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Supply and administration of denosumab for patients with osteoporosis in primary care – a qualitative study to explore the potential for pharmacy practice development

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“If the artist does not perfect a new vision in his process of doing,
he acts mechanically and repeats some old model
fixed like a blueprint in his mind.”

- John Dewey (1859 – 1952),
Art as Experience, 1934, p. 50

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Abstract

Background

Denosumab is a medication for postmenopausal osteoporosis delivered as a subcutaneous injection. Within the National Health Service (NHS) Lothian, Scotland, the treatment is currently administered in a hospital setting. Feedback from patients and staff indicate that the drug could most likely be delivered in a community setting, which is in accordance with Scottish Government policy emphasising a need for local patient care. “Shared care”, which is a mixed model where the hospital and General Practitioners (GPs) share patient responsibility, was not approved by NHS Lothian committees. Consequently, other alternatives for local patient care have been explored. One of the ideas has been to involve community pharmacies in a “shared care” model with hospitals, offering the administration of denosumab.

Aim

To investigate the potential for community pharmacists to deliver a pharmaceutical care package for the management of osteoporosis that includes the supply and administration of denosumab, a medication review and an assessment of falls risk and the need for calcium and vitamin D.

Methods

The current patient journey was defined from literature review and feedback from hospital specialists. The identified pathway formed basis for eleven semi-structured interviews, exploring opinions of three patients, one community pharmacist, one hospital pharmacist, one GP, two nurses and three hospital physicians on the existing patient journey and potential improvements. Information acquired from the interviews informed the design of questionnaires that were distributed to 114 patients, 182 community pharmacies and 500 GPs. Recommendations for a novel pharmaceutical care package as a part of a new patient journey was based on three elements; 1) data collected from the semi-structured interviews, 2) questionnaire responses and 3) the existing legal framework. Finally, the proposed patient journey, including the novel pharmaceutical care package was presented for feedback at the hospital multidisciplinary rheumatology meeting.

Results

From the interviews, 4 main themes and 13 subthemes appeared concerning advantages and disadvantages from different perspectives regarding both current patient journey and the proposed patient journey, including the pharmaceutical care package. Inconvenience for patients with the current journey was acknowledged by the majority of all interviewees. In particular, patients expressed the importance of rapport with health care professionals. The health care professionals

expressed opinions about the competence of community pharmacists to deliver the proposed package of care. The response rates for the questionnaires were 80.7 % (patients), 29.7 % (pharmacists) and 6.6 % (GPs). Over two thirds of the patients preferred the GP practice as the venue to receive denosumab based on convenience and trust in the GP and nurse. Almost three quarters of the pharmacist respondents were willing to deliver the package (39/53), but expressed a need for remuneration and training. Almost a third of the GP respondents were positive to the pharmacist administering the injection (10/33). However, almost two thirds (19/33) were willing to administer denosumab in their own practice, for which resourced capacity was mentioned as the main barrier. The pharmacists' competence and capability in undertaking falls and dietary assessment in addition to medication reviews were acknowledged by all respondents. The proposed pathway of care, including community pharmacy administration of denosumab, was positively received by the current hospital staff.

Conclusion

This study indicates that delivery of the proposed pharmaceutical care package in community pharmacies may be feasible. Current challenges for implementation include funding, gaining trust from the public and GPs and appropriate training of community pharmacists. In addition, effective communication systems and clarification of the roles and responsibilities of health personnel involved are crucial elements. Results from this study can inform the design and evaluation of future services.

Abbreviations

BMD	-	Bone Mineral Density
CMS	-	Chronic Medication Scheme
DXA	-	Dual-Energy X-ray Absorptiometry
FRASE	-	Fall Risk Assessment Scale for the Elderly
FTSST	-	Five-Times-Sit-to-Stand Test
GBP	-	British Pound Sterling
GP	-	General Practitioner
IgG 2	-	Immunoglobin G 2
IQR	-	Inter Quartile Range
NHS	-	National Health Service
NICE	-	National Institute of Health and Care Excellence
RANK	-	Receptor Activator of Nuclear Factor-κ B
RANKL	-	Receptor Activator of Nuclear Factor-κ B Ligand
SBC	-	Shifting the Balance of Care
SIGN	-	Scottish Intercollegiate Guideline Network
SMC	-	Scottish Medicines Consortium
SPC	-	Summary of Product Characteristics
STRATIFY	-	St Thomas's Risk Assessment Tool In Falling elderly patients
UK	-	United Kingdom
VAT	-	Value Added Tax
WGH	-	Western General Hospital

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Definitions and key concepts

Adherence: "The extent to which patients follow the instructions they are given for prescribed treatments" (1)

Clinical medication review: "Clinical medication review is the process where a health professional reviews the patient, their illness and drug treatment in a consultation. The progress of the conditions being treated and the appropriateness and continuing need of each drug are considered. Other issues, such as medication adherence, actual and potential adverse effects, interactions and the patient's understanding of the condition and its treatment are also considered where appropriate." (2)

Drug therapy problem: "A drug therapy problem is any undesirable event experienced by a patient which involves, or is suspected to involve, drug therapy, and that interferes with achieving the desired goals of therapy" (3)

Long-term condition: "A long-term condition – sometimes referred to as chronic diseases – lasts a year or longer, limit what a person can do, and may require ongoing medical care." (4)

Lothian Joint Formulary: "The NHS Lothian Joint Formulary provides drug prescribing guidance on first and second choice of drugs for all general practices and hospitals in Lothian." (5)

Medication review: "A systematic assessment of the pharmacotherapy of an individual patient that aims to evaluate and optimise patient medication by a change (or not) in prescription, either by a recommendation or by a direct change." (6)

Osteoporosis: "A disease characterised by low bone mass and microarchitectural deterioration of bone tissue, leading to enhanced bone fragility and a consequent increase in fracture risk" (7)

Pharmaceutical care:

Original definition (1990); "Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life" (8)

A more recent definition (2004); "Pharmaceutical care is a patient-centered practice in which the practitioner assumes responsibility for a patient's drug-related needs and is held accountable for this commitment" (3).

Pharmaceutical care package: The term "pharmaceutical care package" is used in this thesis to explain the content of the proposed pharmaceutical care service the community pharmacies will offer and deliver to patients receiving denosumab treatment. The pharmaceutical care package comprises the injection of denosumab, a medication review and an assessment of falls risk and the need for calcium and vitamin D supplements.

Patient journey: A patient journey describes (in this thesis) the pathway of care which the patient experiences from diagnosis to treatment for osteoporosis and includes the main venues and interactions. It also includes different pathways after treatment is started, depending on the treatment choice. The patient journey has pharmacological treatment in focus and does not include the non-pharmacological venues where a patient might receive healthcare.

Pharmacist-led osteoporosis service: This study proposes a pharmacist-led osteoporosis service for denosumab patients which is delivered by pharmacists in the community pharmacies in National Health Service (NHS) Lothian. The service would be new and involve delivery of the pharmaceutical care package to patients. It is an appointment-driven service and is explained in further detail in the thesis.

TrakCare®: "InterSystems TrakCare® is a unified healthcare information system based on the most advanced technologies. TrakCare creates a complete view of each patient's history, provides secure access to records at every point of care and on any Internet-connected device, integrates easily with other applications, and delivers real-time active analytics that drive informed actions." (9)

TrakCare® is the system used in hospitals in NHS Lothian.

1 Introduction

Community pharmacies are contracted to deliver services within the National Health Service (NHS) which include the delivery of pharmaceutical care to patients with long-term conditions. Patients with long-term conditions are often initially diagnosed and treated in secondary care with the intention to transfer that care to community based health care teams. Osteoporosis is one example where some treatments are initiated by hospital physicians. The ongoing treatment is then provided by the General Practitioner (GP), but there can be barriers to transferring some treatments to primary care. Some patients require their osteoporosis to be managed with denosumab injections. Currently, access to this treatment is inequitable across Scotland with some areas providing this in primary care and others requiring patients to attend hospital clinics. This thesis describes a qualitative study where the opinions of patients and healthcare professionals have been explored concerning a potential redesign of patient management. The following introduction briefly describes osteoporosis and the current management in Scotland, in addition to the Government drive towards a patient centred management in primary care. The introduction also describes pharmaceutical care services delivered in Scotland and the background for a future pharmaceutical care package.

1.1 Osteoporosis – epidemiology, diagnosis and pathophysiology

1.1.1 Epidemiology

Osteoporosis is a major health problem worldwide. According to the National Osteoporosis Society there are 250,000 people with osteoporosis in Scotland (10). Lothian is the region of Scotland which includes Edinburgh and has an estimated population of about 800,000 (11). The proportions of males, females and elderly people are comparable between Lothian and Scotland* (11). If the prevalence of osteoporosis from National Osteoporosis Society is extrapolated to Lothian, it calculates to 40,000**.

The Scottish Intercollegiate Guidelines Network (SIGN) estimates that there are 20,000 osteoporotic fractures and 6,000 hip fractures in Scottish adults each year (12, 13), the latter being the worst consequence of osteoporosis (14). In England and Wales, the lifetime risk of a hip fracture is 11.4 % for a 50 year old woman, which probably is transferrable to Scotland (15).

*Population in Scotland: 5,254,800 (2,548,200 [48.5 %] males and 2,706,600 [51.5 %] females). People above 65 years: 892,387 (17.0 %). Population in Lothian: 848,727 (410,740 [48.4 %] males and 437,987 [51.6 %] females). People above 65 years: 126,006 (14.8 %).

**Extrapolation: (People with osteoporosis in Scotland / Population in Scotland) * Population Lothian = (250,000 / 5,254,800) * 848,727 = 40,378.65 ≈ 40,000.

Scotland and Norway are comparable with regards to population and the prevalence of osteoporosis (11, 12, 14, 16) (see appendix 1). Although there are no publications of the cost of osteoporosis in Norway or Scotland, the Norwegian Directorate for Health and Social Affairs estimated the cost to be about £165 million (GBP) each year by comparing Norway and Sweden (17). The cost for Scotland is £145 million if calculated from the cost in United Kingdom (see appendix 1).

1.1.2 Diagnosis and risk factors

The investigations to confirm a diagnosis of osteoporosis are usually initiated by GPs. The GP refers the patient for confirmation of the diagnosis by a Dual-energy X-ray Absorptiometry (DXA) scan. The DXA scan compares the patient's bone mineral density (BMD) to the BMD of young adults, which gives a T-score (12). By using the T-score, clinicians differentiate between normal bone mass, osteopaenia (i.e. low bone mass) and osteoporosis (see Table 1-1).

Table 1-1: T-score: Difference between normal, osteopaenia and osteoporosis (7).

Characteristic	T-score
Normal	≤ -1.0
Osteopaenia	Between -1.0 and -2.5
Osteoporosis	≤ -2.5
Established osteoporosis	≤ -2.5 + at least one fragility fracture

Osteoporosis-related fractures are associated with increased morbidity and mortality, and it is therefore a need for prevention of osteoporosis and fractures to decrease morbidity and mortality, and increase the quality of life in the long term (12). The risk of an osteoporotic fracture generally increases as BMD decreases, which may be a consequence of increased age, menopause and/or insufficient intake of vitamin D and calcium (12). Falling is a major risk factor for fractures, and therefore factors that are associated with falling, e.g. slow gait, poor coordination, low muscle strength, influence of alcohol and having trouble protecting against the impact during a fall also contribute to the overall fracture risk.

1.1.3 Pathophysiology

Bone remodelling is a continuous process and involves the resorption (breakdown by osteoclasts) and build-up (formation or synthesis by osteoblasts) of bone. When the balance of bone remodelling is

favoured by resorption, the bone weakens and may result in osteoporosis. The uneven balance may be caused by a decrease in oestrogen-level, age or corticosteroid-use. After menopause the oestrogen-level is decreased, which leads to reduced secretion of osteoprotegerin. Osteoprotegerin inhibits osteoclast formation and activity, and thus, when secretion is reduced, the balance of bone remodelling is favoured by osteoclast (18). Prolonged bone resorption caused by a decrease in oestrogen weakens the bone and may lead to postmenopausal osteoporosis.

1.2 Clinical guidelines of postmenopausal osteoporosis

Four guidelines are especially relevant for the management of postmenopausal osteoporosis in Scotland and Norway (see Table 1-2). The content of the guidelines is mainly the same, but for the purpose of the study, the focus will be on the Scottish guidelines.

Table 1-2: Osteoporosis guidelines in Scotland, Norway, and England and Wales.

Country	Responsible body	Name of guideline	Year (amended)
Scotland (12)	SIGN*	Management of Osteoporosis – A national clinical guideline (71)	2003 (2004 and is currently being updated)
Norway (17)	The Norwegian Directorate for Health and Social Affairs	Professional guidelines for prophylaxis and treatment of osteoporosis and osteoporotic fractures (IS-1322) (NO: Faglige retningslinjer for forebygging og behandling av osteoporose og osteoporotiske brudd)	2005
England and Wales (19)	NICE**	Alendronate, etidronate, risedronate, raloxifen and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women (TA160)	2008 (2011)
England and Wales (20)	NICE**	Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women (amended) (TA161)	2008 (2010 and 2011)

* Scottish Intercollegiate Guidelines Network.

** National Institute for Health and Care Excellence.

Raloxifen, a selective oestrogen receptor modulator, is only recommended in NHS Lothian for use in younger patients with predominantly spinal osteoporosis and is therefore not discussed further due to the focus in this thesis on postmenopausal women (21).

The primary aim of treatment according to the SIGN guideline is to reduce the incidence of fractures and increase BMD through non-pharmacological and pharmacological interventions (12). The SIGN treatment guidelines categorise patients according to the following:

1. Postmenopausal women with multiple vertebral fractures
2. Postmenopausal women with osteoporosis determined by axial DXA and with a history of at least one vertebral fracture
3. Postmenopausal women with osteoporosis (determined by axial DXA) with or without previous non-vertebral fracture
4. Frail, elderly women (aged 80 + years) with a diagnosis of osteoporosis, with or without previous osteoporotic fracture
5. Men with a diagnosis of osteoporosis with or without previous osteoporotic fracture

1.2.1 First line treatment

The first-line treatment for all the five categories is oral bisphosphonates and includes alendronate, risedronate, ibandronate and etidronate. Alendronate is the first choice in NHS Lothian (21).

One of the problems with bisphosphonates is their low bioavailability (typically 1-5%) (12). They must be taken when fasting for a sufficient amount to be absorbed. Furthermore, to avoid oesophageal ulceration, they should be taken whilst standing in an upright position and with an ample amount of water (22). This regimen is known to cause poor compliance which might lead to ineffectiveness, especially in elderly patients who may be confused, suffer from dementia or having learning difficulties (23).

1.2.2 Alternative treatment

Other pharmaceutical alternatives may be given if treatment with oral bisphosphonates is unsuitable due to contraindication, intolerance, ineffectiveness or inability to comply with the special administration instructions. The current alternatives are strontium ranelate (oral treatment), zoledronic acid (intravenous infusion) and denosumab (see section 1.2.3). Zoledronic acid is approved for restricted use in postmenopausal women with increased risk of fractures where oral bisphosphonates are unsuitable or not tolerated (24). Parathyroid hormone is the preferred choice if the T-score < -4.0 and is often given as the 1-34 fragment (teriparatide) (20, 21).

1.2.3 Denosumab

Denosumab is the third-line treatment for postmenopausal osteoporosis and also the only option if the patient has renal impairment (i.e. creatinine clearance < 30 ml/min). The Scottish Medicine Consortium (SMC) approved the use of denosumab in 2010 with the following restriction:

"Use only in patients with a bone mineral density (BMD) T-score < -2.5 and ≥ -4.0 for whom oral bisphosphonates are unsuitable due to contraindication, intolerance or inability to comply with the special administration instructions." (25)

Denosumab is an immunoglobin (IgG2) and a human monoclonal anti-Receptor Activator of Nuclear Factor (RANK)-Ligand that inhibits bone resorption (26). Denosumab increases BMD and reduces the incidence of vertebral fractures, non-vertebral fractures and hip fractures (27). Due to the biologic nature of denosumab it is given as a subcutaneous injection every six months. The device is a prefilled syringe with a safety needle guard which is stored in a refrigerator between 2 and 8 ^{o}C. Denosumab is contraindicated in patients with hypocalcaemia; hence calcium levels must be checked and corrected prior to initiating therapy with denosumab. Monitoring of mineral levels (calcium, phosphorus and magnesium) is only recommended in patients predisposed to hypocalcaemia (e.g. renal impairment and patients receiving dialysis). For details about denosumab such as mechanism of action, effectiveness and adverse effects, see appendix 2.

1.2.3.1 The use of denosumab in NHS Lothian

Denosumab is currently recommended for specialist use in NHS Lothian (28). Thus, the physician in the bone clinic initiates denosumab if third line treatment is indicated and the administration occurs in the osteoporosis clinic at Western General Hospital. In other parts of the United Kingdom, the management of denosumab is moved to primary care after initiation in secondary care (29).

There has been anecdotal feedback from patients that the treatment should preferably be delivered in primary care for convenience reasons (e.g. travel, time consumption and car parking). Although the travel might be inconvenient, treatment with denosumab is a good alternative treatment for some patients (e.g. patients who have reduced renal function or have tried other options without satisfying response or tolerance). However, the delivery of health care should be patient centred with patients' needs and views in focus, according to several Scottish Government policy documents (30-32), to which the local Pharmacy Strategy is assigned (see section 1.3) (33).

The osteoporosis specialist nurses and the consultants at WGH have also expressed that it would be preferred, from a hospital perspective, that denosumab was supplied and administered in a primary care setting. This would allow the nurses to use their time undertaking more specialised tasks and may contribute to the reduction of waiting lists as Government Policy recommends (32).

The cost effectiveness of denosumab when administered in secondary care has led to NICE recommending use in primary care after initiation in secondary care (34). There is inconsistency throughout NHS Scotland as to the approach for its use. Although denosumab was accepted for use within NHS Lothian in April 2011, it was not accepted locally at that time as suitable for "shared care"; a mixed model where the hospital and GPs share patient responsibility (28).

For the treatment to be more convenient for the patients, more cost-effective and to relieve use of specialist health services, denosumab could be delivered in a primary care setting, in accordance with Government drive (see section 1.3). One example of denosumab used in primary care is in Tromso, Norway, where denosumab is initiated by consultants in secondary care and subsequently administered in primary care. It is administered either by the patient in the patient's home, or by a health care professional in the patient's GP practice (2012 Dec 17, e-mail from Dr Farahnaz Saleh to Ben T. Henriksen; unreferenced, see "Notes"). According to the Norwegian Prescription Database at the Norwegian Institute of Public Health, there were 51 patients using denosumab in Troms-county in 2012, 43 of whom are women (35).

1.3 Government drive and framework

1.3.1 Government drive

Convenience for patients and increased pressure in secondary care are driving the development of new services in primary care, although primary care services are also under pressure. The pressure may be a result of an increasing elderly population and an associated increase in prevalence of long-term conditions. This may in turn result in more patients receiving denosumab treatment. The recent drive towards increased prophylaxis and treatment in primary care, as opposed to the current secondary care setting, is described in the initiative "Shifting the Balance of Care" (SBC) (32) and the "Managing Long-term conditions"-document from 2007 (4). The Norwegian Coordination Reform (NO: Samhandlingsreformen) was introduced in 2012 and has the same principal content (36).

As a part of the primary care system, the community pharmacy may contribute as a venue where patients can receive direct clinical health care. This may be particularly important as new drugs are being developed which are often of increased complexity. One of the new, complex drugs is denosumab. This is not a novel idea as it was presented in a strategy from the Scottish Government in 2002. The document, called "The Right Medicine: A strategy for pharmaceutical care in Scotland", is an agenda for the modernisation of pharmacy services and promotes redesign of services (37). Thus, as a part of primary health care, the community pharmacies may have a role in osteoporosis care and in the supply and administration of denosumab in particular. Such future pharmaceutical care services

delivered in community pharmacies must be within a legal, political and practical framework, which also is the case for this study (see figure 1-1).

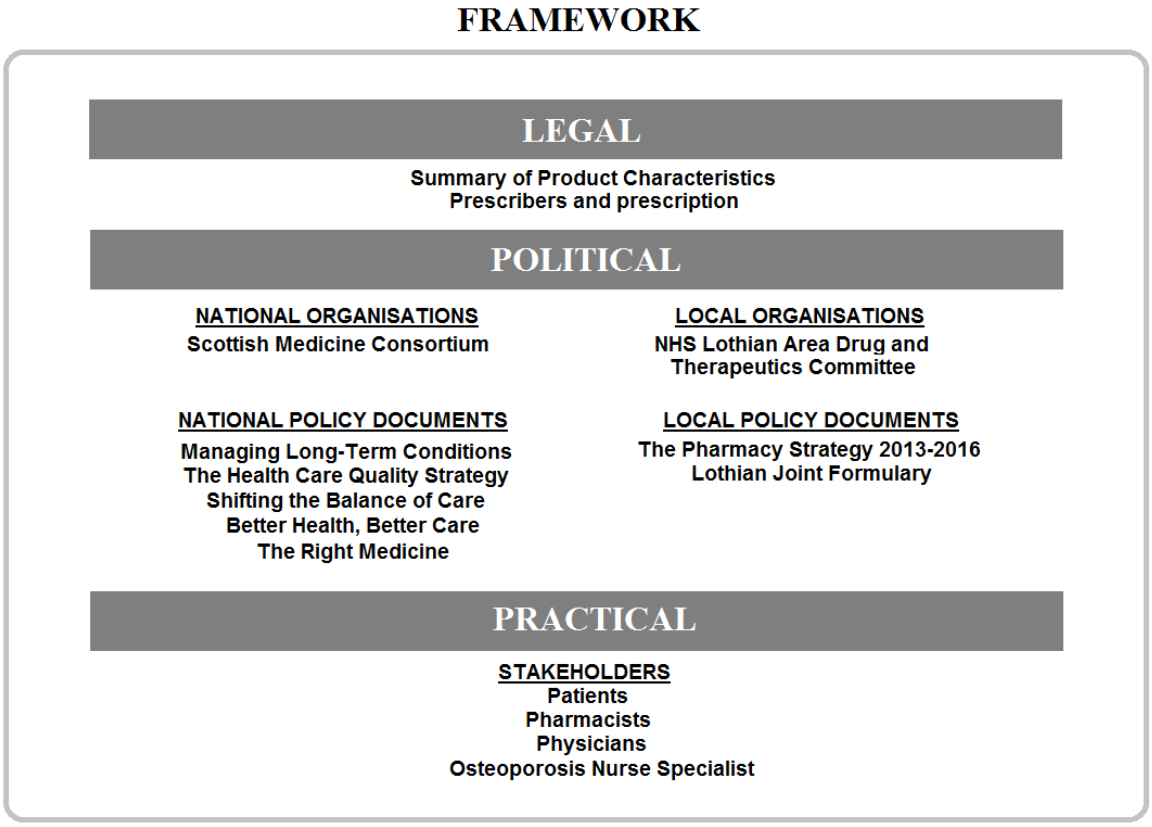

Figure 1-1: Frameworks involved in future pharmaceutical care services.

1.3.2 Framework

Legal framework

The Summary of Product Characteristics (SPC) for denosumab states that it is a prescription only medicine and should only be administered by an adequately trained individual (38). In NHS Scotland there are certain health professionals who are allowed to prescribe prescription only medicines, which includes medical and qualified non-medical prescribers (39, 40). The prescriptions are valid for six months unless it is a repeat prescription which has no legal time limit (39).

Political framework

National and local restrictions are currently in place for the use of denosumab in NHS Lothian (25, 28) (see section 1.2.3.1). There is Scottish Government drive to patients receiving care as close to

their home as possible (32). The SBC initiative is in addition to several national policy documents describing a patient centred health care:

- Managing Long-Term Conditions (4)
- Better Health, Better Care (30)
- The Right Medicine (37)

The SBC initiative has also led to national and local policy documents describing a patient centred health care:

- The Healthcare Quality Strategy (31)
- The Pharmacy Strategy 2013 – 2016 (33)

Practical framework

Future pharmaceutical care services should be convenient for the patients, thus supporting a patient centred healthcare. Secondly, the services should be convenient for the new staff involved (i.e. community pharmacists in this study). Thirdly, it should be convenient for the staff currently responsible for the healthcare who also may be involved in the new pathway of care (i.e. physicians and osteoporosis specialist nurses in this study).

A future pharmaceutical care service for patients suffering from osteoporosis will expand the pharmacists' role in a community pharmacy. It will be a new service for this patient population, but there are already pharmaceutical care services being delivered from community pharmacies in Scotland which may indicate that the idea is feasible.

1.4 Pharmaceutical care

Pharmaceutical care is successfully delivered through several community pharmacy services in Scotland. The services include the Minor Ailment Service, Chronic Medication Scheme (CMS), flu-vaccinations, Acute Medication Service and Public Health Service (e.g. smoking cessation service and sexual health) among others (33, 41).

The current services that can be perceived as most similar to the proposed pharmacist-led osteoporosis service are CMS and flu-vaccinations. The CMS is a free service for people suffering from long-term conditions and includes shared care between GPs and community pharmacists (42). The patient can freely choose and register with the pharmacy where they will receive a pharmaceutical care service based on patients' needs (42). The community pharmacies in Scotland have been providing influenza vaccinations successfully for some years (43). The pharmacists are trained for the necessary

resuscitation skills and anaphylaxis treatment involved. The vaccinations are undertaken in a private consultation area in the pharmacy. In NHS Lothian, 91 % of the community pharmacies have a private consulting area/room (44). "The Right Medicine"-document states that influenza vaccinations in community pharmacies relieves pressure on GP practices (37). The influenza vaccination is paid for by the patients and costs £12-13 (45, 46). Patients at risk are eligible for vaccinations from the GP practice free of charge.

In addition to the Scottish services mentioned, there are several non-dispensing interventions delivered by community pharmacies internationally. A Cochrane review from 2010 explains services for diseases such as asthma, Chronic Obstructive Pulmonary Disease, depression, diabetes, heart failure, hyperlipidemia and hypertension (47).

These services are evidence from a capability perspective, that a change in service delivery involving community pharmacy is feasible and therefore there is potential to promote such a change within appropriate governance frameworks. Ideas for improvement and change require that existing practices are challenged and new practice ideas are appraised.

1.4.1 Background for a future pharmaceutical care package offered to patients with osteoporosis

Medication reviews

The Right Medicine document recommends regular medication reviews for patients with long-term conditions. A medication review is included in the proposed pharmaceutical care package which will accommodate the Government's request and have the potential to identify drug therapy problems. Brief medication reviews are currently delivered by community pharmacists for patients involved in the CMS (42). Some GPs also offer patients a medication review as it is included in the Quality and Outcomes Framework (an incentive scheme for GP practices in the UK) (48). Discussing medicines with the patients and giving information will lead to a focus to optimise adherence. The Scottish Government has expressed that medication reviews would address medication problems and help to reduce falls (37). Casteel et. al. explained a falls prevention program in a community pharmacy which included a medication review. The authors conclude that coordination of care between community pharmacists and prescribers needs to be improved in order to gain the potential benefits (49), but indicates that such an intervention is feasible in the community pharmacy.

Falls assessment

A falls assessment is important because over 90 % of hip fractures are falls related and it is suggested that hip fractures cost the NHS £12,137 each (10). As emphasised earlier, there is an increased risk of morbidity and mortality after a hip fracture (50, 51). There are several assessment tools for use in community and hospital setting (52). In NHS Lothian the falls assessment for inpatients is performed applying a modified version of the St Thomas's risk assessment tool in falling elderly inpatients (STRATIFY) (53). The SRATIFY tool comprises five questions, and is applied at hospital admission. In Mid- and West Lothian, the falls assessment for outpatients is performed using another tool, namely the Fall Risk Assessment Scale for the Elderly (FRASE), which includes an eight item questionnaire (54). Each answer yields a score which is summarised into a total score. In addition to a questionnaire, a falls assessment may include a Five-Times-Sit-to-Stand Test (FTSST) where the patient is asked to sit on a 45-cm high chair, stand up and sit down again as quickly as possible without using hands. If the patient uses more than 15 seconds, the patient has an increased risk of recurrent falls (55). In literature, falls assessment by community pharmacists has been described in Fife and Forth Valley, Scotland and Hertfordshire, England, but information of the outcome is lacking (56, 57). However, it indicates that a community pharmacy based falls assessment is feasible.

Assessment of the need for calcium and vitamin D supplements

Sufficient levels of vitamin D and calcium have been shown to reduce bone loss in elderly (58). Consequently, an assessment of the need for calcium and vitamin D is important in patients suffering from osteoporosis and can be included in a pharmaceutical care package. Philips et. al. illustrated that such an intervention carried out in a community pharmacy did not disrupt workflow or required training (59). Yuksel et. al. compared a community pharmacist intervention with BMD-screening and patient education to no intervention in terms of assessment for calcium and vitamin D intake in a Canadian randomized controlled trial (60). The patient education programme included information about calcium and vitamin D intake, but also risk factors, lifestyle measures, medication and written information. This intervention increased calcium intake in the intervention group (30 % vs 19 %, $p=0.011$). Intake of vitamin D and quality of life did not change significantly. This indicates that the last part of a future pharmaceutical care package also is feasible

On the basis of the Government drive and patient convenience, this study will explore the potential for community pharmacies to deliver a pharmaceutical care package aimed for osteoporosis patients receiving treatment with denosumab. The proposed pharmacist-led service must be within the framework stated above and will require dialogue and debate. Such a service will expand the

pharmacists' role in a community pharmacy. It will be a new pharmaceutical care service in this patient population, but there are already pharmaceutical care services being delivered from community pharmacies in Scotland which may indicate that the idea is feasible. The proposed pharmacist-led service is believed to improve health care for the osteoporosis patients.

2 Aim and objectives

The aim of the study was to investigate the potential for community pharmacists to deliver a pharmaceutical care package for the management of osteoporosis that includes the supply and administration of denosumab, a medication review and an assessment of falls risk and the need for calcium and vitamin D.

The specific objectives were:

1. Propose potential pathway(s) of care for the shared management of osteoporosis across primary and secondary care
2. Design questionnaires to survey stakeholders involved in the delivery of the current and proposed service
3. Explore patients' and health care professionals' experience and thoughts concerning current and future osteoporosis management

3 Subjects and settings

3.1 Study design

The study was a cross-sectional opinion survey seeking the views of NHS staff and patients receiving denosumab on service delivery. Semi-structured interviews were used to obtain opinions from those who currently run the service and to inform questionnaire design. The questionnaires were used to obtain opinions from patients, community pharmacists and GPs. The patients receiving denosumab at Western General Hospital are domiciled in Lothian; the region that includes Edinburgh. Lothian had in 2011 an estimated population of about 850,000, of which approximately 125,000 are above 65 years (11). NHS Lothian is the National Health Service board provided for the citizens of Lothian and is one of 14 regional health boards in Scotland (61).

3.2 Study participants

The study involved obtaining opinions for a service delivered in NHS Lothian, therefore the participants were employed or contracted in NHS Lothian (health care professionals) or received treatment in NHS Lothian (patients). The stakeholders were defined as the healthcare professionals involved in the current and/or future management of denosumab in postmenopausal osteoporosis in NHS Lothian (i.e. community pharmacies, GPs, osteoporosis nurse specialists and physicians) and patients who receive denosumab treatment for osteoporosis in Lothian.

3.2.1 Participants in the qualitative interviews

The interview participants were one hospital pharmacist (pilot), one community pharmacist, one GP, two osteoporosis specialist nurses, three physicians and three patients (one of whom being the pilot) (see Table 3-1). The hospital pharmacist was chosen by the clinical supervisor to be a convenient pharmacist familiar with denosumab. The community pharmacist and GP were selected by the academic supervisor after seeking advice from the Chairman of Lothian Pharmacy Contractors Committee (community pharmacist) and the Associate Medical Director for Primary Care (GP). In NHS Lothian there are two osteoporosis specialist nurses and three physicians who are involved in treatment with denosumab for postmenopausal women. The hospital physicians were prescribing denosumab for patients who received the denosumab injection by the nurses at the Western General Hospital. The clinical supervisor informed them about the study and the investigator invited all five to participate. To select the patients, the investigator sought advice from an osteoporosis specialist nurse to be those interested, not biased, and not suffering from senile dementia. The osteoporosis specialist

nurse invited the patients she considered to be within the criteria and who had an appointment between 5th November and 3rd December 2012. All the 11 interviewees were asked to name a convenient time and place where the interviews could take place. No participants were excluded due to the outreaching nature of invitations. All participants accepted the invitation and gave their consent.

Table 3-1: Description of participants in the qualitative interviews.

Origin of study participants	n (male:female)
Hospital pharmacist (pilot)	1 (0:1)
Community pharmacist	1 (1:0)
General Practitioner	1 (1:0)
Osteoporosis specialist nurse	2 (0:2)
Physician in the osteoporosis service at the Western General Hospital	3 (2:1)
Patient receiving denosumab treatment (including one pilot)	3 (0:3)
Total	11 (4:7)

3.2.2 Participants in the questionnaire survey

The questionnaires were sent to all of the patients who had at least one denosumab injection before 13th December 2012 (n = 114), all the community pharmacies (n = 182) and all of the GPs (n ≈ 500) within NHS Lothian. The patients were identified from medical records kept by the osteoporosis clinic. Those who were allocated a denosumab appointment after 13th December 2012 were excluded to assure that the participants had received at least one injection. The Associate Director for Contracted Community Pharmacy Services facilitated distribution to all community pharmacies in NHS Lothian using normal communication processes. A newsletter routinely sent to all GP practices in NHS Lothian with the link to the questionnaire was used for distribution (see section 4.3.3). No pharmacies or GPs were excluded.

3.3 Approval

The study was considered not to require research ethics review by the South East Scotland Research Ethics Service (appendix 3). The Pharmacy Quality Improvement Team gave their approval to the study in December 2012 (appendix 4).

The investigation team was aware of the names and profession of the interviewees. The interviewees were assured confidentiality by the information leaflet (appendix 5 and 6) and by the investigator before the interview started. Two nurses in the osteoporosis clinic organised the interviews on behalf

of the investigator team and were therefore aware of which patients were interviewed. The audio recordings were kept securely in the office at Pharmacy Education, Research and Development department whilst being transcribed. After anonymous transcription the recordings were deleted.

Names and addresses of the patients on denosumab were known by the investigator to enable questionnaires to be posted to the patients. All participants were assured confidentiality by the questionnaire cover letters (appendix 7, 8 and 9) and the returned questionnaires were anonymous. No patient or staff identifiable data is included in the study report.

4 Methods

According to the objectives presented in section 2, this study is divided into three different parts which are based on each other as described in figure 4-1. First, the current patient journey (described in section 4.1.1) had to be established to work as a foundation for the proposed patient journey (described in section 4.1.2). Second, the current patient journey also served as the basis for the development of the interview guides used in the qualitative interviews (described in section 4.2). Furthermore, the qualitative interviews informed the design of three questionnaires. Consequently, the questionnaire survey is the last part of the methods (described in section 4.3); in accordance with the objectives (see Table 4-1).

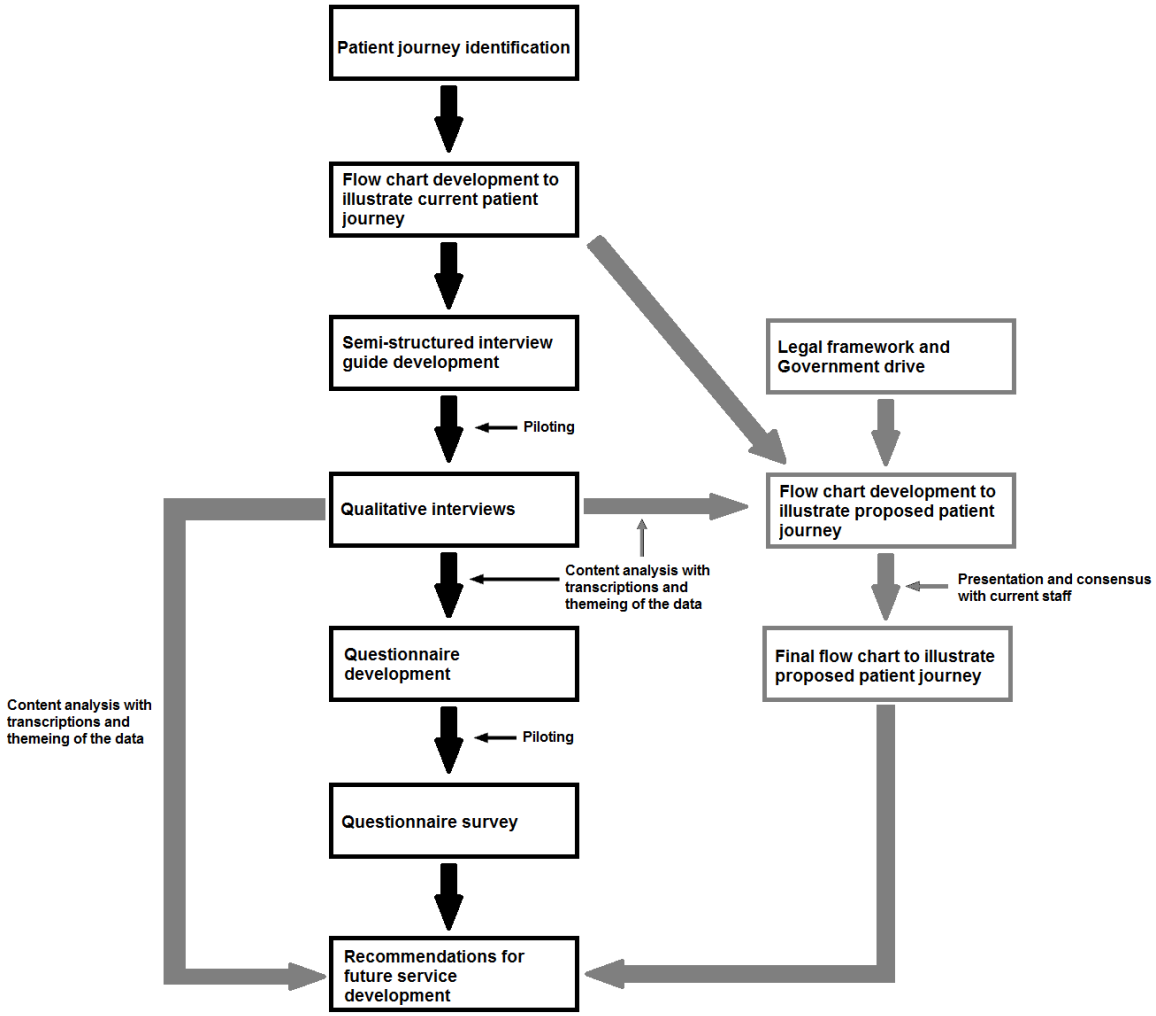

Figure 4-1: Flow chart describing the process of the study and the different study elements.

Table 4-1: The connection between objectives, methods and results of the study, and where the different elements are presented in the thesis.

Objective	Section	Methods and foundation of result	Section	Result
1: Propose potential pathway(s) of care for the shared management of osteoporosis across primary and secondary care	4.1.1	Identification of current patient journey	5.1.1	The current patient journey
	4.1.2	Proposal of current patient journey	5.1.2	The proposed patient journey
	4.2	Qualitative interviews		
	1.3.2	Framework		
2: Design questionnaires to survey stakeholders involved in the delivery of the current and proposed service	4.2	Qualitative interviews	5.2	Qualitative interviews and three different questionnaires
3: Explore patients' and health care professionals' experience and thoughts concerning current and future osteoporosis management	4.3	Questionnaire survey	5.3	Questionnaire survey

4.1 Pathways of care for the shared management of osteoporosis

4.1.1 The current patient journey

Two flow charts were developed following advice from an osteoporosis specialist nurse to illustrate the referrals and the current pathway of care for patients when diagnosed with osteoporosis, referred to in this thesis as "patient journeys". The most experienced osteoporosis specialist nurse was chosen as the most suitable member of staff to instruct the development of the current patient journey flow chart. These were used during the qualitative interviews (see section 4.2) to illustrate to the health care professional interviewees the current patient journey (see appendix 10 and 11 for the flow charts used in the interviews). During interview with physicians 2 and 3 (see appendix 12 for transcriptions of the interviews) some details were corrected by the interviewees and modifications were made (see

section 5.1 and appendix 13 for updated flow charts). The flow chart describing the referrals was considered unnecessary and is not included as a result. The description of the current patient journey, including the updated flow chart, was confirmed by the osteoporosis specialist nurse and a professor involved in the management of osteoporosis. The professor is also a consultant in osteoporosis at the Western General Hospital. The updated flow charts were not used for the later interviews to maintain the continuity of the interviews. The modifications did not influence the interviews.

4.1.2 The proposed patient journey

The proposed patient journey flow chart was made after the qualitative interviews were undertaken. This was to assure every aspect of the current and proposed patient journey was covered. The proposed journey was developed from the current patient journey and was based on legal, political and practical considerations, as described in the introduction (section 1.3.2) and discussions within the study team. The patient journey deemed optimal based on the considerations stated above was described in further detail.

All flow charts used in the study were made by the investigator using a graphic painting programme (Paint; an integrated part of Windows® 7).

The proposed journey was presented at a rheumatology meeting on 8th May 2013 with the option of providing feedback.

4.2 Qualitative interviews and questionnaire design

In this section, the design, planning and the execution of the qualitative interviews are described, in addition to the development of the three questionnaires used in the questionnaire survey.

4.2.1 Qualitative interviews

4.2.1.1 Design of semi-structured interview guide

Literature about semi-structured interviews was read and used to develop questions and appropriate interview technique (62-65). The questions were developed and selected after identification and development of the patient journey flow chart and discussion within the investigation team. The investigator had not met any of the other interviewees prior to the interview, except for the osteoporosis specialist nurse who contributed to the illustration of the current patient journey.

4.2.1.2 Recruiting participants

An invitation letter, information sheet and consent form were designed and agreed (see appendix 6). This was attached to an invitation e-mail sent from the investigator to the health care professionals. The community pharmacist and the GP were contacted via e-mail by the academic supervisor prior to the e-mail invitation. The osteoporosis specialist nurses and the physicians involved in the current osteoporosis service were contacted via e-mail by the clinical supervisor prior to the e-mail invitation. This was to inform the participants that the study was under the auspices of the supervisors. The patients were phoned by an osteoporosis nurse specialist as an invitation to the study. Patient one and two received the patient information leaflet by post (see appendix 5). Patient three received the patient information leaflet from the osteoporosis nurse specialist at the clinic. All participants accepted the invitation.

4.2.1.3 Piloting the interview guide

Only one pilot interview with health care professionals was undertaken based on the interview guide being very much alike for the different professions and the assumption that the health care professionals have a similar focus. The pilot interview was a hospital pharmacist selected and invited via e-mail by the clinical supervisor. The interview guide was commented on after the interview by the interviewee. After the pilot, the question "are you familiar with denosumab?" was added and one question was asked twice and therefore removed.

The first patient interview was treated as a pilot and minor modifications were made to the questions after the interview. Three questions were added, in addition to two prompts and two clarifications. The questions added were:

- "How much time does it take you to travel to the Western?"
- "How much time does it take you to travel to your community pharmacy?"
- "What does the nurse do during the denosumab visits?"

See appendix 14 for pilot and final interview guides.

4.2.1.4 Execution of interviews

The interviews were undertaken one-to-one, from the 5th of November until the 3rd of December 2012, by the investigator using the semi-structured interview guide.

The interviewees received information about the investigator's professional background and the purpose of the interview before it started. All the interviews were audio recorded with a digital voice

recorder (Olympus® DS-50), except for one patient who did not agree to be recorded. Notes were then taken. The interviews lasted between 17 and 38 minutes.

4.2.1.5 Transcription and analysis

After the interviews were undertaken, the investigator manually transcribed the interviews verbatim using a document and word processor software (Microsoft® Office Word, 2007). The interview that was not recorded was transcribed based on physical notes and memory.

If the audio recordings were difficult to interpret (e.g. due to background noise or language difficulties), transcriptions were double checked by an administrator not involved in the study. The interviewees were kept anonymous for the administrator.

All transcriptions were read by the investigator team prior to analysis. The transcriptions were analysed using conventional content analysis (66). The themes were made whilst analysing; an approach consistent with recommendations by Hsieh and Shannen (67).

4.2.2 Questionnaire development

The questionnaires were developed based on the qualitative interviews described in section 4.2.1, literature concerning questionnaire design and discussion within the study team (62, 64, 65, 68, 69).

4.2.2.1 Design of questionnaires

Three specific questionnaires were designed; one for patients (see appendix 15), one for community pharmacies (see appendix 16) and the final for GPs (see appendix 17). The questionnaires were made using a document and word processing software (Microsoft® Office Word, 2007). Due to the distribution mode used for the GP questionnaire, it was transferred from the software to an online survey tool (SurveyMonkey®, https://www.surveymonkey.com) prior to distribution.

4.2.2.2 Piloting

The three questionnaires were piloted separately by the investigator.

The patient questionnaire was piloted on one patient receiving denosumab at the osteoporosis clinic (see pilot version, appendix 18). All questions were read aloud and were fully understood. The results from the pilot was analysed by the study team, and two questions were clarified in addition to the introduction. Three more pilots planned were cancelled because two patients did not attend the clinic appointment and one patient suffered from dementia.

The community pharmacist did not have any comments to the cover letter, understood the questionnaire items and completed the questionnaire without making any comments. The questionnaire was also sent to the Associate Director of Contracted Community Pharmacy Services in NHS Lothian who recommended clarifying the sentence regarding NICE guidelines in the cover letter. The sentence was amended after the feedback.

The pilot GP questionnaire (see pilot version, appendix 19) was sent to the Allied Health Professions Director in NHS Lothian and the Quality and the Safety Assurance Manager for feedback. Feedback was only received from the latter. First, it should be described in more detail how the results will influence future NHS Lothian policy, and second, it should be considered not having the "neither disagree, nor agree" – option. The study team concluded that the "neither disagree, nor agree" – option was appropriate for this study, and decided not to add further information for GPs.

Feedback was provided from only one of three GPs asked to participate in the pilot. The GP reviewed the e-mail invitation and the questionnaire. The feedback from the GP pilot was that the questionnaire asks questions about the use of the drug interspersed with questions about community pharmacy and some statements need rewording. The feedback was discussed by the investigator team which resulted in the removal of one statement and amendment of statement five in the final version.

4.3 Questionnaire survey

4.3.1 Patient survey

One clinic version and one postal version of the patient questionnaire were made. They were identical except for the introduction and cover letter which explained the different methods of returning the questionnaire.

The clinic version was handed to the patients whilst waiting for their appointment between the 28th of January 2013 and the 8th of March 2013. They also gave instructions that the patients should only complete the questionnaire once and that the patient could hand the questionnaire to the nurses after they had completed it. This was also written on the questionnaire to emphasise the importance of only completing it once.

Postal mail with white envelopes was used to distribute the postal questionnaires to the patients. For the patients having an appointment in February or later, their appointment reminder letter was included in the envelope with the questionnaire. The patients having an appointment prior to February, or for those whom appointments were not yet allocated, the appointment letter was not included. The postal patient questionnaires were returned by prepaid return envelopes which was included in the white envelope used for distribution. The postal patient questionnaire was sent the 31st

of January 2013. No questionnaires were returned after the 8th of March 2013, giving the participants 35 days to reply.

4.3.2 Community Pharmacy survey

Fax was used for distribution to the pharmacies and for the return of the questionnaires to the study team, which is the usual process of communication between the NHS board and community pharmacies. A third party administrator, who was not involved in the study, removed the fax numbers to depersonalise the questionnaires prior to analysing. The pharmacy questionnaire was distributed the 11th of February 2013. No questionnaires were returned after the 8th of March 2013, giving the participants 25 days to reply.

4.3.3 GP survey

E-mail was used to distribute the online questionnaires to the GPs using a weekly newsletter normally communicated between the health board and GP practices and then disseminated to individual GPs. The newsletter is distributed to practice managers and the practice senior partner in 126 GP practices in Lothian. The GP practices organise their own dissemination internally to about 500 GPs. The exact number of GPs continually change and is therefore not known. The distribution also goes to key people within NHS Lothian (e.g. Clinical Directors, General Managers and Development Managers). The invitation letter (see appendix 9) was included as an attachment with a link to the electronic survey. The newsletter contained a brief explanation of the study. The GP questionnaire was distributed the 7th of February 2013 and the online survey link was closed on the 11th of March 2013, giving the participants 32 days to reply.

4.3.4 Reminders

All questionnaires had an initial deadline of two weeks. After the two weeks, a reminder was sent giving an additional week as a new deadline (see appendix 20 for all reminder letters). The same method of distribution as the initial questionnaire was used for the reminders. The pharmacy reminder included a second copy of the questionnaire and the GP reminder included the questionnaire link. The patient reminder asked to use the previously sent questionnaire.

4.3.5 Analysis

The questionnaire data were coded (see appendix 21-23) and manually organised using spreadsheet software (Microsoft® Office Excel, 2007). A random sample test was undertaken to validate data entry and coding. The test was undertaken by a third party investigator who took a random sample of at least ten percent of the total included questionnaires and double checked the data entry and coding.

Due to the variation in answers for questions with interval scale (travelling) and open ended questions (comments), some generalisation had to be done for correct analysis. If the time was written in an interval, the middle of the interval was included as the time (e.g. 10-20 minutes was coded as 15 minutes). If a patient chose different methods of travelling, the most inconvenient travel in regards to time was included in analysis, e.g. when a patient answered "bus: 90 minutes" and "car: 45 minutes", 90 minutes were included because this was the most inconvenient travel. Every comment given in the GP or patient questionnaire was content analysed and thus coded under themes.

There were two pharmacies who answered statement 5 ("Through medication reviews I am able to encourage patients to adhere to their medication") with "not applicable" because the pharmacy did not undertake medication reviews. The answer was interpreted as "neither agree, nor disagree" and counted as a fully completed questionnaire.

Some of the returned patient and pharmacy questionnaires were not fully completed. If a participant did not feel comfortable answering some questions or skipped a part of the questionnaire, the response provided was valuable for the purpose of the study. Partial responses were therefore included in analysis. One exemption was made in the patient questionnaire due to a chi square test (see appendix 24). The chi square test compared prior knowledge to community pharmacy services, to being comfortable receiving the denosumab injection by a pharmacist. If either questionnaire item number 13 or 14 was not completed, the item completed was removed from analysis. Another chi square test compared the patient-pharmacy relationship to the patient-nurse relationship, but did not encounter the same problem.

The raw data of the questionnaire were summarized in one table for each question/statement and appropriate descriptive statistical tests were used to obtain the opinions. The statistical methods applied to the data were done by spreadsheet software (Microsoft® Office Excel, 2007), including chi-square test. The data was considered not to be normally distributed by a simple plot and by comparing the mean and standard deviation. If the standard deviation was more than half the mean and/or the simple plot showed that the data was not normally distributed, the median and interquartile range (IQR) was used to describe the interval data.

5 Results

The results are presented in the same order as the objectives and methods. It will start with the current patient journey in NHS Lothian (5.1.1) to form the basis of the proposed patient journey (5.1.2). The journeys are followed by the qualitative interviews (5.2) which served as the foundation for the proposed patient journey, but also informed the design of the questionnaires. The questionnaire survey is presented in 5.3.

5.1 Pathways of care for the shared management of osteoporosis patients treated with denosumab in NHS Lothian

5.1.1 The current patient journey

The current patient journey is described briefly to illustrate the journey from diagnosis to treatment with denosumab (see figure 5-1). It should be emphasised that the following description is a general pathway and cases in clinical practice may differ from this description.

The patient journey starts with investigations to confirm the diagnosis of osteoporosis which can be initiated either by GPs or by physicians in secondary care (e.g. after a fall, low trauma fracture or as an inpatient). The doctor will refer the patient for confirmation of the diagnosis by a DXA scan. A diet questionnaire is given to assess the intake of calcium. By using calculations the nurses assess if the diet contains the recommended amounts of calcium (1,000 mg per day) (12).

After the patient has confirmed osteoporosis by a DXA-scan, the patient may experience one of four different pathways of care, referred to as “patient journeys”:

1. The patient case is osteoporosis (i.e. T-score between -2.5 and -4.0)
   - First line treatment: bisphosphonates
2. The patient case is complicated due to a T-score under -4.0
   - Treatment: parathyroid hormone (teriparatide)
3. The patient case is complicated due to first line treatment being unsuitable
   - Second line treatment: strontium ranelate or zoledronic acid
4. The patient case is complicated due to first and second line treatment is unsuitable
   - Third line treatment: denosumab

The different patient journeys in NHS Lothian are briefly described below and included in the current patient journey flow chart for patients receiving treatment with denosumab.

5.1.1.1 Patient journey 1: First line treatment

After the DXA scan, the GP receives prescribing recommendations according to the Lothian Joint Formulary. Currently, the first choice is oral alendronate, 70 mg orally once a week, 1000 mg calcium and 800 international units of colecalciferol (vitamin D_3) daily (21). All oral treatment with bisphosphonates is prescribed and managed by the GP in primary care.

5.1.1.2 Patient journey 2: Treatment for T-score < -4.0

If the T-score is less than -4.0, the patient is referred to the bone clinic for further evaluation by a physician. Parathyroid hormone is the preferred choice of treatment and is often given as the 1-34 fragment (teriparatide) (20). The patients themselves or their carers must administer teriparatide subcutaneously every day.

5.1.1.3 Patient journey 3: Second line treatment

These patients will also need further evaluation in secondary care and are referred to the bone clinic. Currently, the second line treatment is strontium ranelate or zoledronic acid. Strontium ranelate is initiated in secondary care and the management is in primary care. Feedback from the staff who currently run the osteoporosis service indicate that they initiate strontium ranelate only in patients who refuse injections, although the current Lothian Joint Formulary states that oral osteoporosis treatment as the preferred option (21). Zoledronic acid is administered once every year as an infusion at the Western General Hospital.

5.1.1.4 Patient journey 4: Third line treatment

If denosumab is initiated, the patient has a medicine chart in the osteoporosis clinic and comes back every six months to the osteoporosis specialist nurse at WGH, where the subcutaneous injection is given. The osteoporosis specialist nurse speaks to the patients and asks about side effects. In addition, a brief falls assessment is performed by looking at the patient's gait. If the patient looks unsteady, falls are regarded as more likely than if the patient looks steady. In a few exceptional cases, patients have a special agreement to receive injections at St John's Hospital in Livingston (West Lothian) or a special agreement with one of the osteoporosis specialist nurses to receive the injections in their home. The special agreements are considered individually based on the patient's inability to travel to WGH. No patients in Lothian self-administer denosumab.

As denosumab was introduced in 2010, it has not been formally decided when the patient review of treatment should take place. Every two or three years is suggested by the physicians as an initial recurrence of the review which will include a DXA scan.

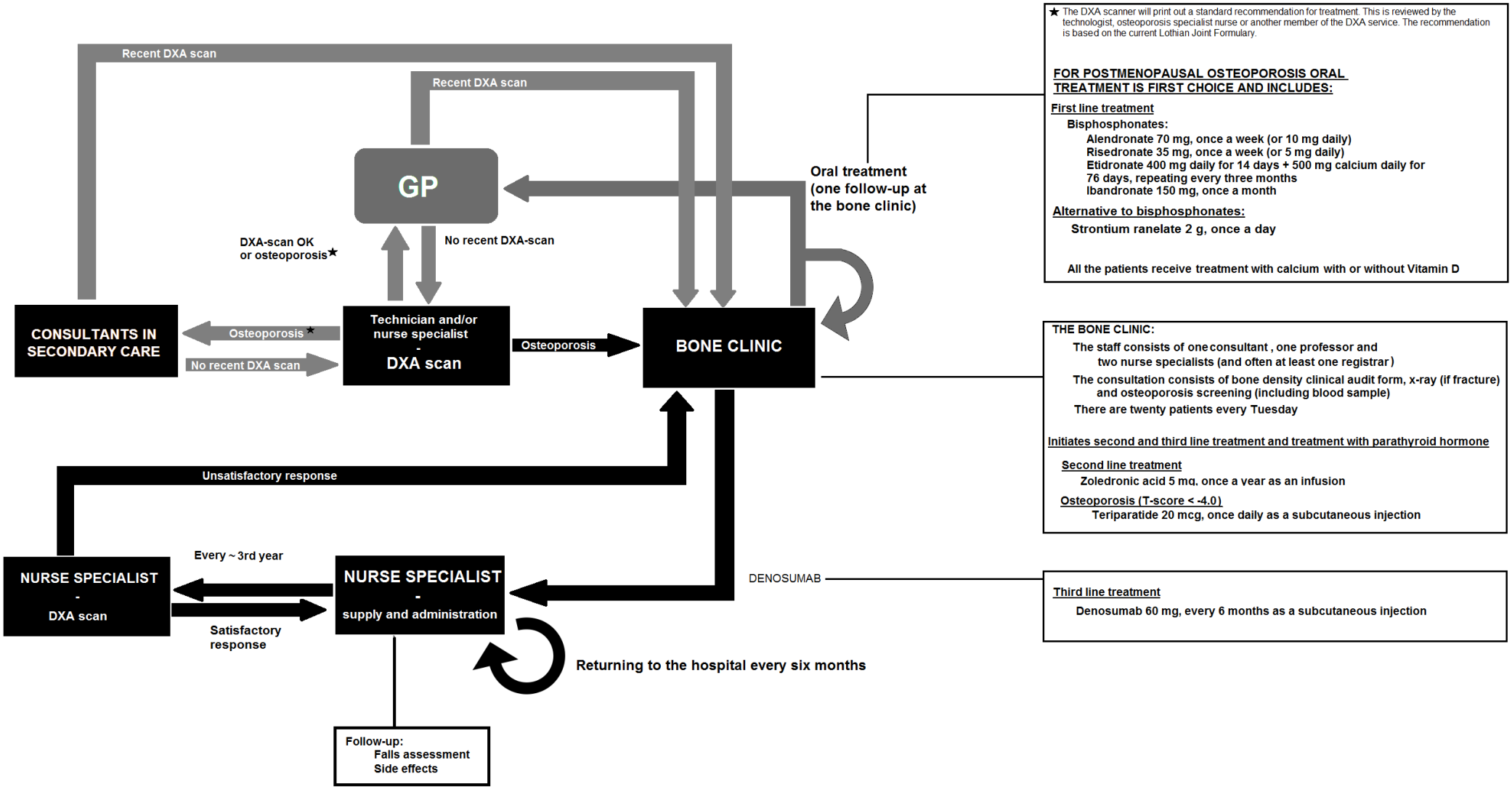

Figure 5-1: Flow chart of the current patient journey for osteoporosis patients receiving treatment with denosumab at the Western General Hospital.

5.1.2 The proposed patient journey

The proposed patient journey has the same journey until denosumab is expected to be initiated (see figure 5-2). There are two scenarios when the patient is expected back to the bone clinic for further evaluation:

1. **Osteoporosis managed in primary care**
   - The patient is treated in primary care
   - The GP identifies that first and second line treatments are unsuitable
   - The patient is referred to the bone clinic by the GP
   - The blood sample requested as a base line investigation is taken at the GP practice
   - Results are communicated to the bone clinic prior to the hospital appointment
   - The patient is prescribed denosumab at the hospital and receives the first injection

2. **Osteoporosis managed in secondary care**
   - The patient is treated in secondary care
   - The patient is deemed to require third line treatment
   - The blood sample requested as a base line investigation is taken in the hospital
   - A second hospital appointment is allocated
   - The patient is prescribed denosumab at the hospital and receives the first injection

5.1.2.1 Hospital appointment with the initial injection of denosumab and choice of community pharmacy

When the initial denosumab injection is given in the hospital, the patient freely chooses a community pharmacy. A review appointment with a consultant in the hospital is scheduled two years from the date of denosumab initiation. This review appointment includes a DXA scan to investigate if the patient has a satisfactory response. A standardised form is sent by fax to the community pharmacy. The form includes details of the patient, such as blood levels of calcium and vitamin D, results from last DXA scan and the date of the next review appointment. The community pharmacy includes the patient in the journal system made especially for denosumab patients, whilst waiting for the prescription.

In the proposed model, there would be agreement to dispense from a hospital prescription in community pharmacies which is a deviation from standard procedure in Scotland. The prescription is a hospital repeat prescription which is valid for two years (until the review appointment). The prescription is sent by post at the same time as the fax and contains the dates denosumab should be

injected. After receiving the repeat prescription, the community pharmacy allocates an initial pharmacy appointment for the patient to receive the injection according to the form sent by the hospital. There is opportunity to provide a wider osteoporosis service from the community pharmacy.

5.1.2.2 Initial pharmacy appointment and proposed service

The initial appointment with the community pharmacist will include the injection of denosumab, assessment of falls risk and need for calcium and vitamin D.

A medication review is not undertaken because the pharmacist needs to gather more information from the patient. For the pharmacist to have an overview of all the medication the patient is receiving, the initial appointment will include a discussion about medication and health issues, including adherence to medication and current diagnoses. This discussion will serve as a baseline investigation for the pharmacist to undertake a thorough medication review on the second pharmacy appointment.

The pharmacist assesses falls risk by using the FRASE questionnaire and by the FTSST (see section 1.4.1). The pharmacist also assess the need for calcium by using an online calcium calculator from the Centre of Molecular Medicine (70). The need for vitamin D is assessed using a questionnaire. This questionnaire needs to be developed prior to implementation of this proposed service (see section 6.4).

Furthermore, a report is sent by fax to the osteoporosis clinic at Western General Hospital and the GP practice to inform that the patient is currently being treated by the pharmacist. The pharmacist now has responsibility for the patient's osteoporosis treatment for the next two years. The results from each element of the pharmaceutical care package are described in the report. The report will also clearly state if the patient needs a GP appointment or to be contacted by the hospital. If there, for any reason is a part of the service that is not delivered, the report must explain the situation and why that part was not delivered. A second report needs to be sent for remuneration of the service, which can be sent via fax or by being linked to the ePharmacy's online reporting scheme.

The second pharmacy appointment is allocated with a written letter for the patient at the end of the initial appointment. A reminder letter is sent to the patient one month before the second appointment.

5.1.2.3 Second pharmacy appointment

The hospital prescription is, as explained above, valid for two years. In that period, the patient receives pharmacist-led health care every six months.

A medication review is undertaken before the patient returns for the second appointment. The medication review will be following a structured protocol which is described in the Polypharmacy Guidance document from 2012 (71). The pharmacist goes through the medications with the patient on

the second appointment and discusses the identified drug therapy problems and potential solutions. Adherence with medicines is in focus throughout the entire medication review. A potential discussion with the responsible doctor about drug therapy problems is done ideally during the appointment or, if not feasible, after the appointment. In the latter scenario, the patient will be contacted by the pharmacist after discussion with the doctor.

In addition to the medication review, the pharmacist administers denosumab and undertakes assessment of falls risk and the need for calcium and vitamin D supplements, as described in the initial pharmacy appointment (section 5.1.2.2).

Furthermore, a report is sent by fax to the osteoporosis clinic at Western General Hospital and the GP practice to inform that the patient has received pharmacist-led health care for the n^{th} time. This is the same report as the initial pharmacy appointment and includes the same elements. A second report is also sent for remuneration of the service, as in the initial appointment.

The next appointment is allocated for the patient with a written letter and reminder letter. The following appointments are delivered in the same manner as the second appointment. It will be the community pharmacists' responsibility to assure that the patients receive the pharmaceutical care package (including administration of denosumab) and that the service is delivered in accordance with set criteria. This means that the pharmacist must follow-up patients who do not attend their allocated appointments.

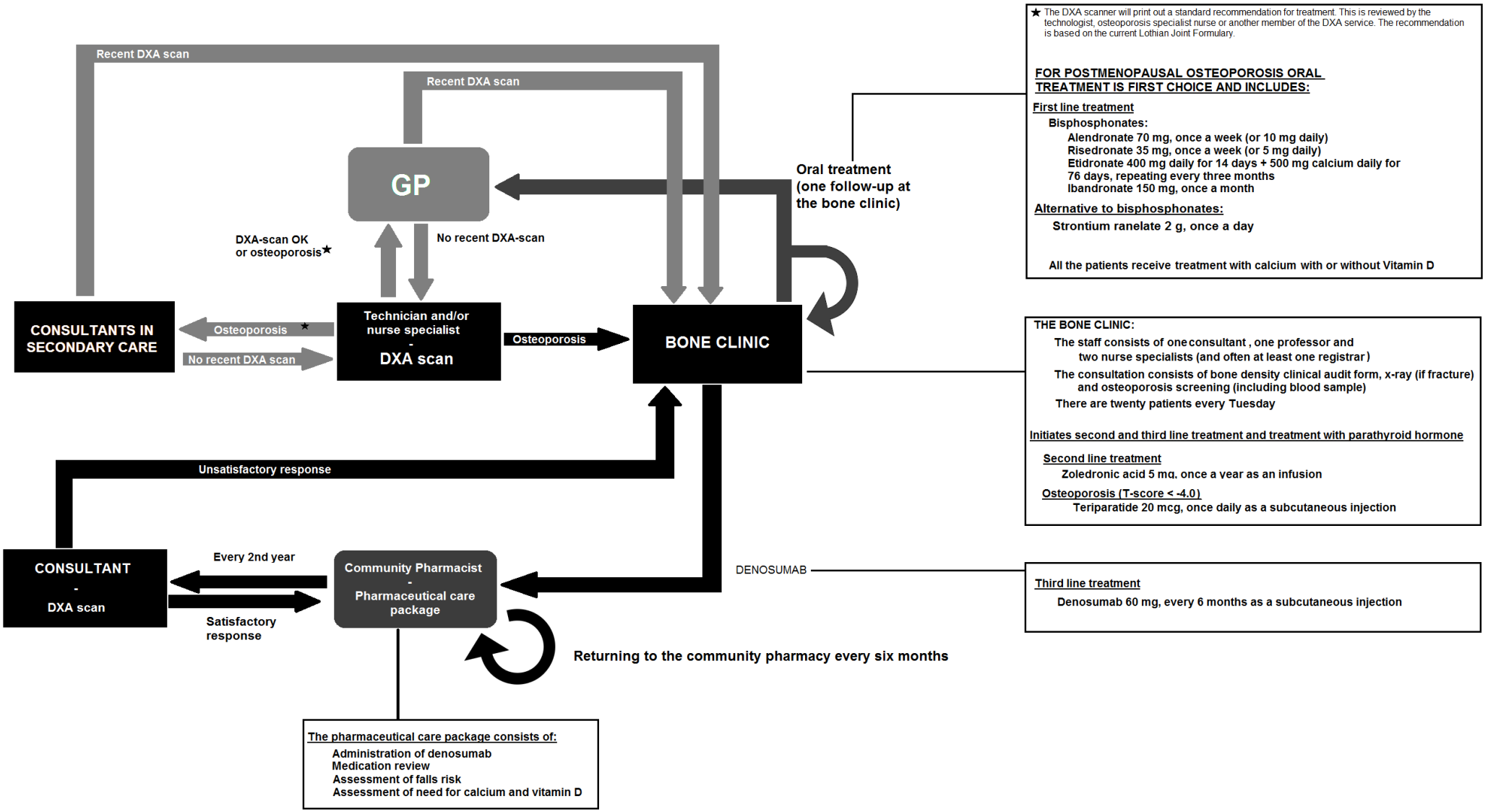

Figure 5-2: Flow chart of the proposed patient journey: shared care between Western General Hospital and community pharmacies in NHS Lothian for patients receiving denosumab treatment.

5.1.2.4 Information in the interviews that led to specific proposals

The semi-structured interviews (see section 5.2) led to some specific questions which were given as details in the proposed journey.

The proposed patient journey will provide care locally and support the government drive towards having treatment in the community. This shift of care was expressed as positive and convenient by all interviewees. Although patient review of denosumab theoretically could be done by a GP, it was perceived by the physicians and patients as best in secondary care. Some suggestions were given on the recurrence of the review and two years was decided as an initial proposal in the light of the recent approval of denosumab and novel approach to care.

The interviews emphasised the need for proper governance of the service and to determine the responsible health care provider. This led to the proposal that a community pharmacist is responsible for the patients' osteoporosis management until the next hospital appointment, i.e. for two years at a time. For the pharmacist to keep track of the patients, it was deemed necessary for the pharmacy to allocate appointments to the patients. To inform the hospital that the patient is being treated by a pharmacist, there was an expressed need for communication and that the modes of communication must be governed to deliver responsible and safe shared healthcare among all professionals involved. Using a fax machine was decided to be practically convenient in the current climate when community pharmacies are not linked electronically. However, it was mentioned that an electronic communication system, where pharmacists, GPs and hospital physicians have access to TrakCare®, would be more secure. This would open up for the community pharmacies to access the patients' medical records, which the hospital pharmacist explained as the optimal foundation of a medication review. As the community pharmacist does not have access in the current climate, it was compensated by the discussion about which medications the patient is currently taking in the initial pharmacy appointment. The information gained from the discussion will serve as proper foundation of a medication review without having access to medical records.

To deliver pharmaceutical care in a community pharmacy, proper remuneration was regarded as compulsory. This requires another form of communication, where a standardised form has been suggested to be sent after the service has been delivered for proper remuneration through the Health Board.

5.1.2.5 Presentation of the proposed patient journey and consensus

The proposed journey was presented at a rheumatology meeting with the option of providing feedback. The staff who attended the presentation was two osteoporosis specialist nurses and one professor. There were seven additional consultants in rheumatology. The feedback was positive and the comments given did not change the proposed patient journey. They were also positive to the idea

of communicating via fax and agreed that an electronic method would be ideal. The professor asked the clinical supervisor when they could implement the proposal. It was also mentioned as transferable to other similar treatments.

5.1.2.6 Alternative pathways of care

Two other alternatives were considered in addition to the proposed patient journey. The first alternative was the same as the proposed patient journey, but with a renewal of the prescription done by a qualified pharmacist independent prescriber. Due to the Joint Formulary Committee's specification of specialist use only, and the limited number of pharmacist prescribers, this alternative was rejected (28). The follow up from the hospital with a DXA scan would also be difficult because of limited communication between the hospital, the GP practice and community pharmacies.

The second alternative was prescribing and administration in a GP practice after having a DXA scan in the hospital. This alternative was rejected for the same reason as for the qualified pharmacist independent prescribers. The alternative pathways of care were not described further.

5.2 Qualitative interviews

One hospital pharmacist (HP), one community pharmacist (CP), one GP, two osteoporosis specialist nurses (N1-2), three physicians (P1-3) and three patients (Pa1-3) were interviewed (see Table 3-1 for details on participants and appendix 12 for transcriptions). The pilot interviews are included in the analysis, as the interview guides were similar to the final version.

From content analysis of the interviews, four themes with a total of thirteen subthemes appeared (see Table 5-1). In the following section, quotes regarded as most important are presented together with the subthemes that led to the questionnaire items and details in the proposed patient journey. Some subthemes were included in the questionnaires and are explained under each applied subtheme. This was to seek wider opinions of the stakeholder groups and to establish where there is no consensus and work would be required to move towards consensus for a future service redesign.

The details that led to the proposed service are explained in section 5.1.2.4.

Table 5-1: Interview themes and subthemes appearing from content analysis of the interviews.

Theme	Subtheme
Advantages from patient perspective	The existing pharmacy services
	The pharmaceutical care package
	Relationship
	Convenience
	Additional ideas*
Advantages from the organisation** perspective	The pharmacist role
	The osteoporosis service
Disadvantages from the patient perspective	Comfortable with GP practices
	Relationship
	Hospital expertise
Challenges from the organisation perspective	Governance and organisation
	Delivery of the service from pharmacies
	Communication

* Additional ideas are described in appendix 25.
** Organisation, i.e. NHS Lothian (including community pharmacies, the GP practices and the hospital).

5.2.1 Advantages from patient perspective

In the following section, a total of four aspects mentioned as advantages from the patient perspective are presented (the existing pharmacy services, the pharmaceutical care package, a good patient-pharmacist relationship and increased convenience).

5.2.1.1 The existing pharmacy services

The idea that the pharmacist-led service is intended to be situated in the community pharmacy was regarded as an advantage. This was due to the impression of patients getting more used to receiving direct clinical care in the pharmacy and not exposing them to something new and unfamiliar, which the GP also recognised:

"(...) *patients are getting more used to pharmacists providing some direct clinical care, so things like blood pressure, blood glucose monitoring, smoking cessation advice, pregnancy testing, and so on* (...)*"* (GP)

In particular, influenza vaccinations were mentioned as similar to the proposed service because the pharmacist is administering an injection. One of the patients expressed:

"That's not a problem [getting the denosumab injection in the pharmacy], *because, as I highlighted earlier, things are being passed more from doctors into pharmacies. People who have expertise that they're doing flu-jabs, so as far as I'm concerned it would just be another injection. Yeah. As long as it's the right inject... No, you know what I mean, but it's just... that it wouldn't faze me at all."* (Pa1)

The community pharmacist described the proposed service as transferable to other services involving injections, one of which is the drug-misusers vaccination programme. This would be an advantage for a wider range of patients if implemented, and was mentioned as following:

"(...) *the skills are transferable and the more you are doing this sort of thing the easier it will be to do... to... to... expand, shall we say, services involving injections?* (...)*"* (CP)

None of the patients interviewed had personal experience of the already existing pharmacist-led clinics, but were aware of services delivered from community pharmacies. A question regarding awareness of existing services was consequently included in all questionnaires.

5.2.1.2 The pharmaceutical care package

The pharmaceutical care package in the community pharmacy was regarded as positive for the patients. As expressed by several interviewees:

"It's kind of all bringing it together." (CP)

"I think the shift of care is, is fine. And it makes sense. There's no reason for someone to go to hospital just to have an injection given by a nurse. It made more sense for that to be done in the community." (GP)

"Well, hopefully, it [the pharmaceutical care package] *would reduce falls and thereby reduce fractures. So, I mean, it's... I think a global package like that, I – I think it gives patients confidence and should be a benefit to them. So from my point of view it's a, it's a no-brainer."* (P1)

If the pharmacist undertook all the elements involved in the service, the interviewees did not have the perception that any part of the current patient care would be missed. This was explained by both osteoporosis specialist nurses and the physicians interviewed:

"No [there's nothing pharmacist couldn't do]*, 'cause all we're checking is that they've not had any new falls or fractures."* (N1)

"I can't think so [that the patients would miss anything]. *Because when patients... at the moment they come up to the hospital and they just come up, "I'm here for my denosumab-injection", we give them the injection and then they go away again."* (P3)

A perception of the pharmacist having a holistic approach, being aware of other medication and being able to share their pharmacological knowledge was considered to be an advantage for encouraging adherence. Delivering the pharmaceutical care package may remove the need for patients to attend the hospital. The hospital pharmacist explained advantages that might benefit the patients:

"(...) *the pharmacists are perhaps more comfortable with dealing with side-effects of the drugs and more familiar with the pharmacology of it, they might be able to give the patients more information.* (…) *The pharmacists might have greater understanding how the drug works.* (…)*"* (HP)

It was recognised that the hospital did not have the capacity to deliver the pharmaceutical care package in the current climate.

"I think that it [delivering the pharmaceutical care package] *would be advantageous because in the hospital there's not the capacity to do these kind of reviews, there just isn't the capacity. And if we had the capacity to bring patients back every six months, do a medication review, check compliance, ask about calcium and vitamin D, that would be ideal, but we cannot. We just don't have the staff. So, if that could be done in community pharmacy it would be great and it would be a big advantage."* (P3)

When discussing the package as a whole, only one interviewee (Pa2) was reluctant and suggested that patients should be able to choose where they receive health care. It was therefore important to include patient choice of preferred venue in the questionnaire.

"I would rather still take it in the hospital, (...) *But we should be given the choice whether to have it in the hospital or in the pharmacy. I'd rather go to the hospital. I would be comfortable with having the injection at my doctor* [GP]*."* (Based on notes from interview with Pa2)

Medication reviews

One element of the proposed pharmaceutical care package is medication reviews. A medication review in the community pharmacy was regarded as a good service for patients. Two physicians stated that a pharmacist might be better than a physician or GP doing the medication review. A medication review was considered to increase adherence to medication, as the GP expressed:

"*It* [a medication review] *would increase, it would increase understanding. And that, and hopefully satisfaction and they usually lead to increased adherence*. (...) *So, pharmacists are experts in medication, so I would expect that they would be better at doing a medication review* [than nurses or physicians]. *I think they have, ehm, the quality is better in many ways, in that it is more detailed and more thorough and, pharmacists often have a better knowledge about side-effects and interactions."* (GP)

The patients described different perception of the information given by a pharmacist, where one patient said the pharmacist goes through medications and one patient said that no one is going through the medication. The last patient explained that the pharmacist gives information if there is anything extraordinary, but did not feel she was provided with enough information and would therefore like more:

"Not usually [pharmacist going through medications]. *They do* (...) *if it was something* (...) *that I was getting that, you know, a pain-killer or something they might say, you know, you have to be careful in how you use it and... if there was some* (...) *codeine in it, so they would just take it for so many days and they might, you know, do that but they don't usually go over the medication with me* (...) *Yes* [it would be a good idea], *because when I came here first... and they were putting me on the... the injection* (...) *he* [the physician in the bone clinic] (...) *handed me this, sort of, leaflet and* (...) *you just don't have time to read it.* (...) *and I thought "oh my God, am I going to have side-effects to this", you know, and I didn't think he gave me the time to actually read through, you know, what he was presenting me with. You know, and it would be quite nice if somebody, sort of, took the time to, sort of, say "well, these are the... the", and I just didn't have time to read it all. You know, and then I had to sign it. You know, to get my consent. I thought "my God, I can't remember what it said!",* (...) *they don't give you enough time to go over it. I don't think."* (Pa3)

The hospital pharmacist had the perception that patients would speak more freely to a pharmacist than a doctor, which may be an advantage in identifying non-compliance, a problem mentioned by several inteviewees:

"My experience sometimes is by asking the right questions and sometimes the patient might be less... less anxious about telling the pharmacist the truth, then they are by, say, telling the consultant or the GP, that's actually prescribing the drugs and he's told them "you have to take it", they don't like to say "oh, I've not managed it"." (HP)

Assessment of falls risk

Assessment of falls risk is another part of the proposed pharmaceutical care package not currently delivered and was described as feasible by most of the participants.

"Well, I think the pharmacist would be well able to cover the side-effects. And, falls assessment is a fairly straight forward thing." (GP)

The community pharmacist explained that if the falls assessment sheet was provided, a pharmacist would be able to undertake the task:

"If we [community pharmacists] *were privy to that, that sheet that we've got to follow, we could do that."* (CP)

However, one physician thought it would be too complicated.

"Whether you can do a falls assessment in pharmacy, I think is more challenging. Because it's quite a complicated, you know, there's so many things that can contribute to falls. I couldn't see that working, I think it be just too complicated." (P3)

The patients expressed that they would be comfortable with a community pharmacist asking about falls.

Assessment of the need for calcium and vitamin D supplements

The last part of the package is an assessment of the need for calcium and vitamin D supplements. One of the issues regarding calcium and vitamin D supplements was non-compliance. If pharmacists were given sufficient time during consultations with the patient, the community pharmacist could increase compliance by talking to the patients about the importance of compliance and by selecting the right preparation for the patient. This was expressed by the community pharmacist:

"I find that possibly giving more time in a consultation you can pick up on the, on words like "I'm supposed to" at the end, then you say "What do you mean by, I'm supposed to?". "Ahh, that's because I don't take them, you know". So we, through counselling skills, we're probably in a better position to identify non-compliance to coax, cajole, whichever word you want us to use, people need to take what's been prescribed or we can come up with an alternative that will do, that is palatable, that they're happy to take." (CP)

The current osteoporosis service includes a questionnaire about diet, where the information given was experienced as unsatisfactory by one patient:

"It was a questionnaire that I had been given to take home, and I... I took it home and filled it in. And then I brought it back. (...) *and then I was to see the nurse after the bone scan and I thought "oh, she'll, she's going to talk to me about this questionnaire", but she didn't. She just said "you have osteoporosis" and that's it really and gave me a leaflet and off I went. So I didn't really know why I had to... to fill this in about my diet. So and I thought "well, my diet must be ok then, otherwise she might have said something", but she didn't explain why I had to fill it in."* (Pa3)

An assessment of the need of calcium and vitamin D could be done by a community pharmacist and perceived as an advantage for patients.

"I suppose you'd have to do a diet questionnaire with them just to know how much they're taking. (...) *that would be good if they* [pharmacists] *have time to do that."* (N1)

"Well, at the hospital we do a diet questionnaire, for example. How much calcium do patients take in their diet? So, maybe a pharmacist could do a diet questionnaire as well, and then nothing would be missed, in that respect." (P2)

All of the patients interviewed were comfortable with a pharmacist asking about diet.

Questions were included in the questionnaires to obtain perceptions from GPs, pharmacists and patients regarding the pharmaceutical care package (i.e. medication review, falls and diet).

5.2.1.3 Relationship

The patient-pharmacist relationship was regarded as important. Two of the patients regarded the relationship with their community pharmacy as good. They were positive about having the service in the pharmacy and based their opinions partly on the relationship.

"Well, I'm very fortunate in the one that I have, sort of, bonded (...) *they know... me and my body and what's happening and they take time to explain things* (...) *I find it* [the community pharmacy delivered care] *excellent. I really do. In fact, I quite look forward to going to them, because they know me when I go in, they name me and – dat, dat, dat – and "what is it that you're getting now?", and then they'll come and they'll explain it all, et cetera, and how often, and if there's any problems that I can get back to them. Yeah, I really like them."* (Pa1)

The hospital pharmacist explained her impression of the patient-pharmacist relationship in most cases as good. The relationship was connected to the issue about which pharmacies that will offer the service and whether or not the patient would be comfortable going to another pharmacy than their local pharmacy, as the hospital pharmacist explained:

"I think that [visiting a community pharmacy instead of the hospital for follow-up treatment and administration of denosumab] (...) *would depend on the patient's relationship with their community pharmacist. Some of them would be familiar with the extended roles and already perhaps attend warfarin clinics at the community pharmacy* (...) *and whether or not their regular community pharmacist could do it or if they had to go to a sort of specialist ones, somewhere else where they didn't know them.* (...) *I say, more often they* [elderly patients] *have a good relationship with their community pharmacy."* (HP)

Questions about the local pharmacy and the relationship with the community pharmacy were therefore included in the patient questionnaire to obtain their opinions.

5.2.1.4 Convenience

The current delivery of denosumab injections was considered to be inconvenient for the patients because of the time and cost involved in travelling. This was especially for the patients who live outside of Edinburgh, where a subcutaneous injection can consume several hours of a day because of the travelling involved. The proposed service was considered to be more convenient due to shorter distance to a community pharmacy. Patient 1 explained the pharmacy to be more convenient due to the different travel:

"It [the travel to the hospital] *can take me probably, depends on the traffic and it can take up to forty-five minutes to an hour, whereas my pharmacy is five minutes."* (Pa1)

If the patients lived further away from the hospital than walking distance, it was expressed as inconvenient to get car parking at the hospital if the patients had a car and was able to drive. If they were not able to drive, they had to either use taxi, public transportation or get someone to drive them to the hospital. As one osteoporosis specialist nurse explained:

"I think often they are harassed because they can't park when they get here. Either that or they come by a bus, then train, then another bus down to the Western [Western General Hospital] *from Waverley* [the train station in Edinburgh]. *So often, you know, when they come in and you administer it, they are like – "is that it?"* [laughter]. (...) *and sometimes, the wait to be seen as well.* (...) *so there is four, five hours of their day is gone. So that, a lot of them* [the patients] *are quite... frustrated."* (N1)

All modes of transportation were expressed as inconvenient, except for patient 2 who did not mind the travelling. All patients interviewed lived in Edinburgh. One of the patients experienced the travel as a potential risk of falling and was uncomfortable with the travel to WGH.

"No, it's not [convenient]. *Let... this morning I left home, now it takes me ten minutes to walk to the bus stop, to get the bus, and it's quite slippery outside this morning.* (...) *And I thought "my God, I'm terrified I'm going to fall", you know, and I thought... And I was, sort of, creeping down the road, and I thought "oh no",* (...) *you're, sort of, terrified you're going to slip.* (...) *And I have an elderly neighbour who has osteoporosis and she's much, much older than me and she has to come here, you know, and you know, it's not everyone that can afford a taxi.* (...) *And she has a stick now. She's quite frail.* (...) *it's...* (...) *a daunting task to come away out here."* (Pa3)

The current hospital service was also regarded to have more limited hours than a pharmacy. The GP also explained that the pharmacy may be more convenient for some patients than the GP surgery:

"Pharmacies are open Saturday mornings, aren't they? And they are open quite often nine till six. So there might be a wider choice of times, so if someone was working it might be easier for them. (...) *people were usually registered with the GP based on where they live, so if the people who work during the day, it's not always convenient to come back to their GP practice, so... A pharmacy could be a good option for some people for that reason."* (GP)

One physician explained more time involved in an injection in the current service as opposed to the same injection given locally:

"I literally see them now for a minute, hand them their kardex and then they go to the ward, so it probably takes an hour – an hour and a half for a simple injection which were to be given in the health centre like a flu-jab which probably take ten minutes, it'd be more convenient for the patient." (P1)

Mode of travelling and time consumption was included in the patient questionnaire to explore the travelling to the hospital and the pharmacy.

5.2.2 Advantages from the organisation perspective

In the following section, a total of two aspects mentioned as advantages from the organisation perspective (i.e. NHS Lothian [including community pharmacies, the GP practices and the hospital]) are presented (widening the pharmacist role and relieving the osteoporosis service).

5.2.2.1 The pharmacist role

Pharmacists could expand their role by giving subcutaneous injections and deliver osteoporosis care, which was perceived as positive for the profession by the community pharmacist and a widening of the role by the GP:

"I'm quite positive about it [the proposed service]*, I'm quite positive about what pharmacy can offer patients.* (...) *I think it's good for the profession"* (CP)

"It would be a good example of widening the role of the community pharmacist." (GP)

The different parts of the pharmaceutical care package were perceived as simple (e.g. questionnaires and tools such as falls assessment). Giving denosumab as a subcutaneous injection was regarded as a task that also could be done by a pharmacist.

"I can't think of anything [the pharmacist cannot do]. (...) *for some of the drugs we use the administration instructions are quite complicated, but for denosumab it's very simple, it's just a subcutaneous injection"* (P3)

Some pharmacists are currently giving influenza vaccinations and were therefore regarded as particularly fit for the task, as the hospital pharmacist explained:

"The nurses would probably more confident administering a drug, although I do know that some community pharmacies already do flu-vaccines and things like that, so they will probably be quite comfortable with it, it's only a subcutaneous injection. I've never done a subcutaneous injection. I don't think it looks very hard, but I don't know." (HP)

A question was included in the pharmacy questionnaire regarding delivery of pharmaceutical care services including influenza vaccinations, as a result of the comments given.

The proposed service was also regarded as something a pharmacist could do without any risks involved. Hypocalcaemia was regarded as a potential risk, but did not have to be addressed by the pharmacist if they were not initiating treatment.

"I don't think so [that pharmacists have to address hypocalcaemia]. *Because we haven't had any problems once people have started.* (...) *if you're already on treatment, then your bone-turnover is low, so the risk of subsequent hypocalcaemia, I think is very low. We... We've not had any instances, not that we know of."* (P3)

5.2.2.2 The osteoporosis service

The proposed service would also benefit the osteoporosis service at the hospital. The current service was regarded as an inefficient use of the osteoporosis clinic. Thus, the proposed service could potentially give more time for the osteoporosis specialist nurses to concentrate on other patients and considered to reduce the waiting time into the service. As one osteoporosis specialist nurse explained:

"I think it [the proposed service] *would release us, about a hundred and twenty appointments per year. So we could maybe use that time to reduce our existing waiting list for new patients."* (N1)

It was also considered to have an economical benefit to the osteoporosis service. Physician 1 expressed that administering denosumab in the hospital is an inefficient use of the clinic:

"Reduced use of secondary care, time and clinic space [is an advantage of the proposed service]. *And, clearly from a secondary care pharmacy cost basis, the cost gets shifted to primary care. It's not huge numbers of patients globally, but it is a bit over three hundred pounds per... per year. I think it must be about a hundred and sixty pounds an injection* (...) *So, there's a cost shift and I mean I have six* (...) *review patients at my clinic and I can have three of those review slots filled with denosumab patients who are really just coming to be given a kardex, so it's not an efficient use of my clinic."* (P1)

"Patients' convenience [is an advantage of the proposed service] *and I think economical, huge economical benefit, now because obviously it would off-load hospital care and also off-load the GP practices, I guess."* (P2)

5.2.3 Disadvantages from the patient perspective

In the following section, a total of three aspects mentioned as disadvantages from the patient perspective are presented (being more comfortable with the GP practice, having a poor patient-pharmacist relationship and missing the hospital expertise).

5.2.3.1 Comfortable with the GP practice

One of these disadvantages with the proposed pharmacist-led service is that the patients seem more comfortable receiving direct clinical care and treatment at the GP practice. Some patients might therefore experience the proposed service as something new and unknown. This was explained from both patients' and health care professionals' point of view:

"I think in Scotland my impression is that patients are more used to going to their general practitioners and seeing (...) *the practice nurse to have injections and immunisations rather than pharmacies, but I can't intrinsically see any problem with that.* (...) *But I think it's maybe a departure for what I understand to be normal practice, but that's all."* (P3)

"For me personally, I still would prefer to go to somebody that I know... I know already, which is the nurse in my GP's practice. (...) *so the pharmacy is a sort of an unknown thing, really."* (Pa3)

This emphasised the need for a question in the patient questionnaire regarding preference of venue to receive denosumab treatment.

5.2.3.2 Relationship

The patient-pharmacist relationship is mentioned as a patient advantage, but also an issue, depending on the relationship. Thus, lack of confidence and trust in a pharmacist giving injections might be a challenge to overcome. The comments under this subtheme emphasised the need for questions regarding relationship between the patient and pharmacist in the patient questionnaire. Patient 2 explained a patient-pharmacist relationship that is not optimal for delivery of pharmacist-led health care:

"The pharmacy is just the place where I collect my medicine. I do not get any counselling in the pharmacy. For me, a pharmacist is there to "dish-out" drugs and nothing else. (...) *If they are going to give any advice or additional care, it would take a lot of time to build up the knowledge and trust that is involved in that."* (Based on notes from interview with Pa2)

The pharmacy environment was also regarded as a barrier for patients to choose the pharmacy as the place to receive treatment, because the pharmacy was experienced as busy by one patient:

"I think my pharmacists are very, really busy. (...) *And there's another chemist that I use occasionally and they are really busy too. So I just cannot see the pharmacist having the time to do that."* (Pa3)

5.2.3.3 Hospital expertise

Another disadvantage for the patients is losing the expertise and trusting relationship they are experiencing in the hospital and at the GP practice. The GP thought a falls assessment offered by a pharmacy would not be to such a high level. These comments led to questions in the GP questionnaire regarding a pharmacist undertaking aspects of osteoporosis, such as falls or dietary assessment.

"I can't see that the pharmacist would have an advantage doing a falls assessment or a fracture risk or talking about a bone scan, compared to an osteoporosis nurse specialist. (...) *I think pharmacists could give a competent service, but perhaps it would be difficult to give an expert service the same way as a nurse specialist who's doing that job all the time, you know, osteoporosis all the time."* (GP)

The hospital pharmacist explained losing the feeling of expertise as a disadvantage for the patients:

"I think psychologically sometimes, there's this feeling of – I'm going to the hospital and seeing a specialist – which they might feel they're not getting [in a community pharmacy]*."* (HP)

Their current relationship with the osteoporosis nurse specialist can also potentially be lost as a consequence of the service being delivered locally, which the patients described as something they would miss. A question was included in the patient questionnaire to investigate the perception of the patients' relationship with the nurses.

"Again, when I was first diagnosed with osteoporosis it was... I was in shock. Absolute shock. But the two people, XXXX [an osteoporosis nurse specialist], *who has now left and XXXX* [one of the osteoporosis specialist nurses currently running the clinic] *who's there – fantastic. They make time for you and,* (...) *I have to say, I look forward to coming to see them, because again you've got this personal,* (...) *bonding with them. You know, they know everybody, they make time for you."* (Pa1)

"There are several things I would miss. The confidence in the nurses' knowledge and the care they deliver. I would miss the camaraderie, because I have a very good relationship with the nurses. (...) *The pharmacy wouldn't give me the same close relationship that I have with the nurses here."* (Based on notes from interview with Pa2)

5.2.4 Challenges from the organisation perspective

Several things need to be addressed before implementing a new service, which became a topic in all the interviews with the health care professionals. In the following section, a total of three aspects mentioned as challenges from the organisation perspective are presented (determining the governance and organisation, delivery of the service from pharmacies and communication).

5.2.4.1 Governance and organisation

Regarding the details in the proposed patient journey (i.e. initiation of treatment, prescribing and review), there seemed to be consensus that denosumab should be initiated by a specialist in secondary care, which is the current Lothian Joint Formulary Committee's specification of use. After initiating treatment and having the injection locally, there was expressed a need for review preferably delivered by a physician in the osteoporosis service in the hospital. The review could include a DXA scan to determine the effectiveness of the drug and a general medical review. Two years were suggested as a potential frequency of the consultations.

"I do think that we need to see them to initiate the treatment and that was always the plan, I think that if we could get this working that it would be shared care, and that the bone clinics or the bone

specialist would be the person who would discuss it with the patient and decide on treatment, and I do think the bone clinic needs to follow these people up. (…) *I would see them coming up for decision about initiation and then perhaps recalling them at two years when they've had a DXA scan to then discuss how they're getting on at two years."* (P1)

Other potential prescribers mentioned were the GP, nurse prescriber and a qualified pharmacist independent prescriber.

"So, unless this bit here [pointing at the patient journey flow chart used in the interviews], *the nurse specialist – administration, is changed to being, sort of, back-up to GP or perhaps a pharmacist prescriber or a nurse prescriber in the community, then that would maybe take out this loop down here* [pointing at the loop where the patients come back for administration]*."* (HP)

"If treatment is transferred to the community then the GP prescribes (...) *They're* [the pharmacists are] *just a bit more separated from GP practices, so they would be a bit more involved in asking for the... for the prescription and then getting the drug"* (GP)

However, the hospital physicians were questioning the safety of other prescribers. Here expressed by physician 3:

"I am aware that, you know, GPs theoretically could initiate treatment, but I'm aware from post-marketing that there has been some fatal hypocalcaemic events with denosumab, so... so if you were a GP doing it, you'd have to be very aware of the... the potential, you know, side-effects. Mainly vitamin D deficiency and hypocalcaemia." (P3)

These comments led to the questions regarding prescribing by GPs and pharmacists in the GP questionnaire.

Funding

Another concern regarding the governance was the funding, which led to the question about remuneration in the pharmacy questionnaire. Remuneration of the service was necessary if the pharmacies would deliver the service. Resources would be released from secondary care as result of less drug cost for denosumab. The cost of denosumab was explained by the hospital pharmacist to be higher in secondary care because they pay Value Added Tax (VAT) as opposed to if the drug were prescribed in primary care where VAT is not included. The shift of funding to primary care was however regarded as difficult and full economic modelling would be necessary.

"You'd have to make sure that sufficient resource was being released from secondary care which, to be able to finance that in primary care, obviously the community pharmacy would need a payment for that. (...) *well we're saving twenty percent on the cost of the drug through not paying VAT* (...) *you'd have to maybe go for one or the other to free up the funding from secondary care to... to transfer that over to primary care* (...)*"* (HP)

5.2.4.2 Delivery of the service from pharmacies

The efficiency of delivering this service from all community pharmacies was raised. If all the community pharmacies were delivering the service, the cost was considered to possibly be more than the resources released from secondary care.

"(...) *you've got to imagine that they're* [the patients are] *scattered all over.* (…) *So I think the cost associated with putting the service out there it could outweigh the... the... the convenience to the patient* (...)*."* (HP)

The community pharmacist and the GP explained a solution where some community pharmacies within a confined area would be more efficient and feasible:

"I already acknowledge there might not be a hundred and eighty two pharmacies, but I think you could get a geographical spread of people that were capable of doing this in facilities that are... that are acceptable and over all I think." (CP)

"How efficient is it going to be to set up a whole system for one, for each pharmacist to see one patient, twice a year? Maybe, it might be better to have certain pharmacies in local geographical areas that would specialize in this? You know, they would see, maybe, four or five patients, maybe one a month" (GP)

However, the ideal solution from the patients' perspective is delivering the service from all community pharmacies in Lothian. This is recognised from the interviews with regards to convenience and relationships (see section 5.2.1: advantage from the patient perspective).

Training

The funding involved in the pharmacist-led service would include remuneration for training and delivery. This was perceived as a must by the community pharmacist:

"I think training of staff as of, think I'd alluded to, I would expect there to be some recognition of the time, whether that be back-filled or ideally back-fill plus, but the administration... per patient, I guess, would be something that would be, I would hope be reflected in... in... by some sort of remuneration package. (...) *I don't think funding from the pharmacists' side would be an issue, but it would be if it was expected to be done for nothing."* (CP)

There were three parts of training that were perceived as needed. Firstly, resuscitation skills if anaphylactic shocks occurred, which was regarded as a rare problem and more likely from an influenza vaccination. The pharmacists should observe the patients after an injection and must have resuscitation equipment.

"(...) *if somebody had an acute anaphylactic reaction in a pharmacy would they be, you know, how would that be managed?* (…) *If it's around community pharmacy,* (...) *would there be any safety concerns about that. Not that either XXX* [physician] *or myself have seen anyone react to denosumab, so I mean, it, it, it would be an extremely rare problem and I suspect you are much more likely to react to a flu-jab than denosumab."* (P1)

"I presume there's a potential for anaphylaxis... (…) *Oh dear... Well, the example I gave you was the private flu vaccination. To be signed off or to be eligible to do that you've got to do yearly* (...) *resuscitation courses.* (…) *So, pharmacists are quite capable of doing that. All they need is the actual investment and their time to cover it."* (CP)

Secondly, training for administering a subcutaneous injection is needed. And thirdly, extra osteoporosis education to deliver an assessment of falls risk and need for calcium and vitamin D is needed. The hospital pharmacist mentioned that possible training could be done by an osteoporosis specialist nurse or specialist pharmacist.

"I think, there's a, a big training need, because of the number of people that would be involved (...) *Would the nurse specialist end up training them or would it have to be specialist pharmacist end up training the community pharmacists in which case would that actually save the NHS any money?* (…) *I don't think it's an in-depth training. I think it's fairly straight forward – "this is how you do a subcutaneous injection" – "this is how you use this particular device". They're quite capable of reading the SPC* [Summary of Product Characterisation] *themselves, but it's just making sure that people have done that."* (HP)

These statements led to questions about training in the pharmacy questionnaire.

Injecting a subcutaneous injection was perceived as a straight forward task, but concerns involved the frequency of administering denosumab. If all the pharmacies in Lothian were to deliver the service,

the injection might be once or twice a year, which can result in loss of confidence in giving injections. An advantage would be for the pharmacies already delivering influenza vaccinations in pharmacies, where injections occur more frequently, although being administered intramuscularly compared to the subcutaneous denosumab injection.

"I think, just making sure that there is a training package and that only people who are... have been through that are dealing with patient and making sure that they... that that's followed and that probably also that there's maybe ongoing refreshers, (...) [to] *remain confident and competent in what you're doing because it's such an infrequent thing."* (HP)

"I know nothing about the drug... something –mab. However it's the old story if you are familiar and using something regularly, you know about it. So... so it's the old story. Conversely if we're trained to use it and never use it, we will lose it." (CP)

In addition to an initial training and refreshers, protected learning time was suggested to keep the pharmacists up-to-date.

"If we had protected learning time that probably would remove... perceived barriers to training." (CP)

Two patients were concerned about pharmacists' knowledge and wanted to feel safe. They seemed to prefer a pharmacist who has expertise in osteoporosis.

"I thought perhaps maybe I should have taken someone with me [when first diagnosed], *but I just thought "I go along – du-tu", so that was the one shock-factor for me. That I really, I came out and I had driven, and I – I sat in the car for ages and I just thought "Oh, gosh! What does this mean now to me?", you know, it was... But there was so much support here, you know, with the groups and things like that, which, that to me is the only thing that if we can go into the pharmacists, pharmacies, if there was going to be more that the real experts who understand can have something."* (Pa1)

Facilities

There were also other challenges regarding the pharmacies that were mentioned in addition to the need of training. Pharmacy facilities that look professional were important for the patients and described as a private consultation room with necessary equipment. Here explained from different perspectives:

"You'd want to be able to take the person into an appropriate room that is designed for doing this sort of things. So they don't have that consultation room if it's just a sort of slightly partitioned-off

section of the shop that is not really going to be appropriate. (...) *whether or not we can make sure that there's a... a uniform approach, if there's a sort of service set of standards that premises have to meet before they can participate in the scheme, I would say personally."* (HP)

"(...) *you need to have a private consulting area in order to do that* [injecting denosumab]*."* (GP)

"It's not like you go into the pharmacy and you're... just saying "oh, right here you are, I'm going to do your injection here" that is done, you know, because the pharmacy could be busy as long as it's a private room." (Pa1)

The necessary equipment mentioned was to handle waste, which was recognised as already provided in pharmacies that provides needle exchange services and in the pharmacies who offer influenza vaccines.

"Some pharmacies that (...) *operate needle-exchange scheme already have that* [sharps uplift-facilities] *in place.* (...) *I don't think it would be any different from disposing of a needle, a syringe, into that waste.* (...) *no it shouldn't be any problems."* (CP)

Practical problems also included ordering the injection from the wholesale and storing in a refrigerator.

"I presume it could be sourced through my normal wholesale as in the wholesale chain which would be... would be UK wholesalers. (...) *Cold chain would have to be maintained. Currently we have procedures in place to maintain a cold chain in the pharmacy. So I don't see that being a problem."* (CP)

All these issues were not regarded as a problem by the community pharmacist as it is no different from other medicines with particular storage requirements.

Appointments

Allocating appointments to receive the injection and delivering the service was regarded as a novel but necessary approach because patients might be lost to follow up if not given appointments.

"Yes, we would have to have appointments for this. We would have to have protected time for this." (CP)

One patient explained that an appointment-driven service could remove the issue with a busy community pharmacy.

"My pharmacists are just so busy, (...) *You know, there's sort of queues of people waiting for their medication and then you're going in with the prescriptions* (...) *I don't know if they really would be able to give you the time* (...) *It would have to be an appointment, yeah."* (Pa3)

The work load involved in the allocation of appointments is new for pharmacies and the GP suggested that they could not predict the work load. One solution was suggested by an osteoporosis nurse where the hospital sent a reminder letter.

"I think you'd be frightened some of them would be lost to follow up. So I would maybe envisage that we would just send them a letter saying - your six monthly injection's due. (...) *I suppose the dementia ones you worry about, but often we've got a contact for a family member and maybe that is where the reminder-letter would go, rather than to the patient."* (N1)

Dementia was described as a challenge due to loss of follow up and further an issue involved in consent, if the patient did not bring a carer or family member.

"(...) *the pharmacists are used to seeing our group of patients anyway, I'm sure.* (...) *that may be the odd patient* [patients suffering from dementia] *we end up keeping anyway, I don't know. They are about the only group. And often the learning difficulties, one, they often have carers with them as well. So it's not usually such a problem for the learning difficulties."* (N1)

Blood monitoring

Several health care professionals mentioned that if the service was delivered by a pharmacist without contact with the hospital or the GP practice, the blood monitoring is not possible to undertake in the current community pharmacy setting. The community pharmacist suggested extension of the use of the existing laboratory van as a possible solution to the problem.

"We don't have that facility [to do blood tests]. *It depends on how coterminous the pharmacy is with a GP surgery, because of the van labs... the vans that run the labs there is... are... are focusing on surgeries, not pharmacies understandably. But it's not inconceivable that where they are coterminous the van service could be used, but that again would have to be negotiated."* (CP)

One physician explained that the hospital does not monitor calcium unless there are signs of hypocalcaemia or reduced renal function.

"No [there is nothing that the nurses do in the follow-up visits that the pharmacist could not do]. (...) *if you follow rigidly the data set suggestion and that you need to check the calcium every time,* (...) *Unless* (...) *the pharmacists are going to start taking blood, then you'd have to have a visit to the*

health centre, and then visit the pharmacy, which is perhaps a bit clumsy, (...) *but I know both XXX XXX* [physician] *and myself feel that we can stop checking the calcium as long as the patient is well and doesn't have any symptoms."* (P1)

5.2.4.3 Communication

Both patients and the health care professionals expressed communication to be an issue involved in a shared care between the community pharmacy and the hospital, which resulted in the last subtheme under challenges from the organisation perspective.

"Communication: that's where things break down." (N2)

To holistically provide care for patients it was expressed that there should be a way of communication between GP practices, the community pharmacy and the secondary health care system.

"I guess if there was a problem, well the nurses would then refer back to the doctor and I think that pharmacies could do that too, then that would be fine." (P3)

If the pharmacies administer denosumab it has to be reported to the osteoporosis service and the GP to ensure records are updated routinely which is essential if patients have adverse reactions to medicines.

"So, currently when we give denosumab, we have to give it at six months intervals and that shouldn't be a problem, but if the patient does develop, unlikely, but osteonecrosis of the jaw or an atypical fracture, you know, what the community pharmacist is going to do about it, (...) *well, it's the link between a community pharmacist and the GP and of the hospital. Is there some sort of pathway of information that could be, you know, used? And the pharmacist of course, I mean, they don't normally have access to clinical records, so somebody would have to make decision somewhere, you know, how long to give the treatment for, when to stop, what to do.* (...) *How would he or she communicate with the doctors who actually prescribe the treatment?"* (P2)

Another need for communication was expressed if the pharmacist was going to refer the patient back to the osteoporosis service at the hospital for review and DXA scan.

"Somewhere in the pathway there might be something that says that the pharmacist has got to refer back to the nurse specialist who will arr... arrange the DXA scan (...)*"* (CP)

This was recognised as a challenge in today's delivery of health care where eHealth systems are yet not compatible. The community pharmacist expressed a wish for such a mode of communication:

"So I would hope by the three – four years there would be an electronic safe mech... mechanism used within pharmacy that connected in to both GP surgeries and secondary care (...) *the advantages and the benefits that the system would have... would... would gain are certainly, are certainly very high."* (CP)

Access to TrakCare® was suggested as a solution to the communication challenge and would give access to patient notes with blood monitoring and diagnosis. This would be an advantage according to the hospital pharmacist who explained that doing a thorough medication review would need information such as blood results and diagnosis:

"(...) *I think what is classed medication review in GP practices often doesn't actually involve the patient* (...) *community pharmacists would be speaking to the patient so that would be an advantage. But they don't have access to their notes, so that's a disadvantage* (...) *you may not have a past medical history, and sometimes you would be having to guess the indications for the medicines it's not obvious...* (...) *Although, if they had access to computer systems, that could overcome a lot of it. If somebody had access to something like Trak* [TrakCare®] *then that would help, but I don't know how realistic that would be, because even GPs are only beginning to get access to Trak now."* (HP)

Although regarded as an issue, communication was not included in the questionnaires because the need for better electronic communication between sectors is well recognised.

The information explained in this section led to the design of three specific questionnaires; one for patients (see appendix 15), one for community pharmacies (see appendix 16) and the final for GPs (see appendix 17).

5.3 Questionnaire survey

All answered questions in all questionnaires were included in the final analysis, despite some of the questionnaires being uncompleted. Questions following unanswered questions were assumed to be unaffected due to the randomness of the missing data (i.e. assumed no item non-response bias). Consequently, the number of respondents may vary throughout the presentation, indicated by "n = X" under each variable.

5.3.1 Patient survey

5.3.1.1 Characteristics of questionnaires

Of the 114 patient questionnaires sent, 92 (80.7 %) were returned and 69/114 (60.5 %) were fully completed (see Table 5-2). One patient returned the questionnaire with no data and commented that denosumab was self-administered. After consultation with an osteoporosis specialist nurse it became clear that this was not the case, and the questionnaire was excluded from analysis.

Table 5-2: Summary of response for the patient questionnaire.

Patient questionnaire	n	
Patients invited	114	(100.0 %)
Questionnaires returned	93	(81.6 %)
Inappropriate response(s)	1	(0.9 %)
Questionnaires included	92	(80.7 %)
Fully completed questionnaires	69*	(60.5 %)

*75.0 % of questionnaires included (69/92)

From this point and throughout the results; when referring to "patients", it implies the "patients who responded to the question in focus". See appendix 24 for additional data and chi square tests.

5.3.1.2 Questionnaire item 1 – 4 and 7 - 8: Convenience – Travel to hospital and use of local pharmacy

More than 2/3 of the patients personally visited the same pharmacy, which was located close to them (i.e. reported less than 10 minutes) (see Table 5-3). The most frequently used modes of transportation were reported as walking (n = 33) and driving (n = 29). All the patients (except one) reports using more time travelling to the hospital than to the local pharmacy (median for hospital: 45 minutes; median for pharmacy: 10 minutes, see Table 5-4). The most frequent modes of transportation to the hospital are bus (n = 34) and car (n = 47).

Table 5-3: Patient questionnaire: The patients' use of the local pharmacy.

Characteristic	n
Patients who personally visit the pharmacy n = 87 (94.6 % of included questionnaires)	62 (71.3 %)
Patients who regularly use the same pharmacy n = 70 (76.1 % of included questionnaires)	69 (98.6 %)

Table 5-4: Patient questionnaire: Mode and time of travelling for patients to the local pharmacy and to Western General Hospital.

Characteristic	Pharmacy	Hospital
Mode of travel	*n = 64	†n = 89
Walk	33 (51.6 %)	4 (4.5 %)
Bus	15 (23.4 %)	34 (38.2 %)
Car	29 (45.3 %)	47 (52.8 %)
Taxi	1 (1.6 %)	10 (11.2 %)
Wheelchair	1 (1.6 %)	-
Bicycle	-	1 (1.1 %)
Train	-	3 (3.4 %)
Ambulance service or patient transport	-	9 (10.1 %)
N/A	-	1 (1.1 %)
Estimated time to travel	**n = 57	**n = 86
Median (IQR)	10 minutes (5.5, 15)	45 minutes (30, 60)
0-10 minutes	47 (70.1 %)	1 (1.2 %)
11-20 minutes	15 (22.4 %)	10 (11.6 %)
21-30 minutes	4 (6.0 %)	16 (18.6 %)
30-40 minutes	1 (1.5 %)	10 (11.6 %)
41-50 minutes	-	19 (22.1 %)
51-60	-	17 (19.8 %)
> 60 minutes (maximum 120)	-	13 (15.1 %)

* Participants use more than one mode of travel (pharmacy: n = 13).

** Burden of travel based on estimated longest mode reported. The median and inter quartile range (IQR) were used because the data is not normally distributed.

† Participants use more than one mode of travel (hospital: n = 18).

5.3.1.3 Questionnaire item 5 and 9: Relationships between patients and healthcare professionals

More patients responded to the question about their relationship with the osteoporosis specialist nurse (n = 90) than those who responded about their relationship with the pharmacist (n = 68) (see Table 5-5). A higher proportion reported that the relationship with the nurse is good (n = 86 [95.6 %]), than proportion reported that the relationship with the pharmacy is good (n = 57 [83.8 %]) ($p < 0.05$, Chi-square test).

Table 5-5: Patient questionnaire: Patient-pharmacy relationship and patient-osteoporosis specialist nurse relationship.

Characteristic	n
Perception of good relationship with local pharmacy n = 68 (73.9 % of included questionnaires)	
Strongly agree	33 (48.5 %)
Agree *(median)*	24 (35.3 %)
Neither agree, nor disagree	10 (14.7 %)
Disagree	1 (1.5 %)
Strongly disagree	0 (0.0 %)
Perception of good relationship with osteoporosis specialist nurse n = 90 (97.8 % of included questionnaires)	
Strongly agree	39 (43.3 %)
Agree *(median)*	47 (52.2 %)
Neither agree, nor disagree	4 (4.4 %)
Disagree	0 (0.0 %)
Strongly disagree	0 (0.0 %)

5.3.1.4 Questionnaire item 6: Patient adherence

The patients could be considered to be adherent with prescribed medicine: 62 patients (67.4 %) strongly agreed and 29 (31.5 %) agreed to be taking all the medications as prescribed.

5.3.1.5 Questionnaire item 10: Preference of venue to receive denosumab injections

To inform about the three most likely options for future delivery, a question was included to obtain information of where the respondents prefer to receive the denosumab injection in the future. Most of the patients reported a preference for the GP practice as the place to receive the denosumab injection (n = 58, see Table 5-6). Three patients preferred either the GP practice or the pharmacy because they were equally convenient compared to the hospital. A higher proportion of patients reported a preference for the pharmacy (n = 18) than the hospital (n = 13). The patients were asked to provide a reason for their choice. These reasons were categorised as follows: convenience, health care

professionals being familiar with other conditions/medication, pharmacy environment, prefer the hospital and relationship with the nurses.

Table 5-6: Patient questionnaire: Preference of venue to receive the injection.

Question		n
* Preference of venue to receive the injection with comment categories n = 84 (91.3 % of included questionnaires)		
The pharmacy		18 (21.4 %)
	Convenience	17
	Health care professionals being familiar with other conditions/medication	0
	Pharmacy environment	1
	Prefer hospital	0
	Relationship with nurses	0
The GP practice		58 (69.0 %)
	Convenience	45
	Health care professionals being familiar with other conditions/medication	7
	Pharmacy environment	7
	Prefer nurses and/or the hospital	2
	Relationship with nurses	6
The hospital		13 (15.5 %)
	Convenience	2
	Health care professionals being familiar with other conditions/medication	1
	Pharmacy environment	2
	Prefer the hospital	10
	Relationship with nurses	2

* Participants preferred more than one of the options (n = 5) and gave comments that covered more than one category (n = 18).

Below are the patients' preferences and explanatory answers elaborated.

1. **Convenience**

Several patients (n = 64) described convenience as a reason for their choice. Comments like the preferred choice is closer, easier to get to and saves a journey were common. Patients described the journey to the hospital as tiresome.

"As I have to travel to the Western Hospital by car, train and taxi, I would prefer to have my injection at either St John's Hospital or my pharmacy or GP practice as I have other health issues." (Patient (Pa) 31)

"I have to take taxi's and it is very expensive to make the long journey to the hospital" (Pa68)

"Our practice is a lot closer, and takes 5 mins to get there, + you don't have to worry about traffic or parking the car." (Pa69)

"(...) *It's having to wait, be ready for 8 am if app. is for 9 am. Tired by the time I get back"* (Pa86)

2. Health care professionals being familiar with other conditions/medication

Some patients (n = 8) mentioned that the health care professionals at their chosen location were familiar with other conditions and medication. Some felt safer at their GP practice than in the pharmacy. Concerns about safety involved denosumab being a novel drug with possible serious side-effects, and the doctor being in a better position to discuss problems or answer questions.

"Denosumab is a new drug with possible serious side-effects. If problems do arise your doctor is aware of your general health, regular medication, in a much better position to discuss any problems or questions you may have and give advice" (Pa2)

Other comments involved the GP having greater expertise and that they needed to consult their GP regularly for other matters.

"I need to consult [the GP] *regularly for other matters"* (Pa30)

3. Pharmacy environment

Ten patients described the pharmacy environment as not satisfying. There were concerns about the pharmacist being qualified to give injections and an uncomfortable environment, including queuing, frequently changes in staff and lack of privacy.

"The staff at the pharmacy changes frequently and you usually have to queue! No privacy. (...)*"* (Pa22)

"This choice [the pharmacy] *is made on the pharmacy I use. Near my home, otherwise I would prefer the hospital – staff there have more expertise."* (Pa11)

"Pharmacy has parking problems and staff are not qualified or acceptable to me. Hospital is best place to check on progress." (Pa4)

"The GP is nearby and I know how experienced the nurses are at giving injections" (Pa7)

4. Prefer the hospital

Patients explained that they chose the hospital because they felt safe and that the staff had great expertise. One patient stated that "the hospital is the only place for me".

"(...) *denosumab is a new drug, which GPs are not knowledgeable. It would be very important to be able to speak to the osteoporosis nurse or the hospital to resolve any queries/concerns"* (Pa61)

"I feel it is better to go into the hospital" (Pa5)

"It is nearest, we were taken on time, the whole procedure was over in a very short time, the staff were very pleasant" (Pa23)

"Would feel more able to ask specific questions regarding my osteoporosis" (Pa24)

5. Relationship with the nurses

Some patients (n = 8) regarded the relationship with the nurses (either practice nurse or osteoporosis specialist nurse) as an important factor to where they wanted to receive the injection.

"I frequently see the nurse at the GP practice and get on with her very well" (Pa43)

"(...) *I also know the practice nurses, and feel able to discuss any problems I may have"* (Pa55)

"I find the nurses [osteoporosis specialist nurse] *very honest and professional, who answer all my questions and allay any fears that I may have"* (Pa74)

"This is difficult because having started at the hospital a bond has been set up with the expert nurses – the disadvantage is the time, distance and parking. Plus the nurses have more knowledge and expertise on your condition in my case. (...)*"* (Pa70)

5.3.1.6 Questionnaire item 11 and 12: Assessment of falls risk, diet and medication review

Almost half of the patients (n = 40) stated that they were not currently asked questions about falls risk, diet or medication by their GP or practice nurse (see Table 5-7). Almost one third of the patients (n = 26) were comfortable with the suggestion of a pharmacist asking questions about falls risk, diet and medication, whereas more than one quarter (n = 22) stated that they were not comfortable being asked about any of these by a pharmacist.

Table 5-7: Patient questionnaire: Perception of questions from health care professionals in primary care regarding falls risk, diet and medication.

Question or statement	n
Perception of being asked about falls risk, diet and/or medication in primary care (GP or practice nurse) n= 85 (92.4 % of included questionnaires)	
Falls risk, diet and medication	10 (11.8 %)
Falls risk and diet	1 (1.2 %)
Falls risk and medication	5 (5. 9 %)
Medication and diet	6 (7.1 %)
Falls risk	3 (3.5 %)
Diet	2 (2.4 %)
Medication	18 (21.2 %)
None of the above	40 (47.1 %)
Patients who are comfortable with being asked about falls risk, diet and/or medication in primary care (by a pharmacist) n = 81 (88.0 % of included questionnaires)	
Falls risk, diet and medication	26 (32.1 %)
Falls risk and diet	2 (2.5 %)
Falls risk and medication	6 (7.4 %)
Medication and diet	3 (3.7 %)
Falls risk	3 (3.7 %)
Diet	0 (0.0 %)
Medication	19 (23.5 %)
None of the above	22 (27.2 %)

5.3.1.7 Questionnaire item 13 and 14: Pharmacist-led clinics and services

Over 2/3 of the patients reported to be aware of the current community pharmacist-led clinics (n = 55, see Table 5-8). Of those 55; 35 were comfortable with the proposal of a community pharmacist administering denosumab and 20 were not comfortable with the proposal (the "neither agree, nor disagree" option was included as "not comfortable"). Of those who reported to be unaware of the current clinics (n = 25), 12 were comfortable with the proposal and 13 were not comfortable with the proposal. There was no statistically significant difference in these proportions ($p > 0.05$, chi square; see appendix 24). There were 23 patients who disagreed or strongly disagreed to be comfortable with a pharmacist giving the denosumab injection.

Table 5-8: Patient questionnaire: Patient awareness of pharmacist-led clinics and being comfortable with the administration of denosumab by a community pharmacist.

Statement	n
Awareness of community pharmacist-led clinics n = 80 (87.0 % of included questionnaires)	
Strongly agree	19 (23.8 %)
Agree *(median)*	36 (45.0 %)
Neither agree, nor disagree	19 (23.8 %)
Disagree	4 (5.0 %)
Strongly disagree	2 (2.5 %)
Patients who would be comfortable with a pharmacist administering denosumab n = 80 (87.0 % of included questionnaires)	
Strongly agree	13 (16.3 %)
Agree *(median)*	34 (42.5 %)
Neither agree, nor disagree	10 (12.5 %)
Disagree	15 (18.8 %)
Strongly disagree	8 (10.0 %)

5.3.1.8 Questionnaire item 15: Additional comments

Patients had the opportunity to give additional comments at the end of the questionnaire. In the majority of comments, the patients reinforced their preference of where to have the denosumab injection which was categorised as their preference of place to receive the injection (questionnaire item 10, section 5.3.1.5), see Table 5-9.

Table 5-9: Patient questionnaire: Additional comments in themes.

Theme of the additional comments n = 38 (41.3 % of included questionnaires)	n
Convenience	9 (23.7 %)
Health care professionals being familiar with other conditions/medication	6 (15.8 %)
Pharmacy environment	7 (18.4 %)
Prefer the hospital	0
Relationship with the nurses	3 (7.9 %)
Other comments	13 (34.2 %)

Below are the patients comments elaborated.

Convenience

Preference of the more convenient location was mentioned in nine comments, explaining that not having to travel will save time and money. Some patients explained that they were physically unable to travel.

"GP and pharmacy are within approx 10 mins walk. I would save an extended journey to hospital (2 buses required). Unsure if GP or practice nurse would administer. Both would require an appointment" (Pa 53)

"I am 84 years of age and not fit to travel" (Pa46)

Health care professionals being familiar with other conditions/medication

From the 58 patients who chose GP practice, the convenience was reinforced by the comments regarding the GP practice at the end of the questionnaire. Patients were also used to going to the GP practice and felt that it was a comfortable choice.

"Would really prefer my doctor or practice nurse for the injections" (Pa48)

"The injection has been very beneficial to me and, if possible, it would be good to receive it at my GPs practice" (Pa43)

One patient was concerned about having one additional health care professional being responsible for health care.

"I already have to deal with a number of health care professionals in several locations. Attending the pharmacy for treatment/advice would add one more point of call. At present collection of medicines there, a straightforward task, can be carried out for me (I have RA [rheumatoid arthritis] *and mobility difficulties)"* (Pa61)

Pharmacy environment

From the 38 comments given, 7 comments were about the environment in the pharmacy. Lack of privacy, lack of trust in pharmacists giving injections and queuing were three of the main concerns.

"Unsure! There is no privacy in Boots and usually a queue + they seem overworked as it is" (Pa22)

"My least desirable option would be the pharmacy. This is due to lack of confidence in staff and lack of privacy. Again, would feel more confident with attending hospital" (Pa24)

"I would be happy to have a trained pharmacist give me the injection provided it could be given in a private room" (Pa78)

"While I agree with pharmacists giving injections, I don't want to be queuing with methadone users, therefore I prefer GP surgery" (Pa73)

Other comments

Over a third of the comments were various thoughts the patients wanted to express and regarded as not suitable for the categories.

"Would still like to have contact with hospital. If we free up the nurse specialists' time would it be possible to have a yearly club to discuss how patients are progressing and new innovations." (Pa70)

"I have no complaints about GP nurse or pharmacist. They are all very helpful and understanding." (Pa51)

"The injection has been very beneficial to me and, if possible, it would be good to receive it at my GPs practice." (Pa43)

"I have no objections where it is done." (Pa86)

5.3.2 Pharmacy survey

Of the 182 questionnaires sent, 54 were returned with 50 (27.5 %) fully completed (see Table 5-10). The results described in this section are based on the 54 questionnaires included and not on the population.

Table 5-10: Summary of response for the community pharmacy questionnaire.

Pharmacy questionnaire	n	
Pharmacies invited	182	(100.0 %)
Questionnaires returned	54	(29.7 %)
Inappropriate response(s)	0	-
Questionnaires included	54	(29.7 %)
Fully completed questionnaires	50*	(27.5 %)

*92.6 % of questionnaires included (50/54)

More multiple pharmacies (n = 34 [63.0 %]) replied than independent pharmacies (n = 20 [37.0 %]) (Table 5-11). This is comparable to the estimated distribution of multiple and independent pharmacies in NHS Lothian. The median duration for pharmacy experience was 15 years (IQR; 7, 25) for the respondents (Table 5-12). Neither the pharmacist questionnaire, nor the cover letter contained information about the alternative of receiving the injection at their GP practice because they were not involved in this option.

Table 5-11: Pharmacy questionnaire: Characteristics of the included community pharmacies compared to all community pharmacies in NHS Lothian.

Characteristics		Pharmacies in NHS Lothian	Pharmacies included
Number of pharmacies		182 (100 %)	54 (29.0 %)
	Multiple pharmacies[‡]	112 (61.5 %)	34 (63.0 %)
	Independent pharmacies[†]	70 (38.5 %)	20 (37.0 %)

[†]An independent pharmacy is defined as a single pharmacy or less than 10 pharmacies in a small chain.
[‡]Multiple pharmacies are defined as 10 or more pharmacies in a chain.

Table 5-12: Pharmacy questionnaire: Details of pharmacy experience of respondents.

*Years of experience n = 54 (100.0 % of included questionnaires)	n
0-5 years	9 (16.7 %)
6-10 years	8 (14.8 %)
11-15 years	11 (20.4 %)
16-20 years	8 (14.8 %)
21-30 years	11 (20.4 %)
Over 30 years	7 (13.0 %)
Minimum	0.25 years
1st quartile	7 years
Median	15 years
3rd quartile	25 years
Maksimum	35 years

*The median and inter quartile range were used because the data is not normally distributed.

The community pharmacy questionnaire contained statements regarding the proposed pharmaceutical care package and training, see Table 5-13. Half of the pharmacists (27 [50.0 %]) would not feel comfortable administering denosumab. Most of the pharmacists (n = 51 [94.5 %]) agreed that they need more training before they could administer a subcutaneous injection of denosumab. Almost ¾ of the pharmacists included said they were comfortable talking about osteoporosis and its treatment with patients (n = 40 [74.1 %]). Five disagreed to the statement, three of whom had three years or less of pharmacy experience whilst the last two had thirteen years of experience. The feedback regarding falls assessment was more difficult to differentiate with 19 (35.9 %) pharmacists stating that they were comfortable doing a falls assessment, whilst 20 pharmacists (37.7 %) were not comfortable. They reported, however, being more comfortable talking about diet with osteoporosis patients (n = 37 [68.5 %]). More than half of the pharmacies (n = 34 [63.0 %]) agreed that they were currently undertaking medication reviews and 39 pharmacists (72.3 %) thought a medication review would increase adherence.

The questionnaire also contained one item regarding provision of other services, where over one third of the pharmacist respondents did not provide clinics for other conditions (n = 21 [38.9 %])

Regarding delivery of the service, the respondents could arrange appointments for the patients (n = 37 [68.5 %]) and would like to deliver the osteoporosis service (n = 39 [73.6 %]) with proper remuneration (n = 45 [84.9 %]).

Although a comment box was not included in the pharmacy questionnaire, there were comments on one questionnaire explaining staff as a problem. The pharmacist explained that he or she would like to deliver the service if there was an extra pharmacist in the pharmacy.

Table 5-13: Pharmacy questionnaire: Opinions from community pharmacies in NHS Lothian.

	Statement	5*† n (%)	4 *† n (%)	3*† n (%)	2*† n (%)	1*† n (%)
1	I feel comfortable talking about osteoporosis and its treatment with patients. n = 54	11 (20.4)	29 (53.7)	9 (16.7)	5 (9.3)	0
2	I feel comfortable doing a falls assessment with an osteoporosis patient. n = 53	3 (5.7)	16 (30.2)	14 (26.4)	12 (22.6)	8 (15.1)
3	I feel comfortable talking to a patient about diet and lifestyle as a part of osteoporosis management. n = 54	8 (14.8)	29 (53.7)	8 (14.8)	7 (13.0)	2 (3.7)
4	My pharmacy currently undertakes medication reviews. n = 54	4 (7.4)	30 (55.6)	7 (13.0)	7 (13.0)	6 (11.1)
5	Through medication reviews I am able to encourage patients to adhere to their medicines. n = 54	9 (16.7)	30 (55.6)	10 (18.5)	2 (3.7)	3 (5.6)
6	I provide clinics/services for other conditions such as flu-vaccines. n = 54	10 (18.5)	11 (20.4)	6 (11.1)	7 (13.0)	20 (37.0)
7	I would feel comfortable administering a subcutaneous injection of denosumab. n = 54	5 (9.3)	16 (29.6)	6 (11.1)	12 (22.2)	15 (27.8)
8	I would need more training before I could administer a subcutaneous injection of denosumab. n = 54	42 (77.8)	9 (16.7)	1 (1.9)	0	2 (3.7)
9	My pharmacy could arrange appointments for the patients to receive denosumab injections in the pharmacy. n = 54	21 (38.9)	16 (29.6)	9 (16.7)	4 (7.4)	4 (7.4)
10	I would be keen to deliver an osteoporosis service n = 53	17 (32.1)	22 (41.5)	9 (17.0)	5 (9.4)	0
11	I would offer the osteoporosis service only if there were proper remuneration. n = 51	35 (66.0)	10 (18.9)	5 (9.4)	1 (1.9)	0

* Median is indicated by shaded background.

†5 = Strongly agree; 4 = Agree; 3 = Neither agree, nor disagree; 2 = Disagree; 1 = Strongly disagree.

5.3.3 GP survey

The GP questionnaire gave a response rate of less than 10 % (33 questionnaires returned). All the questionnaires were fully completed (see Table 5-14). On the basis of a low response rate, the questionnaire result should be read with caution. The results described in this section are based on the 33 questionnaires completed and not the population. The GP questionnaire was in two parts where the first part involved injecting denosumab in the GP practice and the second part involved the community pharmacy.

Table 5-14: Summary of response for the GP questionnaire.

GP questionnaire	n	
GPs invited	500	(100.0 %)
Questionnaires returned	33	(6.6 %)
Inappropriate response(s)	0	-
Questionnaires included	33	(6.6 %)
Fully completed questionnaires	33	(6.6 %)

The GPs were hard to differentiate between those who agreed and those who disagreed the statements in the questionnaire (see Table 5-15). They tended to be equally distributed along the Likert scale with the median being “neither agree, nor disagree”.

However, four statements had a skew to either side. Many of the respondents agreed that denosumab could be administered at their practice (n = 19 [57.5 %]). Most of the respondents also said that a pharmacist can undertake a medication review (n = 21 [63.6 %]), which could increase adherence to medication (n = 32 [96.9 %]). Many of the GPs did not want a pharmacist to administer denosumab (n = 18 [54.6 %]).

The remaining items were hard to differentiate, but more than 1/3 of the GPs said that denosumab should be prescribed by GPs after initiation in the hospital (n = 12 [36.4 %]). The same number said that a GP should be responsible for the blood monitoring related to the use of denosumab.

Regarding other aspects of osteoporosis management that could be provided at the GP practice (such as falls and dietary assessment), 14 GPs (42.4 %) said agree or strongly agree and 14 GPs said disagree or strongly disagree. This equal distribution was also the feedback regarding pharmacists undertaking this service where 11 GPs (33.4 %) said agree or strongly agree to the idea and 11 GPs said disagree or strongly disagree.

More GPs disagreed (n = 11 [33.4 %]) with a qualified pharmacist independent prescriber managing osteoporosis through making appropriate changes to prescription medicine, whilst (n = 8 [24.3 %)]) agreed.

Table 5-15: GP questionnaire: Opinions from GPs in NHS Lothian (n = 33).

	Statement	5*† n (%)	4 *† n (%)	3*† n (%)	2*† n (%)	1*† n (%)
1	After initiation in a hospital setting, denosumab should be prescribed by general practitioners.	0	12 (36.4)	10 (30.3)	8 (24.2)	3 (9.1)
2	The general practitioner should be responsible for blood monitoring related to the use of denosumab, such as calcium and renal function.	0	12 (36.4)	10 (30.3)	6 (18.2)	5 (15.2)
3	Denosumab could be administered at my practice.	1 (3.0)	18 (54.5)	4 (12.1)	8 (24.2)	2 (6.1)
4	Other aspects of osteoporosis management could be provided at my practice, such as falls and dietary assessment.	1 (3.0)	13 (39.4)	5 (15.2)	11 (33.3)	3 (9.1)
5	A community pharmacist could administer the denosumab injection in appropriate facilities similar to those used for other services, such as smoking cessation, asthma and flu-vaccination.	0	10 (30.3)	5 (15.2)	13 (39.4)	5 (15.2)
6	A community pharmacist could undertake other aspects of osteoporosis management, such as falls or dietary assessment.	2 (6.1)	9 (27.3)	11 (33.3)	7 (21.2)	4 (12.1)
7	A community pharmacist could undertake a medication review for patients with osteoporosis.	4 (12.1)	17 (51.5)	4 (12.1)	6 (18.2)	2 (6.1)
8	A community pharmacist can encourage adherence with medicines.	8 (24.2)	24 (72.7)	1 (3.0)	0	0
9	A qualified pharmacist independent prescriber could manage osteoporosis through making appropriate changes to prescription medicine.	2 (6.1)	6 (18.2)	14 (42.4)	9 (27.3)	2 (6.1)

* Median is indicated by shaded background.

*5 = Strongly agree; 4 = Agree; 3 = Neither agree, nor disagree; 2 = Disagree; 1 = Strongly disagree.

5.3.3.1 Additional comments

The GPs had the opportunity to give additional comments. The comments (n = 13 [39.4%]) included concerns about resources (i.e. funding (n = 9), time constrains (n = 4) and training (n = 3)). Two comments explained a lack of trust in pharmacists. The comments below are quoted directly as presented in the online questionnaire and may therefore contain spelling mistakes.

Resources

Funding

Nine comments included concerns about remuneration for the additional work the GPs had to take on and questioned how it would be funded.

"If GP's are to have yet more work transferred to them from secondary care, appropriate funding to provide the service should follow eg prescribing/monitoring of a drug should be part if an Enhanced Service." (GP14)

Some GPs explained that they would not receive the proper remuneration, but would deliver the service if provided.

"Although it should be possible for these activities to be perfored in primary care we do not have the resources to take on this work. If adequate funding could be diverted into practices then I would support practice staff taking on this role. Until that happens, I could not allow this to go ahead in my practice." (GP33)

One GP mentioned that funding a primary care service would be cheaper than hospital care.

"I would be happy for the practice to provide the service and certainly to give the injections. I would want to be sure that we would not be penalised for extra prescribing costs. Alos falls assessment and dietry advice takes considerable time [unlike an injection or blood test] and extra payment would eb needed should these be undertaken. HOwever for many patients getting the medicationin the community would be much easier and so In prinicapl I am very much in favour.[the comments about cost are not because we are greedy but because we are overwhelmed and would need extra nurse time which owuld cost money.It would still most likely be cheaper than hospital treatment." (GP30)

Time constrains

The GP respndents explained that they do not have the time to start an additional service in addition to what they already deliver.

"Primary care is too busy to take on more unfunded work. We are drowning in our current workload- it may seem easy but we would need training and time which does not exist. (...)*"* (GP21)

"Where will GPs and Practice Nurses find the extra time to offer a comprehensive falls and dietary assessment service? (...)*"* (GP24)

Training

Three GPs mentioned that there would have to be training of GPs and practice nurses to deliver such a service.

"Know nothing about this drug! Do dieticians not get involved in OP care?" (GP11)

"(...) *Would there be any further training available around denusumab?"* (GP24)

"Difficult to nswer these questions wihout more knowledge about the drug its side effects and monitoring requirement. (...)*"* (GP28)

Lack of trust in pharmacists

One comment was interpreted as lack of trust in pharmacists administering and changing medicines.
"(...) *pharmacists should not be administering or changing medicines."* (GP27)

Another comment highlights the need for good communication within primary care.

"(...) *Community pharmacists are not integrated with GPs. Would risk duplication of work or patients not having treatment or checks if community pharmacy was involved."* (GP21)

6 Discussion

6.1 Statement of principal findings

The aim of the study was to investigate the potential for community pharmacists to deliver a pharmaceutical care package as a part of osteoporosis management and propose a pharmacist-led service as a part of a new patient journey. No similar study exploring the potential for the delivery of a pharmaceutical care package, or a qualitative exploration of the patient journey for patients suffering from osteoporosis was found in the published literature.

Through interviews and questionnaires, patients, GPs and community pharmacists expressed that the proposed pharmacist-led service seemed to be convenient for patients, and to enhance care. One important reason for this was that assessment of falls risk and the need for calcium and vitamin D is currently not performed. In addition, the delivery of the service was seen as an achievable and expanded role for community pharmacists, which would relieve pressure off the current hospital service and GP practices. However, patients preferred GP practices as a venue for injection administration on the basis of convenience, partly because the confidence and relationship with the nurses was perceived as important. Patients also believed that community pharmacies had less expertise than the hospital or the GP practices.

To meet the patients' preference of receiving denosumab in the GP practice, the barrier mainly seems to be resource capacity which was also regarded as a challenge in the implementation of the proposed pharmaceutical care package in the community pharmacy. In addition, there is a demand that interdisciplinary team communication is performed within secure and efficient mechanisms where each member of the team would have a clear understanding of the roles and responsibilities of each other. In order to deliver the proposed pharmaceutical service as a standard part of osteoporosis care, these challenges need to be overcome and appropriate governance to be defined.

6.2 The proposed patient journey

This study has explored opinions regarding a proposed patient journey. The next section discusses different elements of the journey from different perspectives.

6.2.1 The patient perspective

6.2.1.1 Pharmaceutical care package

The pharmaceutical care package was designed based upon published evidence regarding the separate elements (i.e. medication review, assessment of falls risk and diet). This was to assure delivery of the best possible health care to patients.

Medication reviews

Medication review outcomes are beneficial for patients. The outcomes in different settings have been presented in literature (6, 72). In a recent meta-analysis, Hatah et. al. concluded that medication reviews have a positive impact on hospitalisation rate, increased adherence and some clinical outcomes, such as low density lipoprotein and blood pressure (72). However, the authors also concluded that medication reviews do not influence mortality risk. Vinks et. al. showed that medication reviews undertaken in community pharmacies may lead to a reduction in drug therapy problems (73). In a study where medication reviews were undertaken in care homes for elderly, Zermansky et. al. showed a reduction in falls, which is important in osteoporosis to avoid fractures (74). A Cochrane review concluded that increased adherence to treatment have larger effect then any treatment itself (1). Despite all the evidence, data in this study suggested medication reviews are not currently delivered to all osteoporosis patients, which emphasises the clear need for such an intervention.

Most of the community pharmacies included in the current study reported they were undertaking medication reviews in general and believed that they could help increase adherence through medication reviews, which is the basis for the CMS. This data supports the feasibility of including a medication review in the pharmaceutical care package.

Assessment of falls risk and the need for calcium and vitamin D supplements

Assessment of falls risk using FTSST and FRASE is also evidence based and the latter following the current Lothian protocol (54, 55). No validated tool was found for assuring sufficient intake of both calcium and vitamin D, but is highlighted as important in the SIGN guidelines and is an important part of osteoporosis treatment (12). The intake of calcium alone could be assessed by using an online calculator from the Centre for Molecular Medicine, which is in accordance with the suggestion from National Osteoporosis Society in the Vitamin D Guidelines (70, 75). This is also a relatively simple task for a community pharmacist which indicates feasibility.

Delivery of the pharmaceutical care package

It seems there is insufficient capacity in all professional services and there is a need for multidisciplinary agreement as to who delivers this service. Almost half of the patients did not report being asked about medicines, falling or diet in primary care (i.e. by GP or practice nurse). Most of the GP respondents agreed that medication reviews and encouraging adherence could be done by a community pharmacist and did not disagree with the pharmacist assessing falls risk and the need for calcium and vitamin D. They had more disagreement with pharmacists administering the denosumab injection. This evidence suggests that there is some appetite to explore and agree a defined new model of shared care.

Despite all the evidence of the pharmaceutical care package being beneficial for patients, it is not currently delivered to all osteoporosis patients. Consequently, there is a clear need for such an intervention. The opportunity to deliver a service which includes these elements was embraced by almost ¾ of the community pharmacy respondents. However, some patients would not be comfortable with a pharmacist asking about falls, diet or the medication, perhaps based on their previous experiences or the relationship. As the wording of the questionnaire item did not clarify if it was questions about falls, diet and medication, or the fact that it is the pharmacist who asks these questions that was perceived as uncomfortable, a conclusion cannot be drawn.

6.2.1.2 Relationship

One reason for the patients' preference for GP practices is their relationship with the practice and osteoporosis specialist nurse. This was described in the patient interviews and questionnaire comments as an important factor for the preference of venue. A good relationship with the health care professional was explained to be important in Robben et. al. findings in a qualitative study, which investigated the preference for receiving information among frail older adults and their caregivers (76). The authors do not describe if it is the bond and rapport itself, or if it is important that the bond is with a physician or in this study; a nurse. One of the important factors involved in the patient-nurse relationship is trust, and was explained by some patients as the reason for their choice (77). One of the patient interviewees expressed the relationship with the pharmacy as very good and based her preference of receiving treatment in the pharmacy partially on the relationship. As many patients explained the relationship with the pharmacy as good, it can be questioned if the patient-nurse relationship and the trust involved can be translated to the patient-pharmacy relationship. The chi square did indicate that a higher proportion of patients have a good relationship with the nurse compared to the community pharmacy, but a more thorough study should be undertaken to investigate the relationships. This study does not conclude that a higher proportion of patients have a better relationship with the nurse compared to the community pharmacy.

It is important that the patient-pharmacist relationship is good to deliver health care in community pharmacies. For the pharmacist to a build a good relationship with the patients, continuity in the pharmacist who delivers the service to the patient would be important (76). The continuity may also increase the feeling of expertise, which was commented as a reason to prefer the hospital and is a determinant of patient satisfaction (78). The public must be reassured through revalidation of competence for pharmacists to be trusted delivering direct clinical care (79).

Recognition of the existing pharmacist-led services in community pharmacies was believed to be an advantage for the patients to be comfortable with receiving the denosumab injection and osteoporosis care in a community pharmacy. Over one third of the community pharmacies responded that they deliver the contracted pharmaceutical care services and are leaders in the profession prepared to take responsibility for delivery of clinically based services. However, the data did not indicate that prior knowledge of the clinics results in more patients being comfortable with the proposal.

The implementation of CMS may help to build relationships as pharmacists are required to engage with patients in the delivery of pharmaceutical care.

6.2.1.3 Convenience

The anecdotal feedback from patients regarding inconvenience of the current denosumab administration was confirmed in this study. The patients reported a longer travel to the hospital than to their community pharmacy and several patients explained that the travel was time consuming and inconvenient. Convenience was explained by many patients as the reason for preferring primary care (i.e. community pharmacy or GP practice) as the venue of receiving the denosumab injection. Over half of the GPs agreed that denosumab could be administered in their practice and almost ¾ of the pharmacists respondents reported willingness deliver the proposed service. Delivering the service in a community pharmacy is in accordance with the government policy documents and drive which recommends transfer of healthcare to primary care and to be patient centred (4, 31, 32).

One important disadvantage with the proposed pharmacist-led service is that the majority of patients seem to prefer receiving their injections with their GPs. Although more patients answered the pharmacy rather than the hospital, the high number of preferences for the GP practice might question if the proposed pharmacist-led service will be patient centred. The results might have been different if the question asked to rank the preference of venue from 1 – 3. The GPs did not give a clear response on their views regarding delivering the proposed service from the GP practice, which could have been a lack of capacity and remuneration as some comments suggested.

6.2.2 The organisation perspective

6.2.2.1 Expanding the pharmacist role

The proposed pharmacist-led service would be an example of expanding the pharmacist role, although there are already contracted pharmaceutical care services delivered from community pharmacies.

There were disagreements among the study participants concerning whether community pharmacists should administer denosumab injections. The staff that currently run the osteoporosis clinic suggested in the interviews that subcutaneous injections are a simple task for pharmacists to undertake. Pharmacists responded that training was required, whilst GPs disagreed with a community pharmacist administering denosumab. In the light that some pharmacies already offer influenza vaccinations, these objects are contradictory. Actually, these pharmacists are already trained in resuscitation, anaphylaxis and needle waste handling. Consequently, denosumab administration might not be perceived as a novel approach. The current hospital staff also expressed that it would relieve pressure on their clinic, and make it more efficient and economically beneficial, and that it could reduce the waiting time into the osteoporosis service which would be in line with the Scottish Government's policy documents (31, 80).

6.2.2.2 Funding

Transferring money within NHS is recognised as a challenge for the organisation, but should be overcome to promote patient centred health care and meet patient needs. Government policy documents state that there is a need for redesign of services to move care locally and that the resources should be transferred (4, 81). However, it seems that more work is necessary to ensure resources are appropriately allocated to facilitate such redesign of services.

A financial challenge and pressure on GP practices was expressed by the GPs. With the proposed pharmacist-led service, care would be moved from secondary to primary care and increased pressure on GP practices would be avoided.

One challenge involved in implementation of the proposed pharmacist-led service is funding of a pharmacy remuneration package. This package would include compensation of pharmacist time, drug cost, and training. Parts of the funding of the pharmacy remuneration package could be obtained from the VAT savings (i.e. 20 %) if medication is purchased in primary care. Estimated drug cost for denosumab is £183 per injection (82), which means £366 per patient per year and £41,724 for 114 patients. The VAT savings calculates to £8,344.8 per annum which is unlikely to meet the resources necessary to establish a new model of delivery. Future work is required to estimate the value of improved convenience and delivery of the proposed pharmaceutical care package so that a business case can be made to the health board for transfer of services.

6.2.2.3 Training

In addition to funding, the governance of training for the pharmacists would involve some potential challenges. The training would include resuscitation, injection technique, waste handling, hygiene, a standard approach to medication reviews and how to undertake an assessment of falls risk and assessment of calcium and vitamin D requirements. One solution is to develop the training need into a national training package delivered by NHS Education for Scotland. This package could be generic enough to be applied for all treatments. Since the training would involve resuscitation and injection technique, practical clinical skills development would be required possibly accessed through existing NHS Education for Scotland resources used by other professions.

Community pharmacists have already received training in medication review to support implementation of CMS. All pharmacies could access the osteoporosis training package, but there may be some pharmacies trained to administer the injection, to which the local pharmacy could refer patients. This was suggested as a solution to reduce parts of the cost, where the pharmacies were chosen based on their geographical location, so the patients did not choose any community pharmacy within NHS Lothian, but could choose from a selection of pharmacies which were offering the service. Such a solution may impact on convenience for patients and on the relationship with the local pharmacy. Economic modelling would provide options of service with different associated values.

6.2.2.4 Delivery from pharmacies

Receiving the service at the local pharmacy was mentioned in one of the comments as the reason for preferring the pharmacy as a venue to receive denosumab injections. One reason for this could be the patient-pharmacist bond and rapport as explained in 6.2.1.2. However, to choose specific pharmacies within geographical areas would not only remove parts of the training issue, but would also give each pharmacist more patients, thus delivering the service several times a year. To take it one step further; it would be possible to choose community pharmacies which are already offering influenza vaccinations. This could optimise the resuscitation training or eliminate the need for resuscitation training if it is already covered by the pharmacists. However, a limited selection of pharmacies could be a potential disadvantage from the patient perspective as it may reduce the convenience and continuity of pharmacists. The patient questionnaire was also directed to their local pharmacy, which gives another perspective than a possibly unknown pharmacy. These opposing issues to which pharmacy that should deliver the service makes the decision difficult and needs more work to weigh potential benefits and disadvantages, including economics.

Some patients experienced the pharmacy facilities as not satisfactory. To make patients more comfortable receiving health care in a pharmacy, the pharmacy might have to develop more into a clinic, and meet the patients' requirements regarding a private consultation area and without having to

wait. These requirements have been described in a previous qualitative study (79). An appointment driven service would remove the wait issue and could make the patients perceive the service as more comfortable due to the protected time involved in an appointment. This may remove the patients' experience of a busy pharmacy. Appointments would also assure that the patients are being given the injection and not lost to follow-up, which was a concern expressed by the osteoporosis specialist nurse. The suggestion of allocating appointments was met by two thirds of the pharmacists who replied, which indicates that it is feasible.

To assure that the patients perceive community pharmacies as comfortable, and to maintain the high standard of the pharmacy profession, a set of standard requirements should be developed and fulfilled before being able to deliver the service. The standards could include private consultation area, being able to allocate appointments and having at least two pharmacists available most of the opening hours. The latter standard was based on the questionnaire that commented lack of staff as a problem. All these standards were shown to be involved in patient and pharmacy satisfaction. If the pharmacies were chosen to be the ones delivering influenza vaccinations, the standards could also include having correct governance for needle waste, resuscitations skills and anaphylaxis equipment which would further relieve the resources involved in implementation.

Another challenge involved in the delivery from a community pharmacy is the patients who are housebound and may not be able to visit the pharmacy to receive the pharmaceutical care package. If the community pharmacies were to deliver the service to all the denosumab patients it would therefore involve home visits for some pharmacists. This is not an unusual approach internationally where Australian pharmacists are visiting patients at home and are undertaking medication reviews in the Home Medicine Review Program (83). However, no funded home visit community pharmacy services were found to be delivered in NHS Scotland, so this would be a novel approach for Scottish pharmacists.

6.2.2.5 Communication and collaboration

Communication between the pharmacy, GPs and the hospital is included in the proposal to ensure that every healthcare professional involved is informed and updated on the health care delivered to the patients. This is important to assure that every member of the health care team is updated on the patient's status to make correct decisions. The collaboration is supported by goals in the Healthcare Quality Strategy document (31) and the Shifting the Balance of Care improvement framework (32).

The communication between community pharmacists, the hospital and GPs is challenging as there is currently no system in place for sharing information. This was mentioned in the interviews and questionnaire comments as a concern among some patients and health care professionals. It has been suggested in the proposed pharmacist-led service (section 5.1.2) that a form is sent by fax to the

patient's GP and the osteoporosis service in the hospital. This form needs to follow the internal procedure for the development of new clinical documentation and be reviewed and agreed by the Clinical Documentation Group in NHS Lothian. This form would assure every member of the patients' health care team to be informed about the pharmacies action and would serve as a record of care for other purposes, such as the GPs' Quality and Outcomes Framework.

For the GPs and hospital to be aware of the care provided from pharmacies, medical records need to be updated. An extended version of TrakCare®, would reduce the time and maintain data in one place for access by the team. To assure patient confidentiality each health care professional involved in the proposed service (i.e. GPs, community pharmacists and the osteoporosis service in the hospital) could have access to a partition of TrakCare® where the necessary information was available. This would give the pharmacists diagnoses, treatment and laboratory test results which is required to undertake a level three clinical medication review and has shown to enhance patient outcomes (72, 84).

If the pharmacists are delivering the proposed service and the proper communication is governed, it would not be an obvious truth that the collaboration would be welcomed by the GPs (85). This issue needs to be addressed to assure patient safety. Improving communication to enhance collaboration has been a goal in Scottish Government policy documents (4, 31, 32). The GP and pharmacy relationship has been explored and found to involve GPs lack of trust in pharmacies due to the shopkeeper image (85). Lack of trust was expressed by one GP in the questionnaire and in the interviews. In the current climate, communication is a problem for the SBC and the Managing Long-Term Condition-document to be implemented, which is clear from this study.

Some work has already been done to improve collaboration, where the Royal Pharmaceutical Society and The Royal College of General practitioner have made a joint statement for improved collaboration between community pharmacists and GPs (86). They suggest that the collaboration should start from an undergraduate level, which would ensure both professions' knowledge about each other's educational background (86). They also suggest regular meetings between the professional bodies to provide joint working (86). There are documents that are specifically made to serve as guides and show that work is done to improve communication and collaboration (87, 88). Despite all this formal work being published, the collaboration remains an issue for implementation of enhanced health care.

6.3 Implication of the study results for clinicians, community pharmacies and policymakers

The convenience and trust is important for the patients involved in this study. As they find the current service inconvenient, it should be prioritised and acknowledge by the clinicians and policymakers

involved to meet the patients' requirements. A shared care protocol has not been agreed, but is in keeping with the patient's preference and should be revaluated. If the GPs still do not want a shared care protocol, the proposed pharmacist-led service is a feasible option. If the care is shifted to the community pharmacy, the patients trust needs to be reassured by highlighting the pharmacists competence. There is a need for further studying the clinical outcomes of the proposed pharmacist-led service to assess the clinical and economic value (see section 6.4).

This study has identified several challenges that need to be overcome for a shift in the balance of the care. Although it has been four years since the SBC was introduced in Scotland, the resources and communication needed for such a shift is a barrier for improvement in care. Sharing information electronically between all members of the health care team should be prioritised to ensure safe and efficient patient care.

Despite the limitations of the study (see section 6.5.5), the study serves to underpin the development of pharmaceutical care services in community pharmacies in other countries. As described in the introduction and in appendix 1, there are similarities between osteoporosis in Norway and Scotland. As denosumab is either self-administered or administered in the GP practice in Norway, the convenience issue is not comparable. However, there are possibilities for Norwegian community pharmacies to deliver the remaining pharmaceutical care package to patients suffering from osteoporosis. Administration of injectable medicines would be a novel approach, but may be achievable for Norwegian community pharmacists with the additional training required. The challenges identified in this study may be comparable to challenges involved in similar proposals in Norway. The Norwegian community pharmacies can be considered as an alternative venue to receive direct clinical health care as the Norwegian Coordination Reform is implemented. This will ensure health care locally in accordance with the reform.

6.4 Unanswered questions and future research

The clinical outcomes of the pharmaceutical care package proposed in this study are not known to have been evaluated as a single service. As there is evidence supporting each part separately in different settings, a randomised clinical trial of the proposed pharmacist-led service could be undertaken to evaluate the clinical outcomes to ensure evidence based practice. Potential outcome measures are:

- Adherence using Medication Event Monitoring System (MEMS™) (89)
- Drug therapy problems
- Knowledge using Osteoporosis Knowledge Assessment Tool (OKAT) (90)
- Number of falls and fractures

- Morbidity
- Hospitalisation
- Calcium and vitamin D levels
- Quality of life using Osteoporosis Quality of Life Questionnaire (OQLQ) (91)

A feasibility study could be initiated to define outcome measures and sample sizes using the methodology described in the Medical Research Council framework for complex interventions (92).

Due to the low numbers of patients receiving denosumab in NHS Lothian, it may be a challenge to recruit enough participants to the study. Especially if the participants are included as denosumab is first initiated, preferably from being managed in primary care and consequently unfamiliar with treatment in secondary care. This would be advantageous as the participants will not be biased and compare the community pharmacy to hospital care. A potential solution is to either expand the study to other parts of Scotland or to include patients who are already receiving denosumab treatment, the former being preferable. Arms in the trial could include receiving the community pharmacist-led service and compare to the current hospital treatment. The subjects should be stratified by age, previous fractures, duration of disease, BMD and if they have received treatment in the hospital previously.

The randomised controlled trial could in turn lead to a cost-effectiveness analysis of the proposed pharmacist-led service and explore the financial feasibility of shifting care in the current climate. A financial framework includes NHS budgets to community pharmacy services and the osteoporosis clinic at WGH, where details about drug cost and salary for nurses, physicians and community pharmacists can be investigated in detail. Furthermore, an estimation of cost involved in the implementation of the journey such as training of pharmacists should be explored. Such an analysis would explore the best use of resources at a local level which is in accordance with the Managing Long-Term Conditions policy document (4).

A questionnaire regarding vitamin D intake should be developed and validated for the pharmaceutical care package to be fully completed. It may be more convenient for the community pharmacists to have both calcium and vitamin D in the same questionnaire. The development and validation of the questionnaire should be done before the randomised clinical trial is undertaken.

Lothian Joint Formulary's osteoporosis guideline states that first line treatment is bisphosphonates, second line treatment is either strontium ranelate or zoledronic acid and third line treatment is denosumab. It became clear in this study that clinical practice may deviate from the guidelines. There might be a need for discussion on new guidelines for osteoporosis management in NHS Lothian. Especially in recent light of an increased risk of myocardial infarction after treatment with strontium ranelate, which led to a drug safety update from Medicines and Healthcare Products Regulatory Agency (93). This update led to a recommendation for restricted use of strontium ranelate.

The lack of communication was acknowledged as a barrier and as a Government goal not yet achieved. More work should be done to explore the possibilities of shared information between health care professionals within the NHS to improve collaboration and safe patient health care. One solution is to expand the access to TrakCare® for community pharmacists, GPs and the secondary care ensuring clear understanding of the responsibilities of each health care professional and avoid duplication of work. As there are Government documents already seeking such shared care collaboration, in addition to moving care locally, these documents should be reviewed for further action plans to be developed. This can ensure improved health care in the future, where a shift of care locally will be easier to accomplish.

If such a shared information system was in place, it is not an obvious truth that collaboration would be welcomed by the other health care professionals (as explained in section 6.2.2.5) or patients (as explained in section 6.2.1.2 and 6.2.1.3). The relationship between GPs and pharmacists in particular should be improved for increased collaboration. A qualitative study to explore the barriers involved in the relationship could increase understanding of what makes the collaboration difficult. Focus groups with GPs and community pharmacists separately and both professions together may be a potential method. Further qualitative studies should also explore the barriers for elderly patients to be comfortable receiving health care in a community pharmacy. This type of study could also include focus groups or one-to-one interviews and could potentially further explore what informs the patients' decision of where to receive health care. The outcomes of such studies may help pharmacist-led pharmaceutical care to evolve and expand to meet this patient group's preferences.

6.5 Discussion of methodology

6.5.1 Validity and reliability

Assuring feasibility, validity and reliability is important for newly developed questionnaires. Smith defines validity of an instrument as "the extent to which it actually measures what it is designed to measure" (68).

6.5.1.1 Feasibility

Feasibility of the questionnaires was considered by the investigation team as good. The length, duration to complete and use of colours were considered feasible to be completed by busy professionals. The pharmacy questionnaire was in black and white due to distribution method (i.e. fax). The instructions were regarded as clear by the investigation team and no feedback from the pilots or the questionnaire response indicated misinterpretation or ambiguity. However, one patient

gave feedback through comments in the questionnaire that the Likert scale was confusing and that a straight yes or no answer would have been a better way to ask questions. The Likert scale was used due to its value in obtaining opinions and perceptions and it tends to have good reliability (64).

The pilots also assured feasibility (see section 6.5.1.3).

6.5.1.2 Content validity: qualitative interviews and comment boxes

The use of qualitative data to inform the design of the questionnaires was to assure maximum variability, remove investigator bias and assumption, and partially assure content validity (68). Without the semi-structured interviews, the questionnaires might have been influenced by the study team's perceptions and views. This was particularly important for the investigator who had not been involved in osteoporosis care prior to the project.

To assure content validity all participants were given the option to express any additional comments at the end of the interview and the questionnaire (except the pharmacy questionnaire). This option gave the participants the opportunity to include potentially missed topics and include views not included in the questionnaire. The GP comments were about funding, training and time constraints which were deliberately not included in the questionnaire because it was already recognised as an issue and this would have lengthened the questionnaire. If the funding was described in the introduction to the questionnaire, the results might have been different; for example "Please answer the result on the basis that proper remuneration was given" might have skewed the results to be more positive. A question in the start of the questionnaire asking about the importance of remuneration might also have skewed the results. Per contra, if the funding was described in the introduction stating "no remuneration would be given to the GPs", the results might have been skewed to be more negative, and possibly more positive towards community pharmacists delivering the proposed service.

Other methods such as focus groups could have been used instead of one-to-one interviews which could have changed the content or possibly expanded the range of topics included, but this would have required resources to remove professionals from their workplace to participate in focus groups (see method discussion, section 6.5.3.3). Any future funded research should consider the value of this method, which may have enabled clearer understanding of roles and responsibilities if groups included mixed stakeholders.

6.5.1.3 Face validity

Face validity of the interviews and questionnaires was assured by expert opinion, discussion and piloting. The questions for the semi-structured interviews and the questionnaire items were discussed

by the study team and with colleagues, including an advanced clinical pharmacist in rheumatology, before piloting. The discussion was the first part of assuring face validity (68).

The second part of assuring face validity was piloting the interview and questionnaire. Although pilot participants were chosen by convenience, the selection was partly purposive (except the patient questionnaire pilot). In the interview pilots, the patient was a so-called "expert" patient who has previously been involved in projects and was therefore considered to bring a wider range of opinions than a patient without such experience. The hospital pharmacist who acted as a pilot was a senior pharmacist with views that may unify community pharmacy and the hospital perspective. In the questionnaire pilots the community pharmacist is experienced and involved in the leadership of service developments within the profession. This was regarded as an advantage and may give a wider range of views than from a pharmacist without such experience. The GP was an audit facilitator familiar with views of the wider profession. The interview questions and questionnaire items were easily understood by the pilot participants, which may indicate face validity and feasibility.

It is acknowledged that one pilot for the patient interview and one pilot for all the healthcare professional interviews is not a robust face validity check. The lack of piloting also applies to each questionnaire which was piloted on one occasion only. More piloting is regarded as most important for the questionnaires as they were distributed to all stakeholders and could have confirmed that the questionnaire items were clear for the patients and that it measured what it was intended to measure, i.e. assuring validity. A validated questionnaire would have gained trust in the study. In addition, only the patient questionnaire was piloted face-to-face which ideally should have been the case for all pilots. The piloting should also have included more participants chosen by a judgemental sample (i.e. a wide spread sample of individuals based on the characteristics obtained for the population) and piloted several times (64). More patient pilots could have estimated that it might take more than two minutes to complete the questionnaire which was expressed by one patient as an additional comment. If more pilots amended the wording of the questionnaire item, the outcomes of the study might have changed. However, it is difficult to predict whether or not more pilots would result in such changes. One questionnaire item that may have changed was number 12; regarding patients being comfortable with a pharmacist asking about falls risk, diet and medication. More pilots may have resulted in one more item to explore if it was the question or the fact that the community pharmacist asked the question.

6.5.1.4 Reliability

Smith defines reliability of an instrument as "the extent to which the findings are reproducible or internally consistent." (68).

The questionnaires were discussed by the investigator team and with colleagues to assure reliability before and after the questionnaire pilots. The interviews and the analysis of the interviews and questionnaires were undertaken by one investigator, assuring reliability in interviewing and analysis. However, discussion and piloting is not a robust reliability test and it is recognised that further tests should have been executed to assure reliability. Test-retest, the split-half method and parallel-test are some reliability tests that could have been used. Testing for internal consistency with Cronenbach's alpha was not regarded as feasible due to no interrelation in the questionnaires.

To assure reliability when obtaining opinions about current and future service, a set of questions could have been asked instead of one question for each attitude. This is more accurate than asking one question in different ways to assure reliability when using attitude measurements (64). However, this was assumed to be unsuitable for the questionnaires due to the limited amount of items (see section 6.5.2).

The risk of recall bias is present in the patient questionnaire when asked about travelling. The answer provided is an approximate estimation and should be read with care. It is assumed that the community pharmacy is closer to their home because of the abundance of community pharmacies (n = 182) in Lothian compared to the Western General Hospital (n = 1), and the patients are scattered throughout Lothian.

6.5.1.5 Other validity and reliability issues

In every questionnaire there is a potential for self reporting bias and might therefore not provide accurate data. This can be envisaged by the adherence question (question 5) in the patient questionnaire, where every patient asked, except one, agreed to be taking all their medications as prescribed. As patient adherence is estimated to be about 50 % and self-reporting being a bad estimate for adherence, the patients may have not answered the questions honestly (1). Another explanation is if the patients do not receive treatment for other conditions or were envisaging the denosumab only; in which the adherence is likely to be as high as 100 %. This would be achieved just by attending the hospital appointment.

To improve the validity of the interviews, all the verbatim transcriptions could have been double checked by the administrator (mentioned in section 4.2.1.5) and should ideally have been returned to the interviewee for approval, and clarification if needed. All the transcriptions were read by the investigation team and the questionnaire items were agreed. They were double checked in the results and all members of the study team agreed on the themes and quotes used. The raw coding sheet could have been double checked by another member of the investigation team to assure the right themes to each quote. The questionnaire data was coded by the investigator only and the random sample test

(see section 4.3.4) did not discover any data entry or coding mistakes, assuring coding validity in the questionnaire results.

Two chi square tests were applied to the questionnaire data. The first chi square was to compare the relationship with the nurses and pharmacists (see section 5.3.1.3 and appendix 24). The other was to compare prior knowledge of pharmacist-led clinics and being comfortable receiving the injection from a pharmacist. Asking about patient-nurse relationship and patient-pharmacist relationship was considered to be two independent variables as the setting and the underlying factors to the relationships are different. It was not considered to violate the chi square criteria of being independent for that reason. The second chi square was used to compare those who were aware and unaware of the clinics to those who were comfortable or not comfortable receiving the denosumab injection from the community pharmacist (see section 5.3.1.7 and appendix 24). There were four patients who did not complete both questions and were removed from analysis for these items. This may have skewed the results in favour of being comfortable as the two respondents who were excluded from analysis were not comfortable. The other two patients were aware of the clinics and thus a higher proportion was presented as unaware of the clinics. A more thorough study should be undertaken to further investigate if prior knowledge of pharmacist-led clinics affect patients to be comfortable receiving pharmacist-led health care.

Having assured validity and reliability would have improved trustworthiness of the questionnaires. In addition, the questionnaires could have been used for future studies.

6.5.2 Response rate for the questionnaires

6.5.2.1 Details included to improve response rate

The response rates for the questionnaires were variable, ranging from 6.6 – 80.7 %, although advice was taken to assure as high response rate as possible. An invitation (cover letter and e-mail invitation) was sent with the questionnaire to all participants invited and included information about the project. To increase response rate the invitation also contained explanation for selection, deadline, the NHS Lothian logo, assurance of confidentiality, and offering a copy of the survey results (i.e. the thesis) to pharmacies and GPs (64, 94). For the patients having an appointment in February or later, the appointment reminder letter was included in the envelope with the questionnaire. This was believed to promote a good response rate. The questionnaires were as short as possible to improve response rate (94). In addition, the patient and GP questionnaire contained colours and had a simple header (94, 95). The pharmacy and GP questionnaires also had a white background (94).

The choice of distribution followed regular mode of communication between NHS and the participants. The patient questionnaire was sent with white envelopes, a hand signed cover letter and

pre-paid return envelope, which was regarded as beneficial to conveniently respond. A reminder was sent after two weeks for an additional improvement in response (94).

6.5.2.2 Details that potentially could have improved response rate

The patient reminder did not include an additional copy of the questionnaire due to the expenses involved and might have decreased response rate (94). Other methods, such as having personal invitations with names of GPs and pharmacies, could have improved response rate. Using first class post with handwritten address and recorded delivery has also been proven to increase response rate (94). The use of incentive was not used due to unfunded work, but might have improved the response (94). Under ideal circumstances, the participants would have been pre-notified and provided with further personal follow up (94). Particularly for pharmacists and GPs, where the regional managers for the biggest pharmacy chains and the GP sub-committee of the Lothian Medical Committee could have been notified to give approval of the study and motivate for response.

6.5.2.3 Non response and demographics

The response rate was low for the GP and pharmacy questionnaire. Low response rate was expected as the study team was warned before initiation of the study. As explained above, the questionnaires were made as short as possible, which reduced the priority of including demographics. It is acknowledged that some demographics should have been included to compare the groups and explore the non-response. However, the characteristics of the populations showed to be difficult to find for all groups involved which can question the value and usefulness of including the demographics. A questionnaire containing a bigger number of items could additionally have decreased response rate.

The demographics for the patient questionnaire were limited as all patients were elderly. In addition, the indication for denosumab is postmenopausal women. However, there were nine men which received treatment with denosumab and were therefore included in the study because the potential pharmacist-led service would also include them. This may indicate that including more demographics, such as age and gender could have improved the description of the responders versus non-responders. This could consequently have been used to confirm that the results were generalisable for the whole population.

Establishing characteristics that could be compared between responders and non-responders would be difficult as this is an opinion seeking survey. Thus, the variables central to the study would be more useful to compare, but are hard to access without getting the non-responders' answers through extensive follow-up (such as telephone calls and interviewing). This search for non-response bias would be ideal, although such follow up might have included patients who are not capable of

answering due to illness (i.e. the situational non-response). If non-response bias was established after such work, the results could be justified through weighting the differences in responders and non-responders thus strengthening the generalisability.

The GP and pharmacy questionnaires should be read with care and the results cannot be extrapolated to the population. Increased response rate may have changed the pharmacist and GP result, and could have reached a high enough response rate to be representative for the population, thus increasing the impact of the study. As the response for the pharmacies were anonymous and they were provided with two questionnaires (i.e. the original questionnaire and the reminder), it is theoretically possible that one pharmacy answered twice, yielding a lower response rate than the results presents. It was emphasised that the pharmacies should only complete the questionnaire once, but it was impossible to check due to anonymity. The patient questionnaire had a good response rate, but establishing non-response bias based on demographics was not possible, hence questioning the generalisability of the findings.

The actual response rate for the patients may be higher than presented in the thesis. It was recognised through feedback from the osteoporosis specialist nurses, carers and patients that parts of the non-response was situational, such as inability to complete the form (e.g. dementia, learning difficulties and inpatients). The number of patients being eligible to complete the questionnaire is unknown, but estimated after feedback to be lower than the 114 patients invited, which will increase the response rate.

Item non-response bias was regarded as not likely due to the randomness of the missing data. The last page was not completed in six of the patient questionnaires, which may indicate carelessness in the latter part of the questionnaire. The missing items were left empty in the questionnaire as the questionnaire did not yield a score and hence were regarded to not affect the data. To avoid item non-response, the questionnaires could have been administered by the investigator or asked as a short structured interview, but was not done due to limited time and resources.

6.5.3 Methods

Methods for social sciences such as interviews, group discussion and questionnaires all rely on the participants' personal answers and are not static facts, but rather subjective opinions and perceptions. The study objectives were to gather experience and thoughts of stakeholders, which can justify using the chosen methods.

6.5.3.1 Interviews

The interviews were chosen to be exploratory with open-ended questions asked one-to-one for the participants to respond without being influenced by others. For the interview to be on topic, it was decided that semi-structured interviews would provide the opinions under investigation without having too many digressions. Two advantages with interviews in general are having the opportunity to clarify ambiguous responses and asking for greater depth in their answer if needed, which is not possible with a questionnaire. It is also an advantage that the interviewee can express their opinions freely and provide reasons and experiences which serves as a foundation for their opinions. These advantages may indicate that interviews with all the patients gather more valid data than questionnaires.

The fact that there is an interviewer present may lead to interviewer bias, which in comparison does not exist in questionnaires. The interviewer was inexperienced and unfamiliar with osteoporosis care and qualitative research. The interviewer was also a pharmacy student which may influence the interviewees towards being more positive about pharmacists. However, the interviewer was independent from community pharmacies in Scotland which may remove some bias in the interviews.

Sampling

The community pharmacist and GP were chosen by a purposive sample with the purpose of maximising variability to inform the design of the questionnaire (68). Both of the experienced professionals selected felt they could bring views of their professional groups, rather than just personal opinions.

The inconvenience for the patients to come to the hospital and the project time frame was two of the reasons for choosing a convenience sample of patients.

However, it is recognised that more participants could have been included to reach saturation of views. For the osteoporosis specialist nurses and physicians, it was not possible to include any other due to the inclusion criteria and the purpose of the study. If more patients, GPs and community pharmacists were interviewed until saturation was reached, a broader range of views could have been obtained. This could have led to more detailed questionnaires and may have influenced the proposed journey. The comment box attempted to widen opinions.

Telephone interview is one possibility to have increased response rate using the same questionnaire. It could also have included more in-depth data if changed to a semi-structured interview with closed questions and the option to give additional comments. The time involved in telephone interviews rejected the method.

6.5.3.2 Questionnaires

The strength with using questionnaires is conveniently including all stakeholders and not having to sample the respondents. This gives the whole population the option to respond and provide their opinions in a cost efficient way. When the response rate is too low for making generalisations, there might have been other methods which could gather more generalisable information, such as more interviews or focus groups.

Inclusion criteria and sampling

The patient questionnaire had the inclusion criterion that they must have had one injection or more to participate. If the criterion was changed to two injections or more, it could have changed the answers due to experience with the service, such as building a rapport with the nurses or experiencing travel inconvenience. The outcome of a different inclusion criterion is difficult to predict.

The pharmacy questionnaire used a sample of the community pharmacies rather than the community pharmacists. It was addressed to "the responsible pharmacist" and therefore restricts the number of potential responses and opinions. "The responsible pharmacist" excludes other pharmacists such as the second pharmacist and locum pharmacists. To make the sample of pharmacists wider, one possibility is to send more questionnaires to each pharmacy and thus increasing the range of views and potentially the response rate (68). The number of community pharmacists in NHS Lothian is unknown and would make it impossible to calculate response rate from the latter suggestion. However, it is recognised as ideal to include all community pharmacists in NHS Lothian as opposed to all the pharmacies.

Content

For the questionnaires to provide more accurate opinions about the proposed journey, it should have contained a more detailed explanation of how the proposed service was envisaged. For example, the pharmacy questionnaires could have included waste handling, communication and paperwork involved, which could have resulted in altered answers. This was not provided due to the practicalities not being set in detail and the potential of including incorrect details which could skew the results. In addition, the wording of the questions can have introduced acquiescence bias. One GP gave the feedback that the wording "could" and "should" can sway the answers.

6.5.3.3 Focus groups

Focus groups could potentially have included more participants and gathered more data. This is particularly beneficial for GPs where the response rate was very low. The advantage of focus groups is the interaction between participants to stimulate discussion. This can potentially generate ideas that give a greater depth in the topic discussed, for example details for communication and collaboration (62). It is anticipated that focus groups would have been less costly and time consuming than conducting semi-structured interviews with the same numbers of participants.

6.5.3.4 Analysis

No gold standard was found to explore experience and thoughts. However, grounded theory analysis is an alternative approach to further investigate and establish a theory regarding experience and thoughts concerning current and future practice (67, 96). This method would require more interviews (or focus groups) than were undertaken in this study.

6.5.4 Patient journeys

The current patient journey for patients with osteoporosis at Western General Hospital was made after discussion with an advanced clinical pharmacist in rheumatology and an osteoporosis specialist nurse. It was made for the purpose of giving an overview of the current situation and to be a general journey for most patients. Consequently, there may be patients who experience other journeys than explained. The final version was confirmed by the osteoporosis specialist nurse and a professor involved in osteoporosis management at the Western General Hospital. During the interviews the flow chart was shown to another osteoporosis specialist nurse and to other physicians involved in osteoporosis management at the Western General Hospital, in addition to a GP. Although the current patient journey was not commented on by the interviewees (except for a few minor details, see section 4.1), it should ideally have been confirmed by others who are involved in the journey, such as patients and GPs, to confirm that it was correct from their perspective.

A confirmation of the current patient journey could have been done in a focus group discussion, where the proposed patient journey also could have been presented and discussed in detail. A nominal group technique could have been used. If all stakeholders were involved in such a discussion, all stakeholders would have been together and provided opinions and different approaches. This may approach consensus in a patient centred health care. To have more participants involved would also have strengthened the proposed journey as a broader sample of the populations would have been involved. Although this approach was not used in the study, the influence from stakeholders included is deemed an advantage compared to proposing a patient journey without including stakeholders.

6.5.5 Other limitations

This study was investigating supply and administration for patients with osteoporosis in NHS Lothian, and included participants from NHS Lothian. It does not represent other health boards across Scotland, other parts of the United Kingdom or internationally. Hence, if the results and recommendations were to be compared or extrapolated to other health boards across Scotland, United Kingdom or internationally it must be done with utmost care.

7 Conclusion

Based on the results gathered in this study, a proposed patient journey has been recommended. The patient journey is a novel shared care approach between the hospital and the community pharmacy. The community pharmacy would deliver an evidence based pharmaceutical care package in primary care, which will enhance patient health care. The pharmaceutical care package would include administration of denosumab, medication review and an assessment of falls risk and the need for calcium and vitamin D supplements. The proposed patient journey was presented to the team who currently manage osteoporosis in secondary care and agreed to be feasible from their point of view.

In the questionnaire survey, the patients preferred the GP practice as the venue to receive the denosumab injection on the basis of convenience, patient trust in the GP and nurse, and GP opinion. Most of the patients were comfortable with the proposal of a community pharmacist administration of denosumab which is a possible approach towards management of denosumab in primary care. Most of the community pharmacists were keen to deliver the proposed pharmacist-led service, but expressed a need for remuneration and training. The GPs have decided not to take denosumab as a part of their service, but most of the GP respondents agreed to administer denosumab in their GP practice. The GPs were less enthusiastic about the pharmacists administering the injection. It was acknowledged that pharmacists already undertake medication reviews and are capable of undertaking falls and dietary assessments. Further work is needed to investigate the clinical outcomes and cost-effectiveness of the proposed pathway of care.

In an organisation perspective there will be several advantages following implementation of the proposed journey. The osteoporosis service at the Western General Hospital will be more efficient and may reduce the waiting time for new patients if the proposed patient journey is implemented. If the repeat injection work is offered by community pharmacies, a shift of care will not affect GP practices where resourced capacity has reached its limit.

There is a clear need for transfer of resources, collaboration and communication within NHS Lothian to implement the service. The importance of these issues has been raised through several Scottish Government documents, but remains a barrier for implementation of the Government requirements. Thus, there is a clear need for actions towards patient centred health care delivered locally.

Notes

The e-mail regarding the use of denosumab in Tromso, Norway was sent from Dr Farahnaz Saleh (Senior Consultant, Department of Endocrinology, University Hospital of Northern Norway (UNN), Tromso) to Ben T. Henriksen (pharmacy student, University of Tromso, University of Strathclyde and honorary member of staff in NHS Lothian) 17th December 2012 with the subject "SV: Denosumab-prosjekt i Skottland" ["RE: Denosumab project in Scotland"]. The information in the e-mail was used in the thesis with permission from Dr Farahnaz Saleh and Ben T. Henriksen.

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Appendices

Comparison of osteoporosis in Scotland and Norway (rounded figures)

Comparison	**Scotland**	**Norway**
Population	5,300,000 (1)	5,000,000 (2)
Prevalence	250,000 (3)	240,000 (4)
Annual osteoporotic fractures	20,000 (5)	
Annual hip fractures in adults	6,000 (2007) (6)	9,000 (4)
Annual wrist fractures in adults		15,000 (4)
Changes in vertebra that may be caused by a compression fracture		230,000 (4)
Lifetime risk to have a fracture for 50 year old women	50 **%** (England and Wales) (7)	50 **%** (8)
Lifetime risk to have an osteoporotic fracture for 50 year old women	33 % (1/3) (5)	
Lifetime risk to have a fracture for 50 year old men	20 % (England and Wales) (7)	20 % (8)
Lifetime risk to have an osteoporotic fracture for 50 year old men	8 % (1/12) (5)	
Annual cost	£1.7 billion (UK) (5) £145 million (estimated for Scotland)*	£165 million**

Blank cells indicate that no data was found

*Estimated by the following equation: (Cost UK / Total population of UK (9)) * Total population of Scotland (1) (rounded figures) = (1,700,000,000 / 62,200,000) * 5,300,000 = 144,855,305 ≈ 145,000,000

**1.75 billion SEK (with an exchange rate of 0.094 GBP for 1 SEK)(10)

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Denosumab: More information

Mechanism of action

Denosumab is an immunoglobin (IgG2) which is a human monoclonal anti-Receptor Activator of Nuclear Factor-κB (RANK)-Ligand that inhibits bone resorption (1). When the endogenous RANK-Ligand (RANKL) is active, it binds to RANK on osteoclasts' surface, activating them and promotes formation of new osteoclasts (2). Denosumab inhibits osteoclasts by binding to and inactivating RANKL (1). Thus, the inactivated RANKL leads to an inhibition of bone turnover and an increased BMD (3).

Effectiveness

The phase 3 the Fracture Reduction Evaluation of Denosumab in Osteoporosis Every 6 Months (FREEDOM)-trial included 7,868 women and compared denosumab to placebo (4). They reported that there was a 68% ($p < 0.001$) relative risk reduction of the incidence of vertebral fractures, after 36 months. They also reported a 20 % ($p = 0.01$) relative risk reduction of the incidence of non-vertebral fractures and a 40 % ($p = 0.04$) relative risk reduction of the incidence of hip fractures. The relative increase in BMD was 9.2 % (95 % CI, 8.2 – 10.1) at the lumbar spine and 6.0% (95 % CI, 5.2 – 6.7) at the total hip. A reduced bone resorption was shown by a reduced median of 72 % for serum C-telopeptide levels and 76 % for serum procollagen type I N-terminal propeptide after 36 months. Serum C-telopeptide and serum procollagen type I N-terminal propeptide are known to illustrate bone turnover rate. The FREEDOM trial is now extended and will run for a total of ten years (5). No direct comparison between denosumab and bisphosphonates was found. However, for comparison, The Health Outcomes and Reduced Incidence with Zoledronic Acid Once Yearly (HORIZON) Pivotal Fracture Trial study compared zoledronic acid to placebo (6). The study showed a 70 % reduction (relative risk, 0.30 (0.24 – 0.38, 95 % CI)) of vertebral fractures, 25 % ($p < 0.001$) reduction of non-vertebral fractures and 41 % reduction (hazard ratio, 0.59 (0.42 – 0.83, 95 % CI)) of hip fractures after 36 months.

Adverse effects

The FREEDOM trial reported only mild adverse effects, such as eczema, flatulence and cellulitis, and did not report any serious adverse effects (4). Furthermore, the Summary of Product Characteristics mentions urinary tract infection, upper respiratory tract infection, sciatica, cataracts, constipation and pain in extremity as common adverse effects (7). It also mentions that there have been observed rare

cases of hypocalcaemia and osteonecrosis of the jaw with use of denosumab. A drug safety advice was recently given by the Medicines and Healthcare products Regulatory Agency based on two recently reported cases of atypical femoral fractures. Their advice is to advise patients on denosumab to report new or unusual thigh, hip, or groin pain (8).

Contraindications

Denosumab is contraindicated in patients with hypocalcaemia; hence calcium levels must be checked and corrected prior to initiating therapy with denosumab. Monitoring of mineral levels (calcium, phosphorus and magnesium) is recommended in patients predisposed to hypocalcaemia (e.g. renal impairment and patients receiving dialysis). Monitoring is also recommended in patients with disturbances of mineral metabolism (e.g. thyroid surgery and malabsorption syndromes) for the same reason. These patients should be informed about the symptoms of hypocalcaemia and the importance of maintaining adequate calcium and vitamin D intake. No blood monitoring is required except in the situations explained above (7).

Other information

The device is a prefilled syringe with a safety needle guard and has a volume of 1 ml (60 mg/ml) which is stored in a refrigerator between 2 and 8 ^{o}C. The route of administration is subcutaneously. All patients should receive calcium 1,000 mg daily and at least 400 International Units (IU) vitamin D daily when managed with denosumab, according to the SPC (7).

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South East Scotland Research Ethics Service

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG

NHS Lothian

Name: Moira Kinnear
Address: Dept of Pharmacy
Western General Hospital
Edinburgh
EH4 2XU

Date: 26/09/2012
Your Ref:
Our Ref: NR/1209AB8
Enquiries to: Alex Bailey
Direct Line: 0131 465 5679
Email: alex.bailey@nhslothian.scot.nhs.uk

Dear Moira,

Project Title: Supply and administration of Denosumab for patients with osteoporosis in primary care – a qualitative exploration of opinions to assess feasibility of practice development

You have sought advice from the South East Scotland Research Ethics Service on the above project. This has been considered by the Scientific Officer and you are advised that, based on the submitted documentation (email correspondence, RE Pharmacy project - osteoporosis.rtf, Tromso Denosumab 240912.doc), it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees (A Harmonised Edition). The advice is based on the following:

- *The project is an opinion survey seeking the views of NHS staff and patients on service delivery.*

If this project is being conducted within the NHS you should contact the relevant local Quality Improvement Team(s) who will inform you of the governance procedures required before the study commences

This letter should not be interpreted as giving a form of ethical approval or any endorsement of the project, but it may be provided to a journal or other body as evidence that ethical approval is not required under NHS research governance arrangements. However, if you, your sponsor/funder or any NHS organisation feels that the project should be managed as research and/or that ethical review by a NHS REC is essential, please write setting out your reasons and we will be pleased to consider further. You should retain a copy of this letter with your project file as evidence that you have sought advice from the South East Scotland Research Ethics Service.

Yours sincerely,

Alex Bailey
Scientific Officer
South East Scotland Research Ethics Service

South East Scotland Research Ethics Service

DIFFERENTIATING AUDIT, SERVICE EVALUATION AND RESEARCH

November 2006

The "Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees" recommended NRES should develop guidelines to aid researchers and committees in deciding what is appropriate or inappropriate for submission to RECs, and NRES (with the Health Departments and with advice from REC members) has prepared the guidelines in the form of the attached table.

RESEARCH	**CLINICAL AUDIT**	**SERVICE EVALUATION**
The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted to produce information to inform delivery of best care.	Designed and conducted solely to define or judge current care.
Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.	Designed to answer the question: "Does this service reach a predetermined standard?"	Designed to answer the question: "What standard does this service achieve?"
Addresses clearly defined questions, aims and objectives.	Measures against a standard.	Measures current service without reference to a standard.
Quantitative research -may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.)	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.)
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.
Quantitative research - study design may involve allocating patients to intervention groups. Qualitative research uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.	No allocation to intervention groups: the health care professional and patient have chosen intervention before clinical audit.	No allocation to intervention groups: the health care professional and patient have chosen intervention before service evaluation.
May involve randomisation	No randomisation	No randomisation
ALTHOUGH ANY OF THESE THREE MAY RAISE ETHICAL ISSUES, UNDER CURRENT GUIDANCE:-		
RESEARCH REQUIRES R.E.C. REVIEW	AUDIT DOES NOT REQUIRE R.E.C. REVIEW	SERVICE EVALUATION DOES NOT REQUIRE R.E.C. REVIEW

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Lead Cancer Care Pharmacist, Edinburgh Cancer Centre	Heather Dalrymple	0131 537 2337	heather.dalrymple@luht.scot.nhs.uk
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Fax Number: 0131 537 2370 Main Switchboard: 0131 537 1000

Carole Callagan
Pharmacy Department
WGH

Our Ref: QIT32
Date: 11th Dec 2012

Dear Carole

Project Title: "**Supply and administration of Denosumab for patients with osteoporosis in primary care – a qualitative exploration of opinions to assess feasibility of practice development**."

I am pleased to inform you that the Pharmacy Quality Improvement Team has approved your project titled "Supply and administration of Denosumab for patients with osteoporosis in primary care – a qualitative exploration of opinions to assess feasibility of practice development **"**.

Can I remind you that your project must conform to governance requirements as described in the audit and evaluation workbook. Please complete the feedback form in this workbook once your study is complete and also please keep the Pharmacy ERD administrator informed of your progress and any subsequent conference or publication submissions as detailed in the attached Pharmacy Project Guidance.

Yours sincerely

Moira Kinnear
Head of Education, Research & Development
0131 537 1216
moira.kinnear@luht.scot.nhs.uk

On behalf of Pharmacy QIT

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INVITATION LETTER

Dear [title] [surname]

I am a pharmacy student at the University of Tromso, Norway and an honorary member of pharmacy staff at NHS Lothian. I am currently undertaking an investigational project and I would like to invite you to take part.

Your current treatment for osteoporosis is provided in the hospital. We would like to explore how community pharmacies may contribute to the management of patients with osteoporosis. It is important to us that patient opinions are included in this project.

We would like to obtain your opinion when you attend the hospital for an appointment with the nurse specialist. Please read the patient information sheet given to you with this invitation letter and if you decide to take part in the project, sign the consent form and bring it with you to your clinic appointment.

Kind regards,

Ben T. Henriksen
Masters Student in Pharmacy
and honorary member
of staff,
NHS Lothian,
Pharmacy Service

Carole Callaghan
Advanced Clinical Pharmacist
in Rheumatology
Western General Hospital

PATIENT INFORMATION SHEET

We would like to invite you to take part in a project exploring the provision of denosumab in the treatment of osteoporosis. Before you decide to take part it is important for you to understand why the project is being done, and what it would involve for you. Please take time to read the following information carefully. Talk to others about the project if you wish. If there is anything that is unclear, or if you would like more information, please do not hesitate to contact those listed at the end of the sheet. Take time to decide whether or not you would like to take part.

Why is the project being done?

Denosumab is one of a number of therapies used to treat osteoporosis. Currently in NHS Lothian, patients visit the hospital to receive denosumab treatment. This project will explore alternative settings for this treatment, including community pharmacies.

Why have I been invited?

You have been invited to take part because you currently receive denosumab treatment. Your opinions will be used to design a questionnaire which will be sent to patients currently receiving this treatment. Pharmacists, general practitioners (GP's) and nurses are also being asked about their opinion.

Do I have to take part?

It is up to you to decide whether or not you would like to take part in the project. If you decide to take part, please sign the consent form to show you have agreed to take part. You are free to decline the opportunity to be a part of this project, and if you decide to do this, it will not affect the healthcare that you receive in any way.

What will happen if I take part?

You will be asked to meet with the investigator immediately after your clinic appointment with your nurse specialist. The interview will last for about 30 minutes and will happen one time only. To ensure that nothing is missed, we will ask your permission to audio record the meeting. Once notes have been made, the recording will be destroyed.

Are there any benefits or risks if I choose to take part?

There are no risks if you choose to take part. The only disadvantage will be the time of the interview. The benefits are that your thoughts and ideas will be considered in the design of future services.

Will my statements and opinions be kept confidential?

The audio recording will be kept securely and once notes have been made, the recording will be destroyed.

What will happen to the results of the project?

The results will influence decisions about where denosumab treatment may be provided in the future.

The project is also a thesis and is a part of the Master's degree in pharmacy in Tromso, Norway. The project will therefore be published on a public database in Norway (Munin), which contains the master's theses undertaken at the Faculty of Health, at the University of Tromso.

Who is organising the project and why?

The advanced clinical pharmacist in rheumatology is exploring redesign of pharmaceutical care. Through engagement with Pharmacy Education, Research & Development team there is an opportunity for Master's students to undertake this unfunded work.

Who has reviewed the project?

The project has been reviewed by the South East Scotland Research Ethics Service, who classified the study as not requiring an ethical review. It has also been reviewed by the Quality Improvement Team (QIT).

Further information

If you require any more information, please do not hesitate to contact the investigating team:

Investigators:

Ben T. Henriksen

Masters Student in Pharmacy and honorary member of staff, NHS Lothian, Pharmacy Service.

0131 537 1212

Or investigator supervisor / clinical supervisor:

Carole Callaghan

Advanced Clinical Pharmacist in Rheumatology, Western General Hospital.

0131 537 1204

Or academic supervisor:

Moira Kinnear

Head of Pharmacy Education, Research & Development, NHS Lothian.

0131 537 1216

CONSENT FORM

Investigator: Ben T. Henriksen, Masters Student in Pharmacy and honorary member of staff, NHS Lothian, Pharmacy Service.

Investigator/Clinical supervisor: Carole Callaghan, Advanced Clinical Pharmacist, Rheumatology, Western General Hospital.

Please tick the box if you agree

1. I confirm that I have read the information sheet (version 1 12/10/12) for the above project. I have had the opportunity to consider the information and ask for further information. ☐
2. I understand that the participation in the project is voluntary. ☐
3. I understand that the interview will be audio recorded and that it will be transcribed after the interview. The tape will then be destroyed. Anything I say may be quoted anonymously. ☐
4. I agree to being interviewed. ☐

_____ _____ _____

Name (please print) Date Signature

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Departmental Administrator	Lynn Guyatt	0131 537 2499	lynn.guyatt@luht.scot.nhs.uk

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INVITATION LETTER

I am inviting you to participate in an investigational project that explores opinions about the use of denosumab in osteoporosis treatment. The project is developed by NHS Lothian and is a part of my MSc in pharmacy at the University of Tromso, Norway.

A new treatment for osteoporosis, denosumab, has been approved for use in NHS Scotland by the Scottish Medicine Consortium (SMC). Although NICE suggests that denosumab should be provided in primary care, the current denosumab treatment of osteoporosis in NHS Lothian is provided in the hospital setting. We would like your opinions about an extended role for community pharmacists in the pharmaceutical care of patients with osteoporosis.

In order to obtain you opinions, we would like to invite you to an interview with an investigator. The interview will be arranged at a mutually convenient time and place. We hope to conduct all interviews during November. The attached information leaflet provides more information about your involvement, and we will contact you to confirm your participation in the project.

Thank you in anticipation for your contribution.

Yours sincerely,

Ben T. Henriksen,
Masters Student in Pharmacy

Carole Callaghan
Advanced Clinical Pharmacist in Rheumatology
Western General Hospital

PARTICIPANT INFORMATION SHEET

Why is the project being done?

There is an increasing drive to manage more patients with chronic diseases within the primary health care system. In NHS Lothian denosumab is administered in the hospital setting, despite the NICE suggestion that it should be provided in primary care.

In other centres within the UK denosumab is provided via general practice, as a part of a shared care agreement. This project will consider if denosumab can be provided from community pharmacies and be more convenient for the patients. The pharmacists can be trained to inject the pre-filled syringe subcutaneously, as they do with vaccinations. The community pharmacy could also provide falls assessment and medication review as a part of the pharmaceutical care package for these patients. Patients will still receive hospital outpatient review.

The first part of the project is interviewing patients, pharmacists, doctors and nurses so that every aspect of treatment provision is explored. The next step is to use this information to design a questionnaire. The questionnaire will be sent to all general practitioners (GP's) (n≈500) and community pharmacies (n=180) in NHS Lothian and another questionnaire will be given to all patients (n≈60) who attend the osteoporosis clinic for denosumab treatment. The information gathered will be used to inform service redesign.

Why have I been invited?

You are one of the six healthcare professionals we would like to interview to inform the design of our questionnaire.

Do I have to take part?

You are free to decline the opportunity to be a part of this study without giving an explanation.

What will happen if I take part?

The investigator will arrange to meet with you at a mutually convenient time and place. He will ask questions about the use of denosumab and your opinion about service redesign. The single meeting will

last for about 30 minutes. To ensure that nothing is missed, we will ask for your permission to record the meeting using a digital voice recorder. After anonymous transcription has been made, the recording will be destroyed.

Are there any benefits or risks if I choose to take part?

Although your participation will take about 30 minutes of your time, your contribution may influence the future management of osteoporosis.

Will my statements and opinions be kept confidential?

The interview transcription will be anonymous.

What will happen to the results of the project?

The results will be considered by appropriate policy making committees and will be used to influence the redesign of services to become more patient focused. The results will also be published as a master's thesis.

Who is organising the project and why?

The advanced clinical pharmacist in rheumatology is exploring redesign of pharmaceutical care. Through engagement with Pharmacy Education, Research & Development team there is an opportunity for master's students to undertake this unfunded work.

Who has reviewed the project?

The project has been reviewed by the South East Scotland Research Ethics Service, who classified the study as not requiring an ethical review. It has also been reviewed by the Pharmacy Quality Improvement Team (QIT).

Further information

If you require any more information, please do not hesitate to contact the investigating team:

Investigator:

Ben T. Henriksen

Masters Student in Pharmacy and honorary member of staff, NHS Lothian, Pharmacy Service

0131 537 1212

Or investigator supervisor / clinical supervisor:

Carole Callaghan

Advanced Clinical Pharmacist in Rheumatology, Western General Hospital

0131 537 1204

Or academic supervisor:

Moira Kinnear

Head of Pharmacy Education, Research & Development, NHS Lothian

0131 537 1216

CONSENT FORM

Investigator: Ben T. Henriksen, Masters Student in Pharmacy and honorary member of staff, NHS Lothian, Pharmacy Service.

Investigator/Clinical supervisor: Carole Callaghan, Advanced Clinical Pharmacist in Rheumatology, Western General Hospital.

	Please tick the box if you agree
1. I confirm that I have read the information sheet (version 1 1/10/12) for the above study. I have had the opportunity to consider the information and ask for further information.	☐
2. I understand that the participation of the study is voluntary.	☐
3. I understand that the interview will be audio recorded and that it will be transcribed after the interview. The tape will then be destroyed. Anything I say may be quoted anonymously.	☐
4. I agree to being interviewed.	☐

_____
Health Profession

_____ _____ _____
Name (please print) Date Signature

PARTICIPANT
Supply and administration of denosumab for patients with osteoporosis in primary care – a qualitative exploration of opinions to assess feasibility of practice development

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25/01/2013

INVITATION LETTER

Dear [Title] [Surname]

I would like to invite you to participate in a project regarding osteoporosis and the medicine that you receive, denosumab. Your current treatment for osteoporosis is provided in the hospital. We would like to explore how community pharmacies may contribute to the management of patients with osteoporosis. It is important to us that patient opinions are included in this project and we are therefore asking all the patients in Lothian who receive denosumab treatment to participate. We would like to obtain your opinions by asking you to complete the enclosed questionnaire. Please post the questionnaire in the return envelope provided.

You were chosen to be invited because you are currently receiving denosumab as a part of your osteoporosis treatment. There are no risks if you choose to take part. The benefits are that your thoughts and ideas will be considered in the design of future services. You are free to decline the opportunity to be a part of this project, and if you decide to do this, it will not affect the healthcare that you receive in any way.

If you have any further questions, please do not hesitate to contact us.

Thank you in anticipation for your contribution.

Yours sincerely,

Ben T. Henriksen
Masters Student in Pharmacy
and honorary member of staff,
NHS Lothian, Pharmacy Service
0131 537 1212

Carole Callaghan
Advanced Clinical Pharmacist
in Rheumatology
Western General Hospital
0131 537 4001

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11/02/13

To all pharmacies in Lothian,

I am inviting you to participate in a project that explores opinions about the use of denosumab in osteoporosis treatment within NHS Lothian. Denosumab is approved for use in NHS Scotland by the Scottish Medicine Consortium (SMC). The current denosumab treatment for osteoporosis in NHS Lothian is provided in the hospital setting, although NICE suggests that denosumab should be provided in primary care. This project will consider if denosumab can be provided differently in the future.

We would like to invite the responsible pharmacist to complete the enclosed questionnaire which will be dealt with anonymously.

Your participation will take approximately 2 minutes of your time and your contribution may influence the future management of osteoporosis. Please complete and return the questionnaire before 26th February 2013.

The results will be published as an MSc in Pharmacy at the University of Tromso, Norway (in partnership with NHS Lothian), a copy of which may be available on request.

If you have any further questions, or if you want a copy of the project protocol, please do not hesitate to contact us.

Thank you in anticipation for your contribution.

Yours faithfully,

Ben T. Henriksen,
Masters Student in Pharmacy

0131 537 1212

C. Callaghan
Carole Callaghan
Advanced Clinical Pharmacist in Rheumatology
Western General Hospital
0131 537 4001

Department of Pharmacy
Western General Hospital
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06/02/13

To all GPs in Lothian,

I am inviting you to participate in a project that explores opinions about the use of denosumab in osteoporosis treatment within NHS Lothian. Denosumab is approved for use in NHS Scotland by the Scottish Medicine Consortium (SMC). The current denosumab treatment for osteoporosis in NHS Lothian is provided in the hospital setting, although NICE suggests that denosumab should be provided in primary care.

This project will consider if denosumab can be provided differently in the future.
We would like to invite you to complete the anonymous questionnaire by following this link:

http://www.surveymonkey.com/s/denosumab-in-osteoporosis-management

Your participation will take about 2 minutes of your time and may influence the future management of osteoporosis. Please complete the questionnaire before 21st February 2013.

The results will be published as an MSc in Pharmacy at the University of Tromso, Norway, a copy of which may be available on request.

If you have any further questions, or if you want a copy of the project protocol, please do not hesitate to contact us.

Thank you in anticipation of your contribution.

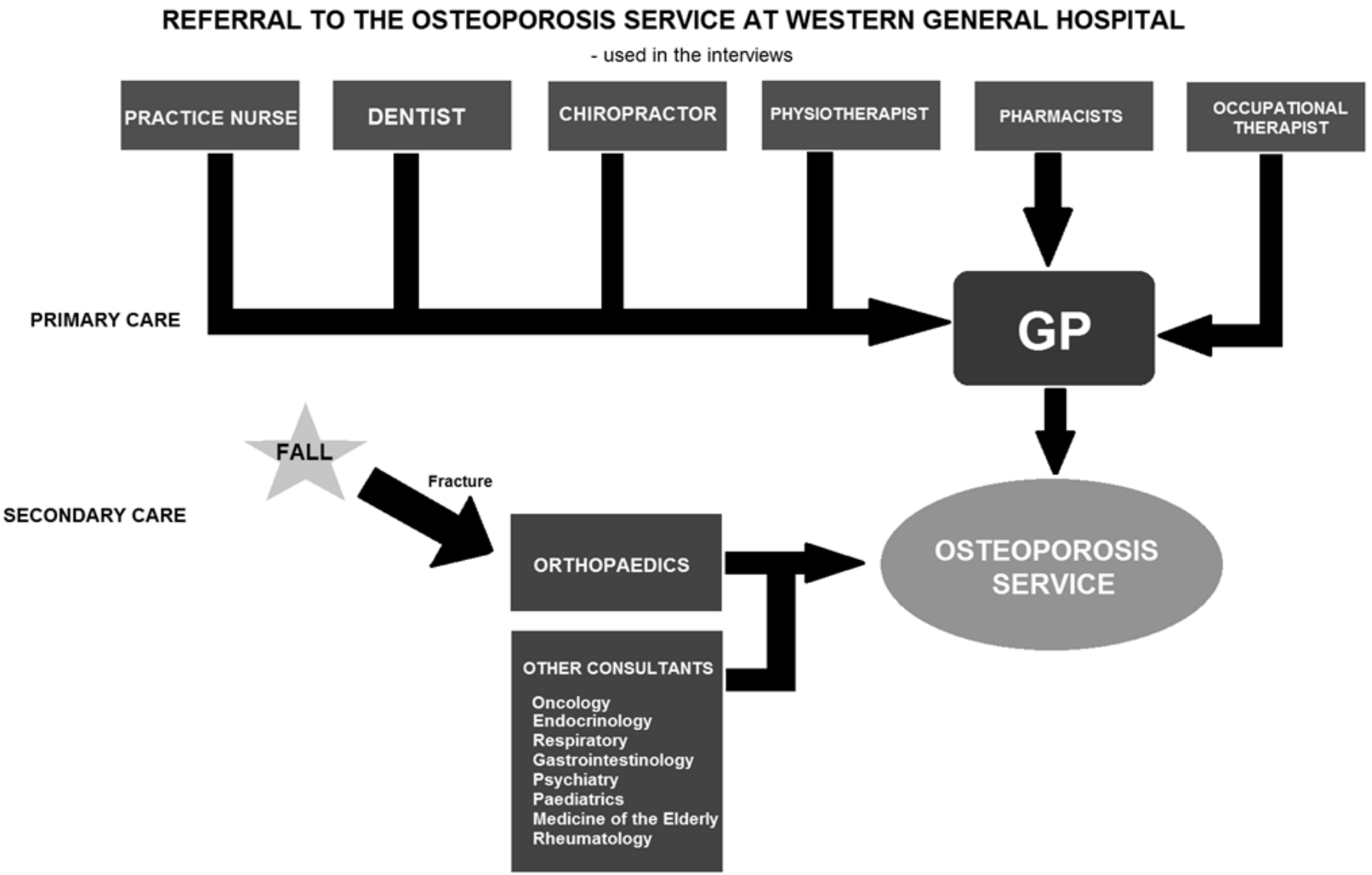
Yours faithfully,

Ben T. Henriksen,
Masters Student in Pharmacy

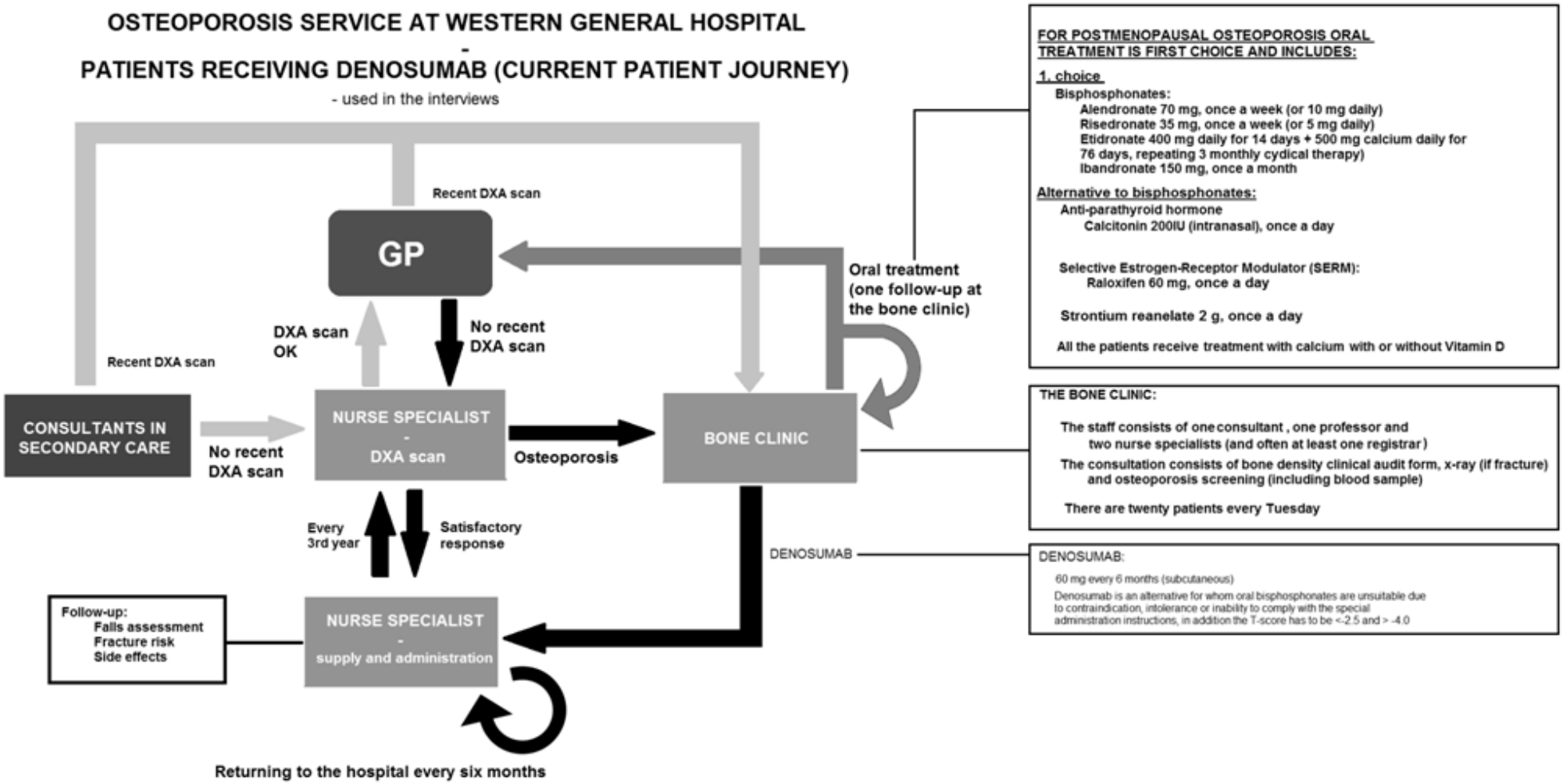
0131 537 1212

Carole Callaghan
Advanced Clinical Pharmacist in Rheumatology
Western General Hospital
0131 537 4001

Flow chart used in the interviews: The referral to the osteoporosis service at Western General Hospital



Flow chart used in the interviews: The osteoporosis service at Western General Hospital – Patients receiving denosumab (current patient journey)



Health care professionals

Interview pilot with hospital pharmacist

Hospital Pharmacist (HP)

Investigator (In)

In: Are you familiar with the drug denosumab?

HP: Not very familiar but I have... have seen it used in one of my patients.

In: Ok, so do you want me to describe the use briefly?

HP: I know the dosage and the indications...

In: Yeah, so it's...

HP: ...and some of the side-effects.

In: Ok. So it's used for... used against postmenopausal osteoporosis.

HP: Yes, that's where I've seen it used, I have not seen it used in any of the other indications, which I think is bone... and prostate...?

In: Yeah, and prostate cancer as well.

HP: That's a higher dose.

In: Yeah. So it's a subcutaneous...

HP: Right, yeah.

In: Yeah. Ok. Do you have any patients or clients who receive denosumab treatment?

HP: I've had one patient on one of my wards who was receiving it and she was receiving it... she received it on the ward while she was in hospital, but she usually got it from the rheumatology clinic.

In: Ok, so are you aware of the current process of management?

HP: Not really, no.

In: No, ok. So I have a flow chart here that I can explain.

[Showing the "referral to the osteoporosis service at Western General Hospital"]

Ok. So this is a flow chart describing the patient journey and this flow chart is into the osteoporosis service that is in secondary care. So these are just the different routes... via the GP into the osteoporosis service or through secondary care. If the patient is... had a fall... goes via the orthopaedics or it might be other consultants referring to the osteoporosis service.

[Showing the "osteoporosis service at Western General Hospital – Patients receiving denosumab (current patient journey)"-flow chart]

So this is the osteoporosis service. So, if the GP refers to a DXA scan which will give the... the... the diagnosis of osteoporosis then they will be referred and if they have osteoporosis then they will be referred to the bone clinic. So that's the first... Yeah. Obviously if they have osteoporosis and if the DXA scan is OK, then they just go back to the GP. And also if there has been a referring by consultants in secondary care then it's the same pathway. So if they've had a recent DXA scan they just avoid the DXA scan. The first choice of treatment is oral and the GP is

doing the follow-up and prescribing the drugs and everything. And they have one follow-up at the bone clinic. Now if denosumab is being used, denosumab is an alternative to oral treatment, if bisphosphonate is not unsui... if it's unsuitable... and it's depending on the T-score as well, because it's restricted use. Now, if they receive denosumab they are going to a nurse specialist every six months who is administering the denosumab and the nurse is doing a follow-up as well, including falls assessment, fracture risk and side-effects. So this is a very brief follow-up. And every third year or so they go for a DXA scan to see if they are responding to the treatment, and if they are... if it is a satisfactory response then they just go back in to this loop. [the investigator is pointing at the loop saying "returning to the hospital every six months"] So that's the current treatment. I can just leave it here.

Ok, so the first questions will be about convenience to the patients when they visit the hospital to receive their injections, for example some patients may travel some distance.

HP: Yeah, I can imagine.

In: Yeah, can you think of any ways that delivery of the service could be improved from the patients' perspective?

HP: Well, I suppose if GPs are prepared to take on the prescribing of it, then it could be delivered in primary care. There would be a financial implication for that for them, although ultimately the NHS is still paying for the drug. If it's done in primary care, then I suppose the option for administration would be practice nurse, district nurse, although I know that XXX [clinical pharmacist] is thinking of perhaps community pharmacists could take that on as well. I suppose that would depend on whether or not you could get sufficient uptake in the right areas of pharmacists are interested in and have the time to do that. I suppose the other thing that could be done would be home care service although that can... really doesn't take the work away from the secondary care, because you have to then tend to manage the home care service. An advantage would be of it being prescribed in primary care through the home care wouldn't be paying the VAT [Value-added tax] of it as well, which we would be paying currently.

In: How do you think the patients would feel about visiting a community pharmacist... a community pharmacy instead of the hospital for follow-up treatment and administration?

HP: I think that would be very variable on... it would depend on the patient's relationship with their community pharmacist. Some of them would be familiar with the extended roles and already perhaps attend warfarin clinics at the community pharmacy, then I think they would be very comfortable with that, if they've got a good relationship. For other people it might be something entirely new, it might be something that they find that a little bit strange, but at the same time if it's a new treatment, then if they... if they've not had it anywhere else then they might just accept that that's what's normal. Yes, it would very much depend on the relationship, I think, with the... their community pharmacy and whether or not their regular community pharmacist could do it or if they had to go to a sort of specialist ones, somewhere else where they didn't know them. Which... if they've got a good relationship with their community pharmacist they might not want to go somewhere else, but if they don't have such a good relationship they might be quite happy to go somewhere else. So... [laughter] I find... because I find it very variable. It tends depends on things, sort of work-load and how organised the pharmacy is and how it's run and that very much depend on the staff and the branch rather than, say, particular companies or independent versus multiple. I think it's very branch, sort of, pharmacist specific probably. That's... I think, I suppose the majority of these patients are going to be older and they're... yeah... they tend to have quite close... I say, more often they have a good relationship with their community pharmacy. There's the occasional patient who's saying... I see who's not so happy, but most of them will be probably fine with it.

In: Do you think they would miss anything?

HP: I think psychologically sometimes, there's this feeling of – I'm going to the hospital and seeing a specialist – which they might feel they're not getting. But if all they're doing is coming in to get the very quick injection and there's nothing else happening at that point, then that's different. Equally, if

they're normally also getting their injection along with, sort of, any questionnaires about falls risk and fracture risk and s... side effects, as long as that's transferred over to... to community pharmacy then I don't think they would... I don't think they would actually miss anything, whether or not, as long as it's well managed and the staff are sufficiently well trained, I think that should be alright.

In: Is there anything else you would like to add about the patients' convenience?

HP: I think it would be a lot more conv... if they could go to a local pharmacy, then yes, that would be better, I think in terms of convenience, the downside would be is, I don't know if some of these patients might be house-bound or might struggle to travel in which case, to come to hospital there is a service they can get transport in, whereas to get to a community pharmacy, although it's nearer, they would presumably have to make their own way there. So it might not work for everyone who is not able to physically get from their house to a community pharmacy. Whether or not that's... community pharmacy could to it in the patient's home, that would be quite... That would be a... That would be quite a sort of resource implication for them in terms of the time required to home visits. I don't know how realistic that would be.

In: Is there anything you would like to add about any concerns you may have associated with such a shift of care?

HP: I think, just making sure that there is a training package and that only people who are... have been through that are dealing with patient and making sure that they... that that's followed and that probably also that there's maybe ongoing refreshers, because I think, the... the nurses who do the clinics in the hospital, will be doing a very, very regularly whereas if it's spread throughout many community pharmacies then they might have one patient, maybe two, they maybe only doing it every six months, so I think it's harder to keep you skills up-to-date and stay... remain confident and competent in what you're doing because it's such an infrequent thing. I know the things that I do every six months, I'm not particularly confident with, so that would be sort of my only concern.

In: What problems might arise if denosumab would be supplied and administered in the community pharmacy?

HP: I'm not sure. Like if...

In: [Talking at the same time as interviewee] Do you think there would be... Sorry.

HP: Really, I suppose, what I was saying before about, sort of, making sure that people remain confident and competent to inspire confidence in the patients. Sorry, you were about to add...

In: Do you think there would be any practical problems regarding the space or waste management?

HP: There cou... I would... I would have thought that waste management could be dealt with, I don't... some pharmacies have needle-exchanges anyway, so I presume they have a process in place for dealing with sharps. But I don't know if all community pharmacies do or not. In terms of space that could be an issue I think, community pharmacies are getting better at having space, but it's not always ideal and you would want to have a... You'd want to be able to take the person in to an appropriate room that is designed for doing this sort of things. So they don't have that consultation room if it's just a sort of slightly partitioned-off section of the shop that is not really going to be appropriate. Wouldn't look very professional, I don't think. Or if they have to sort of go behind the counter and then tell it over there. Again it doesn't look very good. So, some shops, poss... probably quite well set up or another ones, I think would struggle and it's... whether or not we can make sure that there's a... a uniform approach, if there's a sort of service set of standards that premises have to meet before they can participate in the scheme, I would say personally.

In: Do you think financing would be a problem?

HP: You'd have to make sure that sufficient resource was being released from secondary care which, to be able to finance that in primary care, obviously the community pharmacy would need a payment for that. Some of that cost might be, could be perhaps justified through say, well we're saving twenty

percent on the cost of the drug through not paying VAT, but I think we'd have to ensure that there was a post being lost in the hospital and, so it... you couldn't really go along with having potentially both systems running, you'd have to maybe go for one or the other to free up the funding from secondary care to... to transfer that over to primary care and... and I don't know whether or not... the reality is that nurses doing the denosumab administration is probably not just doing denosumab administration you're probably be freeing up a few hours a week and whether or not that... that nurse time is equivalent to paying several different community pharmacists do it, I don't know.

In: Is there anything that the nurses do in these follow-up visits that you think the pharmacist couldn't do? Or... and that... it is... yeah.. in these follow up [pointing at the follow-up section of the "osteoporosis service at Western General Hospital – Patients receiving denosumab (current patient journey)"-flow chart]?

HP: No. No, I don't see why pharmacists couldn't that.

In: What advantages will there be if denosumab would be supplied and administered in the community pharmacy, except the convenience for the patients?

HP: A part from the convenience to the patients, I suppose saving VAT and as the pharmacists are perhaps more comfortable with dealing with side-effects of the drugs and more familiar with the pharmacology of it, they might be able to give the patients more information, but that would depend very much on the... on the training. I'm not sure what other advantages there will be apart from convenience. And, sort of, great familiarity with the drug as well. The pharmacists might have greater understanding how the drug works. The nurses would probably more confident administering a drug, although I do know that some community pharmacies already do flu-vaccines and things like that, so they will probably be quite comfortable with it, it's only a subcutaneous injection. I've never done a subcutaneous injection. I don't think it looks very hard, but I don't know. [laughter]

In: Do you think there are things that the pharmacist could do that the nurses don't do?

HP: I think they probably potential... and again it's very pharmacist dependent, depends on sort of the pharmacists knowledge and training and probably experience as well in terms of how good they are at communicating the patient, but they could probably... they are probably better at going through the side-effects with patients. I think the nurses as a, just to make vast generalisations, and they would have access to the full patients', you would hope, full patients' drug history to look for interactions, which can sometimes be harder in a clinic setting to actually have up-to-date information, if the patient doesn't bring the tablets with them, so they could be... they could be more involved with that. Also, they might be better at checking that the patient is managing their calcium and vitamin D supplements along with it. Better place to make suggestions on, "well, if you don't like that one, perhaps this one is on the formulary, you could try that?". Or if they're having to go off form they may be a greater awareness of what products there are, so they would be able to do that more autonomously whereas a nurse would probably have to ask the pharmacists about that sort of thing.

In: Do you think a medication review could be included?

HP: Yeah. That would be... that would be really good.

In: So, now I would like to discuss the potential role of community pharmacists in the wider management of osteoporosis. How can a community pharmacy help with osteoporosis management, besides administration of denosumab?

HP: Counselling patients on use of bisphosphonates and following patients up with how they're actually getting on with their bisphosphonates, are they managing to take it, are they getting any side-effects, any digestion or heart-burn, or do they just struggle trying to take it. And just reminding them that it won't work if they take it along with their other tablets. If the patient gets a nur... the tablets given to them by a carer or if they get their tablets in a dosett, making sure that whoever's giving them the tablets knows to give bisphosphonates before their other meds, especially their calcium-supplements which they're going to be on as well. And, yes, I think I mentioned counselling them on side-effects and generally just checking compliance as well. If they're not or... if they're ordering

their repeat prescription every two months, but they've not ordered their alendronic acid for six months the chances are that they're not taking it any more, so if they were able to... if they were able to have a more proactive role, and sort of, chasing that up, I don't know realistic that is if... in terms of... if they can keep track of that, but if they were doing a med... a medication review, then that's something they could maybe be picked up. Because I don't think compliance is very good with bisphosphonates from my experience just from looking at repeat prescription lists that people bring in. I had a patient come in who had, you know, a box or two of all his tablets and seven boxes of his alendronic acid, so... [laughter] All the boxes lasted about a month, so it didn't look like he was managing to well. It is quite hard... it is difficult to remember to do take it, a tablet, once a week, so even just saying "well, if you forget taking on Monday, if you forget, do take it on the Tuesday" and just sort of, just giving them some guidance on, sort of, when to take it and if you realize that forgot it for six days, then missed one out but if it was just yesterday, then... then do take it. Maybe giving them some hints and tips on how to remember. Making sure that they know about the, sort of, sitting up straight and sometimes people get... they get to cautious about it and think they have to sit absolutely stationary for half-an-hour after they've had it, so you would just explain "no, no, we just don't want you bending over or lying down, just try to remain upright". That might encourage them to take it a bit more. That's all I can think about at the moment.

In: So how do you think a pharmaceutical care package of medication review, adherence with medicines, falls assessment and need for calcium and vitamin D would help the patients?

HP: I think that would be very useful. It ties them with, sort of, all the aims and that's one of the major aims of NHS Lothian and I think that... a... a need in society as well. There are... Patients with osteoporosis tend to be a part of very vulnerable patient group and yeah... I think that... that service would be very beneficial. It's something that you'd like to think would always happen with somebody's come in to hospital, but I don't think it does. And, not everyone comes in to hospital. So, I think that would be good to go out there in the community and, sort of, be a bit more proactive about looking for these patients and making sure that they're getting on okay.

In: Do you think compliance and adherence would be better?

HP: I would like to think so, yeah. Yeah, I hope so.

In: Do you think the pharmacist could discover more than the nurses or physicians do?

HP: Ehm, yeah... Quite often. My experience sometimes is by asking the right questions and sometimes the patient might be less... less anxious about telling the pharmacist the truth, then they are by, say, telling the consultant or the GP, that's actually prescribing the drugs and he's told them "you have to take it", they don't like to say "oh, I've not managed it". It sometimes is easier to say that to a third party. And I've been on the ward: "Oh, I didn't like to trouble the doctor, but I'm going to tell you all about this"... [laughter] And sometimes that relevant and very useful, and sometimes it's not. [laughter] So, yeah, and it will again depend on the pharmacist and, you know, the relationship that the patient have. But I think a lot of the time they may be a wee bit more open with the pharmacist and it's not, it's not going to say for everyone, but it's possible.

In: What do you think about the quality of medication review compared to physicians or GPs doing it?

HP: I think, in community pharmacy I would find it very difficult to do a good quality medication review, because you don't have access to the notes or the patients' blood results or anything like that. I – I've done medication review in hospital, and I've done medication review in... in primary care, in General Pract... in a GP practice and... in the GP practice I had full access to all of their notes and... some access to hospital stuff, but I would say... without having access to the... the notes and the blood results, I wouldn't feel very comfortable. I don't think you could do as an in-depth review. I think pharmacists probably can do a medication review better than a doctor as a rule. But you need to have that information available, so I think they would need to have access to... to really get down to the, sort of, the... to do it properly. I mean, you can do so much without it, you can talk... talk about compliance, you can educate the patient, you can see the obvious things that perhaps could be

reviewed if somebody's been on something for ages and if it's... it also depends on how well the commun... the patient can communicate with you. I think what is classed medication review in GP practices often doesn't actually involve the patient, and that was the bit that I found quite frustrating and, when I was reviewing in primary care, was the fact that I couldn't speak to the patient or the family or it's much harder to, compared to do... a pharmacists doing medication review in hospital where you've got access to the notes, you've got access to the patient. You can see how they're getting on a day-to-day basis. That's probably the, sort of, best setting to do a medication review, but we'd rather keep patients in the community, so somebody that's... community pharmacists would be speaking to the patient so that would be an advantage. But they don't have access to their notes, so that's a disadvantage, I suppose would summarize it.

In: So, I guess you might have answered it, but what might me missed compared to how the hospital or GP is doing it? The whole pharmaceutical care...

HP: You won't have, you may not have a past medical history, and sometimes you would be having to guess the indications for the medicines it's not obvious... obvious very often I think "oh, we could surely stop that" but I look back a few letters and I realize – oh, no, we can't, you know, for instance I might want to stop PPI [Proton Pump Inhibitors] but discover that actually the patient's just been fairly recent diagnosed with Barret's esophagus, in that case I would not stop their PPI. And the patient's not necessarily going to tell you that in a... they might say "oh, there was a bit of a problem with my gullet, I think" and you might just think it's heart-burn. So, yeah, it's, it's the, sort of, the exact diagnosis you would potentially be missing and be very reliant on the patient form. And it would depend how well the pharmacy, pharmacist knows the patient as well, what their... their background is. Sometimes they may know them very well maybe as well as the GP, but other times they might not. I... Yeah... And blood-results it's hard... I think it would be hard to make a judgement on if somebody needs to still be on or... whether or not they're on a diuretic or an ACE-inhibitor [Angiotensin-Converting Enzyme Inhibitor] is causing a problem without having access to... to blood-results. You could miss that sort of thing, you know, renal function going off or if somebody's renal function is deteriorated and they're on, say, gabapentin and they're getting a bit drowsy, you might suspect that it is the gabapentin but you wouldn't really have anything to back it up with. You would still have to send them back to the GP to get a blood test. [the interviewee's pager start beeping] I better answer that, if you could... could you excuse me a sec?

In: Yeah, sure. No problem.

[interview stopped whilst interviewee makes a phone call]

HP: Alright. Where were we?

In: We were talking about if there was something that might be missed...

HP: Yeah, that's right. Yes, I think blood results, you know, renal failure, LFTs [Liver Function Tests] going off and, like I said, their diagnosis' are harder to come by in community pharmacy than they are in hospital. Although, if they had access to computer systems, that could overcome a lot of it. If somebody had access to something like Trak [TrakCare® the patients' journal system in NHS Lothian] then that would help, but I don't know how realistic that would be, because even GPs are only beginning to get access to Trak now.

In: Is there anything that could make the management of osteoporosis more convenient for the secondary health care system?

HP: I'm not sure... From an outpatient-perspective I don't really know, because I don't deal with outpatients. From an inpatient perspective, I suppose, maybe making sure that all the specialities are aware of the pathways for referral in to the osteoporosis service. I'm not quite sure how well that's known by, let's say, all the consultants. Definitely not by, say, the junior doctors that try to make their referrals, so making sure that that's a nice, easy, clear referral pathway would be, would be a sole. That's all I can, really, think of.

In: Is there anything that you would suggest that would be different, from a patient point-of-view and the secondary health care system's point-of-view, with the... regarding the patient journey?

HP: Oh, on this, sort of diagram here?

[Looking at the "osteoporosis service at Western General Hospital – Patients receiving denosumab (current patient journey)"-flow chart]

In: Yeah. If you would change something in the diagram...

HP: It's not a very complicated pathway, and it does seem fairly logical. So, unless this bit here, the nurse specialist – administration, is changed to being, sort of, back-up to GP or perhaps a pharmacist prescriber or a nurse prescriber in the community, then that would maybe take out this loop down here. So it will just be a, sort of, chop-off the bottom of the diagram, that may... but, whether... how... I – I, that's... that's any sort of change I could see potentially happening as a result of this work perhaps. But that's all.

In: Ok. So all in all, what are your opinions regarding the potential shift of care?

HP: I think it's a... a... I don't have a probably a good enough understanding of what's happening in community pharmacy at the moment to really know. I think, there's a, a big training need, because of the number of people that would be involved versus, say a few nurses in secondary care and whether or not... and who would take that work-load on? Would the nurse specialist end up training them or would it have to be specialist pharmacist end up training the community pharmacists in which case would that actually save the NHS any money? I'm not sure. And the practicalities of it... in terms of whether or not the patient can get the pharmacist or the pharmacist can get to the patient. This is... or maybe... I don't think the... the primary care pharmacists who work with GPs, I don't think they're really.... There's not very many people running clinic, pharmacists lead clinics, I don't think. Possibly not enough to cover... And I think XXX [a clinical pharmacists at Western General Hospital] said there were about ninety on d.. patients on...

In: Yeah....

HP: ...denosumab.

In: Between eighty and a hundred and twenty.

HP: And you've got to imagine that they're scattered all over....

In: They are...

HP: So I think the cost associated with putting the service out there it could outweigh the... the... the convenience to the patient of having a... the cost, the cost of, sort of, putting it out there compared to the convenience to the patient having it out there versus doing it essentially, it might be more efficient in terms of a financial model. But I've... I wouldn't have any concern about community pharmacies doing it, I just think it would need to be a... it's an extended role for them and I wouldn't want them to be a, sort of, they had to done some sort of training to... to do that. I certainly feel that I would need to have training, if I was going to start doing something like that, so I'm assuming that they would need as well. I could be wrong. I don't think it's an in-depth training. I think it's fairly straight forward – "this is how you do a subcutaneous injection" – "this is how you use this particular device". They're quite capable of reading the SPC [Summary of Product Characterisation] themselves, but it's just making sure that people have done that. What was the question again? [laughing]

In: What your opinions regarding the potential shift of care, all in all...

HP: Yeah, I'm... I can't see if I think it's... I don't know if I... if I think it's a good idea or if it's not a good idea. I don't feel I know... I have enough information to make a, sort of, yeah – this is great -, or – mhm... not sure – decision. That's all.

In: Is there anything you would like to add or anything that you would like to elaborate on?

HP: Eh, no, don't think so.

In: Ok. Well, that's it. Thank you very much.

HP: No problem.

Interview with community pharmacist

Community Pharmacist (CP)

Investigator (In)

In: Are you familiar with denosumab?

CP: No.

In: No. So denosumab is a treatment for postmenopausal osteoporosis with a restriction that it is used only in patients with a Bone Mineral Density – T-score between minus two point five and minus four point O. For those who oral bisphosphonates are unsuitable. And it is a pre-filled syringe that is administered every six months as a subcutaneous injection and it is now being administered by a nurse in the hospital although NICE suggests that it is initiated by secondary care and then moved to primary care. And no blood monitoring is required other than in those of risk of hypocalcemia.

CP: Ok... Can I ask, the... the syringe is it pre-filled with a pre... pre... pre-filled dose.

In: Yes.

CP: Or is that graduated.

In: No, that's a... The dose is pre-filled so I think it's one millilitre that is subcutaneously injected. Let me see... I have a picture... of the syringe. [showing the picture of denosumab] Here. So that's the denosumab.

CP: So... That's the... Ok. There is only one strength as far as we're aware. Ok. Good.

In: Yeah.

CP: Ok. Good.

In: Ok. So you do not have any patients who receive denosumab treatment?

CP: No.

In: Are you aware of the current process of management?

CP: No.

In: No. So I've made two flow charts which... one of them is the referral into the osteoporosis service at the Western General Hospital. [Showing the "referral to the osteoporosis service at Western General Hospital"]

CP: Ok.

In: So that's mainly by GPs and the secondary health care system.

CP: Ok.

In:

[Showing the "osteoporosis service at Western General Hospital – Patients receiving denosumab (current patient journey)"-flow chart]

So, if the patient falls, fracture, goes to the orthopaedics and they have an idea that it is osteoporosis... And then it is... it depends whether or not the patient had a decent... a recent DXA scan.

CP: Ok.

In: If the patient needs to go and have a DXA scan or if it can be avoided. So the patient... let's say the patient is referred from the GP. Don't have a DXA scan. Goes to a nurse specialist and get the DXA scan. And if it is osteoporosis they will go to a bone clinic. So if... the first-line treatment is bisphosphonates.

CP: Sure.

In: So then you go back to the GP.

CP: The GP. Right.

In: But if bisphosphonates are unsuitable, denosumab is an alternative and then the patient have to go to a nurse specialist for the supply and administration every six months. And, so that's... And they have to go the, to the hospital every six months. And every third year or so, they have to get another DXA scan to see if they are responding to the treatment.

CP: Ok. Good. I understand.

In: Ok. So I will come back to the flow-charts later. I would like to start to ask you about convenience to patients when they visit the hospital to receive their injections, for example some patients might travel a distance. Can you think of any ways that delivery of the service can be improved from the patients' perspective?

CP: The thing that pharmacists could be trained, if that's the word, to administer this. Currently, some of us administer flu vaccines privately, so we're... we're not... it's not an unu... it's not a novel route of administration for a pharmacist to do. Pharmacists in general are... are... you know... there's... in Lothian there's about a hundred and eighty two, so... most people would have probably a pharmacy within a mile – two miles. Hospitals in Lothian is pretty... pretty... lucky for hospitals. But still travelling across town could take up to an hour. Waiting in a clinic could take another hour. So, the best part of a day taken up by a patient, I would imagine. So, no, I would think that the pharmacy could offer a – an opportunity, I suppose, there's the district nursing teams... there's GPs... Yeah. Care and the government's drive is for the patient to receive the treatment as near to their home as far as possible. So, particularly if there are no interventions or testing that needs to be done, that oft... Yeah... that can't be done in a pharmacy.

In: When the nurse specialist administer the denosumab she or he also goes through the falls assessment and fracture risk and some side-effects as well. How do you think the patients would feel about visiting a community pharmacy instead of the hospital for... for the follow-up treatment and the... the administration of denosumab, similar to that pro... provided by the nurse specialist?

CP: But you suggested to me that you are going to ask patients their views and GPs their views? I think you need to get to how a patient feels, that's probably more direct from a patient. But with other services the patients that have been identified either by the pharmacy or another agency tend to be happy with what they get in a pharmacy. Obviously, we have services such as methadone, methadone-supervision, disulfiram supervision. My understanding of the, I believe there is a... a... it's a pilot, therefore the write-up of the pilot is currently happening for disulfiram, the feedback on the ground we're getting is that patients are more than happy to have disulfiram supervising in pharmacies. So, with suitable training, I – I don't see a patient thinking that there would be any different. And some, some ways we are counselling on side-effects as a matter of course anyway, so we have, I guess, in some projects, falls projects and particular going through an array of questions to establish whether the person needs to be referred for a scan in the past, but very sporadically. You know, it's not... it's not something that is a matter of course, so I... yeah.. from... from basic point of view, I shouldn't... they shouldn't really see any difference beca... from a... from a GP surgery or a district nurse, because in a GP surgery I'd imagine it would be a nurse that would be giving it. But, the... the... the bottom line would be what patient think, would be what the patient think.

In: Yeah.

CP: Yeah.

In: Do you they will be satisfied by pharmacists undertaking this role?

CP: Well, we certainly have a consultation room in here, just now, and they're not going to be in the middle of the shop, they're going to be in an area with a sink and the... the necessary requirements for injection-giving. And if the alternative is half a day travelling either way to a hospital I think you'll find that people are more relaxed and in primary care than in hospital. It's just the general environment. So I'd like to think they feel better or more comfortable.

[laughter]

In: Is there anything you would like to add about the patient's convenience?

CP: Well... I... Other than the flow-charts you've shown me and you're talking nurse specialist so the word mean specialist would suggest that it is a few... a small number of people that are likely to have continuity in the service, therefore the patient in six months might see the same practitioner, so that maybe unusual in hospital in so much as when they speak to patients they, one of their comments is that they never see the same person, they may be seeing a consultant, but they never see the consultant, they see whoever the registrar or house-officer or whoever that rotation is. So they, they don't... My experience is they feedback is they don't think is continuity they feel that they have to go over things again to make sure that everybody knows what they said the last time. It probably doesn't relate to this, because there is a specific reason for going. I would like to think that community pharmacy is... is an area... is an experience that the person feels, because it's in their locality they probably know the people in the... in the pharmacy they'll be probably more relaxed when coming in to a pharmacy they' going to a hospital. So... Sorry, Ben, I forgot another question. [laughter]

In: If there was anything you would like to add...

CP: Alright, so I rea... I realise it was about convenience and, and, and access...

In: Yeah.

CP: I think, you know, pharmacies generally are open probably in the region of fifty hours a week, so that gives a possibility of that procedure being carried out in fifty hours a week. I'm not su... I don't know what the, you know, if that nurse specialist is dealing nine till fi... nine till five, five days a week with these patients, or if they have another discipline or other, other responsibilities. From convenience point of view, I would say – yes it is probably makes... in... in a... a sense, the fact that we are health care professionals, we are... can be trained in... in injection techniques and generally pharmacists tend to follow... follow guidelines to the letter. [laughter] Which worries me at times. [laughter]

In: Is there anything you would like to add about any concerns that you may have about... associated with such a shift of care.

CP: With the... I guess, the... with suitable training that would be my only... Currently as I stated already, I... I – I know nothing about the drug... something –mab. However it's the old story if you are familiar and using something regularly, you know about it. So... so it's the old story. Conversely if we're trained to use it and never use it, we will lose it. So no, I don't have a... any concerns about it. I presume there's a potential for anaphylaxis....

In: Yeah.

CP: Oh dear... [laughter] So...

In: How do you think pharmacists would cope with that?

CP: Well, the example I gave you was the private flu vaccination. To be signed off or to be eligible to do that you've got to do yearly CPD... CPD... CPD plus... what is it? Resuscitation courses.

In: Yeah.

CP: Right. So, pharmacists are quite capable of doing that. All they need is the actual investment and their time to cover it. So, probably not. I think we could quite easily do that.

In: What problems might arise if denosumab would be supplied and adm... adm... administered in the community pharmacy?

CP: Problems... Well... I suppose, not knowing anything about it, I presume I... I presume it could be sourced through my normal wholesale as in the wholesale chain which would be... would be UK wholesalers. Is it a... is it a fridge line? Is it something that has got to be stored between two and eight?

In: Yes.

CP: So... Cold chain would have to be maintained. Currently we have procedures in place to maintain a cold chain in the pharmacy. So I don't see that being a problem. I presume that this may be... sort of, a pathway would be to have a prescription to cover this POM? Prescription of the Medicine, I would imagine. Or other mechanisms might be in place. Or I think pharmacists chosen route would be through their current chain of... of... of sourcing... Other than that, I don't necessarily see a problem.

In: Do you think there would be any practical problems... Regarding space or waste handling?

CP: Well you have to main... if pharmacies currently didn't have waste or... or sharps uplift-facilities they would have to be made available to these pharmacies. Some pharmacies that you... that operate needle-exchange scheme already have that in place. And it would be no different from a... I don't think it would be any different from disposing of a needle, a syringe, in to that waste. But, you know, no it shouldn't be any problems. I take it that this thing is not toxic due to the person who is giving it.

In: No... Yeah... Do you think there would be a problem with training of staff?

CP: We'd be training pharmacists, I guess. We wouldn't be training counter staff or technicians. So, we'd be training pharmacists, so I guess, I mean, there's lots of... what is it?... lots of opinions being sought just now on what pharmacists can do and what they can... what they can't do. One of the things that came out of a recent review, that what was the word; review, was that pharmacists felt that they could do with protected learning time. If we had protected learning time that probably would remove... perceived barriers to training. But again, I suppose, I suppose our training probably should be recognised by the... by the health board or... or health department, and I would expect them to support us in that, whether they be providing the training free of charge, because I think would have to be a... would be a must. Whether they could support the time by back-filling people that were to do this, it may or may not be necessary for a hundred and eighty two pharmacists in Lothian to have this... this... these skills. So, yeah. I guess it's a about strategic approach for the whole thing.

In: Do you think financing would be a problem regarding the... the time it takes to administer and the training of staff?

CP: I think... I think training of staff as of, think I'd alluded to, I would expect there to be some recognition of the time, whether that be back-filled or ideally back-fill plus, but the administration... per patient, I guess, would be something that would be, I would hope be reflected in... in... by some sort of remuneration package. That would re... reflect the... the... the... the shift of care from secondary to primary, or community. So I - I don't, I don't think, well, I don't think funding from the pharmacists side would be an issue, but it would be if it was expected to be done for nothing. [laughter]

In: Is there anything that the nurses do in these follow-up visits that you think the pharmacist couldn't do?

CP: So, one would be counsel on the side-effects and what have you, is that right?

In: Yes.

CP: One would be falls assessment, is that what you've said?

In: Yeah, yeah.

CP: If we were privy to that, that sheet that we've got to follow, we could do that. Up till now, I don't think we've been privy to that sheet. [laughter] Yeah, so, I – I, no, I don't think, I mean, yes, we

would... What I think I've probably have identified is you said after three years there will be a, an requirement for another DXA scan. So, somewhere in the pathway there might be something that says that the pharmacist has got to refer back to the nurse specialist who will arr... arrange the DXA scan, but if it's a service that is being scoped that should be part and parcel of the scoping. That'd probably be better at saying I'm sure somebody that knows what... what needs done that could come up with the answers better than me...

In: But, do you think communication would be a problem?

CP: That was what was going through my mind; communication. So, depends on when this is being proposed and whether, say, it maybe a one – two – three – four year project. So I would hope by the three – four years there would be an electronic safe mech... mechanism used within pharmacy that connected in to both GP surgeries and secondary care. I think it's fair to say we... we... we know, and we've identified that there isn't at the moment, but the advantages and the benefits that the system would have... would... would gain are certainly, are certainly very high. So that's maybe another strand other than this specific project.

In: What advantages will there be if denosumab would be supplied and administered in the community pharmacy, except for the patients convenience?

CP: Well, you would have an up-skilled workforce in pharmacists that were, at least every six months seeing a patient with this treatment. There has been some debate about whether pharmacist could or should get involved in the vaccination program for drug-misusers. I suppose, what I'm saying is, the skills are transferable and the more you are doing this sort of thing the easier it will be to do... to... to... expand, shall we say, services involving injections? So it may not just be this particular... [the interviewee leans forward to read the name of the medicine] denosumab, I'm getting there....

[laughter]

It may be something, it may be something else, maybe even the similar re-alligned line, I don't know. But if the precedence has been set, it kind of opens up to all sorts of things. I mean, there are many, I believe, operations where the word home-care comes to mind where the health boards contract with companies directly to provide a package. Now, I'm aware of instances where a... a... courier company will appear in a pharmacy and say "I can't get this... this... this lady in, but she says... suggests that you could pop it in to the pharmacy because she's in here every day", you know, it's very convenient for her, but actually that's her receiving care in inverted commas that has been at some point decided that should not or could not be delivered through the pharmacy and yet we are the middle man and wittingly to something that we have no site of and I think, I think that there are opportunities there where... where... pharmacists are accountable to the health board in Scotland where some of these companies are based in England and there may not be even a line of governance at all.

In: Are there things the pharmacist can do that the nurses don't do or can't do, including the follow-up?

CP: Oh, I guess, I guess, most of these patients, I'm assuming that the patients will be, probably patients of ours already so we're maybe treating them for other conditions. So, I suspect on a regular basis the nurse specialists are not paying too much attention to their other medications. I wouldn't for one minute suggest that they are not paying attention to their conditions, but the... not familiarity, but the... the... increased contact with a pharmacy, stroke, pharmacists would have with a patient such as this may or may... give the holistic, you know, agree to holistic approach.

In: Are there any elements of the management of osteoporosis that might not be able to be provided by a community pharmacist?

CP: Oh, we don't have DXA scans. [laughter] From what you've... from what you've told me we certainly can screen, we certainly can counsel, in fact we probably do these on a daily basis. If there are other things that are happening within that clinic, I'm not too sure I'm aware of them, other than, other than the facilities to test, and you mentioned calcium. We don't have that facility. It depends on how coterminous the pharmacy is with a GP surgery, because of the van labs... the vans that run the

labs there is... are... are focusing on surgeries, not pharmacies understandably. But it's not inconceivable that where they are coterminous the van service could be used, but that again would have to be negotiated.

In: Now I would like to discuss the potential role of community pharmacists in the wider management of osteoporosis. How can a community... we have mentioned some of this, but if there's anything else that a community pharmacy can help with in the osteoporosis management, besides the... the administration of denosumab?

CP: So I suppose we... we may be alert to the fact that somebody... has a... a steroid prescribed and all the other, sort of, medications that may further expose the person to a... a worsening in their bone density. Counselling regarding diet, I suppose would be very b... I mean, not very basic, but it is a very basic thing that maybe once and again gets overlooked, but that certainly could be reinforced. So all of the lifestyle things that... that could be reinforced on a more regular basis if it was deemed to be important. So that... that... that's advice how… on healthy... healthy living I guess. Not that you would be withdrawing prednisolone, because presumably it will prescribed as a... something that is... is deemed necessary for the management of potentially another condition. But you would have a.... an overview of what was the good or bad for the patient through their medications. What else could we play in that role? I – I mean the... the... CMS Chronic Medication Scheme – is... is giving us the building blocks, I guess, to... to holistically manage that patient, and so much as if we see the... an old lady... I say old lady, could be anybody... that is on drugs that may cause falls through either confusion, sleepiness, whatever it is you want to call it, we're probably in a better position to advise knowing the person is actually at risk of... of... from bone deterioration, because currently somebody who comes in just now will have no idea that they are getting that, you know. So it... it is a bit of filling in the gaps in the patient's picture. We are picking these things up through the CMS consultation, but, but we're certainly not come across from these yet. So I think that's... I think that's where....

In: How would a pharmaceutical care package of medication review, adherence with medicines, falls assessment and the need for calcium and vitamin D help the patients?

CP: It's kind of all bringing it together. So we are... we are... we are currently asking the patients to help us verify what we guess as their diagnosis, so in most cases there is no surprise of medications they're getting fits with the diagnosis. The concordance, if you want to call it that, varies and our PMRs [Patient Medication Record] are of some use currently to us establishing that, but currently a patient can go anywhere with a prescription, so you can't really get a full handle on whether they are complying or not. Because if there's something missing in that record of a two month period, and they say "Well I got it somewhere else" we can't question that. However if you have the SMC-model, which is basically a script for six months, and they don't have two month gap... or they have two month gap, well they could have only got it from here and then we're probably in a better position to drill it down a bit and say "Do you really like that calcium?" or "No, I don't like that calcium". So... Yeah... I mean, the.. the... the calcium is probably one of the through the chalkiness of the... the preparation is the adherence or concordance is basically low. So I suppose, what we're going to be doing there is pointing out the... the... not the complications, but the end result of non-compliance and I would say in a, in a patient... in a langua... in a language that the patients will understand. I'm not suggesting that... that, I mean, let's face it, GPs are a lot better than they used to be, but they are not... patients tend to tell them what they want... what they think wanted to hear and from my experience I find that possibly giving more time in a consultation you can pick up on the, on words like "I'm supposed to" at the end, then you say "What do you mean by, I'm supposed to?". "Ahh, that's because I don't take them, you know". So we through counselling skills, we're probably in a better position to identify non-compliance to coax, cajole, whichever word you want us to use, people need to take what's been prescribed or we can come up with an alternative that will do, that is palatable, that they're happy to take.

In: Do you think the pharmacists can discover more than nurses or physicians or GPs do?

CP: Well, I think that if we're all given... if we're all given the same playing as the same length of consultation time. We probably could. But I suppose what I'm highlighting there is I am aware that... that, yes pharmacists have time constraints but none of us have appointments at the moment. So we speak to a patient and it's... maybe somebody come knocking on the door and says "we're going to shut the shop" that... will curtail it. I'm exaggerating, but we probably have more time to deal with a patient. And more interaction with the patient. Through the dispensing process which is, I've got to say is, the one of the reasons people to us, that GPs spend a lot of time having to write to their patients, saying "Will you please come in...", whereas generally, if the patient's in the habit of picking up a prescription we could also opportunistically have a quick word. So there's... So, sorry you're question was – can we do more than a nurse?

In: Yeah.

CP: Somebody that is trained in consultation skills to the same degree should be able to get that out of the patient. I don't know whether a nurse specialist will have that level of training. A GP should. But the down side is that I don't think they have got the time.

In: You were mentioning appointments, do you think pharmacist could be, you know...

CP: You mean for this?

In: Yeah.

CP: We're going to have appointments? [laughing]

In: Yeah. Do...

CP: Yeah, I mean, it's... it's a... it would be a new service, a new model. So, you know, it would be a case of... yes we would have to have appointments for this. We would have to have protected time for this. It's not something you would drop... drop the dispensering.... dispensing bench and go on and do it. I think you would have to be... I think, a protected time, as I said.

In: Do you see any changes to, to the flow-chart that can make the process of management better?

CP: I honestly couldn't comment on that... I – I... I f... I would have to have greater depth of knowledge over the whole thing.

In: Yeah, no problem. Yeah.

CP: If it works just now, I've no reason to believe that it doesn't work, so... It strikes me, you know, all that comes through one channel. As in the referral pathway, pathway. Other than that, other than that, the electronic referrals... it's not to say that, you know, presumably the GPs as a gateway... could be done by somebody else working to the same algorithm, but I think that's, that's, you know, that's where we are, so that's... that's how it's got to be. Yeah. On the whole. I don't see anything that immediately strikes me. So that was the referral in to it. I don't know anything about the referral... the mechanism of how this works.

In: So, all in all, what are your opinions abou... regarding the shift of care? The potential shift of care?

CP: I'm quite positive about it, I'm quite positive about what pharmacy can offer patients. And I think the, yeah, I already acknowledge there might not be a hundred and eighty two pharmacies, but I think you could get a geographical spread of people that were capable of doing this in facilities that are... that are acceptable and over all I think, you know, I think it's good for the profession and it's certainly from a convenience point of view, it's a lot better for patients than going to hospitals and if we are trained on the same, at the same level as whoever is doing it at the moment the patient really should... shouldn't have a different experience.

In: Is there anything you would like to add or anything you would like to elaborate on?

CP: No. No, I think we've covered... covered most things. Ok. Thank you very much.

In: Ok. That's it. Thank you.

Interview with General Practitioner

General Practitioner (GP)

Investigator (In)

In: Are you familiar with denosumab?

GP: Not really. I know what it is, but I am not familiar with it. I don't have any patients who... who prescribed it.

In: So just to summarize, denosumab is a treatment for postmenopausal osteoporosis, with a restriction that it is used only in patients with a BMD T-score below minus two point five and over four point O, for whom oral bisphosphonates are unsuitable. So it is a pre-filled syringe administered every six months as a subcutaneous injection by a nurse in the hospital. Although NICE states that it should be used in primary care after being initiated by a specialist in secondary care. And no blood monitoring is required other than those at risk of hypocalcemia.

So you do not have any patients who receive denosumab?

GP: No.

In: Are you aware of the current process of management?

GP: For?

In: For denosumab.

GP: No, I'm not, no.

In: Ok, so I've made the flow chart of the current treatment management.

GP: Ok.

In:

[Showing GP the "referral to the osteoporosis service at Western General Hospital"-flow chart]

So, this is the way in to the osteoporosis service in the hospital, at Western General.

GP: Yes.

In:

[Showing GP the "osteoporosis service at Western General Hospital – Patients receiving denosumab (current patient journey)"-flow chart]

So, you can be referring patients in to the osteoporosis service from Primary Care or consultants in secondary care. And depending on if they had a recent DXA scan or not, they are going to the bone clinic. So, if they have had a recent DXA scan then they'll go straight to the bone clinic. Otherwise they would go to a nurse specialist for a DXA scan. So, in the bone clinic the treatment will be... Will be... Proposed. And depending on what kind of treatment it is, it will either go back to the GP or to the nurse specialist. So for denosumab, there will be a six month... administration every six months with denosumab. And it's a nurse specialist. And every third year or so, they are going back to the DXA scan to see if the treatment... if they are responding to the treatment.

GP: So the first choice is the bisphosphonate. And then there are certain alternatives...

In: Yes.

GP: One of them is the denosumab.

In: The denosumab, yes.

GP: Ok, got it.

In: And the nurse specialist is doing some follow up as well. Which is a brief falls assessment and fracture risk and detecting if there's any side-effects or not. So that is included in the supplying and administration, here [pointing at the flow-chart].

GP: And how are patients referred in? Is it because of risk factors, or is it because of osteopenia on an X-ray or maybe a bone-scan from somewhere?

In: Yeah, it can be several things. If they are suspecting...

GP: [Both talking] Of fractures and...

In: Yes. Especially if... in orthopaedics if it's a fracture that...

GP: Ok. So I suppose, what I'm asking is, is the osteoporosis service partly a diagnostic service?

In: Yes, it is.

GP: [Both talking] For people that might have osteoporosis.

In: Yeah.

GP: So it is not just for people that definitely have been established to have...

In: No.

GP: ...osteoporosis on a scanning?

In: No. The scanning is a part...

GP: [Both talking] A part of the service.

In: Yes, it is.

GP: Ok. Got it. Yeah.

In: Ok, so I would like to start with asking about convenience to patients when they visit the hospital to receive their injections. For example some patients may travel a distance. Can you think of any ways that delivery of the service could be improved from the patients' perspective?

GP: Ah, well, for this drug?

In: Yes.

GP: Yeah, it would be better for many patients if they could have the injection done locally... at their GP-practice. Or I guess at a community pharmacy... Or at a local health centre. Having said that, it's only once every six months and some patients are quite reassured by going to the hospital, and they quite like to do that. So, there may be an element of patients' preference in it. But generally I think most people would prefer to have it the injection done locally rather than going to the hospital.

In: How do you think the patients would feel about visiting a community pharmacy instead of the hospital?

GP: I think you would need to explain things to them and give them some written information probably. I think patients are becoming, in... in the UK, in Scotland, patients are getting more used to pharmacists providing some direct clinical care, so things like blood pressure, blood glucose monitoring, smoking cessation advice, pregnancy testing, and so on. Patients are getting used to that and they're getting used to seeing the community pharmacist as a source of advice for health problems. You know, not just for dispensing medication and giving advice about medication. I think actually administering treatment in a community pharmacy would be something new. And, so, patients might be concerned about that, and, pharmacists might not have appropriate facilities, premises for it. It's... Yeah... I mean, I guess it's just a new development. But to have the injection

done at the surgery, by a practice nurse or by a treatment-room nurse or in a health centre I think is completely fine. Patients are quite used to that kind of idea.

In: Do you think they would miss anything, compared to the hospital?

GP: I don't think so, I think if they just going to the hospital to get the injection, most patients would probably prefer to have the injection done locally. Depends a bit how, how, you know, how much time the nurse specialist spends with them. If the nurse specialist does a bit of counselling and reassuring and general, ehm, you know, a general chat with them, then they may miss that. But, I guess that other professionals could be up-skilled to do that routine monitoring and, you know, it would be a process for communicating with the hospital if there were concerns, or if things weren't straight forward.

In: Do you think they would be satisfied by the pharmacist undertaking this role compared to nurse?

GP: I think, I think, there may be a small proportion of patients who would just find the idea to be a bit unusual, or a bit too, too new for them. And just might not go with it. I think that for most people they would be quite happy once you would explain to them, as I said, some written information, I think they would be quite happy. Especially, presumably, there'd be a training programme for the pharmacists so they'd have information sources and there'd be a, you know, be primed about the common questions that the patients might ask and side-effects and advice to give them, and so on, so if all the governance issues are in place, then, then, I -, I-, I think you'd be fine. It would be a good example of widening the role of the community pharmacist.

In: Is there anything you would like to add about patients' convenience?

GP: About patient convenience?

In: Yeah.

GP: Well, I suppose, in practical terms it's... It may be difficult for some people to get to the hospital and there are things about car-parking and waiting for your appointment time, and so on. Generally with a pharmacy or a GP surgery, you can get that quickly, you can park easily, usually you don't have to wait a long time for you appointment. I suppose, the... one of the other things would be that... The issue about medication interactions and other treatment, and sort of in, you know, acute prescriptions and acute illnesses that may develop after the patient has started this treatment, and patients may have more confidence that their GP or their practice nurse or a treatment nurse in the... in their GP practice, you know, would be able to access that information more easily than the pharmacist. Patients aren't really... I don't think they are confident with that the idea that pharmacists have a full record of their medications, although I know that there is... some pharmacies have their own systems, and I know that there is the emergency care summary and so on, but... But that may be an issue for some people.

In: Is there anything you would like to add about any concerns that you may have associated with such a shift of care?

GP: I'm not aware of pharmacists giving treatment by injection in community pharmacies, at the moment. Do they?

In: They give the flu jab.

GP: Right. I was going to ask that, about the flu vaccine, yeah. Because there are just general issues about, you know, injection treatment and things like anaphylaxis training and so on. So if that's covered, then that's fine.

In: What problems do you think might arise if would be supplied and administered in the community pharmacy?

GP: I don't know. Just the logistical one, I suppose, of getting it ordered and getting it transported to the pharmacy and having it... storing it... labelling it, because I think you would need to clarify who's

going to prescribe it, and who is going to supply it. Because usually if transfer... If treatment is transferred to the community then the GP prescribes, so for example a practice nurse or a treatment room nurse could just ask a GP for a prescription when it's due. And, and, collect it from the local pharmacy, whereas, I suppose, a pharmacist would have a... They're just a bit more separated from GP practices, so they would be a bit more involved in asking for the... for the prescription and then getting the drug, and... and is it readily available to the community pharmacies or is it a kind of... Presumably you'd have to order it in. Pharmacies probably wouldn't have it in stock, would they?

In: No, they probably wouldn't. The hospital pharmacy will have.

GP: Yeah... So there's a bit of logistics to work through there. About, you know, trying to get the injection in advance and getting it to the right pharmacy and then maybe if the patient doesn't come, because they forget or if they're not well, or, you know, their, their husband is not well or they have to go to the hospital or something like that. What happens? What's the shelf life? All those kinds of things. Storage arrangements. Is it needed to be kept in a fridge or anything?

In: I can't remember at the moment... No, sorry. You were mentioning about some practical problems regarding space and training of staff. Would you like to elaborate on that?

GP: Well, there's just... there are the general things about providing treatment by injections to patients in pharmacies. So there's, you need to have a private consulting area in order to do that. You need to have anaphylaxis training and equipment for treating anaphylactic reactions, you need to be able to observe the patient afterwards, I think it's for twenty minutes or so is the recommendation. Those are the main things in terms of practical issues.

[pause]

So you know, I can't, I don't see any objections to it in principle. But it doesn't, maybe, thinking it through, it doesn't seem like the most logical next step for pharmacists to be doing. You know, there may be practical difficulties around it. That you don't get, for example for things like checking blood pressure, or checking cholesterol levels, or giving smoking cessation advise, those kind of direct patient care things that pharmacists are starting to do. Giving a drug that is... Indicated for specialist use, well, specialist initiation... What would be the governance around that? Because in a, in a GP practice the practice nurse is an employee of the practice, so they are indemnified by the practice. And if there's a risk or if anything goes wrong, then the... the practice has indemnity covered for them. Community pharmacists are independent contractors aren't they? So presumably they have their own professionally indemnity insurance. Would the... Would the consultants be happy for pharmacists giving the injections?

In: Yeah, that's a question to be asked.

GP: Because, I guess, at some point, somewhere there'd have to be a sheet of paper saying, you know, this is being approved in NHS Lothian and someone needs to sign it.

[laughter]

In: Yeah. Is there anything that the nurses do in these follow-up visits, and the administration, that you think the pharmacist couldn't do?

GP: You mean the nurse specialist?

In: The nurse specialist, yeah.

GP: I am not quite sure what the nurse specialist does at the moment.

In:

[Investigator is showing the GP the "nurse specialist – supply and administration" on the flow chart]

Well, it's this part - with the administration and the falls assessment and the fracture risk and the side-effects...

GP: Well, I think the pharmacist would be well able to cover the side-effects. And, falls assessment is a fairly straight forward thing. So, if a pharmacist had some training and some written information about that, they could do a falls assessment. I suppose, it's this linking in with the, the DXA scan every three years. And, you know, being confident about giving advice based on if the scan was border-line and the next one is not due for three years. It's just, you know, discussing those sorts of issues with the patient. Because to do that, the pharmacist would have to have a copy of the report, wouldn't they? They would have to know how to interpret the report. And I guess for the nurse specialist, if that's their job, they are doing that all the time, every day. So it's, very... very much second nature to them, and whereas for a pharmacist you'd be, you know, a novel area. Maybe difficult initially especially if it's a busy time in the surgery, I mean, in the pharmacy. That's the other thing, I'm not quite clear how pharmacists would allocate appointments to... for people to come in. Because they can't really predict the workload, can they?

In: No

[silence]

GP: What do you see as the advantages of a pharmacist doing it or is it just a kind of feasibility study, or a...?

In: Yes, it is.

GP: Ok.

In: And to take some of the workload off the secondary health care system, and most importantly the convenience for the patients.

GP: Yeah, ok. But do you see any specific advantage in a pharmacist do it, rather than a nurse? A community nurse? I can see why you want to move it out of the hospital setting...

[silence]

In: My opinions are... are not the mo... not important in this interview.

GP: Yeah, sorry.

[laughter]

GP: Sorry, I'll let you get back to you questions in the minute. I was just... Because it's... Made me realize something. You may be coming on to it... But, would the pharmacist be paid for doing this, or how will they be compensated for their time? Is that covered in the questions?

In: No, not directly, but you think that financing would be a problem, or a... a thing to consider?

GP: Yeah, I mean, there may be, you know, a small number of enthusiastic pharmacists in Lothian who would be interested to do it just out of interest. But I think, to roll it out as a general service development. Then pharmacists are self-employed, independent contractors, if they spend time doing this, then it needs to be... you know, they need to have their time compensated, they need some remuneration for the work that they do.

[silence]

The difficult thing is capturing the money that you save by not having the activity in hospitals and transferring out to the community. Because there will be a cost saving, at least notionally, to the hospital, but trying to get hold of that money to give to the pharmacists is really difficult.

In: What advantages will there be if denosumab would be supplied and administered in the community pharmacy, except for the convenience?

GP: What advantages? [silence] Hmm... We have covered that haven't we?

In: Mhm. Yeah, I guess.

GP: Geographical convenience. Pharmacies are open Saturday mornings, aren't they? And they are open quite often nine till six. So there might be a wider choice of times, so if someone was working it might be easier for them. Not to have to take time off work.

[silence]

Patients may be able to attend a pharmacy close to where they work, right? Whereas if it was done through their GP, people were usually registered with the GP based on where they live, so if the people who work during the day, it's not always convenient to come back to their GP practice, so... A pharmacy could be a good option for some people for that reason.

In: Do you think that there are things that the pharmacist could do that the nurses do not do, or can't do, regarding the administration and the follow-up?

GP: I can't think of any, I mean, I think the pharmacists' expertise would be in speaking about perhaps drugs side-effects and possible interactions and so on, with the patients' existing medication. I can't see that the pharmacist would have an advantage doing a falls assessment or a fracture risk or talking about a bone scan, compared to an osteoporosis nurse specialist. I think it would be probably difficult for some pharmacists to give the same level of service. I think pharmacists could give a competent service, but perhaps it would be difficult to give an expert service the same way as a nurse specialist who's doing that job all the time, you know, osteoporosis all the time.

In: Are there any elements of the management of osteoporosis that might not be able to be provided by the community pharmacist, besides the things we've covered?

GP: Well, there's stuff about diet and exercise and smoking and falls prevention and... what else? Other medication. Pharmacists would be able to, you know, advice about steroids and things like that, and about calcium supplements. Pharmacists could give advice about smoking and exercise.

In: Do you think there's something that they are not able to do?

GP: I can't think of anything, you know, that's really essential that they wouldn't be able to do. I mean, a lot of these things are sort of general, fairly generic health-care advice type things, aren't they? So, really any health care professional who's been properly trained... You know, it wouldn't be a very complex training, it would be just be a kind of an awareness raising, perhaps half a day or a day's course, or something like that. With some written information, but it could be a nurse, it could be a pharmacist, it could be a physiotherapist... I think any of the AHP's [Allied Health Professions] or a pharmacist or a nurse, a GP.

In: Now I would like to discuss the potential role of community pharmacists in the wider management of osteoporosis.

GP: Right.

In: How can a community pharmacy help with osteoporosis management besides the administration of denosumab? We have covered some of it but is there something you would like to add?

GP: I think just raising awareness, generally. So information leaflets, posters... They can perhaps prompt patients who are on long term oral steroids or high dose inhaled steroids, ask if they've, you know, discussed it with their GP or if they're aware of the osteoporosis risk of the people who have other risk factors, you know, whatever they are low body weight, family history, smoking, whatever. Fractures. So just like, kind of, opportunistic prompting when patients go forward to collect prescriptions and so on.

In: How would a pharmaceutical care package of medication review, adherence with medicines, falls assessment and need for calcium and vitamin D help the patients?

GP: How would it help the patients?

In: Yeah. Do you think it would increase adherence, or...?

GP: It would increase, it would increase understanding. And that, and hopefully satisfaction and they usually lead to increased adherence. You mean for other medication?

In: Yeah. Yeah, that as well. Especially with a medication review, if we could discover... I can ask another question. Do you think a pharmacist could discover more than a nurse, or a physician do?

GP: Potentially, yeah. More than a nurse, I think. Although nurse... some nurses are nurse prescribers so they are fairly well informed about medication. But no one's done the three or four year training plus their preregistration training that a pharmacist has done. And it's all about medicines, isn't it? So, pharmacists are experts in medication, so I would expect that they would be better at doing a medication review. But pragmatically I guess, it depends on how much time you've got, you know. But yes, they would be better. Short answer. Yeah.

In: What do you think about the quality of a medication review compared to a physician or a GP doing it?

GP: I think they have, ehm, the quality is better in many ways, in that it is more detailed and more thorough and, pharmacists often have a better knowledge about side-effects and interactions. I think, that the bit that's sometimes missing from my perspective is having a clinical picture of the patient so sometimes a prescriber will make decisions that's pharmacologically not the ideal, you know, in other words drugs that have the potential for maybe a mild interaction, so if you to ask a pharmacist may say; "well, it would be best, not to have those to drugs together", but if you're the clinician who needs to treat the patient's symptoms then you've gone through the alternatives and weighed the risks and benefits, then sometimes, you know, life isn't black and white, it's, it's, it's not completely clear cut whether something is right or wrong. So, I think if you take a medication review in to a theoretical domain, and look at it things in theory, then you can often pick up problems and interactions and sometimes they're helpful and sometimes they're not. You know, sometimes they are just inevitable aspects of multimorbidity and polypharmacy in all the people. It's hard to have people on ten or fifteen medications with no interactions and no side-effects. But I suppose what you want to know about, is danger, you know, significant interactions and... Or if the patient is experiencing symptoms that may be, sometimes, you know, prescribers don't realize the full range of adverse effects, we don't have them in the head all the time and, so... A reminder about that can be useful. Then you can discuss whether the patient, you know, "would you rather have the side-effects or would you rather try to manage without the medication?".

In: What do you think might be missed compared to have the hospital or the GP's doing it? I guess we have discussed that part.

GP: [Talking at the same time as the investigator] Yeah, just covered that really... The clinical background, having the clinical picture, you know, knowing what's important to the patient, and knowing whether you've discussed the risks and benefits with the patient, you know, the patient may have severe pain and a m... you know, an opiate painkiller might make them drowsy, but they may choose, they prefer to be drowsy than having sever pain.

In: Is there anything that can make the management more convenient for the secondary health care system?

GP: The management of what?

In: Osteoporosis.

GP: Osteoporosis... I don't know, I think, I think, this is a really good service, the osteoporosis nurse, and it's a nurse-led clinic, so you know it's taking... it's freeing up capacity in consultant-led clinics... And outpatient clinics... So... I think it's a good model, and if you can increase the capacity for this model by removing some of the routine, you know, repeat injection work, then hopefully even more patients could benefit from it, because I'm sure that the service doesn't see everyone who has osteoporosis. It's probably an unmet need, I would think. Maybe, maybe from people not being

referred. So that might be one thing, would be for the nurse specialist to have a role in educating GPs about referring in to the osteoporosis service.

In: So you don't see any changes that can be made to this flow chart, so the process of management would be better, or improved?

GP: Oh, well, just what I've said, just said really. I think this is the key step, is the referring in. Especially from GPs and historically that this didn't exists, so you know, that people would have fragility fractures and seeing orthopaedic surgeon, and get their fracture plates and be sent home. And, you know, no one thought about doing a scan or writing a letter to the GP, and saying; "Could you assess for osteoporosis". It was just, you know, it wasn't something the orthopaedic surgeons covered. So, that, that's the big improvement. And then... Falls are another thing. And also, I think to try and focus on the patient and I think there is a danger of, a bit of getting caught up in the DXA scan and the, you know, the results and their T-score and whether is two point four, or two point six, or two point... What's really important is to prevent fractures, isn't it? And to reduce falls. So in a way, osteoporosis is a kind of, it's, it's almost like a approxi-marker. So you can give treatment, someone treatment for osteoporosis and their T-score improves, but their health might not be any better. Their quality of life might be the same, and they might, still fall over and, and, and, fracture their leg, or their arm.... So it's trying to keep the big, the bigger picture in mind, I think...

In: All in all, what are you opinions regarding the potential shift of care?

GP: I think the shift of care is, is fine. And it makes sense. There's no reason for someone to go to hospital just to have an injection given by a nurse. It made more sense for that to be done in the community. I think there are probably two issues that I would say. One is, I wouldn't immediately have thought of community pharmacists as the first choice. I would probably have thought of community nurses or practice nurses. And secondly, there's the resource issue about how it's going to be funded. I don't think there are major issues about medical governance and about patient safety and about skills and experience and so on. I think you can be transferred out, you know, as I say, it could be a nurse, it could be a physio, it could be a pharmacist. That doesn't really matter. But it's probably easier for community nurses, just in terms of their connection with GP practises, and the linking in to prescribing, in to, to management of the patient.

[silence]

But it would be an interesting pilot.

[laughter]

An interesting pilot...

In: Is there anything you would like to add or anything you would like to elaborate on?

[silence]

GP: No. But there are about a hundred patients in Lothian?

In: Yes.

GP: And they get two injections a year?

In: Yes.

GP: So there's about two hundred injections per year?

In: Yeah.

GP: And there are how many pharmacies in Lothian?

In: About a hundred and eighty five.

GP: So, presumably they would do both of them, so... About two hundred pharmacies... So a pharmacy might have... Would be unlikely to have more than one patient.

In: Yes.

GP: So, it's going to be a... But then you have to think about the... How efficient is it going to be to set up a whole system for one, for each pharmacist to see one patient, twice a year? Maybe, it might be better to have certain pharmacies in local geographical areas that would specialize in this? You know, they would see, maybe, four or five patients, maybe one a month

In: So if there's nothing you'd like to add, then that's it.

Interview with osteoporosis specialist nurse 1

Nurse specialist 1 (N1)

Investigator (In)

In: Are you familiar with denosumab?

N1: Yes.

In: Yes. Do you have any patients who receive denosumab treatment?

N1: Yes.

In: How are you involved in the use of denosumab in osteoporosis management?

N1: We would interview patients and make the decision whether or not to start them on denosumab. And also administer the treatment. At the moment all the denosumab is being administered in the hospital. Although we are looking for it to be delivered elsewhere.

In: Are you aware of the current process of management?

N1: Yes.

In: Yes. So I have made the flow charts, here.

[Showing the "referral to the osteoporosis service at Western General Hospital"- and the "osteoporosis service at Western General Hospital – Patients receiving denosumab (current patient journey)"-flow chart]

So I would like to start and ask you about convenience to patients when they visit the hospital to receive their injections. For example, some patients may travel some distance. What is your impression of the patients experience when they are receiving denosumab treatment in the hospital?

N1: I think they are delighted to be getting the drug, because they know it is a new drug. But some of them are travelling up to four hours, round trip, for what takes a five minute process. And I think a lot of the patients would like it to be delivered locally.

In: What kind of feelings do they express when coming to the hospital?

N1: I think often they are harassed because they can't park when they get here. Either that or they come by a bus, then train, then another bus down to the Western [Western General Hospital] from Waverley [the train station in Edinburgh]. So often, you know, when they come in and you administer it, they are like – is that it? [laughter]. And, and sometimes, the wait to be seen as well. You know, they are offered their appointments at eleven a'clock, you know, it might be ten past, quarter past, as well. So that is another, yeah, so there is four, five hours of their day is gone. So that, a lot of them are quite... frustrated.

In: Are they happy about something?

N1: They are happy they are here and they getting the treatment. Without a doubt. They are not making too much of a fuss. And we have already transferred a couple of patients over to St John's [a hospital located in Livingston, west of Edinburgh]... to have it at St John's, but that's a limited service. And at the moment we are keeping that for immobile patients. It would not be everybody... that is able to have that.

In: So that's to make it more convenient for the patients.

N1: For the patient.

In: Yeah. Can you think of any ways that delivery of the service could be improved from the patients' perspective?

N1: Oh, we had hoped to roll it out to the practice nurses through the share care protocol. But that's not happened at the moment. And I don't know when it will happen.

In: How do you think the patients would feel about visiting a community pharmacy instead of the hospital for follow-up treatment and administration, similar to that provided by you?

N1: I think they'd be quite happy, because they are used to already going to their pharmacist if they're on other medications. And I think, I think the public are getting better. They're much more aware that pharmacists know a lot more about drug interactions and things. And they're used to popping in to the pharmacy for advice. Some of them have their flu-jags there as well, so. And there's a minor ailment-service as well. So I think some of them use that, so it's a service they're used to. Stop smoking. You know, they have taken over all the stop smoking-services in Lothian [the county that includes Edinburgh]. So I think. I don't think it would be a new experience for... some of them. I think they would take, take quite well. I think so.

In: Is there anything you would like to add about patients' convenience?

N1: No, I don't think so. I - I think locally would be the best place. I think if patients didn't want locally, then we would still offer the service here, but I think we would be encouraging them to have it locally.

In: Yeah. Is there anything you would like to add about concerns that you may have associated with such a shift of care?

N1: I think you'd be frightened some of them would be lost to follow up. So I would maybe envisage that we would just send them a letter saying - your six monthly injection's due. I think we would still maybe take that bit and set us on, just a reminder. I, I don't think we would follow it through, I don't think we would have the resources. But I think if we're triggering something to them, you know, and I can see an admin-person doing that. Just, you know, putting out ten to fifteen letters in beginning of the month, of that month's patients. So it's we hold a database more than anything. But I think we would have to rely on patients or a patients relative taking responsibility. I suppose the dementia ones you worry about, but often we've got a contact for a family member and maybe that is where the reminder-letter would go, rather than to the patient.

In: Do you think the lost to follow-up would be a problem in the community pharmacies?

N1: I think potentially it could be, but then they have their own recall-system, I don't know. That's not something we've done before, but hopefully they would have their own recall-system and it wouldn't be a problem.

In: What other problems might arise if denosumab would be supplied and administered in the community pharmacy?

N1: I can't see any other problems. No.

In: Do you think they would miss anything, compared to the hospital?

N1: I don't think so. No.

In: Is there anything that you do in these follow-up visits when you administer denosumab that you think the pharmacist couldn't do?

N1: No, 'cause all we're checking is that they've not had any new falls or fractures. And the GP [General Practitioner] would be taking that on as a part of QOF [The Quality and Outcomes Framework] anyway, so they would be doing that as a part of the QOF work, which started April 2012, so it's something they would be looking at anyway. So, no, you'd hope that they would still get that bit of the care.

In: What advantages will there be if denosumab would be supplied and administered in the community pharmacy, except for the patients convenience?

N1: I think it would release us, about a hundred and twenty appointments per year. So we could maybe use that time to reduce our existing waiting list for new patients.

In: Do you think there is anything that the pharmacist could help with?

N1: For the denosumab or for their own general health?

In: [Both talking] Yeah, or the osteoporosis in general.

N1: I suppose once the drug is administered then, you know, probably reminder about, you know, just the normal, mind you it's something we're not good at either, you know, hearing, fishing, then came lights on general avoiding falls, advice you know maybe, just a leaflet that goes out, you know, just to remind them to keep themselves, you know, to falls prevention more than anything. You know, 'cause in the theory, if they don't fall, they shouldn't fracture. But I supp... maybe that is something we should think about ourselves actually [both laughing]. Giving out a leaflet for falls prevention. But no, I think they could manage.

In: Are there things the pharmacist couldn't do... Or... I'm sorry. Are there things the pharmacist could do that you can't or do not do?

N1: I suppose they could look at more polypharmacy while they're there. We don't have the time. You know, occasionally patients will ask about certain things, and because I do practise nursing my knowledge is probably, you know, it's fairly up-to-date but I am certainly not an expert on medications across the board so that's something that they would be able to help the patients with.

That we're... And I think the longer you do a specialist job, on the whole, the further you are detached from general nursing.

In: Are there any elements of the management of osteoporosis that might not be able to be provided by the community pharmacist?

N1: The only thing is dementia and consent. You know, if there weren't... but then we have that problem as well, you know, if they don't bring a family member with them... then I think they would struggle as well. But that would be no different than we would struggle with. We had a lady recently who came in to have denosumab, she couldn't remember having her first one, then we had this real dilemma, should we give her a second one, but luckily her daughter was out there and came in and said, "no mom, you've had this before and I think you should have it again". So, that's the only thing, but I suppose, you know, the pharmacists are used to seeing our group of patients anyway, I'm sure. Of course the doctor know by other medications that they had other problems, and that may be the odd patient we end up keeping anyway, I don't know. They are about the only group. And often the learning difficulties, one, they often have carers with them as well. So it's not usually such a problem for the learning difficulties.

In: Now I would like to discuss the potential role of community pharmacists in the wider management of osteoporosis. How can a community pharmacy help with osteoporosis management besides the administration of denosumab?

N1: I think checking patients take the drug, you know, they don't go home and stock pile, we're checking it's only eight weeks since they last picked it up, and that there is, you know, not two, three, four months down the line, so check compliance, check that they're taking it properly. And obviously making sure, you know, that they're taking it properly as soon as they are out of bed first thing in the morning and not taking it with any other medications. And we have had quite a lot if incidents where patients start taking Adcal [Adcal D3®, a calcium and vitamin D_3 supplement] weekly and forget about their alendronate. So their bottle of Adcal can last them for fourteen months and these things should be picked up with their yearly medical checks, but often they're not for some reason, so that would be... And I think that's happening in pockets over the city, I do think pharmacists are looking at osteoporosis medications and making sure patients are taking it properly, that would be a big help.

In: How would a pharmaceutical care package of medication review, adherence with medicines, falls assessment and the need for calcium and vitamin D help the patients?

N1: I suppose you'd have to do a diet questionnaire with them just to know how much they're taking. You know, because a lot of patients are taking a thousand milligrams by diet, so you wouldn't really want to be adding too much more then. So you'd have to either get a copy of their original scan, when it's worked out for them, or ask them to do another one. And, no, that would be good if they have time to do that.

In: What do you think might be missed compared to the hospital doing it?

N1: I don't think, I think, you know, if they're as good as their smoking service then... I can't see that they'd be missing anything. And, and I think it would be, I can't imagine these pharmacists have more than one patient, one or two patients, so I think they would do it very well, you know, because they would have the time to do it well.

In: What do you think about the quality compared to you or physicians or GPs doing it?

N1: Don't think there will be any change of quality. Not from what I've seen with pharmacists, you know, more just my own one locally and, when I did the stop smoking service. I don't think you can fault them. Can't think of anything negative to say about them. No.

In: Is there anything that could make the management more convenient for the secondary health care system?

N1: Are we back to denosumab, or...?

In: Yeah, and the whole care package in the wider management of osteoporosis.

N1: I think once we get used to the drug, I think it's often a wasted visit coming to change over to denosumab, but the moment you need a consultant appointment, to change over to denosumab, and often there's straight forward cases.

Especially when the eGFR [estimated Glomerular Filtration Rate] drops to 35, you've got no other medications you can offer the patient. Yet the patients got to travel to the Western, see a consultant in a half hour slot for him to say "yes – you can have denosumab". So I think for a small group of patients, you would like to think that, that service would be happening locally and somebody could make that decision locally and then they could just present to the pharmacist for the denosumab, you know, because it seems crazy, when there's no other drug they can have to go through all these hoops just because of a funding issue. But I don't know if that would be allowed, but certainly that would be a nice add-on to the service, you know, because often they are frail, you know, when their eGFR is getting low. They are a frailer group of patients that are struggling to get to hospital anyway for a drug that there's not really any reason we're going to refuse them the drug, so it seems a bit daft.

In: Do you think that it would be any risks of moving the care?

N1: I can't foresee any. No.

In: Do you see any changes that can be made to this flow chart that can make the process of management better?

N1: I don't think so. We had a good look earlier, so I can't. [pause] The only one as I've said before, to take out the hospital appointment and go straight from GP to pharmacist. And certain not, not every case, but I think, you know, for a small group of patients they could go GP straight to pharmacy in the future.

In: So, get the prescription of the denosumab at their GPs and then get the administration...

[pause]

N1: By the pharmacist.

In: By the pharmacist?

N1: Yeah.

In: All in all, what are your opinions regarding the potential shift of care?

N1: I think it would be a really good service. I think it's one the patients, most patients, you'd get the odd one who still want to come here [to the hospital] without a doubt. I can't imagine, you know, a hundred percent of patients would move on to pharmacy. I think you will get one or two, that quite like coming to the hospital and all the drama that goes with it. You'll always get these patients. But for most patients I think it's where the service should be; definitely locally.

In: Is there anything you would like to add or anything that you would like to elaborate on?

N1: [pause] Something went through my mind a minute ago.

In: Yeah, take your time.

N1: Just when we were talking about something else. [pause] I can't remember. [pause] I can't think of what it was. I don't remember at all. No, I can't think of what it was. When we were speaking earlier, something came into my head. I should have written it down, whenever. But no, I can't think of... I think it's... Whose idea was it?

In: I don't know.

N1: You don't know.

In: Ok, thank you very much.

Interview with osteoporosis specialist nurse 2

In: Investigator

N2: Osteoporosis nurse specialist 2

In: Are you familiar with denosumab?

N2: Yes. I've started here three months ago, but there's a number of patients that come for the injection already, and I've been administering it myself.

In: So you have patients who receive denosumab treatment?

N2: Mhm.

In: How are you involved in the use of denosumab in osteoporosis management?

N2: I'm not at the stage of deciding what treatment patients go on, but I'm administering and follow through their treatment plans. So I've been adm... giving the denosumabs to the patients. Is that the answer?

[laughter]

In: Yeah... No...

[laughter]

N2: I'm not quite sure if it...

In: Are you aware of the current process of management?

N2: [Silence]

In: The patient journey?

N2: That's what I'm... Yes, I'm getting to grips with myself and thinking of the patients' journey, and what treatments they go through and for how long and things, so I'm getting used to that as well, with me just starting in August.

In: So I've made a flow-chart of the patients journey. [Showing the "referral to the osteoporosis service at Western General Hospital"- and the "osteoporosis service at Western General Hospital – Patients receiving denosumab (current patient journey)"-flow chart]

N2: Ah, yes, I did see that. You e-mailed it. Yes. Is that what you were meaning? Yes. I should have read this today, well yesterday... [laughter]

In: No... No problem.

N2: Yes. Going to the GP and then referral through the SCI Gateway [A system in NHS Scotland used to send documents such as referrals and discharges] for DXA scans or going to the bone clinic. And how'd the treatments... deciding what treatment, yeah. And then to the nurse specialist. Yeah. Yes.

In: I would like to ask you about convenience to patients when they visit the hospital to receive their injections, for example some patients might travel some distance.

N2: Yeah.

In: What is your impression of the patients' experience when they are receiving the denosumab treatment in the hospital?

N2: The patients that come to the... they seem fine... There's maybe the ones on the phone that XXX [An osteoporosis nurse specialist] has dealt with that aren't too happy about travelling in from West-Lothian, and understandably, maybe as the winter goes on as well they won't be wanting to come in for, like, something that takes two minutes, they could be in the room at least for an injection when they could have it more... at a local service. I think the inconvenience for them and ambulances... we were talking about elderly frail patients and maybe booking amasses and the resources that they're using is maybe all, you know, for the short time that they attend the appointment they could be treated elsewhere. And less journey for them. And, ehm. Inconvenience. Their families, as well, have to take time off work to bring them.

In: Do they express any feelings when they're coming to the hospital?

N2: Not when they've been here, that I'm aware of because, I suppose, they've got used to the fact well that they have to come. But whether XXX [An osteoporosis nurse specialist] has had more about experiences, and she... she has visited one or two that are elderly frail, I think mainly in East-Lothian, 'cause she lives in that area, being a practice nurse, she goes and does home visits. But I haven't personally had any grievances from patients along these lines.

In: Can you think of any ways that delivery of the service could be improved from the patients' perspective?

N2: Along the lines of giving them it locally, like maybe the practice nurse, although, well, I believe that's gone down in that route and it's the GPs aren't keen to take it over. I don't know if it's a funding aspect or not. But certainly having it carried out locally... having a treatment rather than having to come in miles to a hospital and take up other patients' times. Other patients could have that slot for something else. Because it is still quite a big volume of patients and allocating times. And all the paperwork making the appointments and sending out and things as well. So it would be better for the patients probably to have it done locally.

In: How do you think the patients would feel about visiting a community pharmacy instead of the hospital for administration and the follow-up treatment similar to that provided by you?

N2: I think there's more and more in the pharmacy, so patients are becoming aware of they're not just there to dispense medication. They've taking over the flu-jabs, they're doing the cholesterol-checks and various diabetic... diabetes things. That they're becoming more aware that the pharmacists are extending their roles, but I think the patients, if it was just a matter of giving the injection and it's... it's got a safety-needle and everything, so there's not, you know, it's quite... I think the patients would probably prefer that. I would... I would probably think.

In: Is there anything you would like to add about patients' convenience?

N2: I can't think what I've not covered. No. As I've said about transport and patients' family having to take time off work to bring them in. Whether... I've said all that didn't I?

In: Yeah.

N2: So I can't think of anything else. [laughing]

In: Ok. [laughing] Is there anything you would like to add about any concerns that you may have associated with such a shift of care?

N2: Whether they were just going for... every so often, and then they were coming to us for another... maybe... when... I don't know if ... I - I'm just getting used to things, but whether calcium-levels and things like that need to be monitored. They don't tend to do anyt... Any monitoring of bloods do they once they start the treatment there's no monitoring. It's more at the beginning. I - I maybe, don't know enough yet to comment. Only what I know... I suppose it's pharmacists recognizing side-effects and patients still having a contact with the hospital if they have any concerns about their treatment and side-effects they could phone in and then be reviewed. That would be the... Yeah... Because they're on denosumab for... How long... Ages aren't they?

In: Yeah.

N2: So really, it's a... it's having that link still here. Having a review-system... That may be... Yeah... They would, maybe, still need some contact with the hospital.

In: What problems might arise if denosumab would be supplied and administered in the community pharmacy?

N2: I don't know, how would the funding and all that work? Problems... As I say, patients maybe having side-effects and not openly discussing with the pharmacy. They should still be linking and... There should still be communication links. Still... I don't know if I've covered that in the last one.

In: It's good to repeat it as well.

[laughter]

In: Do you think privacy would be a problem in the pharmacy?

N2: I don't know. I've never had a flu-jab down that the G... the pharmacy. I don't know what the procedure is... I suppose everywhere is different, because they're all the different sizes and I suppose it's not every pharmacy that is going to maybe doing this are they?

In: No.

N2: It's maybe, sort of, a bit... Eh... Privacy and time and maybe patients that want to speak about their concerns, they maybe not got enough... But then they have the link back in. So it's maybe patients being able to get their answers solved quick enough... you know... answers to their questions speedily by the pharmacist. I suppose it's education of the pharmacists as well. Why these are giving... given... do they know... and teaching them how to... well... no, because they do flu-jabs... so they don't need further education do they...

In: They might have... might need some more.

N2: More people as well. There might just be one or two...

In: Yeah. Do you think the patient would miss anything about the care?

N2: They might feel more like a... I don't know - I... There's more that specialized field here... they are able... it's not just the injection, it's more of a holistic approach, whereas maybe with pharmacy it can be limited and it depends on the pharmacy knowledge because it's more wide-spread... that.. that could be a problem maybe.

In: Is there anything that you do in these follow-up visits that you think the pharmacist couldn't do?

N2: It's more along the lines of their osteoporosis giving them advice. Lifestyle... Diet... Calcium and vitamin D. I suppose, we'd look at their blood-levels and we tell them about their... and also do a calcium-intake, diet, and see, see if they could be taking calcium and vitamin D still. And giving them... But then the pharmacy should be more up on vitamin D and calcium than us, but they won't have the patients' blood results, but they might have... They could do a dietary intake... Just general advice of the patient about their osteoporosis.

In: What advantages will there be if denosumab would be supplied and administered in the community pharmacy, except patients' convenience?

N2: Except... ah... well I suppose time slots for other patients and work-load for the osteoporosis nurses, but that doesn't mean that they'd be sitting around doing nothing, because there'd be other people that they could concentrate their service on. And it gives... relieves time to do other things. Convenience for patient. But not just that the ambulance service for some, families as well, convenience, as I've said to you... taking time off work to bring them in. That's it. I'm repeating again. [laughing]

In: Are there things the pharmacist couldn't do that... Sorry. Are there things the pharmacist could do, that you don't do or can't do?

N2: That they could do?

In: Yeah.

N2: Well, they can... They know probably what's available for patients; calcium and vitamin Ds, preparations, prices and things, you know, what they can get through prescription and how easy it is to source these things because there... there's such a wide market knowing which prices and which ones and although Fultium [Fultium-D_3 (colecalciferol)] is now on prescription. What else can the pharmacist do? Offer the service at the local area and they also, could probably offer flu-jabs and various other... make the patients more aware of what they are able to offer. If the patient doesn't already use their services.

In: Are there any elements of the management of osteoporosis that might not be able to be provided by the community pharmacist?

N2: Discussing blood results, but then they don't do them routinely, but that may be that were done last year and you could discuss vitamin D and calcium. And, ehm, side-effects and what other treatments are available or... and when to have their DXA, up for repeat DXA scans. Managament of the... Yeah?

In: Yeah. Ok, so now I would like to discuss the potential role of community pharmacists in the wider management of osteoporosis. How can a community pharmacy help with osteoporosis management besides the administration of denosumab?

N2: As I've said, dietary calcium and vitamin D. Medications that are available. Because they are able if patients are having problems with some and they don't like them and they're able to give them advice and they know more about what's available than us. Yeah? Ehm, life-style, exercise... Yeah?

In: Yeah. How would a pharmaceutical care package of medication review, adherence with medicines, falls assessment and the need for calcium and vitamin D help the patients?

N2: How would it help? They're getting a service locally at the... at their... in their local area. Maybe they could pop in if there was advice in between... about their medication. It's a... it depends on, again, people doesn't it and how accessible it is to them. It's not just the... here but they feel that there's other places of contact if they're not able to...

[silence]

In: What might be missed compared to the hospital doing it?

N2: Now, this is to do more with all the... we moved on to... because I'm kind of repeating again.

In: Yeah, no, besides the denosumab.

N2: Beside... Well the overall management of their treatment, their whole treatment plan, where they would be going from this, what treatment they would be moving on to. DXA scans and things... They would be maybe miss that. So more of their patient management plan, where the... whereas the pharmacist would just know that they're on that treatment and give them the injection and that's all, but wouldn't see the... well, here we go and at what stage, they wouldn't know the patient's results and be able to discuss the DXA scan with them. So more of a... I think I'm repeating myself... of the osteoporosis' holistic side. I think I've repeated it... [laughter]

In: That's not a problem. What do you think about the quality compared to you or physicians or GPs doing it?

N2: Everybody's biased. But it depends on the people and how they're giving the service as well, that's individual, isn't it? No, you can't compare two services. I think, for patients' convenience I think it's a good thing that it is done locally. Yeah...

In: Is there anything that can make the management of osteoporosis more convenient for the secondary health care system, or for you?

N2: Communication and working as a team and feedback and links if they feel issues with certain patients or they're unsure of things. Yeah... Good, sort of, communication and feedback.

In: Do you think communication would be a problem if...?

N2: It always is a problem, isn't it? [laughter] Communication: that's where things break down. Yeah. It depends, how it's allocated like the health care workers, they have an e-mail system that they link in to. But there is a phone help line, but it's getting the time to use it... to deal with these calls, so that's an issue as well, but that's maybe, that's something that... once I get more able to take some servi... work-load of XXX [osteoporosis nurse specialist] then would be able to divide ourself a bit more. The moment it's maybe, she does a lot I'm not able to take off her at the moment. So I'm shadowing her.

In: Do you see any changes that can be made to this flow-chart that can make the process of management better?

[Showing the "referral to the osteoporosis service at Western General Hospital"- and the "osteoporosis service at Western General Hospital – Patients receiving denosumab (current patient journey)"-flow chart]

N2: [silence] Not from... from the flow-chart, no. It's maybe just, making sure that patients have DXA scans before their bone review, and... Not from the flow-chart, no.

In: No. All in all, what are you opinions regarding the potential shift of care?

N2: My... What are my consid... ?

In: What are you opinions...

N2: My opinions.

In: ... all in all?

N2: All in all. I think it's a good thing for the patient and perhaps the service, because we're doing other treatments, and there's new treatments coming on and we can't supply all the services, because we do this all treatments, and we do infusions and we do the denosumab. Well, the patients do their own TPHs. [The phone starts ringing] Oh, the phone will be diverted on to another... But in Glasgow they do... they move them on to day-hospitals and they do any treatments. But they concentrate more, like, you know, on other aspects which doesn't give... if we are bogged down with a lot of the treatments, and we're not getting a chance, there's no treatments coming on it makes sense to move out to the community and make it more convenient for the patient and for the service to develop more. Yeah?

In: Yeah. Is there anything you would like to add or anything that you would like to elaborate on?

N2: I think I'm too new at the moment to, sort of, but I think I've covered every..., or repeated everything, that I'm happy with that bit. Yeah. I think at the moment it's...

In: Ok. Yeah, that's perfect.

N2: Ok.

In: That's it, thank you.

Interview with physician 1

In: Investigator

P1: Physician 1

In: Are you familiar with denosumab?

P1: Yes.

In: Yes. Do you have any patients who receive denosumab treatment?

P1: Yes.

In: How are you involved in the use of denosumab in osteoporosis management?

P1: As the local lead for osteoporosis to my bit of Lothian, West Lothian, and a bit of West Edinburgh, I get the referrals for people who are requiring second line osteoporosis treatment. Who are either non-responders or intolerant to oral bisphosphonates. So those individuals are considered for second line treatment, primarily teriparatide, i.v. zolandronate or denosumab, so we've been using denosumab since it was launched about two years ago.

In: Ok, so you prescribe denosumab for patients?

P1: Yes.

In: Are you aware of the current process of management?

P1: Certainly, there has been, you know XXX XXX [A physician] and myself have agreed a protocol for the way forward and that's been heavily discussed with XXX XXX [clinical pharmacist] as the main pharmacy lead for the drug and I know that she's been involved in the submissions to the formulary committee.

In: So I made a flow chart...

P1: Ok.

In: ... of the patient journey.

P1: Ok.

In:

[pointing at the "referral to the osteoporosis service at Western General Hospital"]

So, this is in to the osteoporosis service.

P1: Ok.

In: Either via GP or via secondary health care system.

P1: Ok.

In:

[Pointing at the "osteoporosis service at Western General Hospital – patients receiving denosumab (current patient journey)]

Then I put the DXA scan as the first, and then the bone clinic, and then to the nurse specialist, which will...

P1: Yeah, it's slightly different. I mean, it's very... It's slightly different in West Lothian, but you know, it's... the... it's actually just one of the wards who provides the supply and administration for me, because we have quite limited nurse specialist input. So... but I mean, it's a minor element and

that my clinic is really a general medical clinic, but half the patients are osteoporosis, rather than a specific bone clinic, but the flow chart is essentially accurate, there's just slight, minor amendments for... for West Lothian, rather than XXX's [physician] set up in Edinburgh. So I mean that is certainly accurate... and the... effectively anyone who's going to get denosumab will have a DXA scan. I wouldn't start denosumab without a DXA scan confirmation that they undoubtedly have it [osteoporosis]. And that they are intolerant to first line treatment or... either intolerant, or non-responders.

In: Ok. So instead of the nurse specialist, there is a nurse at the ward, one of the wards?

P1: Yes.

In: Alright.

P1: There is one... Basically they... they... they... we only have an osteoporosis nurse specialist is one day per week and that day doesn't happen to be the day when the bone clinic runs. So, one of my wards - the charge nurse in there - basically agreed that they would give it. So the patients just go through to one of the general wards because it's a very simple injection. And the... pharmaceutical company, Amgen, came along to the ward and gave some, basically some teaching and information sessions to that ward, so that there's several senior nurses who are aware of the situation and how to give it. So it works quite smoothly.

In: So how is the follow-up?

P1: When... I - I just see them at clinic, complete a kardex, they take the kardex to the ward, the ward then just pops the kardex back to my office, and I... I've automatically given them a six month appointment. So, they just come back in six months for their next injection. So that, at times, can fill two or three of my review slots in clinic. It's purely people coming back for denosumab at the moment. And that's... There's certainly one or two people who have been... who are... live locally, who we've been asked to take on because of the difficulties they have of getting to the Western. I had somebody last week who's wheelchair bound, who lives two miles from St Johns hospital and she said it would be much easier, rather than going to the Western, because she was seen at the bone clinic at the Western and she said, basically, you know, "it's very difficult in my wheelchair to get to the Western, can I have this at St. John's?". So we took her on, but equally, you know, that lady gets the flu jab from her GP, who lives a hundred yards away, and she in a wheelchair still needs to come to the hospital for an injection that could be given very easily in primary care.

In: Ok, so I would like to ask you about convenience to patients when they visit the hospital to receive their injections. As you say, for example they might travel some distance.

P1: Yeah.

In: What is your impression of the patients experience about receiving denosumab when you propose the treatment?

P1: I think, as the clinicians get more confident in using it, that we're much more positive I suspect... I mean, it... Certainly, two years ago it was, you know, this is a new treatment. The trials looked good. We haven't used it extensively ourselves and, I think, at that time quite often it's a, it was a, I liked to give patients choice, and quite often, like I said, I think you could either take i.v. zolendronate or denosumab, there were, the majority took i.v. zolendronate at that point. I think now that we're two years down the track, I know, neither XXX [physician] nor myself have seen anyone who've had any side-effects with the denosumab. There is more extensive five-year data for denosumab that certainly seems to suggest that you may have continuing bone gains, compared to... compared to the oral bisphoshonates and there's also some data, basically a sub-analysis of fractures, suggesting that, basically, there may be further benefits with denosumab, particularly since there's increasing concerns about atypical fractures with, with, basically, oral bisphosphonates or i.v. bisphosphonates. So, I think we're, when I offer denosumab to patients I do it in a more positive, light... two years on than I did at the beginning. And I certainly, I think a number, quite a few people jump for the opportunity. I think there are still quite a lot of people who like the idea of a once a year infusion [referring to the i.v.

zolendronate] in twenty minutes and they're out of the hospital. And that's it for good. So, I would say at the moment, if I offer those to, if I think that both are an option, it's probably fifty-fifty as to whether people want a on one year infusion or come up twice to the clinic to have a subcutaneous injection.

In: Ok, so what kind of feelings do they express? Are they happy? Or are they sad?

P1: [Both talking] I think they're happy. I mean, I think patients, some patients would look at the internet at would look at the National Osteoporosis Society, and are read up about stuff. And they would be informed to make an informed decision, many of the patients haven't done that and they're often looking for, looking for, you know advice from the specialist as to which one they think would be best for them and I think, in that way it's really, both of these are niche-products, both i.v. zoledronate and denosumab. And it will depend on, you know, to a certain extent, on what I think of the patient, as to which one I would push the person towards, if I am asked to push. But I do feel that you could get much better adherence to treatment if the person feels that they were a partied to the decision.

In: Do they express any feelings about going to the hospital every six months?

P1: I – I – When I offer them the treatment I basically tell them that at the moment they will have to come to the hospital, so, when they're agreeing to start the treatment they know that that will entail six monthly injections. I – I've often told them that we are hoping for some form of shared care protocol in the future, but I've said that that could be a lengthy process. And if they decide to go in to this treatment they should assume that they will have to come up every six months. So, I think it's part of the deal that I sell them, is that they going to have to come up every six months. So, I don't get a lot of complaints about it, they just know that if they start that treatment they've agreed to do that.

In: Can you think of any ways that delivery of the service could be improved from the patient's perspective?

P1: I don't think there's any doubt that it would be much easier for them to go to their local health centre. They... You know, we do have patients, so I mean that, many of these patients have multiple fractures, they're not particularly fit. And, they have to find their way to the hospital, car-parking is not easy in the hospital, they will have, you know, perhaps half an hour wait, I literally see them now for a minute, hand them their kardex and then they go to the ward, so it probably takes an hour – an hour and a half for a simple injection which were to be given in the health centre like a flu-jab which probably take ten minutes, it'd be more convenient for the patient, I do think that we need to see them to initiate the treatment and that was always the plan, I think that if we could get this working that it would be shared care, and that the bone clinics or the bone specialist would be the person who would discuss it with the patient and decide on treatment, and I do think the bone clinic needs to follow these people up. For example, I have said to all the patients that they'll come up every six months, but there's two years I'm going to DXA scan them all and then we'll meet with them to talk about what we're going to, you know, whether we should carry on with the treatment, and basically reassess them, and that's sooner than I do with, for example, i.v. zoledronate, where we'll give three... the standard Lothian Protocol which is three infusions and then a DXA scan at five years and then decide whether to reinstitute treatment at year six. PTH [Parathyroid hormone], because it finishes at two years I'd repeat DXA two years, so I've said I'd do the same with denosumab since it is a new agent and since the first people went on to it about two years ago those people are the first people I have, are just coming in to the point where they are getting repeat DXA's requested, so don't think there's any doubt that it would be more convenient in the community for the majority of the injections but I still think they would need to be brought up to the clinic, but I would see them coming up for decision about initiation and then perhaps recalling them at two years when they've had a DXA scan to then discuss how they're getting on at two years, so it would be a shared care system that – that secondary care field would be the way forward for this.

In: How do you think patients would feel about visiting a community pharmacy instead of the hospital for follow-up treatment and administration?

P1: I – I have no problem with a community pharmacy, a pharmacist if they're happy to give the injection, I'm not quite sure whether community pharmacists can give injections, I wasn't aware they could. But I have no particular problem with pharmacists are welled trained. They are often better than doctors at checking, you know, how the patient is and what other drugs they are taking and things like that. So, you know, I think, as long as your professional body, the professional... you know, the pharmacy professional bodies are happy with that approach, I would have no problem with the person getting the treatment there, I think I would still... as I've suggested, think that we need... that the bone clinic needs to review them from time to time to make sure the progress is moving forward.

In: But you think the patients would be happy, or that they would think it's OK?

P1: [Both talking] Yeah, I - I don't see, I - I mean, I – I - I mean, whether, I have never, I've never ever asked a patient and I have to say whether, for example, "would you be happy to have your flu-jab in a community pharmacy, rather than going up to the health centre?". So I'm not really sure what the patients' view about that would be. I suppose, the only medical query would be in the community, would be that very occasionally people can have an anaphylactic reaction from something like a flu-jab and, so I, as I... it's probably only one in a million chance, but it would, you know, sooner or later it will happen and if somebody had an acute anaphylactic reaction in a pharmacy would they be, you know, how would that be managed? We know that there's resuscitation equipment and that GPs would have resuscitation skills, so I don't know, personally what the resuscitation skills are in a pharmacy whether resuscitation equipment and things would be available. You probably know that better than I do.

[laughter]

In: Is there anything you would like to add about patients' convenience?

P1: No, I mean, I certainly, I'm disappointed that, I think that general practitioners, because of pressure that they feel upon themselves have to date to climb to take on a share care system, here. Because, I think what we're basically asking them to do is... is to give these fairly frail patients two subcutaneous injections a year with close monitoring, you know, with... with input from secondary care and that their concerns about their workload are blinding them to the benefits to their patients.

In: Is there anything you would like to add about any concerns that you may have associated with such a shift of care?

P1: I have no concerns about shifting of care to primary care, to health centres, as long as it's shared care between ourselves, ourselves are initiating and intimately seeing the patients to check if the progress is there. If it's around community pharmacy, I would, I would want to understand, you know, I suppose how the patients view that and also, would there be any safety concerns about that. Not that either XXX [physician] or myself have seen anyone react to denosumab, so I mean, it, it, it would be an extremely rare problem and I suspect you are much more likely to react to a flu-jab than denosumab.

In: What problems might arise if denosumab would be supplied and administered in the community pharmacy, except you have mentioned...

P1: [both talking] I – I think that's the only one that I would, that I would have a concern about, would be, would just be any safety concerns. I haven't, I mean, to date it's... it's, it's being given in hospitals for obviously full resuscitations available and there's, you know, is good resuscitation available in health centres and I'm just not quite sure, nor have I looked at the data... have I looked up the data sheet carefully to know, you know, if there are any figures for any form of anaphylactic reactions to denosumab. But, I mean, I think, the idea I had, and, and I think, XXXX [clinical pharmacist] had, was that the first injection would be given in hospital anyway, so that the, the... That would be the one that... where you would be most likely to get a reaction to it and if that's given in hospital, then that's fine. Safety concerns, which are very, very, very minor, probably become even less.

In: Do you think there's anything that would be missed with the care of the patients?

P1: No. I think it's perfectly... It's a good drug. To date we've had no problems with it. And I think, as long as there's some sort of follow-up, at the bone clinic that, you know, we don't want people just to get six monthly injections for the next twenty years. There has got to be some sort of follow-up and review about how long this goes on for.

In: Is there anything that the nurses do in these follow-up visits that you think the pharmacist couldn't do?

P1: No. I mean, they, in the data sheet it still suggests that you should check calcium and that was, but neither XXX XXX [physician] or myself have, now do that. We both have given up, I just give the injection and if the person is feeling well, I just give them the injection, so that again, you know, if... if you follow rigidly the data set suggestion and that you need to check the calcium every time, then potentially they would have to go to the... Unless the pharmacy are going to, the pharmacists are going to start taking blood, then you'd have to have a visit to the health centre, and then visit the pharmacy, which is perhaps a bit clumsy, and that, or they have two visits to the health centre, but I know both XXX XXX [physician] and myself feel that we can stop checking the calcium as long as the patient is well and doesn't have any symptoms.

In: What advantages will there be if denosumab would be supplied and administered in the community pharmacy, except the patients' convenience.

P1: Reduced... Reduced use of secondary care, time and clinic space. And, clearly from a secondary care pharmacy cost basis, the cost gets shifted to primary care. It's not huge numbers of patients globally, but it is a bit over three hundred pounds per... per year. I think it must be about a hundred and sixty pounds an injection, so. So, I mean, that cost gets shifted to secondary care, from secondary care to primary care. So, there's a cost shift and I mean I have six new, six new patients and six review patients at my clinic and I can have three of those review slots filled with denosumab patients who are really just coming to be given a kardex, so it's not an efficient use of my clinic.

In: Are there things the pharmacist could do, that you or the nurses don't do or can't do?

P1: I think, in general doctors break rules, bend rules and nurses, and I suspect pharmacists, would be much better at running to protocols and doing things properly.

[laughter]

So I think that bit would probably work.

[Interruption: Someone enters the room and starts talking with the interviewee]

In: So you were saying about things that the pharmacist could do that...

P1: Yeah, I think, think that just, you probably follow, you know, if there was a Lothian-protocol for community pharmacists, I'm sure pharmacists would follow that protocol more effectively than doctors.

In: Are there any elements of the management of osteoporosis that might not be able to be provided by the community pharmacist?

P1: I think, those that concern, you know, if they had cramps or tetany, which is sort of cramping in the muscles, that would be a concern that they may be hypocalcemic or something, and if that was, you know, if... when you're asking questions that symptoms like that would lead to the need to check bloods, before you gave another denosumab, so that that couldn't be done in the community pharmacies. So it'd be the very rare cases where there was a concern that the patient had symptoms which might be relevant to the treatment, in which case, they're going to need their blood tests, and they'll need to go up to the health centre anyway.

In: Now I would like to discuss the potential role of community pharmacists in the wider management of osteoporosis. How can a community pharmacy help with osteoporosis management besides the administration of denosumab?

P1: I – I think in many ways, really. The... There's a number of bits, I suppose, first of all, people who are on, who are taking oral bisphosphonates, which is main-line treatment, if they... if they are picking up there scripts from, you know, from... from... from a community pharmacist and they pick up their scripts every four months when they only have two months supply, then they could be asking about adherence, and that they could either just be taking that discussion themselves or they could be alerting the health centre, who should know from their computer system that the person is clearly not adhering to treatment. There... There may be people who are on the pharmacy books, who just stop taking – picking up the scripts at all. Again, you know, that who... somebody that... one of the biggest issues is - is non-adherence to the oral first line treatments and there's got to be a role for community pharmacy in spotting that and whether they take that for it themselves or whether they alert the health centre – I'm not quite sure. But there's clearly a role there. There will be people they'll see who are on bisphosphonates but perhaps not taking calcium and vitamin D or who are meant to be taking calcium and vitamin D, but aren't picking up the script for that. So, we know that if they're not adhering to calcium and vitamin D, that they will get a poorer response to the oral bisphosphonate. And there are, also there are... there are now a wide variety of formulations of vitamin D; there's new caplets, there's the dispersible, there's the chewable tablets coming in a wide variety... So if somebody isn't taking because they don't like the gritty, chewable tablets, then there are now caplets to take, there's the soluble versions to take, and, you know, that might easily be something that a community pharmacist could, could say "well, why don't you like this?" "There is...", you know, "Could we try things like Adcal D3?" - come as a solution, come as a chewable tablet and come as a caplet, so, you know, would a different formulation aid adherence to the treatment? So, that's certainly another area. I think, there are also, you know, patients being picked up, where... Who are picking up regular scripts for... for steroids, prednisolone, more than two point five milligram, cause if they're not on bone protection then, you know, should they be suggesting to the patient that, you know, well, "you should"... "Have you discussed this with your doctor?" or alert the doctors themselves that this person is on five milligrams of prednisolone, they're sixty five, and they don't seem to... appear to be on... on... on any bone protection, so, I mean, I think there is an issues along those lines, and as a geriatrician I - I – I have been, you know, there's... there is quite a lot of links to the falls agenda, falls and fractures... And, you know, that, that, there's certainly been said that if people are falling or falling and fracturing that this is another area where community pharmacy could have a role, because, you know, if they're on... if they're on multiple agents, which will cause postural hypotension, are they on continuous high doses of sedative or psychotropic agents, is that... is that in any way, you know, can we discuss whether doses could be reduced or changed? Has postural hypotension been checked? And as far as I understand you can get... you do get your blood pressure and things like that checked in pharmacy, so you know, you could potentially check whether there is... somebody's... what their standing blood pressures are like and see if it drop dramatically when they stand up if they feeling dizzy. And again do we need to adjust the medication, so I would say, there's bone things and there's also falls and postural stability things where a community pharmacists could easily have a role. So, lot's of possibilities.

In: How would a pharmaceutical care package of medication review, adherence with medicines, falls assessment and the need for calcium and vitamin D help the patients?

P1: Well, hopefully, it would reduce falls and thereby reduce fractures. So, I mean, it's... I think a global package like that, I – I think it gives patients confidence and should be a benefit to them. So from my point of view it's a, it's a no-brainer.

In: What might be missed compared to the hospital doing it, or the GP?

P1: I suppose, the ability... The only thing is really the ability to adjust the doses of things, and make decitions that... I think, I could, that they community pharmacist could be very good at identifying a problem, and a problem which frankly someone else should have spotted, but it's a safety check. And that, that safety check, if that had been spotted, you know, if somebody gets admitted with falls and they're dizzy on their feet to my ward, then I can just decide, well I'm going to stop two or three medications. The community pharmacist clearly can't do that, needs to then discuss the situation, so it's... I think they're good at screening and identifying problems the... the issue is that they can't

necessarily, by themselves, amend the dosages or change things, or add in new medications that are, you know, need to be prescribed, clearly they need a prescription unless you're promoting prescribing by the community pharmacists. And frankly I haven't got a problem with prescribing for a community pharmacist, I think, I think that the idea, you know, I think, that many of our specialist nurses obviously are starting to prescribe, but it's very slow and there's clearly many other countries where prescribing by other health care professionals is much more wide-spread than it is in the UK. And I haven't got a problem with... You know, with... with... with pharmacists having a, you know, a list of agents that they would be able to prescribe. If, you know, if... if the protocol or something were set in to that. But my understanding is that that's not feasible at the moment. I don't think any pharmacists are prescribers, are they?

In: Some of them in the UK.

P1: Really? Ok.

In: But not in Norway.

P1: Not in Norway.

In: No.

P1: Alright.

[laughter]

In: What do you think about the quality with the pharmaceutical care package, compared to a nurse or a GP or you doing it?

P1: I – I – I think, if it's run in a protocol there would be no difference in the quality, in fact, in some ways, it might be better. I mean, I think, the... because specialist nurses and other health care professionals follow protocols better than doctors. Often, it's actually... they... it's better. The... the thing that the doctor tends to be able to do, is with their different knowledge base, that if there's a degree of uncertainty or it's... there's other symptoms, and often there's other symptoms coming in that... it's then easier for a doctor to work out... if the those new symptoms are relevant to the... the system that you are working, or the protocol that you are working on, whereas it may be more difficult for another health care professional to understand that. Most of the... most of the patients with osteoporosis don't just have osteoporosis, they've usually got multiple co-morbidities, so there are multiple symptoms, and... and it's really, if they're complaining about something could the osteoporosis treatment be part of that or is it far more likely that it's due to one of their other conditions, or other medications that they're taking and that may not be so easy for people who are working on a protocol, sort of driven system. But, I mean, I think, if there's uncertainty then you refer to a doctor, or, as to whether that's an issue or not.

In: Is there anything that we have not mentioned that could make the management more convenient for the secondary health care system?

P1: I don't think so, I mean, I think, I see secondary care having to initiate the treatment, because I think, I do think it's specialist in bone health needs to be the initiator of the treatment, I don't think it's something that primary care should initiate. You know, it's more expensive. It is a niche product and I think, I just have no confidence that GPs would use it appropriately. And, so I think we need to see them, and I think we need to follow them up, but after perhaps two to three years, so that, regular follow-up, I think is just wasteful to the patient and to secondary care.

In: Do you see any changes that can be made to this flow-chart that can make the process of management better?

P1: No, I mean, I think, I think the flow-chart... I mean it really needs... I think that's reasonable, I mean, I certainly think you need the DXA, and the referrals for denosumab will almost always come from consultants in secondary care, from general practice or from the specialist nurse. So I think those are the three main routes in... because I suspect that if a problem were identified by a community pharmacist that they would probably refer back to the GP and the GP would then make the referral or

there is direct access to DXA, so then you might organise the direct access DXA, and then say, this is... This person has bad osteoporosis, they're intolerant to oral bisphosphonates, please see and advice, and then, obviously, secondary care will... will initiate the treatment at the clinic.

In: So, all in all, what are your opinions regarding the potential shift of care to community pharmacies?

P1: Very positive. Very positive about the shift of care to the community, to primary care. And, as you've heard, I've just got, I suppose, one or two minor concerns about community pharmacists taking it on, but if those minor concerns were, you know, were... were looked at and considered to be, you know, irrelevant, then I would be... I would have no concerns about a moving to community pharmacy.

In: Is there anything you would like to add or anything you would like to elaborate on?

P1: No. I think I've done my bit.

In: Yeah. Ok. I think so too. Thank you very much.

Interview with physician 2

In: Investigator

P2: Physician 2

In: Are you familiar with denosumab?

P2: Yes, I am.

In: Do you have any patients who receive denosumab treatment?

P2: I do.

In: How are you involved in the use of denosumab in osteoporosis management?

P2: So, I prescribe or rather advice... Well, I decide on the treatment and I... If I decide to go ahead with denosumab we give the first injection in hospital and then the GPs carry on. That's how I'm d... That's how... how I'm involved.

In: So do the GPs carry on the treatment?

P2: No, I'm sorry. Sorry. Take it back. That's... that's incorrect. That's incorrect. That's in the ideal world. We decide... I decide and then actually at the moment we still continue to carry on. So that's XXX XXX [An osteoporosis nurse specialist] the osteoporosis nurse who gives the injection every six months. And hopefully at some stage the GPs will take over. Yeah. Sorry, I don't know why I said that. That's completely incorrect.

[laughter]

In: No problem.

P2: I was already thinking ahead on an ideal world. Ok. Sorry.

In: No problem. Are you aware of the current process of management? And I guess you are.

P2: Yes, I think I am aware. [laughter]

In: Ok. So I made some flow-charts that will describe how the... the patients are getting referred into the osteoporosis service.

P2: Ok.

In: And when they are in the service...

P2: Yeah.

In: ...how the patient journey is.

P2: Ok. So, what would you like me to do with this? To show me...

In: I would just like to show you.

P2: Alright, Ok, ok.

In: Yeah. I'm... I'm coming a bit back to...

P2: Yeah. Ok.

In: ...to the journeys. So I would like to start with asking you questions about convenience to patients when they visit the hospital to receive their injections, for example some patient... patients may travel some distance.

P2: Yeah.

In: What is your impression of the patient's experience about receiving denosumab when you propose starting the treatment?

P2: So, the patients usually like the idea of having a subcutaneous injection once, every six months only. So, normally they... they are quite happy to receive the injections. But of course it is inconvenient for them to travel and also, a number of patients don't have the investigations required to instigate denosumab. I... Vitamin D, Calcium levels, renal function which is maybe not that important for denosumab, but generally for all the other treatments... bisphosphonates and then you might met... want to make a decision whether or not to proceed with bisphosphonates or denosumab. So, a number of patients don't have the base-line investigations when they see me. So... Most often there is a delay in giving the first injection unless I have all the information that I need and then we can give the first denosumab injection when they see me.

In: Can you think of any ways that delivery of the service could be improved from the patient's perspective?

P2: So, from the patient's perspective, if we could have all the blood tests, including vitamin D, done by the GP, before the patient sees us, then that would be most convenient for us. And that we could give the first injection there and then. So it would be at least a sort of, you know, one stop approach. So they would see us once... They would see us once, and then we'll, we'll decide on the treatment and give the injection. As it is not happening that way, we have to bring them back for the first injection, so that involves, most of the time, I'm not saying always, but most of the time, so that involves, you know, booking the patient to another clinic for the osteoporosis nurse, whatever other delays then. So the best thing would be for the, you know, for the GPs to do all the blood tests including vitamin D before we see the patient... is number one. Yeah.

In: How do you think the patients would feel about visiting a community pharmacy instead of the hospital for follow-up treatment and administration similar to that provided by the specialist nurse?

P2: So... I... I.... I... I'm not fam... It's a bit unclear to me what would be the role of the community pharmacists. Would the pharmacist administer the injection?

In: Yes.

P2: Is that the idea?

In: Yes.

P2: And the pharmacists are covered for that. I mean they can do injections?

In: Yes. The...

P2: They are not nurses.

In: No.

P2: So can they...? You know, because... because one thing is to visit the pharmacist, community pharmacist, to obtain the injection and then take it to the GP or the nurse, the other thing is to see the pharmacist who would give the injection.

In: Yeah.

P2: So of course that would be most convenient if the pharmacist could give the injection.

In: And how would you think the patients would feel about that?

P2: I – I think the patients would be very happy. I can't see why not. I mean, as long as they trust their pharmacists, because the patients usually see a nurse for injections, not the pharmacists. I haven't come across this before. That the pharmacist could give injection, but if that's how things are evolving and it's all covered by all... everything... you know, then that's fine. Health and safety and... pharmacists are happy, then that's fine.

In: Is there anything else you would like to add about patients' convenience?

P2: It would be most convenient for the patients to have ... to be able to attend either a community pharmacy as I say, or a community GP or community nurse or the... if a community nurse could come out to their house, because some patients are disabled, they can't travel, then.. that... definitely locally delivered denosumab treatment would be much more convenient than the hospital deliver it. It's unsustainable long term, I don't think.

In: Is there anything you would like to add about any concerns you may have associated with such a shift of care?

P2: I think some sort of monitoring would be... would have to be done, because at the moment we don't know how long we can give denosumab for, it's a bit like with bisphosphonates, things evolve as we acquire knowledge and new data from clinical trials and... and... and other data, and... So.. So, currently when we give denosumab, we have to give it at six months intervals and that shouldn't be a problem, but if the patient does develop, unlikely, but osteonecrosis of the jaw or an atypical fracture, you know, what the community pharmacist is going to do about it, and how would they know, you know, because it's a... well, it's the link between a community pharmacist and the GP and of the hospital. Is there some sort of pathway of information that could be, you know, used? And the pharmacist of course, I mean, they don't normally have access to clinical records, so somebody would have to make a decision somewhere, you know, how long to give the treatment for, when to stop, what to do. And the problem with denosumab is that if you stop it, there is a rebound effect, that there is increased bone turnover. So then again if somebody could not receive denosumab for whatever reason, you know, what do we do then? What does the pharmacist do? How would he or she communicate with the doctors who actually prescribe the treatment? So, I think, you know, there are certain unanswered issues there.

In: What problems might arise if denosumab would be supplied and administered in the community pharmacy?

P2: What problems?

In: Yeah.

P2: Well, as I say, I think at the moment we don't know how long to give the denosumab for and therefore the pharmacist would, you know, potentially could be giving it forever and some... also, you know, it could be somehow lost to the records of the GP, you know, it's the... the... the... the control of the... the safety, really. And how does the pharmacist assess whether or not the patient is, you know, is not developing any side effects, unlikely, but it's a new drug, it's just been introduced in two-thousand-and-ten, I think. So it's only two years that we've had it in our hands. What if we had it for twenty years, we would just don't know, like with bisphosphonates. So, it's this kind of, I think... I think it's a very good idea, but there has to be some sort of review of the patient, I think, with regarding the denosumab either by the GP or by the osteoporosis service providers from the hospital. So there has to be some communication back to... It's not up to me to say how... how would that work.

In: No.

P2: Yeah.

In: Yeah. Is there anything that the nurses do in these follow-up visits that you think the pharmacist couldn't do?

P2: Now, that's an interesting question because of course I'm not a nurse. So the nurses would tell you what exactly do they do with the follow-up visits, but I suspect they just ask how the patient is doing and whether they are well, have they had any side-effects and if they... and they just administer the drug, so I think the pharmacist would be perfectly capable of asking those questions. Then it's just a matter, who does the pharmacist report to and who is the pharmacists' line manager in a sense, obviously the pharmacists are responsible to a different regulating body, I guess, from doctors, because the nurse will report to the doctor, I don't know about the pharmacy, so there... Yeah...

In: So the communication again?

P2: Yes, and... and then... who takes responsibility if something has been missed then normally in the hospital of course... It's doctor's responsibility because the nurse reports to a doctor, whereas if community pharmacists, I'm not sure, I think they're quite independent and that they have their own regulatory body, so... What is the communication there? And legal responsibility, because, at the end of the day, you know, things go wrong, then somebody is accountable for that. So...

In: What advantages will there be if denosumab would be supplied and administered in the community pharmacy, except for the patients' convenience?

P2: Patients' convenience and I think economical, huge economical benefit, now because obviously it would off-load hospital care and also off-load the GP practices, I guess. Yeah.

In: Anything else that the pharmacists could help with, regarding osteoporosis and denosumab?

P2: Well, I guess... If... I can notice that a number of pharmacies have sort of, like, mini-clinics about, I don't know, I think about obesity I've seen, some sort of consultations going on in pharmacies. So, so, I guess, you know, how is the lifestyle and advice on health on bone, that could be delivered by community pharmacies... pharmacists... if, you know, if they... I can't see why they can't do it, they are perfectly, they would be perfectly capable of doing it. Yeah. I think so. Leaflets and general education, and... and... yeah... some sort of maintaining the momentum.. that the patient has to get their drug is important and especially with denosumab, because, as I've said, because of its rebound-effect. And it's very important actually to deliver it well pretty much every six months on the dot. So, somebody would have to keep a... you know, the patients can have stickers on their calendars. So register with, I think it's called Prolia plus, or something, for the company to tell them when they are due for their next injection. Well, the pharmacists could do that to, I guess... just locally... If it didn't mind the patients.

In: Are there things the pharmacist could do that you or the nurses don't do or can't do?

P2: Not that.... anything springs to... Well, the pharmacist would have, presumably access to the prescriptions the patients have and just make sure that they take their drugs, and they collect the prescriptions and they comply with all the other medication whether they have to take vitamin D or whatever it is. The nurses might not necessarily always have the information because either the patient forgets to bring the, you know, they can't remember what medication they're on, whatever, then it would be difficult for the nurses, difficult for us, if the patient doesn't know. But the pharmacists have access to obviously the prescriptions, so that's an advantage, I guess.

In: Are there any elements of the management of osteoporosis that might not be able to be provided by the community pharmacist?

P2: Yeah, I think the blood test. And... perhaps some, you know, some sort of side-effects that the pharmacist might not be able to pick up, but then again, if the pharmacists were educated to what to pick-up, I supp... you know... the pharmacist has obviously a huge knowledge of illnesses because they treat, they prescribe, they give medication out to... they have in-depth knowledge of that. So, I think, I think, yeah... I think they should be able to deliver that. Yeah.

In: Now I would like to discuss the potential role of community pharmacists in the wider management of osteoporosis. I guess we have mentioned some points... But how can a community pharmacy help with osteoporosis management beside the administration of denosumab?

P2: Yeah, as I... I think, sort of, you know, education sessions that could be organised locally by community pharmacists or just one-to-one sessions with the patients. Quick overview of health and lifestyle and diet and other medications that they are on. Do they need all the medications? Sometimes people are on so many drugs, polypharmacy, that might be contributing to falls and this and this, et cetera. So the pharmacists could, could... The pharmacists could... have a, have a, sort of, good overview of things, and... Yeah. But I don't know about blood tests. I don't think they would be able to... Yeah... because that is a completely different service. Yeah. But I think, I think it's a big role, yeah.

In: How would a pharmaceutical care package of medication review, adherence with medicines, falls assessment and the need for calcium and vitamin D help the patients?

P2: Say it again, sorry. The... How...?

In: How would a pharmaceutical care package...

P2: Aha...

In: With medication review...

P2: Yes.

In: Adherence with medicines...

P2: Yes.

In: Falls assessment...

P2: Falls assessment?

In: Yeah.

P2: How do you mean falls assessment? Oh, falls! Sorry. Falls. Falls.

In: Yeah.

P2: Falls. Yeah, yes, yes. Yeah.

In: And the need for calcium and vitamin D...

P2: Aha.

In: How would that help the patients?

P2: Yeah, that would help the patients. No question. Yeah.

In: Yeah.

P2: Yeah, yeah. It would. As we've discussed. Yeah.

In: What might be missed compared to the hospital doing that package?

P2: Eh... What might be missed? Well, at the hospital we do a diet questionnaire, for example. How much calcium do patients take in their diet? So, maybe a pharmacist could do a diet questionnaire as well, and then nothing would be missed, in that respect. I think, and an assessment of the patient with blood test is vital, so I don't think I would base the treatment delivered by a community pharmacist without an assessment first, assessment, by a, you know, a doctor, so that all the screening blood tests can be done for secondary cause of osteoporosis and the pharmacists then would be rest assure that there is nothing else going on, it's just straight forward and they can just follow their pathway. But I think the first think the first initial assessment ideally should be done by a doctor. Yeah.

In: Is there anything that could make the management more convenient for the secondary health care system?

P2: So more convenient in a sense that if denosumab was delivered in the community then it would be more convenient. So that is already more convenient. Yeah.

In: Do you think there's any risks with that?

P2: Well. Yeah. As I've said. You know. It depends how the pathway is introduced but missing the secondary causes of osteoporosis if there are over diligent community pharmacists who just take over and deliver the, you know, give advice and give vitamin D or whatever without actually checking the calcium, things like primary hyperparathyroidism could be missed, so I think, so that would be a potential risk, if the pharmacist is taking too much. And then during the follow-up, it just depends how long denosumab would be administered for how many years and then, if the patient is lost to follow-up from a doctor, then I think there is a risk that things can evolve and, and they would be

missed somewhere, some other, you know, illnesses or health issues can be missed if the patient just go to their pharmacist for the denosumab injection and for the, sort of, general advice. So I think it's important that the patient will have follow up with the osteoporosis services. But whether it's once a year, or once every two years or once every five years or whatever, I think there should be some link. Yeah. So risk of missing of secondary causes of osteoporosis basically. And some side-effects that we can't anticipate at the moment, because there's just too early to know.

In: Do you see any changes that can be made to this flow-chart...

[Investigator points at the "osteoporosis service at western general hospital – patients receiving denosumab (current patient journey)"]

P2: This one?

In: Yeah ...that could make the process of management better?

P2: So the flowchart says GP, then nurse specialist, DXA scan, and satisfactory response, nurse specialist supply and administration...

[The interviewee points directly from DXA scan, via satisfactory response to supply administration – the flow-chart was updated after this interview in respect to this issue]

I'm not sure how this works actually. Sorry.

In: So that's the referral in to the service. And, and...

P2: Aha. Consultants in secondary care, no recent DXA, I see.

In: And, and... It goes to the bone clinic, so the loop here [investigator points at the black loop at the bottom of the chart ("returning every six months to receive denosumab")] is if they receive denosumab.

P2: Okay. Hold on a second. So... So... So everything has to go through a DXA scan.

In: Yes.

P2: Regardless of the nurse specialist. No recent.. Consultant... No recent DXA... DXA... And there's the bone clinic, and then it goes back to supply and administration... Right... Ok... And then, there is a loop here? [interviewee points at the black loop at the bottom of the chart ("returning every six months to receive denosumab")]

In: If... If the patient is on denosumab...

P2: Oh, yes, it's every six months. Okay, so that's the loop here.

In: Yes, that's the loop.

P2: Oh, I see.

In: And then they have to go to the DXA scan every third year or so.

P2: Yeah, at the moment it's every five, fifth year actually, here.

In: Ok. Fifth year...

P2: Yeah. So... So, the loop would be... nurse specialist... I think, I think there would have to be still, sort of, some loop, but not every six months. So the loop would be... you know... once every say two years or something.

In: Mhm, so then the administration would be in primary care?

P2: Administration would be in primary care. But then somehow, there would be some sort of review. And I'm not sure if the nurse specialist is actually the answer here. Or... the doctor...

In: That's how the current treatment...

P2: Yes, yes. Of course the bone clinic doesn't exist in every trust.

In: No.

P2: So it's only here [at Western General Hospital] that there is a bone clinic with doctors. But, yeah... Well, every trust have different, sort of, osteoporosis service provision. But, yeah, so basically this would be delivered in the community, and then at some stage there would be a review...

In: Yeah.

P2: ..of the patient.

In: Yeah. So, all in all, what are your opinions regarding the shift of care? The potential shift of care...

P2: [speaking at the same time as the investigator] Oh, I'd be in favour, definitely, I would be in favour.

In: Is there anything you would like to add, or anything you would like to elaborate on?

P2: No, not really. I'm quite happy with denosumab. Patients are happy. It's just a bit of a burden for the hospital to have patients returning every six months to us.

In: Ok. Thank you very much.

P2: Ok. You're welcome.

Interview with physician 3

In: Investigator

P3: Physician 3

In: Are you familiar with denosumab?

P3: Yes.

In: Do you have any patients who receive denosumab treatment?

P3: Yes.

In: How are you involved in the use of denosumab in osteoporosis management?

P3: Yeah, I'm... I prescribe denosumab, so I'm involved in making the decision whether deno... denosumab would be an appropriate treatment or not.

In: Are you aware of the current process of management?

P3: [silence]

In: The patient journey?

P3: Yes, yes, yeah. Yes, so basically the patient... usually it's because they've had a problem with other, like oral osteoporosis treatments and then they could get referred to my clinic usually and then it's one of the options we discuss with them. And, so we go over that and then often initiate treatment and... and actually give treatment and supervise follow-up treatment as well.

In: So I made two, two flow-charts of, of the osteoporosis service. One of... one is of the referral and the other one is the osteoporosis service here at Western General.

[Showing the "referral to the osteoporosis service at Western General Hospital"- and the "osteoporosis service at Western General Hospital – Patients receiving denosumab (current patient journey)"-flow chart]

So, I will come back to... to these...

P3: Ok. [the physician is looking at the flow-chart with a puzzled look]

In: Do you agree with them?

P3: Yes. Well, yes and no.

In: Yeah?

P3: The... the... turning to the osteoporosis service... you've got here fracture through orthopaedics to osteoporosis service. Actually fracture comes directly to the osteoporosis service. Because we run what's called a fracture liaison service, which doesn't involve the referral from orthopaedics. So... but otherwise it's... I think it's fairly... I think it's fairly straight forward. I suppose, patients can self-refer to their GP. I don't think you've got that in. But, anyway, I think... I think broadly speaking it's... it's a reasonable overview.

In: Yeah, and the patients that receive denosumab, do you think that's...

P3: Ok. Let me just have look at that. I'll take that in. GP.... DXA scan...

In: So the black line is....

P3: Yeah.

In: ... in the service and this gray one is just for the oral treatment if they do not receive denosumab.

P3: Yeah. I think that's right. So... You'll have a DXA scan, you may come to the clinic, the oral treatment is the first choice that's correct. Yeah... and yeah... and denosumab is one alternative basically, yeah. I think parathyroid... sorry, calcitonin is no longer used. If I... It's been... Its marketing authorisation has been withdrawn.

In: Really?

P3: Aha. And you haven't got zoledronic acid on your chart which is used a lot. That's our most widely used parenteral treatment. Maybe five times as much as denosumab actually. Ok?

In: Yes. Let me see... Ok, so I would like to ask you about convenience to patients when they visit the hospital to receive their injections, for example some patients might travel some distance.

P3: Yeah.

In: What is your impression of the patients' experience about receiving denosumab when you propose starting the treatment?

P3: Yeah. It's a convenient treatment. Because, obviously you can give it with a subcutaneous injection, that's fine, once every six months is very convenient for the patient. What is less convenient is for the patients having to come up to the hospital every six months for the injection, because there is no real need for that. It could be done... it seems to me in the general practice or maybe in pharmacy in the community. So, I think it's correct that probably the initial prescribing decision is in specialist care. Then I think follow-up would be better in the community, basically.

In: Ok. Yeah. What feelings do the patients express when... when they come to the hospital?

P3: Yeah, usually if we're talking about denosumab specifically...

In: Mhm.

P3: ... of course that is usually a discussion you have with patients that have tried oral treatments and found to be, you know, having side-effects, so it's usually patients that now has osteoporosis, but they've... they've not had a good experience with an oral treatment. So, then we give... we provide options then for a parenteral treatment and the two main parenteral treatments are denosumab and zoledronic acid. We tell them about each treatment. Zoledronic acid is our preferred treatment. It's once a year, it's an infusion. And also, recent evidence suggests that after three infusions the effect lasts for six years, so that's very convenient for us. If for any reason there's a contraindication to zoledronic acid then we offer denosumab, and we do offer it for patients maybe don't want an infusion. And, yeah, they like the idea of it. I think a positive feature is, there's not, like, any obvious side-effects after the initial injection. Less compared with zolendronic acid where you can get the acute phase response, the flu-like illness. They like the idea of only once every six months having to have the injection, so all of those are positive features.

In: Can you think of any ways that delivery of the service could be improved from the patients' perspective?

P3: Yeah, I think if the follow-up injections could be done in... in the community, that would be a big improvement.

In: Yeah. How do you think the patients would feel about visiting a community pharmacy instead of the hospital for follow-up treatment and administration?

P3: I... I – I can't... I don't know. I think in Scotland my impression is that patients are more used to going to their general practitioners and seeing p... let's say the practice nurse to have injections and immunizations rather than pharmacies, but I can't intrinsically see any problem with that. I think... I have to say, I'm not so familiar with the situation in community pharmacies. I can't see any reason

why the treatment couldn't be delivered in a community pharmacy. But I think it's maybe a departure for what I understand to be normal practice, but that's all.

In: Is there anything you would like to add about patients' convenience?

P3: Not really. I think it's in... probably appropriate for the first initiation they come to the hospital, partly because you got to make sure they've not got hypocalcaemia, their vitamin D is... status is correct. There's a few things to address before they start off, but... So I think that's necessary or at least... it... it may be the best way to do things. Although I am aware that, you know, GPs theoretically could initiate treatment, but I'm aware from post-marketing that there has been some fatal hypocalcaemic events with denosumab, so... so if you were a GP doing it, you'd have to be very aware of the... the potential, you know, side-effects. Mainly vitamin D deficiency and hypocalcaemia.

In: Do you think hypocalcaemia is something the pharmacy need to address?

P3: I think if a pharmacy... pharmacists were initiating treatment, yeah, they most definitely.

In: And if they were just administrating?

P3: I don't think so. Because we haven't had any problems once people have started. Because usually people get depleted with vitamin D and then once they're on treatment they're on calcium and vitamin D supplement, and the hypocalcaemia seems to be a problem in a patient who's naive to the treatment, and then you give this drug which massively inhibits bone-turnover. Of course if you're already on treatment, then your bone-turnover is low, so the risk of subsequent hypocalcaemia, I think is very low. We... We've not had any instances, not that we know of.

In: Is there anything you would like to an... sorry. Is there anything you would like to add about any concerns you may have associated with such a shift of care?

P3: No. Absolutely not. I think that would be fine.

In: What problems might arise if denosumab would be supplied and administered in the community pharmacy?

P3: I can't... I can't envisage any specifically. I think it's important that if you have a patient on treatment they're under medical review. So what one wouldn't want is a patient discharged and just having denosumab forever, without ever being reviewed by a physician, you know, by someone. But, with regard to the administration and the set-up, I can't see any problem.

In: Is there anything that would be missed?

P3: By the patient having the injection in the community pharmacy?

In: Yes.

P3: I can't think so.

In: No?

P3: I can't think so. Because when patients... at the moment they come up to the hospital and they just come up, "I'm here for my denosumab-injection", we give them the injection and then they go away again. So I can't... It'd be more conv... It'd be way more convenient for it to be done in the community.

In: Is there anything that the nurses do in these follow-up vi... follow-up visits that you think the pharmacists couldn't do?

P3: I don't think so. I should say, when patients come up for a visit, for the injection, the nurse might say "how are things going?", you know, ask about how things are going. I guess that could be done in pharmacy too actually. So, I... Intrinsically I can't see so much of a difference. I guess if there was a problem, well the nurses would then refer back to the doctor and I think that pharmacies could do that too, then that would be fine.

In: What advantages will there be if denosumab would be supplied and administered in the community pharmacy?

P3: Ok.

In: Except for patients' convenience.

P3: Ok. Well the cost. From my perspective there will be a cost saving for us. I think it would be more convenient for the patients. And not only would it be a cost saving in terms of drug. Because even in a pharmacy someone still has to pay for the drug and in fact it's still NHS [National Health Service] Lothian that is paying for the drug, it's just in a different budget. But if we use a hospital clinic visit, you know, that's... you know, that's, that's using money basically, because it's an unnecessary visit. Because the way our system is set up we have fifteen minutes return visits, so we have to put patients in to those visits, it's just... and where denosumab might only take five minutes. So it... it would, so it would be a time saving for us too.

In: Yeah. Are there things the pharmacist could help with that...

P3: With denosumab? You mean in terms of monitoring? Well, we don't really have any monitoring. I can't think of anything specifically, but maybe I'm missing something, but I can't think of anything. Not once the treatment has been initiated.

In: Are there things the pharmacists could do that the nurses or you don't do or can't do?

P3: I think. I can't think of anything. Obviously pharmacists know a lot about drugs and drug treatments and... and for some of the drugs we use the administration instructions are quite complicated, but for denosumab it's very simple, it's just a subcutaneous injection, so... so I can't think of anything in particular.

In: Are there any elements of the management of osteoporosis that might not be able to be provided by a community pharmacist?

P3: With denosumab?

In: Yeah, or besides...

P3: [Both talking] Or in the con... In... Are you talking about wider... the management of osteoporosis in a wider sense?

In: If we can look at the... just the denosumab first. If there is a part of that...

P3: In terms of administration of denosumab, I can't think of anything.

In: Ok, so now I would like to discuss the potential role of a community pharmacy in the wider management of osteoporosis.

How can a community pharmacy help with osteoporosis management besides the administration of denosumab?

P3: Ok, well, the drugs that we're using, it's known that adherence or compliance isn't fantastic, like with oral bisphosphonates, so that... that might be one area, one particular area might be if the patient picks up a prescription pharmacists could ask about "well, are you taking it in the morning according to instructions", you know, so that is... that is... that's a particular... especially with bisphosphonates. So that... that... that... that could be a real positive thing that the pharmacists could do, I think.

In: How would a pharmaceutical care package of medication review, adherence with medicines, falls assessment and the need for calcium and vitamin D help the patients?

P3: Ok. Well, we've talked about the, you know, adherence, so that would be very, very positive. And we know that bisphosphonates at least, you don't respond so well if your vitamin D is low. So adherence to calcium and vitamin D. Whether you can do a falls assessment in pharmacy, I think is more challenging. Because it's quite a complicated, you know, there's so many things that can contribute to falls. I couldn't see that working, I think it be just too complicated. And what was the other thing you said? I can't remember.

In: Medication review.

P3: Yeah, I think that's... again, pharmacists are well placed to do that. The... I mean. Yeah. Yeah. Pharmacists are well placed to do that. I'm trying to think of interactions between these drugs and other drugs, but... The main thing is not to take the medication along with other drugs, so pharmacists would be well placed to do that.

In: Do you think... Well, what might be missed compared to the hospital doing it?

P3: I... I... Nothing. I mean, I think that it would be advantageous because in the hospital there's not the capacity to do these kind of reviews, there just isn't the capacity. And if we had the capacity to bring patients back every six months, do a medication review, check compliance, ask about calcium and vitamin D, that would be ideal, but we cannot. We just don't have the staff. So, if that could be done in community pharmacy it would be great and it would be a big advantage.

In: What do you think about the quality compared to you or a nurse or a GP doing the pharmaceutical care package?

P3: I can't see a problem with that actually. I mean, I think I know a little bit about pharmacists, you know, as I said pharmacists know all about drugs and, I think in the context we talked about I think they would be equal to or perhaps even better than, in some instances, the doctors or nurses.

In: Is there anything that could make the management more convenient for the secondary health care system?

P3: In terms of... of any management of osteo... any drug, any package of management?

In: Yeah. If you can first take the denosumab. If there's anything...

P3: ...that would make it more convenient?

In: Yes.

P3: Not really. I think, I mean, I think we've... we've got a place for it. The way things work are fine. So, no, I can't think of any... yeah...

In: Ok. And in the wider management?

P3: Yeah, for secondary care, yeah, I think I'm aware that we're not able to follow up patients with compliance because of the issues I've talked about. So... So.. So, having pharmacist involvement, community pharmacists, could be advantageous in respect, or even hospital pharmacist involvement, someone to do that. That would be really good.

In: Do you see any changes that can make... that can be made to this flow chart that can make the process of management better?

[Showing the "osteoporosis service at Western General Hospital – Patients receiving denosumab (current patient journey)"-flow chart]

P3: Not really, I mean, you've got... the flow chart is quite... it's not quite right actually, because the way you... the way you've drawn it is... it kind of figures out that everyone that has osteoporosis and a DXA scan is seen at the bone clinic. And that's not the way it is. So patients with more sever osteoporosis are referred, you know, more complicated cases. And the, what I would call, simple osteoporosis like mild osteoporosis, uncomplicated, treatment recommendation is then sent back to the GP.

In: Ok. So from the DXA scan and straight back to the GP?

P3: You can have simple treatment recommendation and for consultants in secondary care, also many consultants, a report is sent back just with a treatment recommendation for uncomplicated osteoporosis. The one's we see in this service are younger men with osteoporosis, because they more often have other causes like hypogonadism et cetera. More sever osteoporosis, because then you might want to give parathyroid hormone, and some vertebral fractures because the reason is, if you can... there are patients with vertebral fractures that don't have osteoporosis on a DXA scan and the

report is a computer generated report, and they actually do have osteoporosis, so those patients are coming in. So your flow-path isn't quite correct, but it's... it's... Yeah, it's almost correct.

In: Yeah, so if it's simple case and... because the nurse specialist is doing the DXA scan...

P3: It's not a nurse does the DXA scan, it's a technician that does the DXA scan. And then what we have is an alg... we have an algorithm in the DXA scanner that will print out an automated report and if... if the scan shows osteoporosis it will say "Your patient has osteoporosis, we recommend according to the Lothian formulary; oral bisphosphonates", and that's an automated procedure.

In: So is there no physicians involved in...?

P3: That... Those are... It's a decision-tree within the computer in the DXA scanner. Having said that all of the reports are reviewed by one of the technologists or one of the nurses or someone else within the DXA service to check that everything is... is correct.

In: So would you say the flow-chart is... for... for those who receive denosumab, would you say the flow-chart is accurate?

P3: Well... Roughly. Because you would have, for whatever reason the patient comes in to the service, the reason that they would have denosumab is it would very seldom have denosumab first off. There would be some other treatment. So they might be seen back their GP, and then got.. got compliance problems or had side-effects. They might be seen by a con.. secondary care and problems may have developed. They may have renal impairment, which is another indication, where you can use denosumab in others. So, it's more they come in and they might go out back and then they might come in again. So there's a diagonal referral.

In: So if you avoid the DXA scan and it's... it's the line above. [pointing at the light gray line from GP directly to the Bone Clinic]

P3: Yeah, exactly.

In: And then you're going to the bone clinic...

P3: Yeah, so it's... it's... yeah, it's roughly correct, yeah.

In: So all in all, what are your opinions regarding the potential shift of care?

P3: Good.

In: [laughing] Is there anything you would like to add or anything you would like to elaborate on?

P3: Not really. I think... I think the shift of care has potential benefits for the patients. And in terms of convenience the reasons we've talked about. Yeah, so I think it could be potentially beneficial.

In: Ok. Yeah. Well, that was it.

P3: We're done? Ok.

In: Yes, thank you very much.

P3: My pleasure. Ok.

PATIENTS

Interview pilot with patient 1

In: Investigator

Pa1: Patient 1

In: So I will start the interview by asking some questions about your relationship with the community pharmacy. The community pharmacy is the high street pharmacy or the mall pharmacy. And then I will ask you about the denosumab treatment that you receive for the osteoporosis and in the end of the interview I will ask about osteoporosis care in general and how the pharmacy may contribute.

How often do you go to the community pharmacy?

Pa1: At the moment, sort of quite regularly but not about the p... the osteoporosis about... well, it's linked to it in the fact that I have had a fall in July and I have to, I've got... I broke my collar bone and it's not healing well. I've got a frozen shoulder so I had to go get pain-killers. So I have a good relationship with my local pharmacy, I do. And they know me when I go in and they take time to explain everything and I find that useful. Yeah. Very useful.

In: Do you go to the same community pharmacy?

Pa1: Yes, I think you build up a rapport with someone.

In: Have you ever accessed any of the additional services that they provide?

Pa1: [silence] For ex...

In: [both talking] Some pharmacies provides other services such as smoking cessation service, a blood pressure monitoring...

Pa1: No, I haven't, no. I haven't, no.

In: Ok, no. Does the pharmacist go through the medicines with you?

Pa1: Yes. Yes.

In: How does it help you when they do that?

Pa1: Well, I'm very fortunate in the one that I have, sort of, bonded with... with... they know... they know... me and my body and what's happening and they take time to explain things, yes. Yeah. They're very, very good.

In: So, if you can just summarize, what is your opinion about your community pharmacy and the care that they deliver in general?

Pa1: Well, me personally, I find it excellent. I really do. In fact, I quite look forward to going to them, because they know me when I go in, they name me and – dat, dat, dat – and "what is it that you're getting now?", and then they'll come and they'll explain it all, et cetera, and how often and if there's any problems that I can get back to them. Yeah, I really like them.

In: Can you tell me about your experience of visiting the hospital when you receive the denosumab?

Pa1: Here at the Western?

In: Yes.

Pa1: Yeah. Again, when I was first diagnosed with osteoporosis it was... I was in shock. Absolute shock. But the two people, XXXX [an osteoporosis nurse specialist], who has now left and XXXX [one of the osteoporosis nurse specialist currently running the clinic] who's there – fantastic. They make time for you and, you know, I – I just couldn't take it in. So, I have to say, I look forward to coming to see them, because again you've got this personal, you know, if... sort of bonding with them. You know, they know everybody, they make time for you. Just like coming today.

"Hi XXXX [one of the osteoporosis nurse specialist currently running the clinic], dat – dat – dat"

"Oh, I'm seeing you next month"

And, you know, it's, it makes you feel good, the only disadvantage is the travel, but my... I do live in Edinburgh, but I'm on the other side of Edinburgh. Yes, but from that point of view, and they'll answer any questions and et cetera, et cetera. Yeah. I really... I think they're great. Absolutely, yeah.

In: Do you think it's convenient?

Pa1: Well, I... With just what I've been reading and what you're saying, I would be quite happy to have it done at the local pharmacy, because it's.... it's five minutes from my house, I like them as I've just said and there's a rapport there, so... and it would take the pressure off the nurses, but hopefully that... some aren't going to lose their jobs because of it. That would be my one concern because they're such experts and they do extra things for us, like they have meetings every so often for groups of us that we can talk and talk to each other about what was going well, what's not, et cetera and I... there hasn't been as much of that, because of funding and just their time and I do miss that type of thing, you know, because I think it's good to talk to maybe five or six other people and find out how their responding to things. So that would be a miss, but if I went to the local pharmacy there would maybe be more time that they could that if people wish to, to get together as... as a group. Yeah.

In: Does your denosumab injection affect anyone else?

Pa1: No.

In: No one have to take a day off or something?

Pa1: No, no, no, no. No, I'm responsible for that myself.

In: So you take the bus here?

Pa1: Well I drove, I drove. It's easier because it's awkward to get here on the bus.

In: How long time does it take for you to get here?

Pa1: It can take me probably, depends on the traffic and it can take up to forty-five minutes to an hour, whereas my pharmacy is five minutes.

In: How do you feel about attending the hospital for your denosumab treatment?

Pa1: I don't have a problem, because of the, the atmosphere that you receive when you come up here, you know, like I know XXXX [one of the osteoporosis nurse specialist currently running the clinic] and, you know, you're, you're just part of a group that is suffering from this and you don't feel out of things, so it's a, you enjoy the chat. And, you know, you can talk about, well is there going to be another group meetings sometimes, and, you know, you can get a wee bit more information. Aha, yeah, aha.

In: Is there anything about your visit that you dislike?

Pa1: No. No.

In: Do you wait a long time when you come to the hospital?

Pa1: No.

In: How could the pharmacy contribute to the injection of the denosumab that you receive?

Pa1: How could they contribute?

In: Yeah.

Pa1: I'm just trying to think. Well, the contribution would be it's, it's quicker to get there. I'm very fortunate that I got a rapport with my pharmacy. I can't talk for other people who, if this was to go ahead, how they build up a relationship with people. Because I think that's quite important. That people have an understanding, you know, of... of things. But as far as I'm concerned, I'm just going for an injection, you know, as such, you know, a six monthly injection. Aha, yeah.

In: What do you think about the idea that the pharmacy supply and adm.. inject the denosumab?

Pa1: What do I think about?

In: If the pharmacy would inject the denosumab for you.

Pa1: That's not a problem, because, as I highlighted earlier, things are being passed more from doctors into pharmacies. People who have expertise that they're doing flu-jabs, so as far as I'm concerned it would just be another injection. Yeah. As long as it's the right inject... No, you know what I mean, but it's just... that it wouldn't faze me at all. No, mhm.

In: Is there anything you would miss about the hospital?

Pa1: Well, it's just the, sort of, the interaction with the staff, just, you know, they've always got a smile no matter how busy they are. I mean, I'm talking again about when we had XXXX [an osteoporosis nurse specialist who is not working there anymore] but we've now got XXXX [one of the osteoporosis nurse specialist currently running the clinic] and I think she's... I don't know if she's got someone else but, I mean, they just know... They're fingers are on the pulse, she says "oh, well, I'm seeing you next month" you know, there's that sort of type of thing and you think "with them being so busy, they're... they're just a different... sort of type of nurse, they're just... they're great". Yeah. I like them. I would miss that. Yeah.

In: Do you think the pharmacy could contribute in way that the hospital does not?

Pa1: Well... I think, I think it's just the distance really. Just... just the... from my point of view, the distance. Yeah, and I think that might be the s... me talking not just about me, but other people I have met, you know, when we've had our group-session, it's quite a distance because as you said earlier they're travelling from outwith the Edinburgh area. And you imagine it's taking me maybe forty-five minutes to an hour to get here, depending on the time. The other people and maybe people other than myself, you know, having to change buses or rely on people getting them here, you know, that's... that would be for you to find out by interviewing other people. But that would be the only thing. Yeah, mhm.

In: Do you think you would receive the same care?

Pa1: In the... the pharmacy?

In: Yes.

Pa1: Yes.

In: Yeah.

Pa1: Yes.

In: And now I would like to talk about the osteoporosis care in general. So it will be besides the denosumab. Do you have any ideas how a community pharmacy can help you with the osteoporosis care?

Pa1: That would be something... no... I... I wouldn't be sure how... what that would mean. I mean... I mean, can I ask you would... would they all... would be someone specialist in a pharmacy?

In: Yeah... well...

Pa1: It's really... well versed in osteoporosis and you know the denos... aha...

In: There might... they might be trained as a...

Pa1: Yes. Specifically?

In: Yes.

Pa1: Yeah. Aha.

In: Yeah. Can you mention some changes that make the provision of care more convenient for you?

Pa1: In a pharmacy?

In: Yes.

Pa1: Well, in a pharmacy I'm... the one I'm thinking about... I think they have a private room. I think people are beginning to... It's not like you go into the pharmacy and you're... just saying "oh, right here you are, I'm going to do your injection here" that is done, you know, because the pharmacy could be busy as long as it's a private room. Yes, aha. And again it would be an appointment-driven. Yes.

In: Yeah, do you think that would be a must for the thing to...

Pa1: Well, I think perhaps maybe more for them, it would need to be appointment driven. You know, just like coming here, you know, they would need... need to know, aha, if you couldn't go, you would have to cancel. You know, like if something was to happen to me and I couldn't make it. You know, you would out of courtesy, you know, cancel and rearrange. Yeah, mhm.

In: Does anyone ask you about your diet?

Pa1: [laughing]

In: They might ask you about calcium and vitamin D to make your bones...

Pa1: Yeah.

In: ... as strong as possible.

Pa1: Yeah, and I am the worst person, because my diet is all chocolate. I know what I should eat, and I'm not very good at doing it. But, yeah if people would ask, you know, and when you get people asking you, you do tend to suddenly think "yeah, come on XXXX [name of the patient interviewed] you must start to... to do things more", you know, and when you read about things, you think "I could maybe..." I was just thinking after I've had this accident that I should maybe be taking more vitamin D and I don't, but I thought "maybe you should be", and perhaps that would maybe being reinforced a bit more at the pharmacy.

In: So is there a health care professional asking you about your intake of calcium and...

Pa1: At a pharmacy?

In: Yeah, or in... at the hospital or in the pharmacy?

Pa1: I think at the beginning, yes. But because it's all been identified, and I know that I was lacking in so... and my... my diet is bad. [laughing] I think I would sort of maybe make an effort, I would try.

In: How would you feel if a pharmacist asked you about your diet?

Pa1: It's not a problem.

In: Not a problem?

Pa1: No. It's sometimes gives you that – come on.

In: The last push?

Pa1: Yes.

In: [laughing] So, if someone is diagnosed with osteoporosing... osteoporosis, the falling might be a se... might be serious.

Pa1: Yes.

In: Because you might get a fracture more easily.

Pa1: I've had a lot of them.

In: Yeah. So does anyone ask you about falling?

Pa1: [silence]

In: The risk of falling?

Pa1: Oh, wha... at a pharmacy or here?

In: Either the pharmacy or here.

Pa1: I just know it happens anyway. You know, I can fall, and I'm very cautious about myself, you know when I'm out. Sometimes I have a stick, because I had a hip-replacement to, and sometimes I take the stick, you know, just... mostly in the bad weather, because the thought of falling – yeouw... It's not good. Aha. And when I fell on holiday I didn't even bother going to the hospital because I knew it was broken, there was nothing they could do. It just takes its own time, yeah, aha.

In: So does anyone ask you about falling and....

Pa1: I think my friends are more protective of me.

In: Ok, so no health care professional?

Pa1: They say "you shouldn't be doing that" and I go "I know". [laughing]

In: What is your opinion if a pharmacist ask you...

Pa1: It's not a problem.

In: Not a problem?

Pa1: No.

In: Ok. Do you think that there's anything that the pharmacist cannot do in terms of your osteoporosis care that a hospital or the general practitioner can?

Pa1: I – I think because I went through the, you know, the injection I can only do for eighteen months the tra... tira.. tera... What is it called?

In: The denosumab?

Pa1: No, not the denosumab. Before that.

In: Teriparatide?

Pa1: That's. I had that first and that was only for a length of time and then when I went on to this which is coming up for, I think, eighteen months now, maybe two years, I'm not sure. No there's nothing... because I know I'm just going to get my injection. Sorry, what was the question again? It was about?

In: Do you think that there's anything that the pharmacist cannot do that the hospital do or that the GP...?

Pa1: No, because there's no... They will just be doing the injection and... or they would, again, they will just be saying "well, how you had any falls", you know, that.... you know, they will just, sort of, since... in the last six months. "How have you been?" You know, and again it can change depending on the season of the year in the summer-time... I suffer from sad-syndrome, the seasonal affective disorder and I have a bit depression. This... this time of year I don't like it, you know, and I can sort of be "mmhmm" [the interviewee expresses a gesture that is reflecting her being sad] whereas in the

summer-time I just... the sunshine is good, so it's like everything you... how you feel, you know, can have an impact on how you are, you know, as such. Yes, so I – I don't mind. Aha, no.

In: So if you can think about the osteoporosis care as... as a whole, do you think that there is something that the pharmacist cannot do?

Pa1: Well, they can't make me better with anything. They can, as you said, by discussing the diet they can encourage me a bit more. And I think "right, ok, I have to do that", but the f... as part from the falling down, I know myself, in the bad weather I'll take my stick and it is always in the winter I had a bad fall. Last, this time last year and I – I cracked nine ribs and broke three, all in one fall. So that was quite a lot. And... I had to go to the hospital because I thought I didn't bother going to the doctors because I just wanted the confirmation by an X-ray and that's when it came across. And my doctor called me at home and said "XXXX [the name of the interviewee] I just have to let you know, we've had the police in touch because you've been to the hospital so often, in case someone had been...", so from that point of view going to the hospital sort of sets things off in case it was somebody being beating, but because the hospital wouldn't necessarily know I had osteoporosis, they've just treating me for broken ribs and cracked ribs, which my doctor has my file and called me and said "don't worry about it". And by that time I was getting ready to go to Australia and I though "oh my God! Will I have to cancel my trip?" and my doctor said "XXXX [the name of the interviewee] it's the best thing, because the weather is going to be good for you, it's better recovery, sunshine, vitamins". And it was the best thing. You know, so I talked to people so people respond and I'll ask if I want to know things as well, you know, it's just again I'm going to ask you – will there be a lot of training involved in this?

In: Yeah.

Pa1: Within the pharmacies?

In: Yeah.

Pa1: Yes.

In: It will be.

Pa1: To get this up and running?

In: Yeah.

Pa1: So, as far as that's concerned I have no... no problems with that at all.

In: No. So you think the pharmacists' needs some more training and some more...

Pa1: Well, I think, an understanding of things. It's like anything, I mean, as I say, I was in absolute shock. I sat along there, after having the... the... the scan and, you know, I just sat there and she just went "du-tu-tu – well, you're bone density is minus five" and I went "Oh! Is that ok?" and she said "Well, it's a little bit below what it should be" and I'm going "Right", and I though perhaps maybe I should have taken someone with me, but I just thought "I go along – du-tu", so that was the one shock-factor for me. That I really, I came out and I had driven, and I – I sat in the car for ages and I just thought "Oh, gosh! What does this mean now to me?", you know, it was... But there was so much support here, you know, with the groups and things like that, which, that to me is the only thing that if we can go into the pharmacists, pharmacies, if there was going to be more that the real experts who understand can have something, maybe four times a-year, for people to, sort of... We share the experiences... the people, we share these experiences and XXXX [name of the current osteoporosis nurse] has used me a few times to say "XXXX [the name of the interviewee] you're..." I mean I was terrified of injections XXXX [the name of the osteoporosis nurse that is not longer there] to the house the first time to inje... and I thought "Oh, God". And I couldn't get high... but after that it was second nature, I thought "This is for my wellbeing", and did that and I've been talking to other people, I've met them or talked to them on the phone about the fear that they have and tried to take that out with my own experience and hope that that has helped, but they have done that. And that what's these working groups, I think, are great for. Absolutely.

In: Is the working group something that the pharmacists could do, or...?

Pa1: I suppose they co... they possible could, but it's where they would hold... Yeah.. so more local to the community. That people didn't have so much travelling. That's a good idea. Yeah. It is good. Yeah.

In: So, can you explain what the... the nurse do when you get the denosumab?

Pa1: Well, here at the hospital?

In: Yes.

Pa1: Well, XXXX [the osteoporosis nurse] talks away as she normally does and she... and it's over... I think "Oh, are we finished?", but you know, she'll say.. and how are things been and I'll just update her on what I've been up to with... and you know, if I've had a fall or something like that, so I don't see there's anything different that the hospital offer that the pharmacy couldn't. Yeah. I'm... I'm behind that. I think it's a good idea.

In: So, all in all what are your opinions regarding shifting the care from the hospital to the community pharmacy?

Pa1: I'm all for it. Yeah, I think it's a really good idea. Again, I'm visioning my own pharmacy, because I – I like them. Yeah. Mhm.

In: Do you think there are some pharmacists that couldn't do this?

Pa1: Which is like anywhere. It... There could be... I could come to the hospital and maybe not had the same rapport with someone. It's like anything, you could go in to a shop, you can get a good shop-assistant, you can get another person who.., you know, and I'm... I'm the type of person... if someone wants something I will tell them as much as they want to know, instead of saying "oh, well, you have to experience it for yourself, you know" and we are all different and we all handle it differently as well, you know, aha. So it, it, it could be you could get a good person, it's like anything. Mhm. Yeah.

In: Is there anything you would like to add anything you would like to elaborate on?

Pa1: I don't think so. No. No, I don't think so. No, no. I think it's.. it's really good. Yeah, I mean, if this is with what you're doing put together, how long do you see if this is going to go that way, how long would you say that sort of taking time to, sort of, you know, be taken on?

In: Yeah, that's very difficult to say. But it might take some time, yeah. This is just the very first...

Pa1: I might not see it in my life time.

[laughing]

In: I don't think it will take that long. It depends on which way it goes.

Pa1: And again, it's all for funding and things like that isn't it?

In: Yeah, yeah.

Pa1: You know, that... that's... that's a big thing to. But at the same time I don't want to see these great people like XXXX [one of the osteoporosis nurse specialist currently running the clinic] and that losing a job because of it.

In: No.

Pa1: You know. Aha. That would be something I would think... Because they're so knowledgeable and specialist in what they do that... if it was people like themselves going out with and training up the pharmacists, to me that would be a benefit. Yeah. Working hand and glove to begin with and maybe, sort of, going out occasionally and just to, sort of, see how... how they're doing. You know. And obviously maybe surveys once it is going out. How it is working. You know, do a survey and analysis of it, you know, how that's going. Mhm, yeah.

In: Ok, well that was all...

Pa1: Is that ok? [both talking]

In: ...the questions I had.

Pa1: Oh, good. [laughing]

In: Thank you very much.

Minute of the interview with patient 2

It should be highlighted that this is not a transcription of the interview, but a minute based on the investigator's notes and the remembrance of the interview. The interview was undertaken as if it was recorded, but with the investigator taking notes whilst the interviewee was answering.

In: Investigator

Pa2: Patient 2

In: How often do you go to the pharmacy?
Pa2: Once every two months.

In: Do you always go to the same community pharmacy?
Pa2: Yes.

In: Have you accessed any of the additional services that they provide? Some pharmacies provide other services, such as stop smoking services and flu-vaccines.
Pa2: No. I have never accessed any of the additional services.

In: Does the pharmacist go through your medicines with you?
Pa2: No.

In: Does anyone else do it?
Pa2: No.

In: Do you think it's a good idea?
Pa2: Yes and no. I know the medication that I am using and I don't feel I need any more information. If I have any questions I will ask my GP who is the one giving me information about medicines.

In: What is your opinion about your community pharmacy and the care they deliver in general?
Pa2: The pharmacy is just the place where I collect my medicine. I do not get any counselling in the pharmacy. For me, a pharmacist is there to "dish-out" drugs and nothing else. They are just there to hand over drugs and not to give advice. If they are going to give any advice or additional care, it would take a lot of time to build up the knowledge and trust that is involved in that.

In: Can you tell me about your experience of visiting the hospital to receive denosumab treatment?
Pa2: It is a very pleasant experience. I enjoy going to the hospital. The osteoporosis nurses are very helpful and I feel very safe.

In: Do you think it's convenient?
Pa2: Yes. I have to take two busses, but that is no hassle for me.

In: Does anyone come with you to the hospital or drive you there?
Pa2: No, I take the bus.

In: How do you feel about attending the hospital for your denosumab treatment?
Pa2: I am very happy. It is always a nice experience. I feel I have this comfort blanket around me. I feel safe.

In: Is there anything about your visit you like or dislike?

Pa2: I like the staff. They are very friendly and have a great knowledge of osteoporosis. There's not a single thing that I dislike.

In: How much time does it take you to travel to the Western?
Pa2: It depends on traffic and the weather, but I would say forty-five minutes up to one hour and a half.

In: Do you wait a long time to see the nurse or the consultant when you are in the hospital?
Pa2: No. I see them on my appointment slot, as scheduled. I do not wait.

In: How much time does it take you to travel to your community pharmacy?
Pa2: Depending on the traffic and the weather as well, but I would say about twenty minutes, or half-an-hour. No, twenty minutes.

In: What does the nurse do during the denosumab visits?
Pa2: We have a general chat and they ask me, or I ask them, about side-effects. We can talk about general things and of course it's the injection.

In: How could the pharmacy contribute or help you with the injection of denosumab that you receive?
Pa2: I can't see any way. They don't have the experience to do anything. They can't answer my questions. I doubt that they know enough about the drug because it's very new.

In: What do you think about the idea of the pharmacy supplying and administering denosumab?
Pa2: I'm not keen on the idea at all.

In: Is there anything you would miss about the hospital visit?
Pa2: There are several things I would miss. The confidence in the nurses knowledge and the care they deliver. I would miss the camaraderie, because I have a very good relationship with the nurses. It's very easy to phone the osteoporosis nurse if I have any questions or there's something I would like to talk to her about. I don't think I could have done that with a pharmacy. The pharmacy wouldn't give me the same close relationship that I have with the nurses here.

In: Do you think the pharmacy could contribute or help you in a way that the hospital does not?
Pa2: No.

In: Do you think you would receive the same care in the pharmacy?
Pa2: No. I feel very comfortable and safe in the hospital. I don't think the pharmacy could provide me with the same comfort and feeling of being safe.

In: Do you have any ideas how a community pharmacy can help with your osteoporosis care?
Pa2: I have no idea at all. How would they know if the drug works? Today I asked XXXX [Osteoporosis specialist nurse] that question and she said that I'm having a [DXA] scan the next time. If I had asked the pharmacist that question, they couldn't probably answer that question and they had to ask the hospital, which takes a lot of time. As I said, the pharmacist doesn't know enough about osteoporosis.

In: Can you tell me of any changes that might make providing care more convenient for you?
Pa2: I don't know.

In: Is there any health care professional that asks you about your diet? They might ask you about how much calcium and vitamin D you consume. This is to ensure that you get sufficient amounts of nutrients to keep your bones as strong as possible.

Pa2: Yes, the osteoporosis nurse does.

In: How would you feel if a pharmacist asked you about your diet, particularly calcium and vitamin D intake?
Pa2: I would be fine.

In: If someone is diagnosed with osteoporosis, falling might be serious because the person might get a fracture, break a bone. Does any health care professional ask you about falling?
Pa2: No.

In: What is your opinion about the pharmacist asking you questions about the risk of falling?
Pa2: I would be fine. It wouldn't bother me.

In: Do you think there is anything that the pharmacist cannot do in terms of your osteoporosis care (or management) that the hospital or general practitioner (GP) can?
Pa2: Yes. I don't think they could give any advice. This is all new to them, so it would take time for them to get general knowledge about the drug and osteoporosis care. I think information and communication would be a problem. How would the hospital know about what the pharmacist does and how would the pharmacist know about what the hospital does?

In: All in all, what are your opinions regarding the potential moving of care from the hospital to the community pharmacy?
Pa2: I would rather still take it in the hospital, although I can understand that it's not convenient for some patients to travel to the hospital. I think they would like having the injection at their pharmacy. But we should be given the choice whether to have it in the hospital or in the pharmacy. I'd rather go to the hospital. I would be comfortable with having the injection at my doctor [General Practitioner].

In: Is there anything you would like to add, or anything that you would like to elaborate on?
Pa2: No. I think you covered everything in the questions. But it might be that my experience with my pharmacy is not that good, and that may be the reason why I am sceptical.

Interview with patient 3

In: Investigator

Pa3: Patient 3

In: How often do you go to a community pharmacy?

Pa3: I have a repeat prescription that I get. I have a sort of mild dermatitis that... local dermatitis I get. And I have to take antihistamine tablets quite a lot and, and sort of, washing with, sort of, a dermal crème which I get on a repeat prescription and I use my local supermarket's pharmacy, because they're, you know, quite close to where I stay. So, I just need to take my prescription down to them and then they take it up to the... the GP surgery and then I collect it again from the supermarket. So I use that all the time.

In: So how often do you think...

Pa3: It would be every few months I would think. You know, not... probably about every three months or so.

In: Every three months?

Pa3: Yeah, something like that.

In: Do you always go to the same community pharmacy?

Pa3: Usually, I do. Occasionally I might use another one, but not very often. Because it's.. it's... it's just that it's closer to where I stay.

In: Have you accessed any of the additional services that they provide? Some pharmacies provide other services such as stop smoking service and blood...

Pa3: No, I haven't... haven't used that, no.

In: Does that pharmacist go through your medicines with you?

Pa3: No. Not usually. They do s... well, if there's nothing that I get that's, you know, if it was something that perhaps something that I was getting that, you know, a pain-killer or something they might say, you know, you have to be careful in how you use it and... if there was some cod... you know, codeine in it, so they would just take it for so many days and they might, you know, do that but they don't usually go over the medication with me.

In: Ok. Does anyone else do it?

Pa3: If I was at the GP... it just depends, I'm not... I re... I tend to react sometimes, I don't like taking antibiotics. And I take them as rarely as possible, you know, because I tend to react to some of them and... So I go over with the doctor, we go over, and if... if I have to, which isn't very often, if I have to take one, sort of go over the one's I know that I've reacted to in the past, and then she'll look at, you know, other antibiotics that might be ok, but usually I react to that anyway, so it's... so it's you know, I absolutely hate taking antibiotics. If there's something else, I'll take it. Because I have reacted to medication in the past. The same with the osteoporosis drugs, the first drug that I was given, I can't remember the name [probably alendronate or another bisphosphonate], it was a tablet that you took once a week and I reacted to it really badly, and I had uveitis in my eye quite badly. So and the other two I had after that and I reacted to them to. You know, I have the skin problems, so that's why they put me on the injections.

In: Do you think it's a good idea if anyone went through the medicines with you?

Pa3: Yes, because when I came here first... and they were putting me on the... the injection and the...the doct... the doctor that I saw, I mean it's... he... you know, he talked about this... it reacted

differently to the other drugs that I'd had. And he, sort of, gave me this, sort of, handed me this, sort of, leaflet and I... you know, you just don't have time to read all this, you know there... you know, you just don't have time to read it. Explaining that.. and I thought "oh my God, am I going to have side-effects to this", you know, and I didn't think he gave me the time to actually read through, you know, what he was presenting me with. You know, and it would be quite nice if somebody, sort of, took the time to, sort of, say "well, these are the... the", and I just didn't have time to read it all. You know, and then I had to sign it. You know, to get my consent. I thought "my God, I can't remember what it said!", you know, so... They don't give you enough time to go over it. I don't think.

In: Ok. What is your opinion about your community pharmacy and the care that they deliver in general?

Pa3: It's good. It's quite a good... good... a good service, yes.

In: Ok. Can you tell me about your experience of visiting the hospital to receive the denosumab treatment?

Pa3: It's been good.

In: It's been good?

Pa3: Yes. Aha.

In: Do you think it's convenient?

Pa3: To come here?

In: To come here.

Pa3: No. No, it's not.

In: Ok.

Pa3: [laughing] Just... No, it's not. Let... this morning I left home, now it takes me ten minutes to walk to the bus stop, to get the bus, and it's quite slippery outside this morning.

In: It is.

Pa3: And I thought "my God, I'm terrified I'm going to fall", you know, and I thought... And I was, sort of, creeping down the road, and I thought "oh no", so I got on the bus, now if I only want to get one bus, I have to get it to... it's another ten minutes... another ten minutes walk down here and then again you're, sort of, terrified you're going to slip. So there isn't a direct bus route to here. And I have an elderly neighbour who has osteoporosis and she's much, much older than me and she has to come here, you know, and you know, it's not everyone that can afford a taxi. You know, they just can't afford to get taxi. And she has a stick now. She's quite frail. You know, so for m... you know, patients that are older than me, you know, it's... it's, you know, it's quite a ta... you know, a daunting task to come away out here. And it..

In: Does anyone come with you to the hospital or drive you here?

Pa3: Occasionally someone comes in with me, it just depends, but usually I just come by myself.

In: And by a bus?

Pa3: By bus, yes, I don't drive anymore.

In: Ok. So how do you feel about attending the hospital for your denosumab treatment?

Pa3: I would prefer to be able to go my GP surgery and see the nurse, you know, over the years the nurse knows who you are, and she also has a little bit more time to, sort of, talk to you. Like a couple of weeks ago when I came for my injection and I've been having really awful, sort of, aching pains in my muscles and the tops of my legs, which I hadn't had before, and, you know, really, really sore. My muscles on the top of my legs are really tight and, you know, I sort of wanted to say to them, you know, yeah, you know, "this is new, I don't know what this is. Is it something to do with the osteoporosis or is it something else?", and she says "well, you better just to go see your GP" now if I

had been at the surgery, you know, I could have had a... the nurse would have, well my... the nurse in my surgery does, you know spends time talking to you, and then she'd probably say "we'll just make an appointment now", you know, so I would be there and just make an appointment. So whereas when I was here, I had to go home and then telephone and make the appointment, and they do have a little bit more time to spend with you. Well, I feel anyway, anytime I've had to go to see the nurse.

In: Is there anything about you visit that you like or dislike?

Pa3: No, I don't think so. They... No, the nurses are very nice here. They really are. But no, I don't think there's anything that I could say I've disliked.

In: How much time does it take you to travel to the Western?

Pa3: Now, I left home at ten o'clock this morning, and I got here at ten, quarter, ten to eleven, so that'll be fifty minutes.

In: Fifty minutes.

Pa3: Yes.

In: Yeah, when do you... When you come here, do you wait a long time to see the nurse or the consultants?

Pa3: Sometimes you do. Sometimes you can be lucky and just wait maybe ten – fifteen minutes and other times it's longer. You know, you could wait much longer than that.

In: And how much time does it take you to travel to your pharmacy?

Pa3: I walk there. It would take me, what? About, less than ten minutes.

In: Less than ten minutes.

Pa3: Yeah, to walk.

In: Yeah. What does the nurse do during the denosumab visits?

Pa3: The first time I was here she... she weighed me and took a urine sample. And this visit she just gave me the injection and that was it really.

In: How could the pharmacy contribute or help you with the injection of the denosumab?

Pa3: I'm not sure. Would there be a nurse in the pharmacy?

In: No. The pharmacist would do it.

Pa3: So it would be the pharmacist that would give the injection?

In: Yes.

Pa3: Hmm... See, I think my pharmacists are very, really busy.

In: OK.

Pa3: [laughter] You know, they're really, really busy, you know, and I thought "God, I couldn't imagine them having the time to do that".

In: Ok.

Pa3: You know, they're... they're... they're quite busy. And there's another chemist that I use occasionally and they are really busy too. So I just cannot see the pharmacist having the time to do that. If there was someone there specifically to do that, but I can't see the actual pharmacist having time. They're very busy.

In: What if you had an appointment with the pharmacist?

Pa3: Yeah, I could see that working, because I can't, you know, it's not like the flu-jag, when everybody is sort of going at the one time, sort of November – December and there's this great rush of sort of old people for their injections. So there might not be that many to do. That might be possible.

In: Yeah. Would you be more comfortable if you had an appointment?

Pa3: Yes. It would have to be an appointment, yeah.

In: So what do you think about the idea that the pharmacy supplying you and administrating denosumab?

Pa3: Yes, I wouldn't mind that.

In: Ok. Is there anything you would miss about the hospital visit?

Pa3: No.

In: No?

In and Pa3: [laughing]

In: Ok.

Pa3: Not really.

In: Do you think the pharmacy could contribute or help you in a way that the hospital does not?

Pa3: I'm not sure really. As I say, my pharmacists are just so busy, I can... you know, I know when I go in. You know, there's sort of queues of people waiting for their medication and then you're going in with the prescriptions and they are just so busy. I don't know if they really would be able to give you the time and I just don't know whether they could. Unless you had an appointment, but they are very, very busy.

In: Do you think you would receive the same care in the pharmacy?

Pa3: I'm not sure I could really answer that. I mean, really, basically all... when I'm coming here is just getting an injection and going home. Really. So probably yes. Yeah.

In: And now I would like to talk about the osteoporosis care in general. So this is other than the injection of denosumab. Do you have any ideas how a community pharmacy can help you with your osteoporosis care in general?

Pa3: I would have liked a bit more... when I... when I... I didn't realize that I had osteoporosis until... and I've never fallen. They keep telling me, you know, "how did you fall?" and I said, "I didn't fall", [laughing], "I didn't fall", and I was actually skipping, you know, the skipping ropes, with some children and it's when I came down and I had very flat shoes on at the time, so it was when I came down I fractured my spine, and because I've never broken anything before. And that's when they discovered I had osteoporosis. And I just didn't feel... anybody had the time to, sort of, talk to me about it, you know, I was like, here's a thingy to, a leaflet, sort of a booklet thing and then "off you go", really. That was about... that was about it. And then I rem... I remem... my sister who has slight, mild osteoporosis, I have it quite badly apparently. She has been going for quite some time to... for t'ai chi, and she said it really helps. So, the last time I came here, I asked, you know, did they know anywhere I could go for t'ai chi, it was really difficult to find anything and then they gave me a telephone number that... oh, this was in the summertime I think. So, I telephoned this number, and it obviously was probably somewhere down in England and I said, "look, I'm looking for a, sort of, beginners class for t'ai chi and I live in Edinburgh" and then she said, "I don't know if there's any beginners classes, so she had a look and she was... she obviously didn't know Edinburgh very well, so she was giving me places that were thirty miles away, you know, I thought "my God", and, you know, so that I wasn't getting the information I wanted. And I still haven't been able to find a beginners class which is quite near where I stay, you know, I can't travel twenty miles for a t'ai chi class. And they have classes that, you know, I'm looking for a class that's for beginners. So I still haven't found one.

In: Do you think a pharmacy can give you a lot of information about osteoporosis? Would you feel comfortable?

Pa3: Yes. Aha. I just don't think when you come to the hospital they have the time to actually sit down and really, sort of, talk through, you know, I mean, I know what it is and I have a healthy diet. You know, I've always... and I've thought "how have I've got this?", you know, "why have I got this, like I've been active all my life", and, you know, I couldn't imagine why I had it. But, my mother apparently had osteoporosis. So it can, sort of, you know, and I thought, you know, if I'd probably sat at a desk all my life I probably wouldn't have it, but I've just been a very active person and they tell you to be active, you know and, you can still get it so... I just, you know, didn't feel that, well, you know, anybody really had the time to really sit down and talk to you about, you know, what you could do.

In: So that's something you miss?

Pa3: Yeah.

In: Do you think a pharmacy could take over that role of giving you information?

Pa3: I think they could if they had the time to do that.

In: Ok. So let's say you had an appointment and...

Pa3: Yes.

In: ... if they had the time.

Pa3: Mhm.

In: Yeah.

Pa3: But certainly the hospitals just don't have the time.

In: No.

Pa3: No, they... they just don't seem to have the time and... Because when I first came to have... here, they gave me a questionnaire to fill in before I came, about, you know, what I ate. You know, how many times I ate, and I thought "what is this for?". You know, so when I had filled it in, I took it in, I gave it to the nurse, but nobody explained to me why I had, you know, what this was all about, and nobody spoke to me about it, so I thought, "well, why did I have to fill this in?". So, I didn't really know.

In: So where there nurses that asked you about your diet?

Pa3: It was a questionnaire that I had been given to take home, and I... I took it home and filled it in. And then I brought it back.

In: Ok. And you gave it to a nurse?

Pa3: I gave it to the nurse and then I had my scan, you know, sort of, the bone scan. I had the bone scan and then I was to see the nurse after the bone scan and I thought "oh, she'll, she's going to talk to me about this questionnaire", but she didn't. She just said "you have osteoporosis" and that's it really and gave me a leaflet and off I went. So I didn't really know why I had to... to fill this in about my diet. So and I thought "well, my diet must be ok then, otherwise she might have said something", but she didn't explain why I had to fill it in.

In: So no one has mentioned the diet afterwards? After the questionnaire, I mean?

Pa3: No.

In: No.

Pa3: No, they didn't.

In: How would you feel if a pharmacy asked you about your diet?

Pa3: Yes, that would be fine.

In: That would be fine, yeah. If someone is diagnosed with osteoporosis, falling might be a serious... because the person might get a fracture. Does any health care professional ask you about falling?

Pa3: When I came here, the... the doctor said, he said, you know, "how did you fall?", they always ask you if you fall. And I said "I don't fall", you know, I've never fallen. It was just... probably if I hadn't been skipping and jumped, I wouldn't still not known I had it. Until I probably fractured some bone. I probably still wouldn't know I had osteoporosis. You know, it was the.. jumping down, and I had gone, I was at physio, I used to go to... for physiotherapy and she said to me that probably I had indoor-shoes on, which were really flat, and she said "had you probably got outdoor-shoes on, you know, it would have cushioned you coming and down, and you wouldn't, probably wouldn't fractured your spine", but the shoes were very flat. You know, so I knew I had done something. It was like a chest felt, sort of as if it was caving in.

In: How would you feel if a pharmacy asked you about the risk of falling?

Pa3: Yes, I wouldn't mind.

In: Ok. Do you think that there's anything that the pharmacist cannot do in terms of your osteoporosis care that the hospital or the GP can do?

Pa3: No, I don't think so. No, I think they could do the same.

In: All in all, what are your opinions regarding the potential moving from... from the hospital to the community pharmacy?

Pa3: I would prefer it to be moved from the hospital. Yes, definitely.

In: Ok. Is there anything you would like to add or anything you would like to elaborate on?

Pa3: I don't think so. For me personally, I still would prefer to go to somebody that I know... I know already, which is the nurse in my GP's practice. And you make an appointment and she's... because I know her over the years, and she, you know, she'll ask you questions and she'll... She's just that type of nurse, you know, and if you want to ask her anything she's really helpful and I find her a very helpful person, you know, so the pharmacy is a sort of an unknown thing, really. And as I've said before, I just don't know how they would have the time to do that. That might be very, it's a sort of unknown, unknown really. You know, how they would feel about , you know, are you now going to say what...? "You are now going to have to take on patients and give them injections and sit and chat", because they're just so busy.

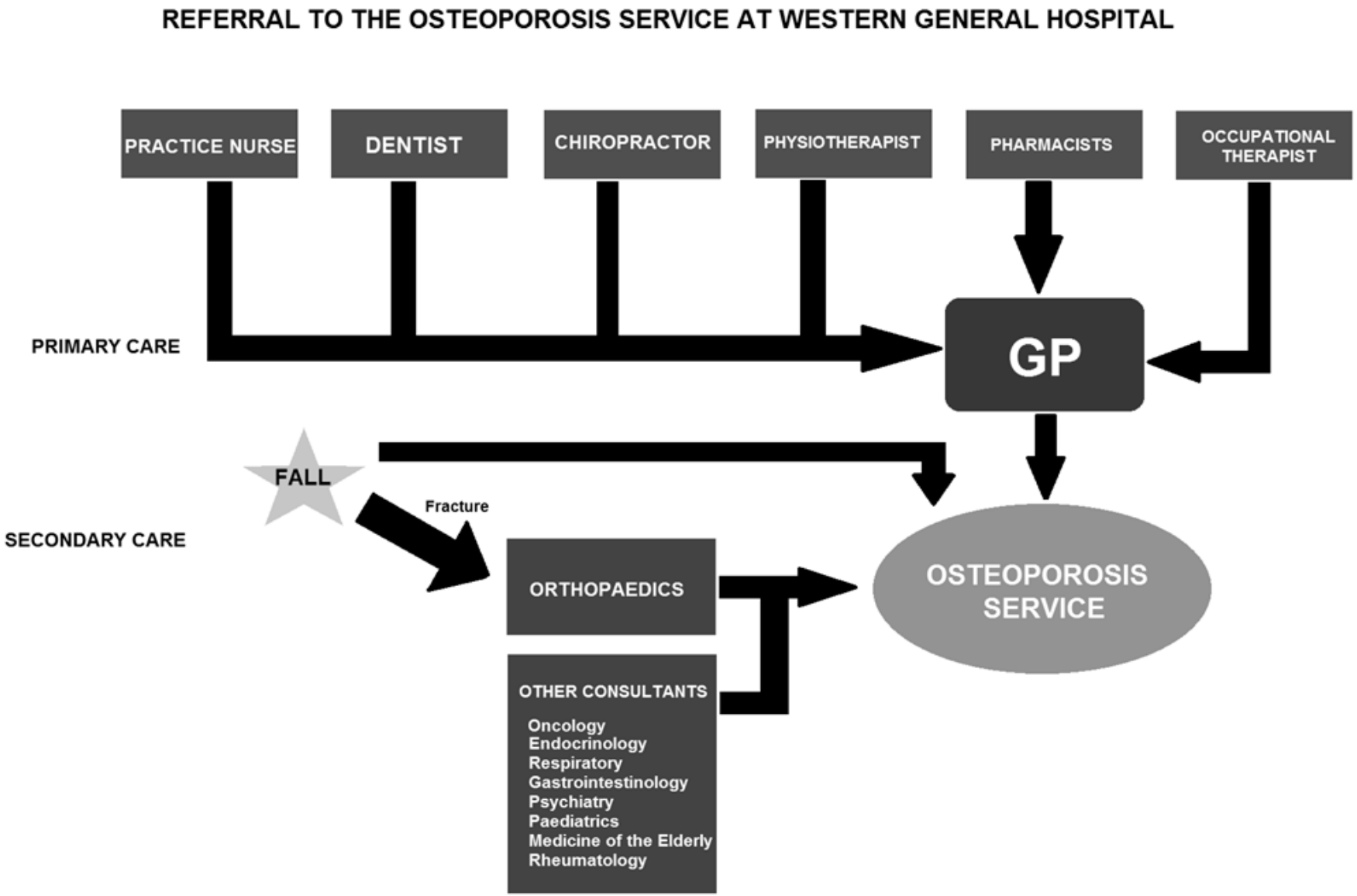
In: Ok. So you think it... it has to be a... appointment driven thing?

Pa3: Yes. Definitely an appointment. I don't think it would be fair on them to just turn up and say, you know, "I'm here for an injection", you know, I don't think that would be a good idea. No.

In: Ok. Well, thank you very much.

Pa3: Is that it?

In: Yes.


REFERRAL TO THE OSTEOPOROSIS SERVICE AT WESTERN GENERAL HOSPITAL
PRACTICE NURSE
DENTIST
CHIROPRACTOR
PHYSIOTHERAPIST
PHARMACISTS
OCCUPATIONAL THERAPIST
PRIMARY CARE
GP
FALL
Fracture
SECONDARY CARE
ORTHOPAEDICS
OSTEOPOROSIS SERVICE
OTHER CONSULTANTS
Oncology
Endocrinology
Respiratory
Gastrointestinology
Psychiatry
Paediatrics
Medicine of the Elderly
Rheumatology

INTERVIEW GUIDE

Questions for the community pharmacists (pilot with hospital pharmacist)

- Are you familiar with the drug denosumab? *(Included in that moment based on the investigator's intuition. Was later included in the final interview guide)*
    - **If yes:** Next question
    - **If no:** Briefly inform about denosumab

- Do you have any patients who receive denosumab treatment?
    - **If yes**:
        - How are you involved in the use of denosumab in osteoporosis management?
            - Prompts:
                - What do you perceive is your role?
        - Are you aware of the current process of management?
            - **If no:**
                - Describe denosumab and the current patient journey, using a flow chart
            - **If yes:**
                - Refer to the flow chart
    - **If no**: Are you aware of the current process of management?
        - **If no:**
            - Describe denosumab and the current patient journey, using a flow chart
        - **If yes:**
            - Refer to the flow chart

I would like to ask you about convenience to patients when they visit the hospital to receive their injections, for example some patients may travel some distance.

- Can you think of any ways that delivery of the service could be improved from the patient's perspective?
    - **Explain the follow-up that the nurses do**
    - How do you think the patients would feel about visiting a community pharmacy instead of the hospital for follow up treatment and administration, similar to that provided by the specialist nurses?
        - Would they miss anything?
        - Would they be satisfied by the pharmacist undertaking this role compared to the nurse?

- Is there anything you would like to add about patient's convenience?

Acceptance of community pharmacist supply and administration of denosumab

- Is there anything you would like to add about any concerns you may have associated with such a shift of care?

- What problems might arise if the denosumab would be supplied and administered in the community pharmacy?
  - Practical problems
    - Space
    - Waste handling
  - Training of staff
  - Financing
  - Is there anything that the nurses do in these follow up visits that you think the pharmacists could not do, including the follow-up?

- What advantages will there be if the denosumab would be supplied and administered in the community pharmacy (except convenience)?
  - Patients adherence
  - Are there things the pharmacists could do, that the nurses do not do / can't do, including the follow-up?
- Are there any elements of the management of osteoporosis that might not be able to be provided by the community pharmacist?
  - Put in some examples of elements

Acceptance of community pharmacist led pharmaceutical care package of medication review, adherence with medicines, falls assessment and need for calcium & vitamin D

Now I would like to discuss the potential role of community pharmacists in the wider management of osteoporosis

- How can a community pharmacy help with osteoporosis management (besides administration of denosumab)?
  - How would a pharmaceutical care package of medication review, adherence with medicines, falls assessment and need for calcium and Vitamin D help the patients?
    - Adherence
    - Discovering more than nurses or physicians do
    - What do you think about the quality of a medication review compared to physicians or General Practitioner doing the review?
  - What might be missed compared to how the hospital or the GP is doing it?

  - Is there anything else that could make the management more convenient for patients? Have I already ask about this
    - Risks
    - Benefits
  - Is there anything that could make the management more convenient for the secondary health care system?
    - Risks
    - Benefits

- All in all, what are opinions regarding the potential shift of care?

- Is there anything you would like to add, or anything that you would like to elaborate on?

Questions for the community pharmacist

- Are you familiar with denosumab?
    - **Yes**: Go to the next question
    - **No:** Denosumab is a treatment for postmenopausal osteoporosis, with a restriction that it is used only in patients with a bone mineral density (BMD) T-score < -2.5 and ≥ -4.0 for whom oral bisphosphonates are unsuitable. It is a pre-filled syringe administered every six months as a subcutaneous injection by a nurse in the hospital, although NICE states that it should be used in Primary Care after being initiated by a specialist in secondary care. No blood monitoring is required other than in those at risk of hypocalcaemia (for example renal impairment).

- Do you have any patients who receive denosumab as a treatment for postmenopausal osteoporosis?
    - **Yes**: How are you involved in the use of denosumab in osteoporosis management?
        - What do you perceive is your role?
        - Are you aware of the current process of management?
            - **Yes:** Refer to the flow chart
            - **No:** Describe denosumab and the current patient journey, using a flow chart
    - **No**: Are you aware of the current process of management?
        - **Yes:** Refer to the flow chart
        - **No:** Describe denosumab and the current patient journey, using a flow chart

I would like to ask you about <u>convenience to patients</u> when they visit the hospital to receive their injections, for example some patients may travel some distance.

- Can you think of any ways that delivery of the service could be improved from <u>the patient's perspective</u>?
    - **Explain briefly the follow-up that the nurses do**
    - How do you think <u>the patients would feel</u> about visiting a community pharmacy instead of the hospital for follow up treatment and administration, similar to that provided by the specialist nurses?
        - Would they miss anything?
        - Would they be satisfied by the pharmacist undertaking this role compared to the nurse?

- Is there anything you would like to add about patient's convenience?

Acceptance of community pharmacist supply and administration of denosumab

- Is there anything you would like to add about any concerns <u>you may have</u> associated with such a shift of care?
    - What problems might arise if the denosumab would be supplied and administered in the community pharmacy?
        - Practical problems
            - Space
            - Waste handling
        - Training of staff

- Financing

- Is there anything that the nurses do in these follow up visits that you think the pharmacists could not do?

- What advantages will there be if the denosumab would be supplied and administered in the community pharmacy (except convenience)?
  - Patients adherence
  - Are there things the pharmacists could do, that the nurses do not do / can't do, including the follow-up?
    - Medication review

- Are there any elements of the management of osteoporosis that might not be able to be provided by the community pharmacist?

Acceptance of community pharmacist led pharmaceutical care package of medication review, adherence with medicines, falls assessment and need for calcium & vitamin D

Now I would like to discuss the potential role of community pharmacists in the wider management of osteoporosis

- How can a community pharmacy help with osteoporosis management (besides administration of denosumab)?
  - How would a pharmaceutical care package of medication review, adherence with medicines, falls assessment and need for calcium and Vitamin D help the patients?
    - Adherence
    - Discovering more than nurses or physicians do
    - What do you think about the quality of a medication review compared to physicians or General Practitioner doing the review?
  - What might be missed compared to how the hospital or the GP is doing it?
  - Is there anything that could make the management of osteoporosis more convenient for the secondary health care system?
    - Risks
    - Benefits

- Do you see any changes that can be made to this flow chart that can make the process of management better?

- All in all, what are opinions regarding the potential shift of care?

- Is there anything you would like to add, or anything that you would like to elaborate on?

Questions for the General Practitioner

- Are you familiar with denosumab?
    - **Yes**: Go to the next question
    - **No:** Denosumab is a treatment for postmenopausal osteoporosis, with a restriction that it is used only in patients with a bone mineral density (BMD) T-score < -2.5 and ≥ -4.0 for whom oral bisphosphonates are unsuitable. It is a pre-filled syringe administered every six months as a subcutaneous injection by a nurse in the hospital, although NICE states that it should be used in Primary Care after being initiated by a specialist in secondary care. No blood monitoring is required other than in those at risk of hypocalcaemia (for example renal impairment).

- Do you have any patients who receive denosumab as a treatment for postmenopausal osteoporosis?
    - **Yes**: How are you involved in the use of denosumab in osteoporosis management?
        - What do you perceive is your role?
        - Are you aware of the current process of management?
            - **Yes:** Refer to the flow chart
            - **No:** Describe denosumab and the current patient journey, using a flow chart
    - **No**: Are you aware of the current process of management?
        - **Yes:** Refer to the flow chart
        - **No:** Describe denosumab and the current patient journey, using a flow chart

I would like to ask you about <u>convenience to patients</u> when they visit the hospital to receive their injections, for example some patients may travel some distance.

- Can you think of any ways that delivery of the service could be improved from <u>the patient's perspective</u>?
    - **Explain briefly the follow-up that the nurses do**
    - How do you think <u>the patients would feel</u> about visiting a community pharmacy instead of the hospital for follow up treatment and administration, similar to that provided by the specialist nurses?
        - Would they miss anything?
        - Would they be satisfied by the pharmacist undertaking this role compared to the nurse?

- Is there anything you would like to add about patient's convenience?

Acceptance of community pharmacist supply and administration of denosumab

- Is there anything you would like to add about any concerns <u>you may have</u> associated with such a shift of care?
    - What problems might arise if the denosumab would be supplied and administered in the community pharmacy?
        - Practical problems
            - Space
            - Waste handling
        - Training of staff

- Financing

- Is there anything that the nurses do in these follow up visits that you think the pharmacists could not do?

- What advantages will there be if the denosumab would be supplied and administered in the community pharmacy (except convenience)?
  - Patients adherence
  - Are there things the pharmacists could do, that the nurses do not do / can't do, including the follow-up?
    - Medication review

- Are there any elements of the management of osteoporosis that might not be able to be provided by the community pharmacist?

Acceptance of community pharmacist led pharmaceutical care package of medication review, adherence with medicines, falls assessment and need for calcium & vitamin D

Now I would like to discuss the potential role of community pharmacists in the wider management of osteoporosis

- How can a community pharmacy help with osteoporosis management (besides administration of denosumab)?
  - How would a pharmaceutical care package of medication review, adherence with medicines, falls assessment and need for calcium and Vitamin D help the patients?
    - Adherence
    - Discovering more than nurses or physicians do
    - What do you think about the quality of a medication review compared to physicians or General Practitioner doing the review?
  - What might be missed compared to how the hospital or the GP is doing it?

  - Is there anything that could make the management more convenient for the secondary health care system?
    - Risks
    - Benefits

- Do you see any changes that can be made to this flow chart that can make the process of management better?

- All in all, what are opinions regarding the potential shift of care?

- Is there anything you would like to add, or anything that you would like to elaborate on?

Questions for the osteoporosis nurse specialists

- Are you familiar with denosumab?
    - **Yes**: Go to the next question
    - **No:** Denosumab is a treatment for postmenopausal osteoporosis, with a restriction that it is used only in patients with a bone mineral density (BMD) T-score < -2.5 and ≥ -4.0 for whom oral bisphosphonates are unsuitable. It is a pre-filled syringe administered every six months as a subcutaneous injection by a nurse in the hospital, although NICE states that it should be used in Primary Care after being initiated by a specialist in secondary care. No blood monitoring is required other than in those at risk of hypocalcaemia (for example renal impairment).

- Do you have any patients who receive denosumab treatment?
    - **Yes**: How are you involved in the use of denosumab in osteoporosis management?
        - What do you perceive is your role?
        - Are you aware of the current process of management?
            - **Yes:** Refer to the flow chart
            - **No:** Describe denosumab and the current patient journey, using a flow chart
    - **No**: Are you aware of the current process of management?
        - **Yes:** Refer to the flow chart
        - **No:** Describe denosumab and the current patient journey, using a flow chart

I would like to ask you about <u>convenience to patients</u> when they visit the hospital to receive their injections, for example some patients may travel some distance.

- What is your impression of the patients experience when they are receiving denosumab treatment in the hospital?
    - What feelings do they express when coming to the hospital?
        - Are they happy about something?
        - Are they looking forward to the visits or the treatment?
        - Sad?
        - Annoyed?
        - Nervous?
- Can you think of any ways that delivery of the service could be improved from the patient's perspective?
    - How do you think the patients would feel about visiting a community pharmacy instead of the hospital for follow up treatment and administration, similar to that provided by you?

- Is there anything you would like to add about <u>patient's convenience</u>?

Acceptance of community pharmacist supply and administration of denosumab

- Is there anything you would like to add about any concerns <u>you may have</u> associated with such a shift of care?
    - What problems might arise if the denosumab would be supplied and administered in the community pharmacy?
        - Is there anything that would be missed?
    - Is there anything that you do in these follow up visits that you think the pharmacists couldn't do?

- What advantages will there be if the denosumab would be supplied and administered in the community pharmacy (except patient convenience?
    - Anything the pharmacist could help with?
    - Are there things the pharmacists could do, that you don't do / can't do?
- Are there any elements of the management of osteoporosis that might not be able to be provided by the community pharmacist?

Acceptance of community pharmacist led pharmaceutical care package of medication review, adherence with medicines, falls assessment and need for calcium & vitamin D

Now I would like to discuss the potential role of community pharmacists in the wider management of osteoporosis

- How can a community pharmacy help with osteoporosis management besides administration of denosumab?
    - How would a pharmaceutical care package of medication review, adherence with medicines, falls assessment and need for calcium and Vitamin D help the patients
    - What might be missed compared to the hospital doing it?
        - What do you think about the quality compared to you, physicians or GPs doing it?
    - Is there anything that could make the management more convenient for the secondary health care system?
        - Risks
        - Benefits

- Do you see any changes that can be made to this flow chart that can make the process of management better?

- All in all, what are opinions regarding the potential shift of care?

- Is there anything you would like to add, or anything that you would like to elaborate on?

Questions for physicians

- Are you familiar with denosumab?
    - **Yes**: Go to the next question
    - **No:** Denosumab is a treatment for postmenopausal osteoporosis, with a restriction that it is used only in patients with a bone mineral density (BMD) T-score < -2.5 and ≥ -4.0 for whom oral bisphosphonates are unsuitable. It is a pre-filled syringe administered every six months as a subcutaneous injection by a nurse in the hospital, although NICE states that it should be used in Primary Care after being initiated by a specialist in secondary care. No blood monitoring is required other than in those at risk of hypocalcaemia (for example renal impairment).

- Do you have any patients who receive denosumab treatment?
    - **Yes**: How are you involved in the use of denosumab in osteoporosis management?
        - What do you perceive is your role?
        - Are you aware of the current process of management?
            - **Yes:** Refer to the flow chart
            - **No:** Describe denosumab and the current patient journey, using a flow chart
    - **No**: Are you aware of the current process of management?
        - **Yes:** Refer to the flow chart
        - **No:** Describe denosumab and the current patient journey, using a flow chart

I would like to ask you about <u>convenience to patients</u> when they visit the hospital to receive their injections, for example some patients may travel some distance.

- What is your impression of the patients experience about receiving denosumab when you propose starting the treatment?
    - What feelings do they express when coming to the hospital?
        - Are they happy about something?
        - Are they looking forward to the visits or the treatment?
        - Sad?
        - Annoyed?
        - Nervous?
- Can you think of any ways that delivery of the service could be improved from the patient's perspective?
    - How do you think the patients would feel about visiting a community pharmacy instead of the hospital for follow up treatment and administration, similar to that provided by the specialist nurses?

- Is there anything you would like to add about <u>patient's convenience</u>?

Acceptance of community pharmacist supply and administration of denosumab

- Is there anything you would like to add about any concerns <u>you may have</u> associated with such a shift of care?
    - What problems might arise if the denosumab would be supplied and administered in the community pharmacy?
        - Is there anything that would be missed?
    - Is there anything that the nurses do in these follow up visits that you think the pharmacists couldn't do?

- What advantages will there be if the denosumab would be supplied and administered in the community pharmacy, except patient convenience?
    - Anything the pharmacist could help with?
    - Are there things the pharmacists could do, that you don't do / can't do?
- Are there any elements of the management of osteoporosis that might not be able to be provided by the community pharmacist?

Acceptance of community pharmacist led pharmaceutical care package of medication review, adherence with medicines, falls assessment and need for calcium & vitamin D

Now I would like to discuss the potential role of community pharmacists in the wider management of osteoporosis

- How can a community pharmacy help with osteoporosis management besides administration of denosumab?
    - How would a pharmaceutical care package of medication review, adherence with medicines, falls assessment and need for calcium and Vitamin D help the patients
    - What might be missed compared to the hospital doing it?
        - What do you think about the quality compared to you, a nurse or a GP doing it?
    - Is there anything that could make the management more convenient for the secondary health care system?
        - Risks
        - Benefits

- Do you see any changes that can be made to this flow chart that can make the process of management better?

- All in all, what are opinions regarding the potential shift of care?

- Is there anything you would like to add, or anything that you would like to elaborate on?

Questions for patients (pilot)

I will start the interview by asking questions about your relationship with the community pharmacy. Community pharmacies are the local pharmacies in the high street or the mall, also known as the chemist. Then I will ask you about the denosumab treatment that you receive for the osteoporosis. In the end of the interview I will ask about osteoporosis care in general and how the pharmacy may contribute.

Establishing the interviewee's relationship with the pharmacy

- □ How often do you go to the community pharmacy?
- □ Do you go to the same community pharmacy?
- □ Have you accessed any of the additional services that they provide?
    - Some pharmacies provide other services, such as smoking cessation service, blood pressure monitoring or diabetes consultations
    - Does the pharmacist go through the medicines with you?
        - **Yes:** How does it help you?
        - **No:** Does anyone else do it?
            - Do you think it's a good idea?
            - How may it help you?
- □ What is your opinion about your community pharmacy and the care they deliver in general?

Current denosumab treatment and acceptance of community pharmacists supplying and administer denosumab

- □ Can you tell me about your experience of visiting the hospital to receive denosumab treatment?
    - Do you think it's convenient?
    - Does your denosumab injection affect anyone else?
        - Does anyone follow you to the hospital or drive you?
    - How do you feel about attending the hospital for your denosumab treatment?
        - Is there anything about your visit you like or dislike?
        - How much time does it take you to travel to the Western? *(Included in that moment based on the investigator's intuition. Was later included in the final interview guide)*
            - Do you wait a long time to see the nurse or the consultant when you are in the hospital? *(Included in that moment based on the investigator's intuition. Was later included in the final interview guide)*
        - How much time does it take you to travel to your community pharmacy? *(Included in that moment based on the investigator's intuition. Was later included in the final interview guide)*
- □ How could the pharmacy contribute or help you with the injection of denosumab that you receive?
- □ What do you think about the idea that the pharmacy supply and inject denosumab?
    - How would you feel about visiting a community pharmacy instead of the hospital?
    - Is there anything you would miss about the hospital?
        - □ Regarding the care you receive
    - Do you think the pharmacy could contribute or help you in a way that the hospital does not?
    - Do you think you would receive the same care in the pharmacy?

Acceptance of community pharmacist led pharmaceutical care package of medication review, adherence with medicines, falls assessment and need for calcium & vitamin D

Now I would like to talk about the osteoporosis care in general. So this is beside the denosumab injection.

- □ Do you have any ideas how a community pharmacy can help with your osteoporosis care?
  - Can you mention some changes that might make the provision of care more convenient for you?
- □ Is there any health care professional that ask you about your diet?
  - They might ask you about how much calcium and vitamin D you consume. This is to ensure that you get sufficient amounts of nutrients to keep your bone as strong as possible.
  - How would you feel if a pharmacist asked you about your diet, particularly calcium and vitamin D intake?
- □ If someone is diagnosed with osteoporosis, falling might be serious because the person might get a fracture. Does any health care professional ask you about falling?
  - What is your opinion about the pharmacist asking you questions about the risk of falling?
- □ Do you think there is anything that the pharmacist cannot do in terms of your osteoporosis care (or management) that the hospital or general practitioner (GP) can?
  - Is there anything that the hospital offers that the pharmacist couldn't offer?

□ All in all, what are your opinions regarding the potential shift of care from the hospital to the community pharmacy?

□ Is there anything you would like to add, or anything that you would like to elaborate on?

Questions for patients

I would like to start the interview by asking questions about your relationship with your community pharmacy. Community pharmacies are the local pharmacies on the high street or the shopping centre, also known as the chemist. Then I would like to ask you about the denosumab treatment that you receive for your osteoporosis. At the end of the interview I would like to ask about osteoporosis care in general and how the pharmacy may contribute.

Establishing the interviewee's relationship with the pharmacy.

- □ How often do you go to the community pharmacy?
  - How many times a month would you say you visit the community pharmacy?
- □ Do you always go to the same community pharmacy?
- □ Have you accessed any of the additional services that they provide?
  - Some pharmacies provide other services, such as stop smoking services, blood pressure monitoring or diabetes consultations.
  - Does the pharmacist go through your medicines with you?
    - **Yes:** How does it help you?
    - **No:** Does anyone else do it?
      - Do you think it's a good idea?
      - How may it help you?
- □ What is your opinion about your community pharmacy and the care they deliver in general?

Current denosumab treatment and acceptance of community pharmacists supplying and administering denosumab.

- □ Can you tell me about your experience of visiting the hospital to receive denosumab treatment?
  - Do you think it's convenient?
  - Does anyone come with you to the hospital or drive you there?
    - **Yes:** Can you explain?
  - How do you feel about attending the hospital for your denosumab treatment?
    - The pharmacist would receive the proper training that is needed to administer the injection.
    - Is there anything about your visit you like or dislike?
    - How much time does it take you to travel to the Western?
      - Do you wait a long time to see the nurse or the consultant when you are in the hospital?
    - How much time does it take you to travel to your community pharmacy?
- □ What does the nurse do during the denosumab visits?
- □ How could the pharmacy contribute or help you with the injection of denosumab that you receive?
- □ What do you think about the idea of the pharmacy supplying and administering denosumab?
  - Is there anything you would miss about the hospital visit?
    - □ Regarding the care you receive

- Do you think the pharmacy could contribute or help you in a way that the hospital does not?
- Do you think you would receive the same care in the pharmacy?

Acceptance of community pharmacist led pharmaceutical care package of medication review, adherence with medicines, falls assessment and need for calcium & vitamin D.

Now I would like to talk about osteoporosis care in general. So this is other than the denosumab injection.

□ Do you have any ideas how a community pharmacy can help with your osteoporosis care?
- Can you tell me of any changes that might make providing care more convenient for you?

□ Is there any health care professional that asks you about your diet?
- They might ask you about how much calcium and vitamin D you consume. This is to ensure that you get sufficient amounts of nutrients to keep your bones as strong as possible.
- How would you feel if a pharmacist asked you about your diet, particularly calcium and vitamin D intake?

□ If someone is diagnosed with osteoporosis, falling might be serious because the person might get a fracture (break a bone). Does any health care professional ask you about falling?
- What is your opinion about the pharmacist asking you questions about the risk of falling?

□ Do you think there is anything that the pharmacist cannot do in terms of your osteoporosis care (or management) that the hospital or general practitioner (GP) can?
- Is there anything that the hospital offers that the pharmacist couldn't offer?

□ All in all, what are your opinions regarding the potential moving of care from the hospital to the community pharmacy?

□ Is there anything you would like to add, or anything that you would like to elaborate on?

All patient questionnaires where in colours. Only the clinic version is presented with colours in the appendices.

DENOSUMAB TREATMENT OF OSTEOPOROSIS

Patient questionnaire

Denosumab (60 mg) is a medication used to treat postmenopausal osteoporosis. It is given as an injection under the skin, every six months. The patients usually attend the hospital to receive the injection.

Please answer the following questions honestly. It will take approximately 2 minutes. Please note that there are some statements which should be answered on a scale from strongly agree to strongly disagree. Your views are very important to the project and are highly appreciated. All responses are anonymous and confidential.
Please return the questionnaire to the osteoporosis specialist nurse.
Please only complete the questionnaire once – you may also receive a copy in the post.

Please tick the box that most closely matches your personal opinions (one tick per question or as specified).

Part 1:
Your local pharmacy (the pharmacy that you most often visit).

1. Do you personally visit the pharmacy to get your general medication/repeat prescription?

☐ **Yes** ☐ **No (skip to question 6)**

2. Do you regularly use the same pharmacy?

☐ **Yes** ☐ **No (skip to question 6)**

3. How do you travel to your local pharmacy?
You can tick more than one box.

☐ **Walk** ☐ **Bus** ☐ **Car** ☐ **Taxi** ☐ **Bicycle** _____ **Other (please specify)**

4. How much time does it take you to travel to your local pharmacy?

Please write the approximate time: _____ minutes.

5. I have a good relationship with my local pharmacy.

☐ **Strongly agree** ☐ **Agree** ☐ **Neither agree nor disagree** ☐ **Disagree** ☐ **Strongly disagree**

6. I take all my medication as prescribed.

☐ **Strongly agree** ☐ **Agree** ☐ **Neither agree nor disagree** ☐ **Disagree** ☐ **Strongly disagree**

DENOSUMAB TREATMENT OF OSTEOPOROSIS

Patient questionnaire

Please tick the box that most closely matches your personal opinions (one tick per question or as specified).

Part 2:
The hospital.

7. How do you travel to the hospital?
You can tick more than one box.

☐ Walk ☐ Bus ☐ Car ☐ Taxi ☐ Bicycle ☐ Train ☐ N/A _____ Other (please specify)

8. How much time does it take you to travel to the hospital?

Please write the approximate time: _____ minutes.

9. I have a good relationship with the nurses that give me the injection.

☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree

10. If you could choose to receive the injection at the hospital, the GP practice or the pharmacy, which one would you prefer?

☐ The pharmacy ☐ The GP practice ☐ The Hospital

Please provide a reason for your choice in the box below:

DENOSUMAB TREATMENT OF OSTEOPOROSIS

Patient questionnaire

Please tick the box that most closely matches your personal opinions (one tick per question or as specified).

Part 3:
The pharmacy delivering osteoporosis care and denosumab injection.

11. Does your GP or practice nurse currently ask you questions about risk of falling, your diet and/or your medicines?
You can tick more than one box.

☐ **Risk of falling** ☐ **Diet** ☐ **Medicines** ☐ **None of these**

12. Would you be comfortable with your pharmacist asking you questions about risk of falling, your diet and/or your medicines?
You can tick more than one box.

☐ **Risk of falling** ☐ **Diet** ☐ **Medicines** ☐ **None of these**

13. I am aware that community pharmacies currently provide services such as stop smoking, asthma and flu-vaccination.

☐ **Strongly agree** ☐ **Agree** ☐ **Neither agree nor disagree** ☐ **Disagree** ☐ **Strongly disagree**

14. I would be comfortable with a suitably trained pharmacist giving me the denosumab injection.

☐ **Strongly agree** ☐ **Agree** ☐ **Neither agree nor disagree** ☐ **Disagree** ☐ **Strongly disagree**

15. Additional comments: Please add any additional comments that you may have.

Thank you very much for your contribution to the project.

DENOSUMAB TREATMENT OF OSTEOPOROSIS

Patient questionnaire

Denosumab (60 mg) is a medication used to treat postmenopausal osteoporosis. It is given as an injection under the skin, every six months. The patients usually attend the hospital to receive the injection.

Please answer the following questions honestly. It will take approximately 2 minutes. Please note that there are some statements which should be answered on a scale from strongly agree to strongly disagree. Your views are very important to the project and are highly appreciated. All responses are anonymous and confidential.
Please return the questionnaire in the enclosed return envelope before 13th February 2013.

Please tick the box that most closely matches your personal opinions (one tick per question or as specified).

Part 1:
Your local pharmacy (the pharmacy that you most often visit).

1. Do you personally visit the pharmacy to get your general medication/repeat prescription?

☐ **Yes** ☐ **No (skip to question 6)**

2. Do you regularly use the same pharmacy?

☐ **Yes** ☐ **No (skip to question 6)**

3. How do you travel to your local pharmacy?
You can tick more than one box.

☐ **Walk** ☐ **Bus** ☐ **Car** ☐ **Taxi** ☐ **Bicycle** _____ **Other (please specify)**

4. How much time does it take you to travel to your local pharmacy?

Please write the approximate time: _____ minutes.

5. I have a good relationship with my local pharmacy.

☐ **Strongly agree** ☐ **Agree** ☐ **Neither agree nor disagree** ☐ **Disagree** ☐ **Strongly disagree**

6. I take all my medication as prescribed.

☐ **Strongly agree** ☐ **Agree** ☐ **Neither agree nor disagree** ☐ **Disagree** ☐ **Strongly disagree**

DENOSUMAB TREATMENT OF OSTEOPOROSIS

Patient questionnaire

Please tick the box that most closely matches your personal opinions (one tick per question or as specified).

Part 2:
The hospital.

7. How do you travel to the hospital?
You can tick more than one box.

☐ **Walk** ☐ **Bus** ☐ **Car** ☐ **Taxi** ☐ **Bicycle** ☐ **Train** ☐ **N/A** _____ **Other (please specify)**

8. How much time does it take you to travel to the hospital?

Please write the approximate time: _____ minutes.

9. I have a good relationship with the nurses that give me the injection.

☐ **Strongly agree** ☐ **Agree** ☐ **Neither agree nor disagree** ☐ **Disagree** ☐ **Strongly disagree**

10. If you could choose to receive the injection at the hospital, the GP practice or the pharmacy, which one would you prefer?

☐ **The pharmacy** ☐ **The GP practice** ☐ **The Hospital**

Please provide a reason for your choice in the box below:

DENOSUMAB TREATMENT OF OSTEOPOROSIS

Patient questionnaire

Please tick the box that most closely matches your personal opinions (one tick per question or as specified).

Part 3:
The pharmacy delivering osteoporosis care and denosumab injection.

11. Does your GP or practice nurse currently ask you questions about risk of falling, your diet and/or your medicines?
You can tick more than one box.

☐ **Risk of falling** ☐ **Diet** ☐ **Medicines** ☐ **None of these**

12. Would you be comfortable with your pharmacist asking you questions about risk of falling, your diet and/or your medicines?
You can tick more than one box.

☐ **Risk of falling** ☐ **Diet** ☐ **Medicines** ☐ **None of these**

13. I am aware that community pharmacies currently provide services such as stop smoking, asthma and flu-vaccination.

☐ **Strongly agree** ☐ **Agree** ☐ **Neither agree nor disagree** ☐ **Disagree** ☐ **Strongly disagree**

14. I would be comfortable with a suitably trained pharmacist giving me the denosumab injection.

☐ **Strongly agree** ☐ **Agree** ☐ **Neither agree nor disagree** ☐ **Disagree** ☐ **Strongly disagree**

15. Additional comments: Please add any additional comments that you may have.

Thank you very much for your contribution to the project.

PHARMACEUTICAL CARE OF OSTEOPOROSIS AND DENOSUMAB INJECTION IN COMMUNITY PHARMACIES

Pharmacist questionnaire

Denosumab is approved in NHS Scotland for the treatment of postmenopausal osteoporosis, with a restriction that it is used only in patients with a bone mineral density (BMD) T-score < -2.5 and ≥ -4.0 for whom oral bisphosphonates are unsuitable.
Denosumab (60 mg) is currently provided as a single dose in a prefilled syringe which is administered subcutaneously every six months.

Please answer the following questions honestly. It will take approximately 2 minutes. Your views are very important to the project and are highly appreciated. All responses are anonymous and confidential.
Please return the questionnaire by sending it by fax to 0 131 537 2370 before 26th February 2013.

The questionnaire contains statements that are answered on a scale from strongly disagree to strongly agree. Please tick the box that most closely matches your personal opinions (one tick per statement).

Q	**1 = Strongly agree 2 = Agree**	**3 = Neither agree nor disagree**	**4 = Disagree 5 = Strongly disagree**	**1**	**2**	**3**	**4**	**5**
1	I feel comfortable talking about osteoporosis and its treatment with patients.							
2	I feel comfortable doing a falls assessment with an osteoporosis patient.							
3	I feel comfortable talking to a patient about diet and lifestyle as a part of osteoporosis management.							
4	My pharmacy currently undertakes medication reviews.							
5	Through medication reviews I am able to encourage patients to adhere to their medicines.							
6	I provide clinics/services for other conditions such as flu-vaccines.							
7	I would feel comfortable administering a subcutaneous injection of denosumab.							
8	I would need more training before I could administer a subcutaneous injection of denosumab.							
9	My pharmacy could arrange appointments for the patients to receive denosumab injections in the pharmacy.							
10	I would be keen to deliver an osteoporosis service.							
11	I would offer the osteoporosis service only if there were proper remuneration.							
12	Is the pharmacy independent or multiple? (please tick appropriate box)							
			Independent					
			Multiple					
13	How many years of pharmacy experience do you have?							
			Please write number of years:					

Thank you very much for your contribution to the project

11/02/2013 Department of Pharmacy, Western General Hospital

NHS Lothian

NHS Lothian

Denosumab in osteoporosis management

GP questionnaire

This is not the design of the questionnaire in Surveymonkey. Due to copyright issues, the screen capture from Surveymonkey® is not included as an appendix. It should be emphasised that the content is identical.

Page 1/2:

Denosumab is approved in NHS Scotland for the treatment of postmenopausal osteoporosis, with a restriction that it is used only in patients with a bone mineral density (BMD) T-score < -2.5 and ≥ -4.0 for whom oral bisphosphonates are unsuitable.

Denosumab (60 mg) is currently provided as a single dose in a prefilled syringe which is administered subcutaneously every six months by a nurse at the hospital.

The questionnaire contains statements that are answered on a scale from strongly agree to strongly disagree. Please tick the box that most closely matches your personal opinions (one tick per statement).

Page 2/2:

Q	**1 = Strongly agree 2 = Agree**	**3 = Neither agree nor disagree**	**4 = Disagree 5 = Strongly disagree**	**1**	**2**	**3**	**4**	**5**
1	After initiation in a hospital setting, denosumab should be prescribed by general practitioners.							
2	The general practitioner should be responsible for blood monitoring related to the use of denosumab, such as calcium and renal function.							
3	Denosumab could be administered at my practice.							
4	Other aspects of osteoporosis management could be provided at my practice, such as falls and dietary assessment.							
5	A community pharmacist could administer the denosumab injection in appropriate facilities similar to those used for other services, such as smoking cessation, asthma and flu-vaccination.							
6	A community pharmacist could undertake other aspects of osteoporosis management, such as falls or dietary assessment.							
7	A community pharmacist could undertake a medication review for patients with osteoporosis.							
8	A community pharmacist can encourage adherence with medicines.							
9	A qualified pharmacist independent prescriber could manage osteoporosis through making appropriate changes to prescription medicine.							

Please write any additional comments in this textbox

Thank you very much for your contribution to the project

11/02/2013 Department of Pharmacy, Western General Hospital

DENOSUMAB TREATMENT OF OSTEOPOROSIS

Patient questionnaire

Denosumab (60 mg) is a medication used to treat postmenopausal osteoporosis. It is given as a subcutaneous injection every six months. The patients usually attend the hospital to receive the injection.

Please answer the following questions honestly. It will take approximately 2 minutes. Your views are very important to the project and are highly appreciated. All responses are anonymous and confidential.

Please return the questionnaire in the enclosed envelope.

Please tick the box that most closely matches your personal opinions (one tick per question) or as specified.

Part 1:
Your local pharmacy (the pharmacy that you most often visit).

QUESTION 1: Do you personally visit the pharmacy to get your medication?

☐ **Yes** ☐ **No (skip to question 6)**

QUESTION 2: Do you regularly use the same pharmacy?

☐ **Yes** ☐ **No (skip to question 6)**

QUESTION 3: How do you travel to your local pharmacy?
You can tick more than one box.

☐ **Walk** ☐ **Bus** ☐ **Car** ☐ **Taxi** ☐ **Bicycle** _____ **Other (please specify)**

QUESTION 4: How much time does it take you to travel to your local pharmacy?

Please write the approximate time: _____ minutes.

QUESTION 5: I have a good relationship with my local pharmacy.

☐ **Strongly agree** ☐ **Agree** ☐ **Neither agree nor disagree** ☐ **Disagree** ☐ **Strongly disagree**

QUESTION 6: I take all my medication as prescribed.

☐ **Strongly agree** ☐ **Agree** ☐ **Neither agree nor disagree** ☐ **Disagree** ☐ **Strongly disagree**

DENOSUMAB TREATMENT OF OSTEOPOROSIS

Patient questionnaire

Please tick the box that most closely matches your personal opinions (one tick per question) or as specified.

Part 2:
The hospital.

QUESTION 7: How do you travel to the hospital?
You can tick more than one box.

☐ Walk ☐ Bus ☐ Car ☐ Taxi ☐ Bicycle ☐ Train ☐ N/A _____ Other (please specify)

QUESTION 8: How much time does it take you to travel to the hospital?

Please write the approximate time: _____ minutes.

QUESTION 9: I have a good relationship with the nurses that give me the injection.

☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree

QUESTION 10: If you could choose to receive the injection at the hospital, the GP practice or the pharmacy, which one would you choose?

☐ The pharmacy ☐ The GP practice ☐ The Hospital

Please provide a reason for your choice in the box below:

DENOSUMAB TREATMENT OF OSTEOPOROSIS

Patient questionnaire

Please tick the box that most closely matches your personal opinions (one tick per question) or as specified.

Part 3:
The pharmacy delivering osteoporosis care and denosumab injection.

QUESTION 11: Does your GP or practice nurse currently ask you questions about risk of falling, your diet and/or your medicines?
You can tick more than one box.

☐ Risk of falling ☐ Diet ☐ Medicines ☐ None of these

QUESTION 12: Would you be comfortable with your pharmacist asking you questions about risk of falling, your diet and/or your medicines?
You can tick more than one box.

☐ Risk of falling ☐ Diet ☐ Medicines ☐ None of these

QUESTION 13: I am aware that community pharmacies currently provide services such as stop smoking, asthma and flu-vaccination.

☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree

QUESTION 14: I would be comfortable with a suitably trained pharmacist giving me the denosumab injection.

☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree

Additional comments: Please add any additional comments that you may have.

Thank you very much for your contribution to the project.

Questionnaire to the GPs in Lothian

Information in Surveymonkey (first page of the questionnaire):

Denosumab is approved in NHS Scotland for the treatment for postmenopausal osteoporosis, with a restriction that it is used only in patients with a bone mineral density (BMD) T-score < -2.5 and ≥ -4.0 for whom oral bisphosphonates are unsuitable.

Denosumab (60 mg) is currently provided as a single dose in a prefilled syringe which is administered subcutaneously every six months by a nurse at the hospital.

The questionnaire contains statements that is answered on a scale from strongly disagree to strongly agree. Please tick the box that most closely matches your personal opinions (one tick per question).

Question 1: After initiation in a hospital setting, denosumab should be prescribed by general practitioners.
Strongly agree – Agree - Neither agree, nor disagree – Disagree - Strongly disagree

Question 2: The general practitioner should be responsible for blood monitoring related to the use of denosumab, such as calcium and renal function.
Strongly agree – Agree - Neither agree, nor disagree – Disagree - Strongly disagree

Question 3: Denosumab could be administered at my practice.
Strongly agree – Agree - Neither agree, nor disagree – Disagree - Strongly disagree

Question 4: Other aspects of osteoporosis management could be provided at my practice, such as falls and dietary assessment.
Strongly agree – Agree - Neither agree, nor disagree – Disagree - Strongly disagree

Question 5: I am aware that community pharmacies currently provide services such as stop smoking, asthma and flu-vaccination.
Strongly agree – Agree - Neither agree, nor disagree – Disagree - Strongly disagree

Question 6: A community pharmacist could administer denosumab injection in appropriate facilities.
Strongly agree – Agree - Neither agree, nor disagree – Disagree - Strongly disagree

Question 7: A community pharmacist could undertake other aspects of osteoporosis management, such as falls or dietary assessment.
Strongly agree – Agree - Neither agree, nor disagree – Disagree - Strongly disagree

Question 8: A community pharmacist could undertake a medication review for patients with osteoporosis.
Strongly agree – Agree - Neither agree, nor disagree – Disagree - Strongly disagree

Question 9: A community pharmacist can encourage adherence with medicines.
Strongly agree – Agree - Neither agree, nor disagree – Disagree - Strongly disagree

Question 10: A qualified pharmacist independent prescriber could manage osteoporosis through making appropriate changes to prescription medicine.
Strongly agree – Agree - Neither agree, nor disagree – Disagree - Strongly disagree

Thank you very much for your contribution to the project

Please write any additional comments in this textbox

Department of Pharmacy
Western General Hospital
Crewe Road South
Edinburgh
EH4 2XU

CERTIFICATE NO: FS 31228

NHS Lothian

Lead Pharmacist WGH	Sheena Kerr	0131 537 1206
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Head of Education, Research and Development:	Moira Kinnear	0131 537 1216
Lead Pharmacist, Edinburgh Cancer Centre	Heather Dalrymple	0131 537 2337
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Fax Number: 0131 537 2370

Main Switchboard Tel: 0131 537 1000

14/02/13

REMINDER LETTER

Dear [title] [surname]

You have received this letter because we previously (31st January 2013) sent a questionnaire about osteoporosis care and denosumab. We would like to invite you to participate in a project regarding osteoporosis and the medicine that you receive, denosumab.

If you have already completed the survey, we would like to thank you for your contribution. If you did not receive the initial questionnaire please contact us and we will send a questionnaire. If you have not yet found time to respond, we would appreciate if you are able to provide your opinions by completing and returning the questionnaire before 21st February. Please use the return envelope which was sent with the questionnaire.

We would like to remind you that there are no risks if you choose to take part. The benefits are that your thoughts and ideas will be considered in the design of future services. You are free to decline the opportunity to be a part of this project, and if you decide to do this, it will not affect the healthcare that you receive in any way.

If you have any further questions, please do not hesitate to contact us.

Thank you in anticipation for your contribution.

Yours sincerely,

Ben T. Henriksen
Masters Student in Pharmacy
and honorary member of staff,
NHS Lothian, Pharmacy Service
0131 537 1212

C. Callaghan
Carole Callaghan
Advanced Clinical Pharmacist
in Rheumatology
Western General Hospital
0131 537 4001

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Departmental Administrator	Lynn Guyatt	0131 537 2499	lynn.guyatt@luht.scot.nhs.uk

Fax Number: 0131 537 2370

Main Switchboard Tel: 0131 537 1000

19/02/13

REMINDER LETTER

To all the community pharmacies in Lothian,

You have received this letter because we previously (11th February 2013) sent a questionnaire about osteoporosis care and denosumab.

This is a reminder of an invitation to take part in a project that explores opinions about the use of denosumab in osteoporosis treatment in NHS Lothian. This project will consider if denosumab can be provided differently in the future.

If you have already completed the survey, we would like to thank you for your contribution and you can ignore this reminder. If you did not receive the initial questionnaire or if you have not found time to respond, we would appreciate if the responsible pharmacist is able to provide his/hers opinions and return the questionnaire by sending it by fax to 0 131 537 2370.

Your participation will take about 2 minutes of your time and your contribution may influence the future management of osteoporosis. Please complete and return the questionnaire before 4th March 2013.

If you have any further questions, please do not hesitate to contact us.

Thank you in anticipation for your contribution.

Yours faithfully,

Ben T. Henriksen,
Masters Student in Pharmacy

0131 537 1212

C. Callaghan
Carole Callaghan
Advanced Clinical Pharmacist in Rheumatology
Western General Hospital

0131 537 4001

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Fax Number: 0131 537 2370

Main Switchboard Tel: 0131 537 1000

NHS Lothian

19/02/13

To all GPs in Lothian,

You have received this e-mail because we previously (7th February 2013) sent a questionnaire about osteoporosis care and denosumab.

This is a reminder of an invitation to take part in a project that explores opinions about the use of denosumab in osteoporosis treatment in NHS Lothian. This project will consider if denosumab can be provided differently in the future.

If you have already completed the survey, we would like to thank you for your contribution and you can ignore this reminder. If you did not receive the initial questionnaire or if you have not found time to respond, we would appreciate if you are able to provide your opinions and return the questionnaire by following this link:

http://www.surveymonkey.com/s/denosumab-in-osteoporosis-management

Your participation will take about 2 minutes of your time and your contribution may influence the future management of osteoporosis. Please complete the questionnaire before 28th February 2013.

The results will be published as an MSc in Pharmacy at the University of Tromso, Norway, a copy of which may be available on request.

If you have any further questions, or if you want a copy of the project protocol, please do not hesitate to contact us.

Thank you in anticipation of your contribution.

Yours faithfully,

Ben T. Henriksen,
Masters Student in Pharmacy

0131 537 1212

Carole Callaghan
Advanced Clinical Pharmacist in Rheumatology
Western General Hospital
0131 537 1710

Supply and administration of denosumab for patients with osteoporosis in primary care – a qualitative exploration of opinions to assess feasibility of practice development

PART 1: The pharmacy					
1: Do you personally visit the pharmacy to get your general medication/repeat prescription?	**2: Do you regularly use the same pharmacy?**	**3: How do you travel to your local pharmacy?**	**4: How much time does it take you to travel to your local pharmacy?**	**5: I have a good relationship with my local pharmacy**	**6: I take all my medication as prescribed**
1 = Yes	1 = Yes	1 = Walk	Time in minutes	5 = Strongly agree	5 = Strongly agree
0 = No	0 = No	2 = Bus		4 = Agree	4 = Agree
		3 = Car		3 = Neither agree nor disagree	3 = Neither agree nor disagree
		4 = Taxi		2 = Disagree	2 = Disagree
		5 = Bicycle		1 = Strongly disagree	1 = Strongly disagree
		6 = Wheelchair			

PART 2: The hospital			
7: How do you travel to the hospital?	8: How much time does it take you to travel to the hospital?	9: I have a good relationship with the nurses that give me the injection	10: If you could choose to receive the injection at the hospital, the GP practice or the pharmacy, which one would you prefer?
1 = Walk	Time in minutes	5 = Strongly agree	1 = The pharmacy
2 = Bus		4 = Agree	2= The GP practice
3 = Car		3 = Neither agree nor disagree	3 = The hospital
4 = Taxi		2 = Disagree	
5 = Bicycle		1 = Strongly disagree	
6 = Train			
7 = Ambulance service or patient transportation			
0 = N/A			

PART 3: The pharmacy delivering osteoporosis care and denosumab injection				
11: Does your GP or practice nurse currently ask you questions about risk of falling, your diet and/or your medicines?	12: Would you be comfortable with your pharmacist asking you questions about risk of falling, your diet and/or your medicines?	13: I am aware that community pharmacies currently provide services such as stop smoking, asthma and flu-vaccination	14: I would be comfortable with a suitably trained pharmacist giving me the denosumab injection	15: Additional comments
0 = None of these	0 = None of these	5 = Strongly agree	5 = Strongly agree	Written as text
1 = Risk of falling	1 = Risk of falling	4 = Agree	4 = Agree	
2 = Diet	2 = Diet	3 = Neither agree nor disagree	3 = Neither agree nor disagree	
3 = Medicines	3 = Medicines	2 = Disagree	2 = Disagree	
		1 = Strongly disagree	1 = Strongly disagree	

Statement or question	Coding
1 to 10	5: Strongly agree
	4: Agree
	3: Neither agree, nor disagree
	2: Disagree
	1: Strongly disagree
12	1: Independent
	2: Multiple
13	Time in years

Statement or question	Coding
All statements (1-9)	5: Strongly agree
	4: Agree
	3: Neither agree, nor disagree
	2: Disagree
	1: Strongly disagree

The patient questionnaire

4: How much time does it take you to travel to your local pharmacy?	n	Percent
0-10 minutes	47	70.1 %
11-20 minutes	15	22.4 %
21-30 minutes	4	6.0 %
31-40 minutes	1	1.5 %
Total (percent of questionnaires included)	67	(72.8 %)
Mean	11.6	minutes
SD	7.0	minutes
Minimum	4	minutes
1st quartile	5.5	minutes
Median	10	minutes
3rd quartile	15	minutes
Maksimum	35	minutes

8: How much time does it take you to travel to the hospital?	n	Percent
0-10 minutes	1	1.2 %
11-20 minutes	10	11.6 %
21-30 minutes	16	18.6 %
31-40 minutes	10	11.6 %
41-50 minutes	19	22.1 %
51-60 minutes	17	19.8 %
>60 minutes	13	15.1 %
Total (percent of questionnaires included)	86	(93.5 %)
Mean	46.3	minutes
SD	21.7	minutes
CI	4.6	minutes
Upper CI	50.9	minutes
Lower CI	41.7	minutes
Minimum	7	minutes
1st quartile	30	minutes
Median	45	minutes
3rd quartile	60	minutes
Maximum	120	minutes

10: If you could choose to receive the injection at the hospital, the GP practice or the pharmacy, which one would you prefer?	n	Percent
The pharmacy	18	21.4 %
The GP practice	58	69.0 %
The hospital	13	15.5 %
Total	89	
Some patients ticked more than one box:		
Completed questions (percent of questionnaires included)	84	(91.3%)

10: Comments
Convenience (n = 83) Patients who stated convenience as a reason for their choice: n = 61*
The one I chose is closer than the hospital (saves a travel) (n = 50)
Easier to get to (n = 14)
The nurse comes to my house to give the injection (n = 3)
I am currently happy going to the hospital, but when I can't drive I would rather og to the GP practice (n = 1)
It's difficult getting a parking spot at the hospital (n = 4)
More flexibility with appointments (n = 1)
As I have to travel to the Western Hospital by car or train and taxi, I would prefer to have my injection done at either St. Johns Hospital or my pharmacy or GP practice as I have other health issues (n = 1)
The pharmacy and the GP practice are in the same health centre. So I would be happy to attend either (n = 1)
As long as I get injections or any other treatment to help my condition, any of them would do
I am physically unable to travel (n = 1)
I am depending on help to get to the hospital (n = 3)
I am happy to get the injection at the pharmacy (n = 1)
No appointment required (n = 1)
The pharmacy might be very busy if many people went for their injections (n = 1)
It's closer to my home (NRIE). Otherwise I would choose GP practice (n = 1)

*Patients stated more than one of the convenience comments, but was counted as one

Health care professionals being familiar with other conditions/medication (n = 13) Patients who stated convenience as a reason for their choice: n = 8*
Denosumab is a very new drug with possible serious side effects (n = 2)
The doctor is aware of your general health (n = 2)
The doctor is aware of your regular medication (n = 2)
The doctor is in a better position to discuss any problems or questions and give advice (n = 1)
I need to consult regularly for other matters (n = 4)
The GP have more expertise than in the pharmacies (n = 1)
The staff at the pharmacy is not qualified giving injections (n = 1)

*Patients stated more than one of the convenience comments, but was counted as one

Pharmacy environment (n = 13)
Patients who stated convenience as a reason for their choice: n = 10*
Local pharmacies do not do injections (n = 1)
The pharmacy has parking problems (n = 1)
The staff at the pharmacy is not acceptable to me (n = 1)
The nurses are more experienced giving injections (n = 2)
The pharmacy environment is not comfortable (n = 1)
I will only choose the pharmacy if it is my local pharmacy (n = 1)
The staff at the pharmacy changes frequently (n = 2)
I have to queue at the pharmacy (n = 1)
There is no privacy at the pharmacy (n = 3)

*Patients stated more than one of the convenience comments, but was counted as one

Prefer the hospital (n = 17)
Patients who stated convenience as a reason for their choice: n = 12*
I feel it is better to og into the hospital (n = 1)
The hospital staff have more expertise than in the pharmacies (n = 7)
The GP practice is full of infectious patients (n = 1)
The procedure was over in a very short time without waiting for our appointment (n = 1)
I'm used to the hospital (n = 2)
I may change my mind in the future (n = 1)
I am physically unable to attend the pharmacy (n = 2)
The hospital is the only option (n = 1)
It's day out for me. I don't go out on my own (n = 1)

*Patients stated more than one of the convenience comments, but was counted as one

Relationship with the nurses (n = 11)
Patients who stated convenience as a reason for their choice: n = 8*
I have a good relationship with the nurses (n = 6)
I'm used to the practice nurse doing other tasks such as BP and blood tests (n = 1)
The osteoporosis nurse specialists can reduce the queue (n = 2)
I am used to the nurses (n = 2)

*Patients stated more than one of the convenience comments, but was counted as one

PART 3: The pharmacy delivering osteoporosis care and denosumab injection		
11: Does your GP or practice nurse currently ask you questions about risk of falling, your diet and/or your medicines?	n	Percent
0 = None of these	40	47.1 %
1 = Risk of falling	19	22.4 %
2 = Diet	19	22.4 %
3 = Medicines	39	45.9 %
Total	117	
Total answers	85	(74.6 %)

See results for details regarding the combinations of answers

12: Would you be comfortable with your pharmacist asking you questions about risk of falling, your diet and/or your medicines?	n	Percent
0 = None of these	22	27.2 %
1 = Risk of falling	37	45.7 %
2 = Diet	31	38.3 %
3 = Medicines	54	66.7 %
Total	144	
Total answers	81	(71.1 %)

See results for details regarding the combinations of answers

15: Additional comments
Convenience (n = 9)
I think my comments at question 10 would apply here also [comment from 10: I am currently happy going to the hospital, but when I can't drive I would rather og to the GP practice]
Would strongly prefer to have injections administered at GP surgery rather than having to attend hospital
Save a journey
GP and pharmacy are within approx 10 mins walk. I would save an extended journey to hospital (2 buses required). Unsure if GP or practice nurse would administer. Both would require an appointment
But GP practice is nearer to my home
It would be much easier to receive this injection locally, saving time and money
Would rather go to local GP
Nurse came to my house gave me the injection on XX/XX/XXXX
But would much prefer my own doctor or local nurse
Health care professionals being familiar with other conditions/medication (n = 6)
Is there any reason why patients cannot have the choice of where they receive their injection, rather than perhaps having to attend someone they are not comfortable with?
I only go to the doctor if it is necessary and find he is very understanding
I would be more comfortable with a doctor available
Would really prefer my doctor or practice nurse for the injections
I already have to deal with a number of health care professionals in several locations. Attending the pharmacy for treatment/advice would add one more point of call. At present collection of medicines there, a straightforward task, can be carried out for me (I have RA and mobility difficulties)
I prefer a doctor to deal with all my medical problems
Pharmacy environment (n = 7)
Pharmacists are not acceptable and there are parking problems
Not aware that pharmacists are qualified to discuss or give advice on osteoporosis. Concerned whether one would still be monitored in the long run by the hospital
Unsure! There is no privacy in Boots and usually a queue + they seem overworked as it is
My least desirable option would be the pharmacy. This is due to lack of confidence in staff and lack of privacy. Again would feel more confident with attending hospital
Regarding question 12: Do not mind as long as there was element of privacy involved

While I agree with pharmacists giving injections, I don't want to be queuing with methadone users, therefore I prefer GP surgery
I would be happy to have a trained pharmacist give me the injection provided it could be given in a private room

Prefer the hospital (n = 0)

Relationship with the nurses (n = 3)
I think I would prefer the nurse to give me the denosumab injection
The injection has been very beneficial to me and, if possible, it would be good to receive it at my GPs practice
I have nothing but praise for all the assistance received from hospital. Best surgery and nursing services which I have received since coming to reside in Edinburgh.

Other comments (n = 13)
I am not able to answer 11-14. This form has taken longer than 2 minutes of my time
For myself the injection is most suitable. The tablets do not agree with me. Makes me unwell. There were no reactions from the injection.
Unable to attend
I have discussed with my GP, who would be happy for me to have it at the surgery
I have now decided, after consultation with the hospital doctor to discontinue the injection
I am deaf. I have angina, asthma, osteoporosis and rheumatism? Wrong spelling sorry. And always sick many times. But otherwise I am fine. Thanks to my GP.
I am 84 years of age and not to fit to travel
Wish to have som information about visiting the osteoporosis clinic, as pain in back is getting crippling
I have no complaints about GP nurse or pharmacist. They are all very helpful and understanding
My daughter speaks to the girls in the pharmacy who are very kind and helpful
Would still like to have contact with hospital. If we free up the nurse specialists' time would it be possible to have a yearly club to discuss how patients are progressing and new innovations.
Found the answer boxes unsuitable and confusing and feel a straight yes or no would have been more helpful
I have no objections where it is done

Chi square – question 13 and 14

	Clinic aware (expected)	Clinic not aware (expected	Total
Denosumab comfortable	35 (32.3)	12 (14.7)	47
Denosumab not comfortable	20 (22.7)	13 (10.3)	33
Total	55	25	80

The neither agree, nor disagree category was included as "clinic not aware" and "denosumab not comfortable"

Chi square = 1.734 with 1 degree of freedom – p-value = 0.19

Only the patients who answered to both questions were included in the analysis to be able to compare the two items. The patients who answered to either item 13 or 14 were excluded.

Excluded: Patient 26 – completed item 13 only (Agree)
Patient 63 – completed item 14 only (Disagree)
Patient 64 – completed item 13 only (Strongly agree)
Patient 66 – completed item 14 only (Strongly disagree)

Chi square – statement 5 and 9

	Pharmacy (expected)	Nurse (expected)	Total
Good relationship	57 (61.5)	86 (81.5)	143
Not good relationship	11 (6.5)	4 (8.5)	15
Total	68	90	158

The neither agree, nor disagree category was included as "not a good relationship".

Chi- square = 6.205 with 1 degree of freedom – p-value = 0.013

The pharmacy questionnaire

Additional data

Question 13: How many years of pharmacy experience do you have?	Number	Percentage
1: 0-5 years	9	16.7 %
2: 6-10 years	8	14.8 %
3: 11-15 years	11	20.4 %
4: 16-20 years	8	14.8 %
5: 21-30 years	11	20.4 %
6: Over 30 years	7	13.0 %
Total	54	100.0 %

Mean	16.8	years
SD	10.8	years
Minimum	0.25	years
1st quartile	7	years
Median	15	years
3rd quartile	25	years
Maximum	35	years

Advantages from patient perspective – subtheme: Additional ideas

Two additional ideas were suggested by the interviewees in addition to the proposed service. Prevention of osteoporosis was proposed as a possible additional service in community pharmacies where recommending bone protecting medication to those who receive steroid treatment was one group of patients mentioned in particular. Recommendation would be done by contacting their GP.

Extra information about osteoporosis in general and general medication was regarded as beneficial for the patients, and a task a pharmacist could carry out. A local education or awareness night for patients was also mentioned as a potential service delivered by a pharmacist to offer more information and regarded as convenient when delivered locally. A question was included in the pharmacy questionnaire to obtain opinions regarding discussing osteoporosis with the patient.

"I think, sort of, you know, education sessions that could be organised locally by community pharmacists or just one-to-one sessions with the patients. Quick overview of health and lifestyle and diet and other medications that they are on." (P2)

"I just don't think when you come to the hospital they have the time to actually sit down and really, sort of, talk through, (...) *I just, you know, didn't feel that, well, you know, anybody really had the time to really sit down and talk to you about, you know, what you could do.* (...) *I think they* [pharmacists] *could* [give information about osteoporosis] *if they had the time to do that.* (...) *But certainly the hospital just don't have time."* (Pa3)

Physician 1 expressed that assessment of postural hypotension could be included in the assessment of falls risk.

"And as far as I understand you can get... you do get your blood pressure and things like that checked in pharmacy, so you know, you could potentially check whether there is... somebody's... what their standing blood pressures are like and see if it drop dramatically when they stand up if they feeling dizzy. And again do we need to adjust the medication, so I would say, there's bone things and there's also falls and postural stability things where a community pharmacists could easily have a role." (P1)

Supply and administration of denosumab for patients with osteoporosis in primary care – a qualitative exploration of opinions to assess feasibility of practice development

PROJECT PROTOCOL

Investigator: Ben T. Henriksen, Pharmacy Student, University of Tromso and University of Strathclyde,

Honorary member of staff, NHS Lothian, Pharmacy Service

Clinical supervisor: Carole Callaghan, Advanced clinical Pharmacist, Rheumatology, Western General Hospital and Honorary Lecturer, University of Strathclyde

Academic supervisor: Moira Kinnear, Head of Pharmacy Education, Research & Development, NHS Lothian and Honorary Senior Lecturer University of Strathclyde

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Introduction

Denosumab (Prolia®) is a human monoclonal immunoglobin G2 (IgG2) antibody, licensed in the UK for the treatment of osteoporosis in postmenopausal women at increased risk of fractures (1, 2). It is also licensed for the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures (3), but this indication will not be included for the purposes of this project.

Denosumab targets and binds with high affinity and specificity to RANKL (receptor activator of nuclear factor-κ B (NFκB) ligand), preventing activation of its receptor, RANK (receptor activator of nuclear factor-κ B (NFκB)), on the surface of osteoclast precursors and osteoclasts (4). Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function and survival, thereby decreasing bone resorption in cortical and trabecular bone (5).

Denosumab was approved for use in Scotland by the Scottish Medicines Consortium (SMC) in November 2010, with a restriction that it is used only in patients with a bone mineral density (BMD) T-score < -2.5 and ≥ -4.0 for whom oral bisphosphonates are unsuitable due to contraindication, intolerance or inability to comply with the special administration instructions (2). Denosumab was then accepted for use within National Health Service (NHS) Lothian by the Formulary Committee (FC) in April 2011 (6). It was not accepted at that time as suitable for shared care, as the General Practice Prescribing Committee (GPPC) stated:

"Denosumab is a recently licensed drug and there is no experience of its use in Lothian. Therefore, in line with advice given by Formulary Committee, it is felt that it is inappropriate for this drug to be used under a shared care agreement until there is more experience of its use locally.

Pressure on Practice Nurse and GP (General Practitioner) time for drug administration and monitoring, including taking blood tests and interpreting and communicating results, is steadily increasing. At the same time, phlebotomy services in the community have been withdrawn. This is particularly relevant for drugs like denosumab which is likely to be prescribed for a number of housebound patients, where monitoring and administration would involve home visits. This is another important factor in the committee's decision not to approve the denosumab SCP (Shared Care Protocol)."

The decision to initiate denosumab is made by a consultant in secondary care, where baseline investigations are completed. It is administered at a dose of 60mg by the subcutaneous route every 6 months (4). No additional blood monitoring is required other than in those at risk of hypocalcaemia e.g. renal impairment or on dialysis (4), where monitoring would be undertaken as a matter of routine anyway. As a result of the rejection of a shared care approach (6), patients eligible for this treatment are required to attend the Western General Hospital every 6 months for the purposes of receiving this injection (self-administration by the patient is not considered a viable option as most patients are

elderly, on many medications and may find it difficult to remember to inject on a 6-monthly basis). The current practice is not a patient-focused approach to care.

Denosumab is recommended by the National Institute of Health and Clinical Excellence (NICE) as a treatment option for primary and secondary prevention of osteoporotic fractures in postmenopausal women at increased risk of fractures who are “unable to comply with the special instructions for administering” alendronic acid and either risedronate or etidronate, or, who have a contraindication to or intolerance of these treatments (1). This NICE guidance has been accepted in Wales where the All Wales Medicines Strategy Group guidance on the use of denosumab states that “denosumab should be initiated by a specialist within secondary care for the first two doses (one year) and thereafter prescribing and administration responsibility may be transferred to primary care” (7). Indeed, many health boards throughout Scotland have adopted a similar approach, with the first dose provided in secondary care and subsequent doses provided in primary care (usually associated with a contract cost).

This project proposes to evaluate the potential for community pharmacy involvement in the provision of pharmaceutical care to patients initiated on treatment with denosumab for the treatment of postmenopausal osteoporosis. This would involve canvassing the opinions of community pharmacists throughout NHS Lothian regarding:

- Provision of a medication review
- Administration of denosumab following assessment to ensure appropriateness of subsequent dose
- Falls assessment through administration of a questionnaire and sit-to-stand test.

This potential shift of care would imply that the pharmacists in the community pharmacies would have to learn how to inject denosumab subcutaneously. This challenge has been solved before when pharmacists started injecting influenza-vaccines about ten years ago (8).

Denosumab (Prolia®) is a pre-filled syringe, so a challenge regarding the pharmacy premises will be the space required for the employees, as well as the privacy for the patient. According to NHS Lothian, 92% of the pharmacies have a private area or room (9). Another issue is the handling of waste (including syringes) although this was not reported as a problem in vaccination (8).

There are several examples of assessments and interventions in community pharmacies regarding the treatment for osteoporosis (10). A recently published article describes how a community

pharmacy can determine overall calcium intake and to calculate fracture risk (FRAX®-score) by collecting information over the phone (11).

There is a potential for community pharmacies to extend the role in the management of this condition. Future research should evaluate pharmacist interventions. This project explores opinions to inform the design of such interventions.

Aim

To investigate the potential for community pharmacists to deliver a pharmaceutical care service for the management of osteoporosis that includes supply and administration of denosumab in addition to adherence, falls assessment, medication review and need for calcium and vitamin D.

Objectives

1. Propose potential pathway(s) of care for the shared management of osteoporosis across secondary and primary care

2. Through semi-structured interviews obtain opinions from a range of healthcare professionals and patients about processes for management of osteoporosis to inform design of questionnaires to send to community pharmacists, GPs and patients who attend hospital for denosumab treatment

3. Obtain views of stakeholders in the potential re-design of services

4. Make recommendations for future service delivery

Subjects and Setting

A convenience sample of two specialist nurses, three physicians, a GP and a community pharmacist in addition to two patients who attend the osteoporosis clinic shall be invited to participate in semi-structured interviews.

A self-administered questionnaire will be sent to all GPs (n ≈ 500) and community pharmacies (n ≈ 180) in NHS Lothian and a third questionnaire will be sent to all patients (n ≈ 112) who attend the osteoporosis clinic at Western General Hospital for denosumab treatment.

Design

The project is an opinion survey seeking the views of NHS staff and patients on service delivery.

Methods

1. Process map(s) will be designed based on current local service delivery plans
   1.1. A flow diagram will be made as an overview of the pathway in the current management
      1.1.1. Advice will be sought from a nurse specialist in osteoporosis
      1.1.2. Risks will be commented

2. Interviews will be designed and piloted for a convenient sample of health care professionals and patients
   2.1. Separate invitation letters, information sheets and consent forms for the health care professionals and the patients based on National Research Ethics Service's (NRES) guidelines will be designed (12)

   2.2. Two specialist nurses and three physicians will be invited from the department of rheumatology

      2.2.1. The participants will be selected by the clinical supervisor to be those interested and working with patients with osteoporosis
      2.2.2. The clinical supervisor will distribute invitations via e-mail
      2.2.3. The clinical supervisor will receive their answer and the investigator will then arrange a convenient time and place via e-mail
         2.2.3.1. If there is no answer within two weeks they will be contacted by the clinical investigator to confirm the participation
         2.2.3.2. If there is no answer one week after the investigator has asked to arrange the interviews, the investigator will send a reminder by e-mail

   2.3. A GP and a community pharmacist will be invited
      2.3.1. Advice will be sought from the Associate Medical Director for Primary Care (GP) and the Chairman of Lothian Pharmacy Contractors Committee in terms of inviting a community pharmacist and GP to participate
         2.3.1.1. The academic supervisor will seek the advice from the mentioned authorities
      2.3.2. The academic supervisor will send the invitation via e-mail to the GP and the community pharmacist

2.3.2.1. The academic supervisor will receive their answer and the investigator will then arrange a convenient time and place via e-mail

2.3.2.1.1. If there is no answer within two weeks they will be contacted by the clinical investigator to confirm the participation

2.4. The investigator will seek advice by a nurse specialist in the osteoporosis service that will pick three patients who are not biased, not suffering of dementia and will give the interview a wide range of views

2.4.1. The nurse specialist will contact them and ask for a convenient time and place

2.4.2. If the nurse specialist asks a patient who is in the clinic to receive denosumab injection, the nurse will give them the invitation letter, information sheet and consent form.

2.4.3. The investigator will distribute invitation letters, information sheets and consent forms by post and will give them at least 24 hours to read it

2.4.4. The investigator will interview the patients on the scheduled day

2.5. The interview will be designed and piloted for a convenient sample of healthcare professional and patients. Questions will ask about

- Convenience for patients to have less hospital visits (maintain clinical review by specialist but reduce visits which are solely to receive injections)
- Acceptance of community pharmacist supply and administration of denosumab
- Acceptance of community pharmacist led pharmaceutical care package of medication review, adherence with medicines, falls assessment and need for calcium & vitamin D

2.6. The interviews will be piloted

2.6.1. The clinical supervisor will invite a pharmacist on a convenient day

2.6.2. The nurse specialist will invite a patient on a convenient day

2.7. The interviews will be reviewed with regards to the information that was collected from the pilot

2.8. The participants and patients will be interviewed as scheduled

2.8.1. The interviews will be audio recorded using Olympus Digital Voice Recorder DS-50

2.9. The interviews will be anonymously transcribed

2.9.1. The interviews will be manually transcribed by the investigator to Microsoft Word®

2.10. Data from the semi-structured interviews will be analysed and used to develop a short postal questionnaire

2.10.1. The data will be analysed qualitatively and using theme coding

3. The questionnaire will be designed and piloted for all community pharmacies, GP's and patients receiving denosumab treatment

3.1. Two questionnaires will be designed; one for the health care professionals and one for the patients. The anonymous postal questionnaire will be designed to obtain optimum response rate.

3.1.1. There will be asked closed questions.

3.1.1.1. Ordinal scale (Likert scale; strongly disagree, disagree, neither disagree, nor agree, agree, strongly agree)

3.1.1.2. The patient questionnaire will also include nominal scale questions including yes/no, multiple choice and interval scale

3.2. A cover letter will be made by the investigator for the patients and the community pharmacies to describe the project and the purpose of the questionnaire

3.3. An e-mail invitation letter will be made by the investigator to the GPs to describe the project and the purpose of the questionnaire

3.4. The questionnaires will be piloted on at least one pharmacist, GP and patient

3.4.1. A sample of patients will be invited to fill out the questionnaire on a convenient day

3.4.2. A sample of pharmacists and GPs will be invited to fill out the questionnaire

3.4.2.1. The academic supervisor will ask the GP who was interviewed and at least one other GP interested to complete the questionnaire and give feedback

3.4.2.2. The academic supervisor will ask a pharmacist to complete the questionnaire and give feedback

3.5. The questionnaire will be reviewed with regards to the information that has been collected from the pilot

3.6. The questionnaires will be sent to all community pharmacies and GPs via telefax and an electronic survey service respectively. The final questionnaire for patients will be sent to all patients who receive denosumab via osteoporosis service at Western General Hospital

3.6.1. Inclusion criteria will be:

- All community pharmacies in NHS Lothian
- All the GPs in NHS Lothian

- All the patients currently attending Western General Hospital for denosumab treatment identified from rheumatology records, who have at least had one injection of denosumab

3.6.2. The questionnaire will be sent to the general practitioners via an electronic survey service (Surveymonkey®)

3.6.2.1. The dead-line for return will be two weeks after the date it was posted

3.6.3. The questionnaire will be sent to community pharmacies via telefax

3.6.3.1. The dead-line for return will be two weeks after the date it was posted

3.6.4. The questionnaire will be sent to the patients via mail

3.6.4.1. The dead-line for return will be two weeks after the date it was posted

3.6.5. The pharmacies, GP's and patients will receive a reminder after two weeks, with a new dead-line within one week

3.7. The results will be analysed using a Microsoft Excel® spread sheet

3.7.1. Data will be structured in to coded themes and analysed

4. Recommendations for service development will be made

4.1. Process map(s) will be designed based on proposed local service delivery plans

4.1.1. A second flow diagram will be made as an overview of the pathway in the potential management

Ethics

The project has been reviewed by the South East Scotland Research Ethics Service, who classified the study as not requiring an ethical review. It has also been reviewed by the Pharmacy Quality Improvement Team (QIT).

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