



Innovative Medical Technology Overview | December 2024 Digitally enhanced fracture liaison services

## **Key points**

Digitally enhanced fracture liaison services (DFLS) use software to automate key steps within a fracture liaison service (FLS), including patient identification, creation and circulation of patient letters and clinician reminders for patient reviews. By speeding up the administrative process, DFLS have the potential to reduce clinical workload as well as improving outcomes (preventing future fractures, reduced waiting times) due to earlier diagnosis of osteoporosis.

The evidence on the effectiveness of DFLS is limited in quantity and quality:

- We identified one published retrospective observational study, based in China, that compared routine fragility fracture management with a digitally enhanced fragility fracture management service. The digitally enhanced service contributed to improvements in reduced all-cause and fall-related mortality, reduced refracture and increased dual-energy X-ray absorptiometry (DEXA) testing and treatment initiation rates.
- Local audit data from a DFLS in NHS Greater Glasgow and Clyde (NHS GGC), analysed by the manufacturer RedStar<sup>®</sup>, reported system improvements such as increased identification of fragility fractures and reduced scan backlog.
- We also identified one unpublished ongoing mixed-methods study and six ongoing service evaluations. No results are available for these studies.

We did not identify any evidence that looked at safety implications of DFLS, the costeffectiveness of DFLS, or patient and staff views of DFLS. One economic study on the use of (non-digital) FLS may help to illustrate the potential benefits of a DFLS (that is, if the digital component helps to facilitate the effectiveness of an FLS).

## Definitions

**Fragility fracture:** is a fracture associated with low-level trauma, following a fall from standing height and below. Associated spinal fractures (vertebral) may happen spontaneously and occur from routine activities such as bending, or lifting.<sup>1, 2</sup>

**Fracture Liaison Service (FLS):** a clinical service that identifies, assesses and treats patients with osteoporosis.<sup>3, 4</sup>

**Osteoporosis:** a common bone disease characterised by reduced bone mass and often only diagnosed following a fragility fracture.<sup>2, 5, 6</sup>

**Dual-energy X-ray absorptiometry (DEXA):** is a scan that uses X-rays to see how dense, or strong, a person's bones are.<sup>7</sup>

## The technology and its use

FLS are important in the identification of people with fragility fractures associated with osteoporosis and prevention of secondary (further) fractures for people over the age of 50.<sup>3, 4</sup>

FLS include patient screening, coordination of multidisciplinary teams and treatment implementation and monitoring.<sup>8,9</sup> FLS processes can be labour-intensive as they require manual identification of adults presenting in a healthcare setting following a fracture.

A DFLS provides a way to automate the manual processes within an FLS, offering improvements in service efficiency and subsequently service and patient outcomes.<sup>10, 11</sup>

Abbreviations are outlined in Appendix 1.

### What is innovative about the technology?

NHS GGC has implemented an automated FLS solution using software produced by Red Star<sup>©</sup>. In NHSScotland, this is the first case of a digital platform being used to support FLS.

#### **Regulatory information**

The software provided by RedStar<sup>©</sup> to deliver the automated DFLS solution in NHS GGC software does not have regulatory markings at present. It is the view of RedStar<sup>©</sup> that the software should not be classed as a medical device.

### Population, setting and intended use

#### Population

In Scotland, 300,000 people are estimated to be living with osteoporosis. In the United Kingdom (UK) one in two women and one in five men over 50 years old will have experienced an osteoporotic fracture in their lifetime.<sup>12</sup> Rates of osteoporosis are higher in Scotland for women and men over the age of 50 years old, compared to the rest of the UK.<sup>13</sup>

Risk factors for osteoporosis may be modifiable (for example, lifestyle) or non-modifiable (for example, age, gender, ethnicity) and include comorbidities (for example, coeliac disease) and certain medications such as anticoagulants.<sup>5</sup>

The burden of osteoporosis includes severe pain, disability and reduced quality of life.<sup>14, 15</sup> The disability-adjusted life years (DALY) for people aged over 50 years with osteoporosis (24 DALYs per 1,000 population) is comparable to that reported for people with dementia.<sup>16</sup>

Hip and vertebral fractures are associated with increased mortality five years following the fracture for women and men. $^{17}$ 

#### Setting and intended user

The intended users of DFLS are the same as FLS: adults  $\geq$  50 years old who have presented to emergency departments or fracture clinics with a fragility fracture, or have been identified (fracture or at risk of osteoporosis) in primary care by a healthcare professional.<sup>18</sup>

#### Current care pathway in Scotland

#### Use of FLS

The Scottish Intercollegiate Guidelines Network (SIGN) guideline for managing osteoporosis recommends that adults ≥50 years old who have experienced a fragility fracture be managed by a system of care that includes an FLS.<sup>5</sup> In an FLS model of care, adults are identified using manual systems and are eligible for FLS referral if they are ≥50 years old and have recently had a fragility fracture.<sup>18</sup>

Clinical standards for FLS indicate that assessment should be completed within 12 weeks of diagnosis of the fracture. Assessment usually includes the use of online risk assessment tools such as Fracture Risk Assessment (FRAX<sup>©</sup>) or QFracture<sup>©</sup>, as well as DEXA to assess bone mineral density. To reduce the risk of future fractures in adults at identified at high-risk, medication (for example, calcium supplementation) should be started within 16 weeks of diagnosis of osteoporosis and a referral be made to a local falls prevention service. Patients being supported within an FLS should be reviewed within 16 weeks and 52 weeks of their fracture diagnosis to check treatment progress and to follow-up with any referrals as necessary.<sup>2, 4</sup>

All 14 territorial health boards implement a version of FLS, but the potential for variation in processes exists. A national FLS audit is underway.<sup>18</sup>

#### **Implementation of DFLS**

The FLS model in the south sector of NHS GGC (Queen Elizabeth University Hospital and West Glasgow Ambulatory Care Hospital) was adjusted in 2022 following funding from Innovate UK and the Scottish Enterprise Grant to use innovative software to automate certain administrative processes. Following the award of the grant, NHS GGC used innovative software to automate certain administrative processes. With use of automation, the model in NHS GGC differs from other FLS in NHSScotland.

Prior to the introduction of the software, FLS staff visited hospital wards and reviewed documentation to create a manual spreadsheet of adults who had sustained a fracture. The approach prior to introduction of the software contributed to a backlog of DEXA scans and missed fractures. The updated FLS model by RedStar<sup>©</sup> was co-designed with and for NHS GGC to improve the identification of patients (inpatients, outpatients, emergency department (ED)) at high-risk of or who have had vertebral and non-vertebral fractures.

The RedStar<sup>©</sup> FLS software automates fracture identification by using a text-based daily search of radiology reports looking for pre-specified criteria, for example, age  $\geq$ 50 years old. Results are presented using a cloud-based platform for review by FLS staff.

Presently, five osteoporosis nurse specialists and one Consultant in Diabetes and Endocrinology use the software in NHS GGC.

The report includes clinical information such as current medication, laboratory results and demographic details. The software allows staff to automatically arrange clinical reviews and generate appointment. The software has bespoke elements including audits and monitoring key performance indicators (KPIs), similar to the FLS database (FLS-DB) used by FLS in England and Wales.<sup>19</sup>

#### Equality and access considerations

Equality considerations relevant to DFLS include age, sex, ethnicity.

- The risk of osteoporotic and hip fractures increases with age, with the risk increasing more steeply after 65 years in women and 75 years in men.<sup>20</sup>
- Women are at higher risk of osteoporotic (distal radius, hip or vertebral) and hip fractures compared with men.<sup>20</sup> The increased risk identified for women is related to accelerated bone loss following the menopause.<sup>21</sup>
- We identified evidence that suggested there may be differences in the risk of osteoporosis and fragility fractures between different ethnicities. Poor quality of the evidence and inconsistency of the findings limit conclusions that can be drawn.

We did not identify any studies that described the equality impacts of DFLS.

## Summary of clinical evidence

This section summarises the retrospective observational study and one local audit found on the use of DFLS to prevent secondary fractures in people who have experienced fragility fractures.

#### Published evidence

Lu et al (2024)<sup>22</sup>

#### Study size, design and location

This is a retrospective observational study of 2,317 patients who experienced an osteoporotic fracture requiring hospitalisation. The study was conducted in a secondary care setting in China.<sup>22</sup>

#### Interventions and comparator

A routine fragility fracture management service (that is, no-FLS) was compared with a fracture liaison service, referred to as the Kunshan (FLS-KS) model. The FLS-KS model consisted of three independent modules (management and statistical platform, medical staff mobile workstation and patient mobile client), held within private cloud storage. The model facilitated automatic capture of patient data and results.<sup>22</sup>

#### Results

- seven hundred and fifty-six patients received FLS-KS and 1,561 received routine fracture fragility management (no-FLS)
- patients who received FLS-KS, compared with no-FLS:
  - showed lower all-cause mortality rates (hazard ratio (HR)=0.72, 95% confidence interval (CI)=0.54 to 0.97, p=0.03)
  - experienced less fall-related mortality (sub-distribution HR=0.38, 95% CI=0.19 to 0.76, p=0.006)
  - were less prone to refracture (sub-distribution HR=0.58, 95% CI=0.31 to 0.74, p=0.001)
  - experienced increased DEXA testing after the first identified fracture (60.7%) compared with the no-FLS-group (30.7%, fully adjusted odds ratio (OR)=3.8, 95% CI=3.1 to 4.6, p<0.001)</li>
  - experienced increased treatment initiation rates (fully adjusted OR=2.3, 95% CI=2.0 to 2.8, p<0.001).<sup>22</sup>

### Unpublished evidence

#### RedStar<sup>©24</sup>

#### Study size, design and location

This is an unpublished local audit of the implementation of a DFLS in secondary care in the south sector based of NHS GGC (Queen Elizabeth University Hospital, West Glasgow Ambulatory Care Hospital), conducted by RedStar<sup>©</sup> and available on the manufacturer's website.<sup>24</sup>

#### Interventions and comparator

RedStar<sup>©</sup> compared descriptive outcomes data from the NHS GGC FLS (no automation), obtained in November 2022, with data from the DFLS solution, obtained from July 2023 to June 2024.<sup>24</sup>

#### Results

After implementing a DFLS in NHS GGC and compared with the previous FLS model (no automation), RedStar<sup>©</sup> reported that the number of patients enrolled onto the pathway increased and the backlog of scans reduced. RedStar<sup>©</sup> also reported that the time to identify a vertebral fracture and fractures other than the hip had also reduced, as did the processing time per patient.<sup>24</sup> There may be other contributory factors to the results reported by RedStar<sup>©</sup> (for example, staffing) for the NHS GGC DFLS and may not be due to implementation of the software in isolation.

#### Talla (2024)<sup>24</sup>

#### Study size, design and location

This is an unpublished local audit of the implementation of a DFLS in secondary care in the south sector based of NHS GGC (Queen Elizabeth University Hospital, West Glasgow Ambulatory Care Hospital), conducted by a local clinical lead for the DFLS in NHS GGC.<sup>25</sup>

#### Interventions and comparator

The local clinical lead for the DFLS in NHS GGC compared KPI data from the DFLS with KPIs outlined by the FLS-DB in England and Wales. The time-period for comparison was 2020 (calendar year) for the FLS-DB and November 2022 to December 2023 for the DFLS in NHS GGC.<sup>24</sup>

#### Results

The local clinical lead for DFLS in NHS GGC reported that more fragility fractures and vertebral fractures were being identified in the DFLS, compared with predicted numbers by FLS-DB. The local clinical lead also reported that all patients were identified within 90 days with the implementation of the DFLS.<sup>24</sup>

### Ongoing studies

We identified one ongoing mixed-methods study and six service evaluations in NHS Trusts in England (*Table 1*). None of the studies are registered as clinical trials and no results have been published.

UK country	NHS trust(s) or areas	Study description	Companies involved
England	Area not reported (n=6 trusts)	Support the automation of data collection for FLS in six NHS Trusts (two yet to be recruited)	UCB, Open Medical
England	Bradford, Cambridge, Cardiff, Nottingham, Southampton (n=5 trusts) <sup>25</sup>	Use AI to review CT scans to identify undiagnosed spinal fractures and improve patient outcomes with FLS	Nanox.AI

Table 1: Ongoing work implementing a digital (automated) or AI-enabled solution within FLS

## Summary of safety evidence

We did not identify any published or unpublished studies describing the impact of DFLS on safety outcomes.

## Summary of economic evidence

We did not identify any published or unpublished studies describing the cost-effectiveness of DFLS.

### Costs

There are no publicly available costs for RedStar<sup>©</sup> AI that we can include in this Innovative Medical Technology Overview (IMTO) as their costs remain commercial in confidence.

### Value proposition of DFLS

Despite the lack of direct economic evidence, the potential value proposition of DFLS (that is, its intended effect on outcomes and costs) can be considered.

A DFLS potentially offers value in two areas:

- improving the case finding and referral system used by the FLS, reducing clinical workload, reducing waiting times and eliminating the backlog of unprocessed cases
- preventing future fragility fractures by improving detection of osteoporosis and starting treatment, which itself will help reduce:

- mortality from osteoporotic fractures
- number of surgical interventions
- hospitalisation time
- utility loss from the decreased mobility and pain
- amount of care needed (provided by NHS and informal)

#### NHS GGC (south sector) potential workforce impact

Data provided by NHS GGC (south sector) illustrates the potential workforce impact of a DFLS in Scotland. Using case finding as an example, within their original FLS it currently takes four nurses 60% of their time to process 42% of cases

NHS GGC (south sector) report that after introducing the DFLS, the four nurses spent 50% their time on case finding, processing 100% of cases. This equates to two full-time equivalent nurses, illustrating the potential for DFLS to reduce workforce pressure (Personal communication: Dr Maria Talla, Consultant in Diabetes and Endocrinology, NHS GGC on 11 Nov 2024).

#### Potential resource cost impact

Preventing fractures using a more effective FLS has the potential to significantly reduce the cost of treatment associated with fragility fractures to the NHSScotland. The hospital inpatient cost for a hip fracture is estimated to be £14,528. Including the costs of GP and ED attendances, ambulance call-outs, and potential discharge for the short- or long-term supported care and nursing homes, the total cost of a hip fracture may reach £39,490.<sup>26</sup>

### Indirect economic evidence on the use of a non-digital FLS

Although we did not find any published economic studies on DFLS, a study by Pinedo-Villanueve et al (2023)<sup>27</sup> looking at the cost-effectiveness of FLS has relevance to the potential value of digital FLS solutions.

The study included a cost-utility model-based analysis that represented a generic FLS pathway developed with the clinical FLS experts from Japan, Spain, and the UK. The target population was people aged 50 years or more with a sentinel fracture (a first fracture of hip, spine, wrist, or humerus that can be a sign of osteoporosis). The patients entered the pathway once they experienced a fragility fracture, presented in ED or trauma clinics and underwent treatment. On discharge, the patients lived independently, with relatives, under supported care, or in the nursing homes. The model investigated how many people experienced a future fracture. The model incorporates mortality from fractures and from unrelated cause.<sup>27</sup>

The FLS engages before or after the patient had been discharged, with activities such as identification of those who have sustained a fracture, assessment, treatment and further monitoring.

The aim of FLS was to reduce the number of future fractures by increasing the identification of patients diagnosed with osteoporosis and reducing time to treatment and improving adherence to treatments offered.<sup>27</sup>

Pinedo-Villanueve et al (2023) used the following outcomes to determine effectiveness of the FLS:

- probability of patients with a fragility fracture being identified
- proportion of patients recommended treatment to improve bone density
- time to treatment.<sup>27</sup>

The values for the parameters for the FLS and no-FLS care pathway are presented in the *Table 2*.

Fracture type	No-FLS	With FLS		
Probability of being identified (%)				
Hip fracture	0.2	0.95		
Spine fracture	0.1	0.8		
Other fracture	0.1	0.8		
Proportion of patients recommended treatment				
Hip fracture	0.4 men 0.6 women	0.85 men and women		
Spine fracture	0.05 men 0.1 women	0.8 men and women		
Other fracture	0.1 men 0.2 women	0.5 men 0.6 women		
Time to treatment in months				
Hip fracture	3	1		
Spine fracture	6	2		
Other fracture	6	2		

The study concluded that FLS cost an additional £96,689,612, prevented 13,149 refractures, and yielded 11,709 quality-adjusted life years (QALYs, a measure that takes into account gained life years and adjusts them with the estimated quality of life). The incremental cost-effectiveness ratio (ICER) for the intervention was £8,258 per QALY gained, which is deemed to be cost effective. The model was driven by uptake and adherence to treatment and given the lack of data on these outcomes, the conclusions of the analysis must be treated with caution.

Although not directly relevant to DFLS, the analysis by Pinedo-Villanueve et al illustrates the value of an FLS in delivering improved identification of people with fragility fractures, improved diagnosis of osteoporosis, a timely introduction to treatment, and increased adherence to the treatment. A DFLS is intended to facilitate these improvements to care pathways in Scotland, which currently experience bottlenecks due to manual identification and referral processes (Personal communication: Dr Maria Talla, Consultant in Diabetes and Endocrinology, NHS GGC on 18 Oct 2024).

### Data requirements for the economic evaluation of DFLS

An economic model is required to inform the cost-effectiveness of DFLS:

- Health outcome data from preventing fragility fractures may not need to be directly observed but could be extrapolated from time to diagnosis, time to treatment, detection rate, risk of fractures with and without the treatment.
- The value of diagnostic intervention will depend on treatment offered, uptake, and adherence to the treatment. These factors should be included within the economic model.
- A model-based cost-effectiveness analysis should include scenario analyses, testing different levels/rates of patient identification as well as uptake and adherence to treatment.
- Cost data requirements:
  - o referral, diagnosis, and treatment costs
  - o follow-up costs
  - o costs associated with treatment of the osteoporotic fractures
  - $\circ$   $\;$  unit costs of the healthcare professionals' time/resource
  - DFLS technology costs
- Health consequence data requirements:
  - quality of life (disutilities) associated with different types of fractures (treatment of the fracture and long-term consequences)
  - o quality of life (disutilities) associated with treatment
  - o mortality rates associated with the osteoporotic fractures
  - o risk for particular types of fractures

## Patient/user experience

We did not identify any published or unpublished studies describing the patient or staff perspective of DFLS.

## Conclusions

The use of a DFLS modernises traditional FLS, but evidence for its effectiveness in preventing future fractures and reducing waiting times is limited in both quantity and quality.

We identified one published retrospective observational study, based in China, that explored the clinical and cost-effectiveness of a digital solution for FLS. We also identified one cost-effectiveness study for FLS.

Evidence for DFLS in the UK comes from implementation of an automated FLS in NHS GGC. Promising results have been observed for system improvements such as identification of fractures and clearing the backlog of scans in NHS GGC. No patient outcome data are available for the implementation of DFLS in NHS GGC.

Further evidence is required to inform the provision of DFLS within Scotland.

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# **Appendix 1: Abbreviations**

AI	artificial intelligence
ANIA	Accelerated National Innovation Adoption
DALY	disability-adjusted life years
DEXA	dual-energy X-ray absorptiometry
DFLS	digitally enhanced fracture liaison service
ED	emergency department
FLS-DB	fracture liaison service database
FTE	full-time equivalent
FRAX	Fracture Risk Assessment
GGC	Greater Glasgow and Clyde
HR	hazard ratio
ICER	incremental cost-effectiveness ratio
ΙΜΤΟ	Innovative Medical Technology Overview
NHS	National Health Service
OR	odds ratio
QALY	quality-adjusted life year
SIGN	Scottish Intercollegiate Guidelines Network
UK	United Kingdom