

Why you should read this article:

- To learn about the experience of two trusts that set up a home denosumab self-administration service for patients during the coronavirus disease 2019 (COVID-19) pandemic
- To recognise the need for a robust, comprehensive and consistent training process for patients to self-administer denosumab at home safely
- To identify the benefits for patients and their families of a home denosumab self-administration service

Home denosumab self-administration: a service development project

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Citation

Farrington N, Newey L, Cook A et al (2022) Home denosumab self-administration: a service development project. *Cancer Nursing Practice*. doi: 10.7748/cnp.2022.e1803

Peer review

This article has been subject to external double-blind peer review and checked for plagiarism using automated software

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Conflict of interest

This is an Open Access paper, published under a CC-BY-NC license. The Open Access fee was funded by Amgen. Amgen have no commercial interest in the paper. The biotechnology company Amgen provided funding support to create a patient training video and supplied patient information material. Amgen had no input into the clinical decisions made during the project

Accepted

11 November 2021

Published online

March 2022

Abstract

In October 2012 the National Institute for Health and Care Excellence approved the use of subcutaneous denosumab for the management of bone metastases from solid tumours. For patients receiving intravenous chemotherapy, denosumab can be administered in parallel with this, obviating the need for additional hospital visits. However, patients receiving oral chemotherapy or denosumab alone often must attend hospital solely for a subcutaneous injection of the latter. This article describes the experience of two NHS trusts in setting up a home self-administration service for denosumab during the coronavirus disease 2019 (COVID-19) pandemic. The service development project took place during 2020-2021. The article explores the barriers to and facilitators of this project and reports the results of a patient feedback survey which showed that all respondents wished to continue self-administration of denosumab at home.

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Keywords

cancer, cancer treatments, clinical, medicines, patients, patient education, patient experience, professional, service development

Introduction

The use of denosumab for the management of bone metastases from solid tumours was approved by the National Institute for Health and Care Excellence (NICE) in October 2012. Denosumab is a human monoclonal antibody which acts by inhibiting the growth and development of osteoclasts – large cells responsible for the dissolution and absorption of bone – meaning that bone reabsorption is decreased (Joint Formulary Committee 2021). This can reduce pain and prevent pathological fractures. Denosumab for the management of bone metastases is administered as

a subcutaneous injection every four weeks. Side effects include pain at the injection site, hypocalcaemia and, rarely but significantly, osteonecrosis (Joint Formulary Committee 2021). For patients receiving intravenous chemotherapy, denosumab can be administered in parallel, obviating the need for additional hospital visits. However, patients who are receiving oral chemotherapy or denosumab alone often have to attend hospital solely for a subcutaneous injection.

Delivering care closer to home is a priority for the NHS and is set out in the NHS Long Term Plan (NHS England 2019). There is

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precedent for administration of denosumab and other subcutaneous medicines outside of secondary care. Before the coronavirus disease 2019 (COVID-19) pandemic some hospitals, for example University College London Hospitals NHS Foundation Trust (UCLH), had started to create pathways for home administration of denosumab under the responsibility of a healthcare professional. As well as having benefits for patients, this type of service can reduce the burden on chemotherapy units which have struggled for some years to cope with increased patient capacity and reduced staffing levels. The COVID-19 pandemic provided a further incentive to treat patients out of hospital where possible.

This article describes a service development project that aimed to support patients to self-administer denosumab subcutaneous injection at home instead of having to come into hospital. University Hospital Southampton (UHS) NHS Foundation Trust and Dorset County Hospital (DCH) NHS Foundation Trust worked together on the project, assisted by Amgen, the biotechnology company that developed denosumab, by sharing information and materials. The different structures and working practices of the two trusts meant that the project worked differently in each organisation.

Project development

The process of denosumab administration at the two trusts before March 2020 is illustrated in Figure 1. The COVID-19 pandemic that began in early 2020 was the primary driving force for the project, although the value of treating patients closer to their own homes and outside of a hospital setting is widely recognised (Edridge and Wagland 2019). In addition to attending hospital for treatment, patients often attended for pre-treatment review.

In the authors' clinical experience, not all patients would wish to self-administer denosumab at home or would be capable of self-administration. Therefore, the aim was to make the service voluntary and as easy as possible for patients, their families and the staff supporting them.

University Hospital Southampton

At UHS the first step was to write a standard operating procedure setting out how the service would work. Other trusts that had established a home self-administration service for denosumab, including UCLH, provided support for writing this by sharing their process. The standard operating procedure then went through trust governance and the trust's drugs and therapies committee for approval.

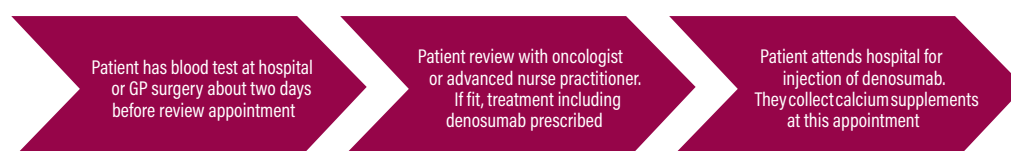
A patient information leaflet was designed with the support of the UHS publications department. Funding support from Amgen enabled the creation of a patient training video demonstrating how to inject denosumab safely. A checklist that could be scanned into electronic patient records was also developed for nurses at the cancer treatment centre to use when training patients to inject denosumab safely.

These documents and resources were created through a collaboration between the systemic anticancer therapy (SACT) advanced nurse practitioner team, pharmacy staff, medical oncology and nursing colleagues in the hospital's cancer treatment centre. To bring the documents together and make the transition to self-administration at home easier, a 'survival guide' for prescribers and nurse trainers was developed. This described the complete process, including identification of those who wish to use the service, training patients, prescribing practices, who to notify to ensure that medicines and equipment are delivered to patients' homes and patient follow-up.

Dorset County Hospital

The experience at DCH was different because there was already a precedent for home self-administration of denosumab. DCH employs a community-based metastatic breast clinical nurse specialist (CNS) who, alongside providing psychological support, reviews and monitors patients who self-administer oral SACT and undertakes toxicity assessment. If a patient was receiving denosumab at home, the CNS would administer this. Before the COVID-19 pandemic, when patients stopped taking oral SACT but continued

Figure 1. Pre-March 2020 process of denosumab administration at University Hospital Southampton NHS Foundation Trust and Dorset County Hospital NHS Foundation Trust



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having subcutaneous denosumab, a small number were taught to administer it under the supervision of the CNS.

In spring 2020, when the pandemic was at a critical stage, the trust wanted to minimise footfall through the hospital to reduce the risk of infection of patients and staff while maintaining the patient treatment pathway. Therefore, a standard operating procedure for administration of subcutaneous denosumab at home was developed and agreed with trust governance, the therapeutic drug committee and oncology consultants.

Training materials for patients were developed alongside the standard operating procedure, including a self-administration training booklet and a training 'mat' – that is, a paper mat that can be laid on a table on which patients set out the equipment they need, and which details the process of administration in easy steps (Amgen 2020). Informally, patients reported to clinicians that these materials were user-friendly and visually simple for the layperson to follow. The materials also assisted the CNS to train patients and/or their relatives, and when used in conjunction with the CNS's skills and knowledge were regarded as valuable in educating patients about the medicine, including administration, storage and disposal. Patients were also given administration equipment.

Barriers

In both trusts, anecdotal reports indicated that patients were often worried about whether they would be able to draw up the denosumab and inject it safely, concerns echoed by cancer treatment centre nursing staff. When used for the management of bone metastases from solid tumours denosumab is regarded as SACT, which must be administered under the responsibility of an expert clinician (EMC 2021). Therefore, some nursing staff expressed concern about whether the drug should be administered outside of hospital.

The use of a closed-system drug-transfer device, designed to reduce the risk of exposure to hazardous drugs, was another concern. Staff involved in the project at both trusts debated whether asking patients to use a closed-system drug-transfer device would make the process more complicated as they are designed to reduce occupational exposure to hazardous drugs in healthcare staff who administer many doses. A Cochrane review of the devices plus safe handling of hazardous drugs compared with safe handling alone for reducing exposure to infusional hazardous

drugs in healthcare staff drew no firm conclusions due to very low certainty evidence (Gurusamy et al 2018). The Health and Safety Executive (2021) recommends using a totally enclosed system 'where reasonably practicable' to control exposure to cytotoxic drugs. Therefore, it was decided that it would be safer to include the closed-system drug-transfer devices in the process.

Staff at both trusts also had questions about responsibilities and practicalities, for example who would be responsible for patients on home self-administration of denosumab, including checking blood tests and reviewing patients, and who be responsible for prescribing denosumab and supportive medicines such as calcium supplements.

The process of setting up this service at UHS was made more challenging because some project team members were redeployed due to the COVID-19 pandemic, and the increased pressure on trusts meant that the governance process slowed down. But despite these challenges the project continued. Project team members who were redeployed handed over to other colleagues who continued the momentum. The overall driving force was a desire to improve the patient experience.

Facilitators

At UHS, support from the SACT advanced nurse practitioner team was vital and enabled the training process described above to be embedded in practice, which reassured patients and staff that home denosumab self-administration would be safe. Cancer treatment centre nurses were sometimes concerned that patients would not inject denosumab safely and effectively at home, but the comprehensive training process reduced these concerns.

Training patients to self-administer denosumab at home

Staff at UHS and DCH worked in different ways to teach patients how to self-administer denosumab. At UHS, patients came to the cancer treatment centre for two injection administration appointments. At the first appointment nurses demonstrated the process of drawing up and injecting denosumab, and at the second appointment they supervised the patient self-administering the injection. If the patient and the nurse felt confident that administration would be safe, arrangements were made to have the treatment at home. If the patient believed they needed more time they could attend another appointment.

Key points

- A comprehensive and consistent training process means patients can self-administer denosumab at home safely
- Using existing organisational processes can help embed a service development project in practice
- Engagement with stakeholders such as oncology pharmacy staff, cancer treatment nurses and prescribers, as well as patients and families, ensured feasibility of and support for the service development
- Patient feedback indicated that the service development project improved their experience

At DCH, the presence of a SACT CNS in addition to the metastatic breast CNS, who work across the community and secondary care sectors, meant that patients could be trained at home as well as in the outpatient chemotherapy unit. This eased the transition from hospital administration to home self-administration. After two training sessions, during which the patient drew up and administered denosumab under supervision from a nurse, they were signed off as competent if both parties were satisfied. Patients retained the original sign-off sheet and a copy was scanned and uploaded to the electronic patient record.

The SACT CNS set up an outreach SACT telephone clinic to monitor and record denosumab self-administration activity. All patients who use the self-administration service have bloods taken on a Monday either at their GP practice, at hospital or at home by community nurses, and have an appointment scheduled with the outreach SACT telephone clinic on a Tuesday. An assessment by phone is conducted by the SACT CNS, the patient's blood results are reviewed and a decision is made on whether to proceed with the injection on the Thursday. At both trusts patients received ongoing indirect supervision by phone and/or video calls from expert healthcare professionals, which reduced their anxiety.

For both trusts the involvement of Amgen was valuable. The company provided its own patient information leaflets, adapted to include information about the closed-system drug-transfer device, to complement trust-specific leaflets. It also connected the two trusts with others at which self-administration of denosumab was established so they could share their experiences.

At UHS it was felt useful to embed the denosumab self-administration service into existing processes. Setting up a separate clinic for patients self-administering denosumab at home was considered, but there was no capacity for this in the trust's SACT advanced nurse practitioner or CNS teams. Therefore, it was decided that patients using this service would remain in their existing tumour-specific clinics. The clinicians who run these, who are either oncologists or SACT advanced nurse practitioners, retained responsibility for monitoring patients' bloods and prescribing treatment.

Support from the oncology pharmacy at UHS was also valuable, as the project team could make use of processes that had been set up in response to the COVID-19 pandemic, for example an expanded courier service. Pharmacy staff could also assist with

practicalities such as how to ensure that the screening pharmacist – who reviews and checks prescriptions – could identify self-administering patients. This was important to ensure that treatment was sent to patients' homes. An icon was used on the electronic prescribing system to identify these patients and the prescriber would write a note on the tumour-specific clinic electronic outcome document – which is used to plan the next appointment – to alert administrative staff that the patient self-administered at home and therefore did not require a treatment clinic appointment. The expansion of remote monitoring by phone and video clinics in general in response to the COVID-19 pandemic meant that it was easier to support home self-administration of denosumab.

DCH subcontracted a separate pharmacy service to deliver medication and equipment to patients' homes. A colour code was used on the electronic prescribing system to identify that a treatment was for home delivery. The pharmacy and SACT CNS would communicate weekly about which patients were due a delivery, or if there were concerns or delays.

Process map

The processes used at UHS and DCH were designed to meet the needs of each trust's patient population and organisation of services. The process maps in Figures 2 and 3 show how denosumab home self-administration is arranged at each trust.

Patient feedback

To assess the effectiveness of the process of self-administering denosumab at home, patients at the two trusts were asked to complete a short questionnaire after they had done it at least once. The questionnaire was developed with the assistance of the patient experience team at UHS using a template, with permission, from Cornwall Partnership NHS Foundation Trust. Patients were sent an electronic link to the questionnaire by email or text but could request a paper copy from the cancer treatment centre if they preferred.

Patients were asked about their experience of having denosumab before and after self-administering at home. There was also space for free-text responses. The number of patients who were sent the questionnaire link is unknown, but 14 completed and returned the questionnaire, which was anonymous. Table 1, accessed from rcni.com/denosumab-questionnaire, shows the denosumab self-administration questionnaire and results.

The project was considered a pilot of a service development and therefore research ethics committee approval was neither sought nor required.

Most respondents found travelling to hospital for their denosumab injection inconvenient and it sometimes caused them stress and/or anxiety. They also felt they often had to spend a long time in the hospital waiting for their injection. For one respondent, from leaving home until returning after their injection at the hospital took more than four hours. Some respondents had to take time off work to attend hospital for their denosumab injection and sometimes the person who accompanied them also had to do so. Respondents often had to pay for petrol, parking or public transport.

At DCH all respondents were retired, therefore attending hospital did not require them to take time off work or find childcare. However, many came a long distance because of the rural nature of Dorset and commented on the inconvenience of a long journey to attend a short appointment.

In contrast, most respondents found that waiting for denosumab to be delivered to their home was not inconvenient. Most respondents did not feel stressed and/or anxious about self-injecting at home, although some were nervous at the start of the process, and none believed that self-administration was time-consuming. Not all respondents administered the injections themselves and the task was often undertaken by family members. In general, respondents felt supported by the training process and all of them said they would prefer to continue self-administering at home rather than returning to hospital for injections. Some of the reasons for this are shown in Box 1.

Some challenges were highlighted by the patient feedback questionnaire. For example, at UHS the main issue for patients was obtaining administration equipment such as needles and syringes. One respondent stated:

'Need to have an easier way of obtaining syringes and needles as always proves difficult in getting someone to arrange.'

The medicine is dispensed and couriered to the patient's home directly from pharmacy, but this is not the case with the equipment. Patients reported having to visit the hospital to collect supplies, or even having to purchase the equipment themselves:

'I have subsequently purchased my own needles and syringes as getting hold of new ones from hospital involved stress and needless trips to chemotherapy ward.'

To avoid these issues in future the equipment will be sent to the patient with the medication. One patient who has been self-administering for a long time reported that the processes had much improved since the pandemic, which is likely due to improvements in the remote provision of care in general since the pandemic.

Project outcomes and recommendations

During the project there were no safety concerns or adverse events reported by patients or staff. Patients can receive denosumab in hospital in both trusts if they do not wish to self-administer. Ongoing evaluation of patient experience using the questionnaire will ensure the service continues to meet the needs of patients self-administering denosumab at home. Economic benefits of the service are not being addressed at present.

Figure 2. The process of denosumab home self-administration at University Hospital Southampton NHS Foundation Trust

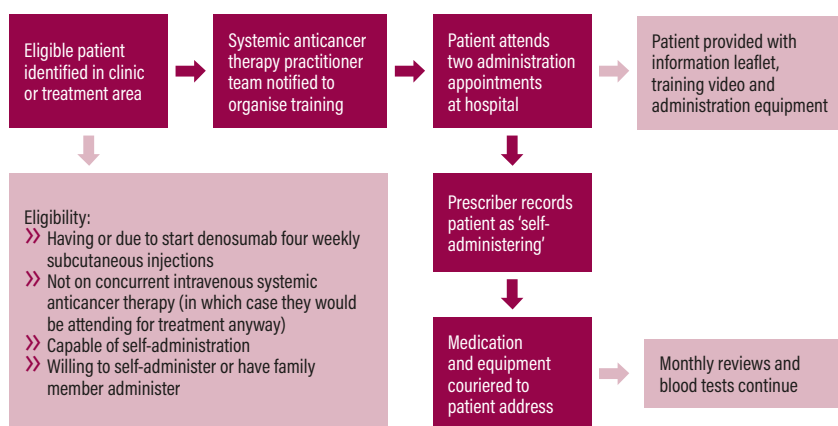
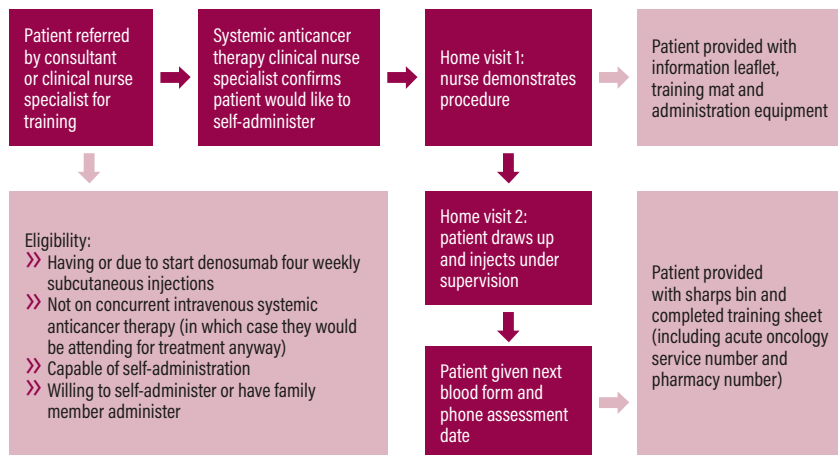


Figure 3. The process of denosumab home self-administration at Dorset County Hospital NHS Foundation Trust



Patients can also attend the hospital for training if they wish

The main recommendations for trusts considering the introduction of denosumab home self-administration are:

- » Establish a comprehensive and consistent training process to ensure that patients can administer denosumab safely.
- » Enlist the support of patients' family or friends if the patient wishes to self-administer at home but may not have the dexterity to do so.
- » Before starting the project, engage with oncology pharmacy staff, cancer treatment nurses and prescribers, as well as patients and families, to ensure support and that the project is feasible
- » Use existing processes in your organisation, such as clinics, for monitoring and prescribing rather than developing a completely new pathway.

Conclusion

This article described the experience of two trusts which set up a home self-administration service for patients having denosumab during the COVID-19 pandemic, including the barriers and facilitators. A safe, effective, robust and clear process for training patients and delivering the service has been developed that could be applied to other hospitals, with minor alterations if required.

Patient feedback indicates that the service development project at UHS and DCH has improved patients' experience and given them independence without compromising support from or contact with nursing staff.

UHS and DCH are happy to share training materials with other trusts considering the introduction of denosumab home self-administration.

Box 1. Some of the reasons given by respondents for wanting to continue self-administration of denosumab at home

- » 'It gives the staff more time to see other patients if you can do it yourself at home'
- » 'My husband gives it to me and we are confident'
- » 'It seems a very simple procedure and it seems ridiculous to waste precious NHS resources and time'
- » 'It's been so much easier; my sister-in-law is doing it at present then hopefully my daughter will do it'
- » 'My husband administers the injection which is far better than coming to the hospital and taking up [treatment room] chair time'
- » 'Although the hospital is within walking distance of my home, it is significantly more convenient to have my husband do the injection for me. It is very simple and I could easily do it myself. The one and only time I went to hospital, I had to wait in chemo ward for several hours. Very depressing for me and I feel a waste of time for qualified nurses who could be better employed to do things I can't do for myself'
- » 'The nurses have been brilliant and all the team, but so much easier and safer not having to attend hospital'
- » 'I prefer to have my injection at home as it is so much more convenient. My wife is a retired nurse so has no problem with giving the injection. The blood tests are done by the district nurse prior to the injection and [name of healthcare professional] phones me with the results and checks how I am'
- » 'It works out easier all round: 1) no transport needed, 2) convenience when administering the injection, 3) good communications with DCH nurse'
- » 'Either with me, but home is more convenient'
- » 'I would prefer to administer the injection at home as it is more convenient, and I do not have the stress of travelling to the hospital. Now that I have done it myself at home, I am happy to continue to do so'

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