and management.
Awareness about MRONJ is crucial for all dental practitioners to identify 'at risk' patients for appropriate advice and management. This cross-sectional survey was based in Iraq and aimed to determine MRONJ awareness and knowledge amongst dental professionals. One hundred and seventy-eight dentists completed a questionnaire-based survey. The group consisted of 113 general dental practitioners (GDPs), 33 dental radiologists (DR) and 32 oral and maxillofacial surgeons (OMS). A significant difference existed amongst the groups with a rate of MRONJ's awareness of 34%, 49%, and 84% for GDPs, DRs, and OMSs respectively. Concerning MRONJ knowledge, significantly higher rates were seen in the OMSs set with a score of 49%. In contrast, the score for DRs was 31%, and the GDP group had the lowest score of 17%. The authors commented on the imperative need to strengthen MRONJ awareness and knowledge amongst dental professionals.

DOI: 10.1038/s41415-019-0377-5

RESEARCH INSIGHTS

Can poor oral health lead to dementia?

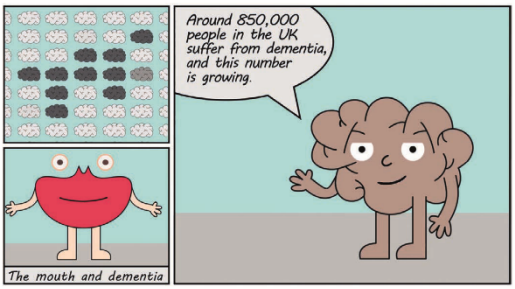
Evidence Summary: The relationship between oral health and dementia
Br Dent J 2017; **223:** 846–853; http://dx.doi.org/10.1038/sj.bdj.2017.992

It is easy to understand how cognitive decline can lead to poor oral health, but could the converse also be true? Dementia is a syndrome which causes chronic impairment in cognitive function, hugely impacting the sufferer and those around them. It can affect dental health in many ways: from a reluctance to attend long appointments to forgetfulness when it comes to home care. General dental health professionals see patients (hopefully) over long periods of their life so are in prime position to notice a decline in both their oral and cognitive health.

In this review, Daly and co-authors consider the outcomes of a decade of studies to find a strong association between cognitive decline and poor oral health. They present compelling evidence that dementia can affect oral health in a number of ways. Patients with dementia are less likely to brush twice a day and are more likely to have plaque, caries and poor denture hygiene. This seems logical; patients with dementia may not remember to brush their teeth and may find it difficult to communicate problems with their oral health.

However, unexpectedly, the authors also propose that poor oral health is a risk factor for dementia. Patients with increased plaque and caries were found to be at risk of cognitive decline. Amongst denture wearers, being able to chew properly was linked to a lower risk of dementia. This is a bold claim, suggesting that not looking after your teeth could put you at risk of dementia. The authors are quick to point out that these studies are of variable quality and further well-designed studies are necessary before definitive conclusions can be drawn.

Considering the increasing prevalence of dementia, it is surprising there



is little well-designed research into dementia and oral health. This should concern us as this review suggests dental professionals may have a role to play in dementia prevention. The authors rightly suggest declining oral health should be a red-flag to consider causes such as dementia. One thing is certain: these patients and their carers should be shown how to keep a mouth healthy.

In summary, those with dementia are more likely to have poor oral hygiene with a suggestion that this relationship is reciprocal. The authors suggest that further research is desperately needed. Nevertheless this review is an important reminder that, regardless of whether poor oral health increases dementia risk, we must always consider the wider possibilities for declining oral health.

Katherine Kaczmarczyk, Dental Undergraduate,
University of Leeds

Learn more about these findings via the 'Oral health is not just about the mouth' animation on the BDJ Youtube channel
http://bit.ly/BDJYouTube

To find out more about work being carried out looking at the feasibility of oral health promotion using community pharmacists, we spoke to Dr Andrew Sturrock from the University of Sunderland about his recent BDJ paper. If you are interested in learning even more why not read Stephen Hancocks' summary of the paper here: http://go.nature.com/2B8mqG8 or the full paper at http://go.nature.com/2BkamTi

Author Q&A

Andrew Sturrock
University of Sunderland

Why do think providing oral health advice is a new thing to pharmacies?

I don't think that the provision of oral health advice is necessarily a new thing for pharmacies. Pharmacists and their staff have always provided oral health advice to patients or signposted them to dental services. What this pilot facilitated was a more structured and targeted approach with pharmacists actively looking to engage patients with oral healthcare.

This pilot allowed pharmacists to take advantage of their location in communities and unique access to patients who otherwise would not seek oral healthcare.

Did any of the results surprise you?

I expected that patients would be receptive to receiving oral health advice in pharmacies as community pharmacies already engage with many other health promotion initiatives and services. The most pleasing finding was that 66% of participants reported that they intended to change their oral health habits as a result of the intervention.

What do you think the next steps considering your findings?

I would like commissioners to embrace the potential of pharmacies in providing oral health advice and hope that the pharmacy and dental professions can work closely to improve patient care. From a research perspective it would be great if we could explore the actual patient benefits of such services, as although patients reported improved knowledge and intension to change current behaviour there is no evidence of any lasting health improvements. There is also great potential for pharmacists to expand their role into other areas of oral health, the prevention or screening of oral cancer, managing adverse drug reactions such as xerostomia or in the prevention of MRONJ and the links with chronic diseases such as diabetes all warrant further research. ■

Appendix 8

NIHR | Clinical Research Network North East and North Cumbria

Mr Andrew Sturrock
The University of Sunderland
Edinburgh Building
City Campus
Chester Road
Sunderland
SR1 3SD

Dear Andrew

On behalf of the NIHR North East and North Cumbria Clinical Research Network we would like to congratulate you, your team and The University of Sunderland on recruiting to time and target (RTT) in:

Study title: MAP-BRONJ
Portfolio ID: 33238

Recruitment to time and target (RTT) is a significant achievement and one which is only delivered through effective and well managed feasibility, study set-up and recruitment, reflecting the dedication and efforts of yourselves and colleagues within the Trust. Our priority is the delivery of locally-led portfolio studies and on behalf of the North East and North Cumbria Local Research network we would like to thank you for contributing to our annual performance objectives

Achievements such as RTT are a testament to our ability to effectively deliver research opportunities for NHS patients. Congratulations again and we hope the follow-up phase is equally successful.

Your work is greatly appreciated and we hope this certificate of completion is a useful way of documenting both our appreciation and your successful study delivery. You may consider retaining this for your records and consider using this in future funding applications and site selection visits?

If you would like to tweet your success, please take a photo of your team and include the hashtag #ResearchNENC and tag the CRN by using @NIHRCRN_nencumb in your tweet.

Kind Regards

Professor Stephen Robson
NENC Clinical Director

Morag Burton
NENC Chief Operating Officer

Appendix 9

NIHR | Clinical Research Network North East and North Cumbria

Certificate of Achievement

Successful Recruitment to Time and Target

Awarded to

Mr Andrew Sturrock

Chief Investigator

Study Lead ..... (Research Nurse/Research Midwife/CTO)
and the Research Team

Sponsor: The University of Sunderland

Study Details:	Study Acronym:	MAP-BRONJ
	Portfolio ID Number:	33238
	England Sample Size:	20
	England Total Achieved:	23

20 June 2019

Professor Stephen Robson
Clinical Director NIHR CRN: NENC

Appendix 10

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Communication key to preventing rare bone disease

Andrew Sturrock (inset image: Professor Scott Wilkes)

A rare disease of the jaw which causes pain for sufferers and can lead to reconstructive surgery could be prevented if healthcare professionals improve their communication, research has revealed.

> our evidence suggests that the best way to treat this is to prevent it happening in the first place"

Osteonecrosis, which means death of bone tissue, can develop in the jaw following certain dental procedures, such as tooth extractions, in some patients who are prescribed certain medicines, known as bisphosphonates, for the treatment of osteoporosis and cancer.

A team of researchers at the University of Sunderland carried out a study into the disease, and the impact it had on patients' lives, funded by Pharmacy Research UK and a UK Clinical Pharmacy Association Clinical Research Grant.

The study found that much more communication was needed between those GPs prescribing the medicine to patients, pharmacists supplying the medicines and dentists managing patient's oral health.

Lead researcher Andrew Sturrock, Principal Lecturer and Programme Leader for the Master of Pharmacy programme, explained: "Osteonecrosis of the jaw is a really rare side effect that some patients taking particular medicines experience if they require a dental extraction, in rare cases the bone dies. It causes significant pain and is incredibly difficult to treat, it can be quite disfiguring in some cases.

"All of our evidence suggests that the best way to treat this is to prevent it happening in the first place, making sure a patient prescribed these medicines have any dental treatment done before they start taking the drug and ensuring they maintain good oral hygiene and good oral health whilst taking the medicine.

"Our findings, however, established that this was not being done. GPs and pharmacists weren't telling people about the risks for all sorts of reasons; because the disease is so rare, it wasn't a priority, it's been forgotten about, or in some cases the patient didn't disclose they were taking the medicine when needing to have dental treatment.

"Ultimately, the patients were poorly informed about the disease and the preventive measures that should be taken. This is a communication issue and dentists are definitely out of the loop, they want to be more involved in the care of this patient group at a much earlier stage.

"The patients just expect the system to work and it's up to healthcare professionals to improve and make sure there is good communication to prevent osteonecrosis of the jaw."

The team interviewed 23 patients nationwide who described significant physical, psychological and social consequences as a result of developing this disease, from suffering depression due to the pain, to feeling embarrassed eating in front of others.

Their only treatment is pain relief, or sometimes surgery can be performed in which the dead bone is removed, this can be a small operation or can lead to patients needing reconstructive surgery. Patients can become prone to infections and sometimes require regular courses of antibiotics and ongoing dental management.

Andrew said: “Although it’s a rare disease, there are still big costs to the NHS in terms of on-going treatment. Yet it is fairly simple for prescribers and pharmacists to say ‘this is your new drug, this is how you take it and ensure you see you dentist before taking it’.”

Andrew explained that dentists are receptive to getting referrals from other professional groups, as he explains it is easier to treat their dental needs before they begin their medication.

Philip Preshaw, a dental professor and a consultant in restorative dentistry, said: “Medication-related osteonecrosis of the jaw is thankfully quite rare, but when it does occur it has a profound impact on patients’ quality of life and can cause significant levels of pain. It is also very difficult to treat, as surgical procedures to remove the necrotic bone can sometimes fail due to poor blood supply in the region.

“Prevention is always better than cure, and better communication between doctors, pharmacists and dentists would ensure that the dental team know which patients are going to start taking the implicated medications, so that they can assess and optimize their oral health before they start taking them, to reduce the risk of osteonecrosis developing later.”

Professor Scott Wilkes, Head of the University’s new School of Medicine, added: “GPs see a lot of patients who take bisphosphonate medications to protect against osteoporosis and Pharmacists dispense a lot of these medications every day.

“There are two opportunities missed for relatively simple interventions. The first is brief advice from the GP or Pharmacist to attend a dental check-up and the second is fully informed consent about the risk albeit uncommon. Pharmacy may have an opportunity to embed such a service into a New Medicines Service. Although rare, it is a devastating disease and any reduction in the number of cases is welcome.”

The research has now been published in the BMJ Open:
https://bmjopen.bmj.com/content/9/3/e024376

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Appendix 11

University of Sunderland

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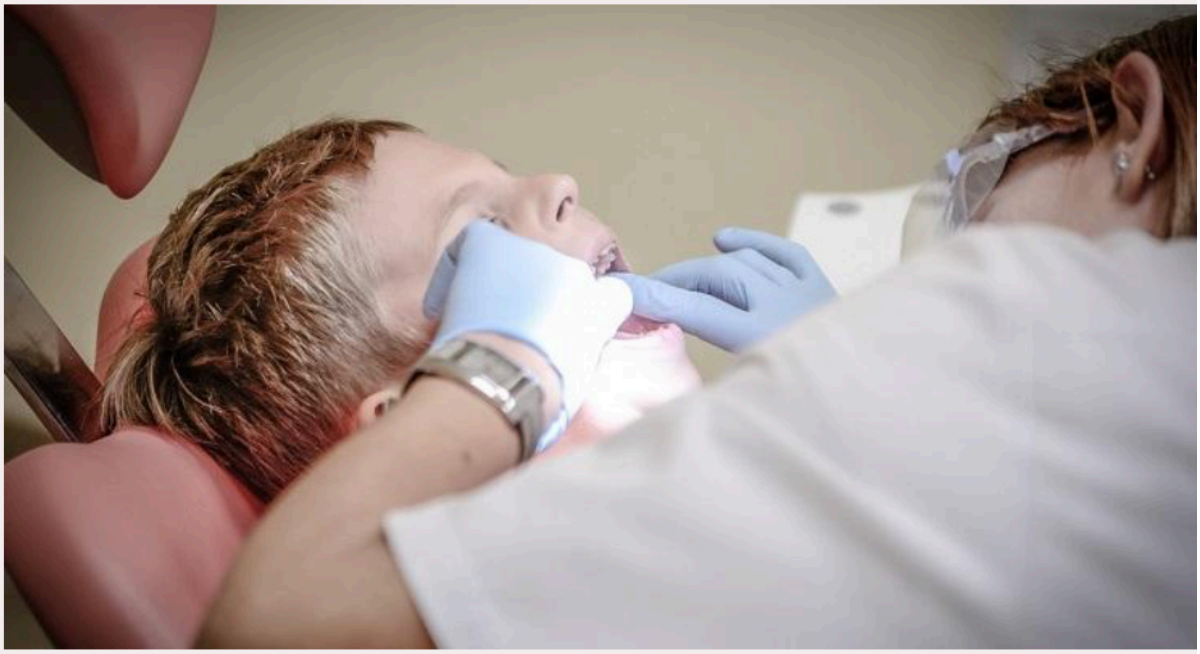
Oral health advice aiming to save NHS millions



A pilot scheme to improve oral health through pharmacies proved so successful that it is being rolled out across the North East in a bid to save the NHS money.

Poor oral health is a significant public health concern, costing the NHS in England £3.4bn annually, with tooth decay becoming the most common reason for hospital admissions among children aged five to nine.

But a project between the University of Sunderland and the Public Health Team at Durham County Council has harnessed the accessibility of community pharmacies, frequently visited by patients, by offering a venue to deliver vital oral health advice and information.

Five pharmacies in deprived areas of County Durham took part in the pilot in 2016 and introduced a five-minute oral health intervention to patients as they waited for prescriptions or had just popped in for advice and medications.

More than 1,000 patients took part in the intervention, which included advising patients on how to brush their teeth properly, checking they were using the right products and providing key information on how to look after teeth and gums. The results were impressive with 72 per cent of participants reporting that their knowledge of oral health was much better and 66 per cent saying that they would definitely makes changes to their oral health habits. Meanwhile, 64 per cent definitely thought a pharmacy was the right place to receive oral health advice.

Andrew Sturrock, Principal Lecturer and Programme Leader for the Master of Pharmacy programme in the School of Pharmacy and Pharmaceutical Sciences at the University of Sunderland, worked with Durham County Council's Public Health team to develop the project based on his previous research assessing the impact of community pharmacies.

He explained: "This started as a simple idea, based on my research looking at the role of community pharmacies, who are well trained healthcare professionals, easily accessible and frequently visited by patients, and required to provide healthy living advice to patients - therefore offering a little explored avenue for the delivery of oral health interventions.

"We already know there are lots of people who don't have a dentist, have phobias about dental treatment or avoid regular check-ups, especially in deprived areas. The pharmacy is certainly not taking over the dentists' role – this is just about giving some really basic healthcare advice and signposting patients in the right direction.

"It's also about trying to prevent people from needing dental treatment later on, potentially saving millions on NHS treatment. We know that poor oral health can have a big impact on patients and improving oral health can even have positive benefits in other systemic health conditions, such as diabetes."

He added: "The study provides evidence that a community pharmacy is perceived by patients as an acceptable provider of oral health interventions and has the potential to provide positive changes to the oral health of the population."

Claire Jones, Public Health Pharmacy Adviser, Durham County Council said: "The success of this scheme did help to keep oral health training on the agenda for community pharmacies through regional pharmacy training sessions that were subsequently run by the regional oral health team at Health Education England in 2018. In addition, oral health became one of the local targets for HLPs in County Durham in the 2018/19 Award. And lastly, of course, oral health in children is now a focus in the current national quality payment scheme for pharmacies."

Rachel Lish, Clinical Lead for Multi-Disciplinary Oral Health, Health Education England North East, commented: "We are delighted to have been able to provide educational input into this pilot.

"The Directorate is committed to promoting the importance of good oral health, including its relevance to general health. It currently delivers a comprehensive oral health training programme for community pharmacists which aims to provide a greater understanding of the importance of oral health in general health, including, particularly in relation to diabetes control, dementia and mental health. This supports the objectives set out in 'The NHS Long Term Plan' of joined up care at the right time, strengthening prevention and addressing health inequalities."

The evaluation was performed using a patient evaluation questionnaire and interviews with pharmacy staff. The research has been published in the British Dental Journal: https://www.nature.com/articles/sj.bdj.2017.784

To find out more about Pharmacy courses at the University of Sunderland, click here

Scheme for pharmacists to give oral health advice rolls outs

Andrew Sturrock, Principal Lecturer and Programme Leader for the Master of Pharmacy programme in the School of Pharmacy and Pharmaceutical Sciences at the University of Sunderland

A pilot scheme designed to improve oral health by pharmacists giving advice is being rolled out across the North East to try and save the NHS money.

A project between the University of Sunderland and the Public Health Team at Durham County Council is using the accessibility of community pharmacies that are often visited by patients to offer a venue in which pharmacists can deliver oral health advice and information.

Currently, poor oral health is estimated to cost the NHS in England £3.4 billion annually and tooth decay is the most common reason for hospital admissions among children aged five to nine.

A pilot – detailed in research published in the *BDJ* in 2017[1] – was carried out in 2016 at five pharmacies in deprived areas of County Durham.

It involved a five-minute oral health intervention to patients as they waited for prescriptions or when they had come in for advice and medications.

In all, 1,089 patients took part in the intervention, which included advising patients on how to brush their teeth properly, checking they were using the right products and providing key information on how to look after teeth and gums.

Results from evaluation questionnaires showed that 72% of participants reported that their knowledge of oral health was much better, 66% said they would make changes to their oral health habits, and 64% thought a pharmacy was the right place to receive oral health advice.

The study concluded that a community pharmacy was seen by patients as an acceptable provider of oral health interventions and had the potential to provide positive changes to the oral health of the population.

Andrew Sturrock, Principal Lecturer and Programme Leader for the Master of Pharmacy programme in the School of Pharmacy and Pharmaceutical Sciences at the University of Sunderland, worked with Durham County Council's Public Health team to develop the project based on his previous research assessing the impact of community pharmacies.

Mr Sturrock said: 'This started as a simple idea, based on my research looking at the role of community pharmacies, who are well-trained healthcare professionals, easily accessible and frequently visited by patients, and required to provide healthy living advice to patients – therefore offering a little explored avenue for the delivery of oral health interventions.

'We already know there are lots of people who don't have a dentist, have phobias about dental treatment or avoid regular check-ups, especially in deprived areas. The pharmacy is certainly not taking over the dentists' role – this is just about giving some really basic healthcare advice and signposting patients in the right direction.

'It's also about trying to prevent people from needing dental treatment later on, potentially saving millions on NHS treatment.'

The scheme has now been rolled out across Tyneside, Teesside, County Durham and Carlisle.

Claire Jones, Public Health Pharmacy Adviser at Durham County Council said: 'The success of this scheme did help to keep oral health training on the agenda for community pharmacies through regional pharmacy training sessions that were subsequently run by the regional oral health team at Health Education England in 2018.

'In addition, oral health became one of the local targets for HLPs [healthy living pharmacy] in County Durham and oral health in children is now a focus in the current national quality payment scheme for pharmacies.'

References

1. Sturrock A, Cussons H, Jones C, Woodcock C and Bird L. Oral health promotion in the community pharmacy: an evaluation of a pilot oral health promotion intervention. *Br Dent J* 2017; **223:** 521–525.

Appendix 13

Press release: UKCPA and PRUK award their 2016 grant

by **Dave_admin** on November 7, 2016 in **News**

UKCPA and PRUK are delighted to grant the 2016 UKCPA-PRUK Research Awards to Andrew Sturrock, Senior Lecturer in Pharmacy Practice and Clinical Therapeutics at the University of Sunderland; and to Daniel Greenwood, a PhD student in Pharmacy and Pharmaceutical Sciences at the University of Manchester.

UKCPA (the UK Clinical Pharmacy Association) and PRUK (Pharmacy Research UK) are working together to support pharmacy practitioners to take forward their research within clinical pharmacy. This year two projects have been awarded funding:

1. The multidisciplinary approach to the prevention of bisphosphonate related osteonecrosis of the jaw (BRONJ). A qualitative study into the attitudes and perceptions of patients.
2. Enhanced clinical pharmacy practice in the emergency department: what is it and what does it mean for patient care?

Ann Page, Chair of UKCPA, said, "UKCPA are delighted to be working with PRUK to fund these important projects. The high morbidity level of osteonecrosis means that it is important to prevent this condition and this project should result in better patient care for those taking bisphosphonate. The role of the Pharmacist in A&E is a new and exciting role and we look forward to seeing the evidence around the impact they can make in emergency care."

Prevention of Osteonecrosis

Bisphosphonates are used to treat a number of conditions that effect bones, such as osteoporosis and certain cancers. However, they can cause the rare but unpleasant and painful condition osteonecrosis. This affects the patient's jaw bones and is very difficult to treat, so healthcare professionals try to prevent it occurring. Current evidence suggests knowledge of this condition among healthcare professionals is poor and that patients are unaware of this potential side effect and how to mitigate against it. This study is designed to look at the attitudes of patients towards this risk, the ways in which this risk can be minimised and how healthcare professionals can work together to prevent it from occurring. The results of this project should help with the development of services that can reduce the risk of patients experiencing osteonecrosis of the jaw and to gain an understanding of the role of each healthcare professional in the management of this condition.

Andrew Sturrock said, “We are delighted to have received the UKCPA-PRUK award. Osteonecrosis of the jaw is a rare adverse effect of bisphosphonate therapy, however it can cause significant morbidity for patients and it is largely preventable with appropriate management and inter-professional collaboration. By speaking to patients we hope to develop an understanding of the impact of this condition on their lives and how patients prescribed bisphosphonates perceive this risk. This will allow us to gain an understanding of the roles and responsibilities of the various healthcare professionals, as perceived by patients and provide an evidence base for the development of patient centred collaborative care in this patient group.”

Pharmacy practice in A&E

Many UK emergency departments are struggling to meet demand. Due to staff shortages, the NHS has started to use pharmacists with enhanced clinical skills to care for emergency department patients. In addition to being medicines experts, this new type of pharmacist can diagnose some types of patient and write prescriptions.

This research will collect information about what these pharmacists do when they are working in the emergency department. This will include activities that pharmacists have always done, such as helping doctors to choose the best medicines for patients, as well as new responsibilities, such as examining patients. We will also investigate how these pharmacists affect patient care.

The results of this research will be presented and distributed to many different healthcare professionals, hospitals, universities, and government organisations including Health Education England who are responsible for healthcare professional training. By informing these groups of this research, we hope that they will learn and understand more about what pharmacists with enhanced clinical skills training can do, and consequently help more emergency departments to hire pharmacists.

For more information please contact PRUK at practice.research@rpharms.com

Appendix 14

The attitudes and perceptions of patients towards the multi-disciplinary approach to the prevention of Medication Related Osteonecrosis of The Jaw (MRONJ): A qualitative study in England.
Andrew Sturrock et al,
University of Sunderland

Medication related osteonecrosis of the jaw (MRONJ) is a rare adverse effect of anti-resorptive or anti-angiogenic drug therapy that can cause significant morbidity. Commonly prescribed drugs such as bisphosphonates have been associated with MRONJ.

Research shows that general medical practitioners and pharmacists have limited knowledge and awareness of MRONJ and practitioners often fail to provide advice related to it. This is thought to consequently result in poor patient awareness of the condition.

In one study, when asked to identify side effects of bisphosphonate therapy, only a minority of patients receiving IV or oral bisphosphonates were aware of the potential risk of developing osteonecrosis of the jaw.

The aim of this study was to explore the attitudes and perceptions of patients towards the multidisciplinary approach to the prevention of MRONJ.

The research team undertook qualitative interviews with a total of 23 patients; six of whom were diagnosed with MRONJ, 13 who were prescribed bisphosphonates and four patients with osteoporosis not currently prescribed any medication.

Five salient and inter-related themes emerged from the analysed data:

- Quality of life, indicating the physical, psychological and social impact of MRONJ
- Limited knowledge, indicating limited awareness of the condition, risk factors and preventative strategies
- Patient specific themes, referring to the complexity of patients, polypharmacy, prioritising aspects of care and personal responsibility
- Inter-professional management, indicating a perceived organisational hierarchy, professional roles and responsibilities, articulation of risk and communication
- Wider context, indicating demands on NHS resources, and barriers to dental care.

The researchers concluded that MRONJ has a significant effect on the quality of life of patients diagnosed with the condition. Patients described both the physical and psychological impact and challenges related to its ongoing management.

Patients from across the three groups all had limited knowledge of the association between bisphosphonates and osteonecrosis of the jaw, and when patients possessed some knowledge, this typically came from the patient information leaflets supplied with medication or from the internet. However, given the demographics of this patient group, access to online information is potentially a challenge for some patients.

Participants described a perceived hierarchy in relation to the management of their health. They expected prescribers to utilise professional judgment on the suitability of the medication for them, and to provide information related to the adverse effects of medications.

They believed that the pharmacist has an important role in reinforcing advice and were positive towards the pharmacist's role in providing information on medications and conducting medication reviews.

"Published clinical guidelines recommend that patients should be referred for dental assessment and treatment prior to initiation of bisphosphonate therapy, but this is not happening."

"As this condition can, in many cases, be prevented with appropriate oral health advice and preventative care, the importance of such measures should be stressed to healthcare professionals managing this particular patient group", says Andrew Sturrock.

"Published clinical guidelines recommend that patients should be referred for dental assessment and treatment prior to initiation of bisphosphonate therapy", says Andrew Sturrock. "But it is apparent this is not happening."

So what can be done? "The inclusion of bisphosphonates in the MUR and NMS service specifications could provide an opportunity for reinforcement of preventative advice during the initiation stages of treatment with bisphosphonates", says Sturrock.

"Participants were receptive to information being shared between the medical and dental services [so] further work to develop interprofessional working between pharmacy and dental professionals could be of particular benefit to this patient group."

Daniel Greenwood and **Andrew Sturrock** are both presenting their work at the Pharmacy Together conference on 2 November 2018

Appendix 15

AdvanceHE

‹ Back to National Teaching Fellow Listing Page

Mr Andrew Sturrock

Andrew Sturrock is a Principal Lecturer at the University of Sunderland and the MPharm Programme Leader. He has introduced novel interprofessional education initiatives, in the field of oral health and mental ill health. He works with patients and utilises simulation-based learning to enhance the authenticity of clinical teaching and the student experience.

Year

2019

Institution

University of Sunderland

Job Title

Principal Lecturer - MPharm Programme Leader

Andrew Sturrock qualified as a pharmacist in 2008 and is a Principal Lecturer at the University of Sunderland. He is the Master of Pharmacy Programme Leader and is responsible for a cohort of approximately 750 students. Andrew teaches clinical pharmacy and pharmacy practice across all four stages of the MPharm, with a particular focus on preparing students to enter clinical practice.

Andrew began his academic career as a teacher practitioner, before taking up a permanent role as a Senior Lecturer in Pharmacy Practice and Clinical Therapeutics. He was quickly promoted to his current role as Principal Lecturer and was awarded Senior Fellowship in 2019. He is currently working towards the submission of his PhD by Publication in 2020, exploring the pharmacists' role in the management of oral health, a subject closely aligned to the teaching and learning developments that he leads.

Andrew has introduced novel interprofessional education (IPE) initiatives with a focus on oral health and mental ill health. These initiatives have involved working closely with academics from other professional groups and introducing IPE into the curricula of programmes internally at the University of Sunderland and with external partners. He has worked with the University of Sunderland Patient Carer and Public Involvement group to co-construct

and deliver teaching and learning activities with patients that have mental health problems, providing an eye opening and inspirational opportunity for students.

Andrew has worked to transform the student experience on the MPharm Programme, introducing simulation-based learning to enhance the authenticity of the clinical content of the programme and preparing students to enter clinical practice. He also mentors new academic staff, this includes preregistration pharmacists undertaking a novel academic/community pharmacy training programme. On completion of this training, many of these pharmacists have progressed to formal teacher practitioner roles at the University.