NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

GID-HTE10059 Artificial intelligence technologies to aid the opportunistic detection of vertebral fragility fractures

Final scope

1 Introduction

The prioritisation board identified artificial intelligence technologies to help detect vertebral fragility fractures on radiographic imaging as suitable for early value assessment (EVA) by the HealthTech Programme based on a topic intelligence briefing.

2 Technologies

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts, and publicly available information. NICE has not carried out an independent evaluation of these descriptions.

2.1 Purpose of the technologies

Vertebral fragility fractures (VFFs) are diagnosed on radiographic images involving the spine, including X-ray, CT, MRI and dual-energy X-ray absorptiometry (DXA) scans. However, up to 70% of VFFs are missed or underdiagnosed (Royal Osteoporosis Society, 2021). The Royal College of Radiologists' Radiological guidance for the recognition and reporting of osteoporotic VFFs notes several reasons why VFFs are missed:

- the spine is not routinely reviewed during reporting by the radiologist or radiographer

- a lack of awareness of the importance of early diagnosis of VFFs and use of ambiguous and inconsistent terms during reporting
- immature or underdeveloped departmental radiology information systems (RIS) and alert processes
- onward referral systems (in particular, fracture liaison services [FLSs]) may not be well developed locally.

Artificial intelligence (AI) technologies offer potential for improving the detection of VFFs, especially opportunistically (on images involving the spine taken for reasons other than VFF detection). AI technologies could be used to assist radiologists and radiographers when they interpret images. This could improve detection rates, leading to more people receiving care when necessary. The technologies may also reduce the time taken to interpret images, facilitating timelier referral for further evaluation.

Missed VFFs lead to complications such as a curved spine (causing the person to lean forward), height loss, immobility, pain, as well as loss of function. This can impact the person's quality of life and ability to perform daily tasks. VFFs are also associated with an increased risk of death and are a significant predictor of future fractures (Gonnelli et al. 2013). Over 55% of people with a hip fracture have evidence of previous VFFs (Royal College of Radiologists, 2021). The costs associated with VFFs and hip fractures are significant – the health and social care costs in the first year of post-hip fracture are over £33,000 per person (Royal College of Radiologists, 2021). Missed and delayed fracture diagnoses can also have an impact on service delivery, for example, increased waiting times, delays in people being discharged, people being recalled, additional medical appointments, surgical procedures and physiotherapy.

2.2 Product properties

Several companies offer software with AI derived algorithms for analysing radiographic images to opportunistically detect VFFs. They use radiographs in DICOM (digital imaging and communications in medicine) format which are stored on the hospital's PACS (picture archiving and communications system). These technologies are designed to assist healthcare professionals in the interpretation of radiographic images to help diagnose VFFs. NICE notes that the ionising radiation (medical exposure) regulations (IRMER) state that clinical evaluation of X-rays requires a trained person. Therefore, AI technologies cannot currently be used autonomously without human interpretation. All of the identified technologies have algorithms that are fixed, but can be updated periodically. All of the technologies utilise either X-ray images or CT scans. Some of the technologies include additional features. Some of the companies provide their software directly on their own platforms, whereas others are available via multivendor platforms (for example, the Blackford Platform).

2.2.1 Annalise Enterprise (CXR) and Annalise Container (CXR) (Annalise.AI)

Annalise Enterprise (CXR) is a class IIb CE marked AI medical device intended to assist clinicians with the interpretation of X-ray images (both lateral and anterior-posterior) of people ≥16 years of age. The technology uses AI algorithms to notify of suspected findings, including VFFs. The company states that it is used in 48 trusts in the NHS. Suspected findings are displayed immediately alongside associated localisation information to the clinician as they view the study in the PACS viewer. Annalise Enterprise (CXR) is used in 48 trusts in the NHS. Annalise Container (CXR) has the same capabilities as Annalise Enterprise (CXR) and uses the same AI model, but it is a cloud-based technology that is hosted by AI marketplace platforms, such as Sectra Amplifier and Blackford.

2.2.2 BoneView (Gleamer)

BoneView is a class IIa CE marked software designed to assist clinicians in the interpretation of X-ray images. BoneView uses AI (deep learning) to detect anomalies in the appendicular skeleton, ribs and thoracic-lumbar spine. The company states that the software can detect VFFs, as well as other fractures, dislocations, effusions and bone lesions. Healthcare professionals view the results as DICOM secondary captures with bounding boxes around any abnormalities; a results summary sheet is also provided. The technology is currently available in the NHS.

2.2.3 BriefCase-Triage (Aidoc Medical)

BriefCase-Triage is a class I UKCA and class IIa CE marked software which uses an AI algorithm to analyse abdominal and chest CT images on adults ≥18 years of age. This technology is intended to detect suspected VFFs of the thoracic and/or lumbar spine (both acute and chronic). Suspected findings are notified to the clinician on annotated images. The technology includes additional features, such as image prioritisation options. BriefCase-Triage is currently being piloted in one centre in the NHS.

2.2.4 CINA-VCF Quantix (Avicenna.AI)

CINA-VCF Quantix is an AI algorithm that detects and labels VFFs on CT images of adults ≥50 years of age. The technology uses the Genant classification system. Suspected findings are displayed on annotated images along with a notification to the clinician and can be reviewed immediately. The technology is available as a cloud-based solution on the Sectra Amplifier and Blackford platforms. The company is in the process of obtaining CE certification and expects it to be certified as a Class IIb medical device. CINA-VCF Quantix has not been used in the NHS.

2.2.5 HealthVCF and HealthOST (Nanox AI)

HealthVCF is a cloud-based software which uses AI algorithms to detect VFFs on chest and abdominal pelvic CT scans of adults ≥50 years of age involving the T1-L5 portion of the spine. The technology uses the Genant classification system. Suspected findings are highlighted on a standalone desktop application in parallel with the standard of care. HealthVCF is CE certified and is currently used in several NHS trusts. HealthOST is a newer version of the algorithm, which includes additional features, such as analysis of low bone mineral density, labelling of vertebrae and measurement of the mean Hounsfield Units. CE certification of HealthOST is expected in 2025. The technology has not been used in the NHS.

2.2.6 IB Lab FLAMINGO (IB Lab)

IB Lab FLAMINGO is a software that uses AI algorithms to detect VFFs in CT scans of adults ≥50 years of age involving the thoracic and/or lumbar spine. The technology uses the Genant classification system. Suspected findings are displayed within a report which includes annotated images and other information, such as the range of vertebrae examined and labelling of the vertebrae, which can be reviewed immediately. The technology allows for image prioritisation based on risk. IB Lab FLAMINGO is CE certified as a class IIa medical device. It has not been used in the NHS.

2.2.7 TechCare Spine (Milvue)

TechCare Spine is a software which uses AI algorithms to detect VFFs in lateral X-ray images involving the lumbar and/or thoracic spine. The technology uses the Genant classification system. Suspected findings are displayed on annotated images along with a notification to the clinician and can be reviewed within 1-2 minutes. It is available as a cloud-based solution. CE certification of TechCare Spine is expected in June 2025, with anticipated classification as a class IIa medical device. The technology has not been used in the NHS.

3 Target conditions

A VFF is a break in the spine that occurs when bones are weaker than normal. It is defined as a reduction in vertebral height or vertebral deformity as a result of structural failure (when there is a height reduction or 20% or more, or an endplate deformation) after a fall from standing height or less. But they can also occur spontaneously as a result of day-to-day activities involving very little trauma or stress. VFFs are the most common type of fragility fractures caused by osteoporosis (a result of bone weakness) which reduces bone density and strength. They are often described as vertebral compression fractures. Other informal synonyms include wedge fractures, wedge deformity, collapse, compression and loss of height. Osteoporotic VFFs are common in the elderly and particularly in postmenopausal women, but they can also be associated with other conditions or factors, such as chronic or long-term corticosteroid/glucocorticoid usage or malignancy in the vertebrae. Other risk factors include history of falls, family history of hip fracture, low BMI (less than 18.5kg/m^2), smoking, alcohol intake of more than 3.5 units per day and secondary causes of osteoporosis such as rheumatoid arthritis, inflammatory bowel disease or malabsorption (CG146, 2017).

Many people with VFFs have no specific clinical signs, but they may experience sudden acute pain with local tenderness and chronic back pain in thoracic or lumbar spine, which gets worse when sitting and leaning backwards or standing and leaning forward, curved spine (causing the person to lean forward), limited mobility, functional disability or loss of height (more than 2.5cm). They may also have difficulties in breathing, performing daily activities, gastrointestinal problems, sleep disturbances and a range of psychological symptoms including anxiety, low mood, depression and low self-esteem. Multiple VFFs result in progressive height loss and abnormal curvature of the spine (kyphosis/hyperkyphosis). Therefore, VFFs cause significant morbidity and have a significant impact on a person's quality of life, while also being associated with an increase in mortality (Clynes et al. 2020).

3.1 Epidemiology

It is estimated that approximately 2.5 million people in England and Wales have osteoporosis. Approximately, one in two women and one in five men will sustain one or more fragility fractures in their lifetime.

The incidence of VFFs increases with age. Recent data shows an incidence rate of 7.1 per 10 000 person years in adults aged over 50 (Curtis et al. 2016). Women are more commonly affected at all ages. An incidence of 12% has been reported in women aged 50 to 79 years, increasing to 20% in women over 80 years old.

4 Current management and care pathway

4.1 Identification, assessment and diagnosis of VFFs

VFFs can be identified when a person presents to a healthcare setting with symptoms suggestive of a VFF (Clinical Guidance for the Effective Identification of Vertebral Fractures, 2017). They can also be identified on DXA scans performed for bone densitometry as part of osteoporosis or secondary fracture prevention pathway. In addition, VFFs can be identified when a person has an imaging investigation involving the spine taken for reasons other than VFF detection. This is known as opportunistic detection. This can involve imaging for any reason and can be unrelated to the spine (for example, an X-ray for a chest malignancy), or further imaging of the spine (for example, DXA following a diagnosis of low bone mineral density). VFFs are most likely to be underreported on imaging obtained for non-musculoskeletal indications. Therefore, increasing the opportunistic detection of VFFs would be of most value.

In 2018/19, over 43 million radiological examinations were performed across the NHS in England (GIRFT Radiology Report, 2020). The specific imaging approach depends on the care setting, pathway and condition. NICE's guidelines on non-complex (NG38) and complex fractures (NG37) make recommendations on when different imaging modalities should be considered. Recommendations on imaging are also made in NICE's guidelines on suspected cancer (NG12), early and locally advanced breast cancer (NG101), advanced breast cancer (CG81), lung cancer (NG122), pancreatic cancer (NG85), oesophago-gastric cancer (NG83), prostate cancer (NG131), cancer of the upper aerodigestive tract (NG36), diverticular disease (NG147) and chronic obstructive pulmonary disease (NG115). Imaging can also be done for orthopaedic conditions.

There are several methods for the diagnosis and grading of VFFs. The semi-quantitative (Genant) and quantitative morphometric methods are primarily used in research, but they may also be applied in clinical practice. However, experienced radiologists will generally undertake a less formal visual read of the radiographic image.

The Royal College of Radiologists has made recommendations about the radiological reporting of VFFs. These include using standard terminology, indicating that the bones have been reviewed, if a VFF is diagnosed it, looking for and commenting on the presence of additional VFFs, the levels of fractures and their severity and if there is evidence of canal/cord/cauda equina compromise and discussing the reporting of VFFs at a departmental radiology events and learning meeting (REALM).

4.2 Treatment and management of VFFs

For people with osteoporosis and a new VFF confirmed on imaging, the clinician will assess using a recognised fracture risk assessment tool such as QFracture, FRAX or NOGG, urgent DXA and consider osteoporosis medication. NICE's guideline on Osteoporosis: assessing the risk of fragility fracture (CG146) recommends using either FRAX (without a bone mineral density value if a DXA scan has not previously been undertaken) or QFracture, within their allowed age ranges, to estimate 10-year predicted absolute fracture risk when assessing risk of fracture. CG146 is being updated to include up-to-date recommendations on risk assessment, as well as recommendations on the treatment and prevention of fragility fractures.

If a person has a new fracture while on osteoporosis treatment, they are referred to a metabolic/rheumatology clinic or local fracture liaison service (FLS). FLSs are specialised services that co-ordinate and deliver secondary fracture prevention through systematic identification, investigation, treatment recommendation and monitoring. These services are normally located within the acute hospital, community and primary care settings.

Management of VFFs is multidisciplinary and aims to reduce pain, restore mobility and minimise the incidence of new fractures. Conventional treatment plans include pain management with a range of pharmacological treatments, physical therapy including bed rest and supporting the spine to reduce the risk of further VFFs (Guidance for the management of symptomatic vertebral fragility fractures, 2022). Most people become symptom free through these measures and surgery is rarely indicated. However, if necessary, cement augmentation (percutaneous balloon kyphoplasty with or without stenting or vertebroplasty) or spinal fusion may be considered (IPG12, 2003, IPG166, 2006, TA279, 2013).

The Royal Osteoporosis Society recommends that people at high risk of fragility fracture are initiated on an appropriate osteoporosis drug treatment within 16 weeks of fracture diagnosis (i.e. within 4 weeks of the assessment being completed). People who are recommended interventions to reduce risk of fracture will be reviewed by the FLS within 16 weeks of fracture and at 52 weeks.

4.3 Position of AI technologies in the care pathway

The AI technologies described in section 2.2 can be used for the opportunistic detection of VFFs on images involving the spine taken for reasons other than VFF detection.

5 Comparator

The comparator is standard care where the radiologist or radiographer interprets the radiograph without AI assistance, usually within 24 hours of the image being taken. Retrospective assessment of radiographic images represents a form of screening and is outside the scope of this assessment.

The reference standard or assessment of ground truth is based on the consultant radiologist or reporting radiographer's (ideally with specialist training in musculoskeletal imaging) interpretation and report. Although considered the reference standard, fracture detection by a radiologist or reporting radiographer is not 100% accurate as fractures may still be missed.

6 Decision problem

Decision question	Does the use of software with artificial intelligence (AI) derived algorithms for analysing radiographic images as an aid for the opportunistic detection of vertebral fragility fractures (VFFs) have the potential to be clinically and cost-effective to the NHS?
Population	People who have had a radiographic image involving the spine taken for reasons other than VFF detection
Subgroups	Depending on the availability of evidence, the following subpopulations may be included: • People aged 50 or older • People with osteoporosis or those who are at risk of osteoporosis • People with osteogenesis imperfecta • People with cancer.
Intervention	AI used as a decision aid for radiographic image interpretation and fracture assessment prior to radiology review, using any of the following softwares: • Annalise Enterprise (CXR) (Annalise.AI) • Annalise Container (CXR) (Annalise.AI) • BoneView (Gleamer) • BriefCase-Triage (Aidoc Medical) • CINA-VCF Quantix (Avicenna.AI) • HealthVCF (Nanox AI) • HealthOST (Nanox AI) • IB Lab FLAMINGO (IB Lab) • TechCare Spine (Milvue).
Comparator(s)	Radiologist or radiographer interpretation of the radiographic image without AI assistance.
Healthcare setting	Secondary care and community diagnostic centres
Outcomes	The outcome measures to consider include: **Intermediate outcomes** • Measures of diagnostic accuracy to detect VFFs • Accuracy when used by different healthcare professionals (radiologists, radiographers and other healthcare professionals) • Failure rate or rate of inconclusive AI reports • Number of missed fractures • Rate of missed fracture-related further injury • Proportion of people that need further imaging • Intervention related adverse events • Healthcare professional user acceptability of AI tools

	• Changes to clinical management. **Patient-reported outcomes** • Health-related quality of life. **Costs and resource use** • Cost of the AI software • Staff costs • Training and implementation costs • Other downstream costs for diagnosis or treatment • Time to produce a radiography report • Time to diagnosis or time to definitive radiology report • Time to further referral or treatment • Number of treatments and extent of treatments • Number of hospital appointment/visits, including referrals to fracture clinics and orthopaedic assessment • Number of hospital admissions • Type of healthcare professional interpreting the radiograph.

6.1 Patient issues and considerations

People may have concerns about the use of or sharing of their data when AI technologies are involved, and the need for consent. They value being well-informed about the decision-making process, including AI involvement and whether the clinician agrees with the AI output. People may also have concerns about whether their radiographic image will still be interpreted by a qualified clinician when AI is in use.

People may experience additional stress and require additional time to discuss the results of their scan if they receive a diagnosis with a VFF which has been identified opportunistically, because this will not have been the primary reason for imaging. Many of those people are likely to have other conditions as well.

6.2 Implementation issues

IT and workforce

The AI technologies will need to integrate into existing hospital PACS systems to ensure there is no disruption or delays to the workflow and will need to ensure compliance with cyber risk, information governance and data protection law. Some of the AI technologies require access to the internet for installation and/or running. All require hardware to run on if they are not available as a cloud-based option. There may be differences between trusts in the proportion of radiographic images interpreted by radiologists compared with radiographers or other staff. Companies have suggested that radiographs can also be interpreted by other health professionals, such as nurses, after appropriate training. However, clinical experts advised that this may lead to overdiagnosis and overtreatment. Increased detection of VFFs may temporarily or permanently increase the workload of radiologists and other clinicians.

The GIRFT Radiology Report highlights that many departments currently struggle to meet what might be deemed the minimum IT requirements for a modern radiology service. In addition, it notes that when considering the impact on staff, it should be noted that although there has been an overall growth in the demand for radiology services, the fastest increase in demand is for more complex imaging modalities such as CT and MRI.

Clinical experts highlighted that in order to benefit from identifying more VFFs, effective mechanisms need to be in place to communicate findings, with a structure established to receive and act upon each radiology report. A 2019 audit found that in 95% of cases people could access an appropriate bone service. But, only 19% of radiology departments had a defined pathway for people with a vertebral fracture to FLS or osteoporosis service (Royal Osteoporosis Society, 2021). The audit also highlighted that offsite ‘teleradiology’ reporting services (outsourcing a proportion of their reporting of CT imaging) are commonplace in the NHS.

Clinical experts explained that implementation may be more difficult in smaller hospitals, which are likely to have less technical staff.

Diversity in the technologies included

Although the technologies included are all based on AI, there are differences in the image used by each technology. Also, some of the technologies offer additional functions, for example prioritisation of high-risk cases. The technologies might also differ by the populations indicated for use, such as restrictions to specific age groups.

Procurement

Procurement may differ between the technologies with companies offering various pricing options including annual subscriptions and pay per use. Smaller or rural centres that see less people and perform fewer X-rays/CT scans may not have a sufficient volume to justify the cost of an annual site licence. Any requirement for the use of specific multi-vendor platforms may limit which trusts can access specific technologies. Any additional, bespoke company software may also be a potential barrier to implementation and may increase the risk of vendor lock-in.

6.3 Equality issues and considerations

There are geographical inequalities related to radiology services and service capacity. AI technologies to aid the opportunistic detection of VFFs can improve accessibility and equity of access by providing diagnostic services in areas lacking specialised radiologists.

Some bone disorders (for example, scoliosis, ankylosing spondylitis, bridging osteophytes, Scheuermann’s disease and degenerative disc disease) might affect the performance of the technologies. Clinical experts explained that AI technologies may also be less effective when detecting VFFs on images of people who are very elderly.

The incidence of VFFs increases with age from around the age of 50 years. VFFs occur more commonly in women than men at all ages. Osteoporosis is also more common in people of lower socioeconomic status.

People with certain conditions that affect bone density like osteoporosis are more likely to have VFFs. Certain medications like glucocorticoids, which are taken for a number of long-term conditions, may cause a reduction in bone density leading to osteoporosis and subsequently VFFs.

Compared to other ethnic groups, white men and women are at an increased risk of fragility fractures. Also, some ethnic groups may be underrepresented in the population used to train AI to detect VFFs. This may result in the algorithm performing differently in ethnic groups in which it was not developed, trained or validated with. There is a lack of a race-specific reference standard for measurement of bone density, noting that variations exist in bone mineral density across various ethnic groups, which could be a contributory factor to the misdiagnosis of VFF. The effectiveness of DXA and CT also varies significantly across different racial and ethnic groups.

Age, sex, disability and ethnicity are protected characteristics under the Equality Act 2010.

6.4 Other issues for consideration

There are several national datasets, the most established of which is the Digital Imaging Dataset (DID), managed by NHS Digital. In addition, there is the National Imaging Data Collection (NIDC), information from which is visible on the Model Hospital website. These datasets may contain relevant real-world data for this assessment.

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Appendix A. Related guidance

- **Related Guidelines:**

  Osteoporosis: assessing the risk of fragility fracture (2017). Clinical guideline 146.

  Management of osteoporosis and the prevention of fragility fractures (2021). SIGN national clinical guideline 142.

- **Guidelines in development:**

  Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update). Publication date to be confirmed.

- **Related Interventional Procedures Guidance:**

  Percutaneous vertebroplasty (2003). Interventional procedures guidance 12.

  Balloon kyphoplasty for vertebral compression fractures (2006). Interventional procedures guidance 166.

- **Related Technology Appraisals:**

  Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures (2013). Technology appraisal guidance 79.

- **Related Quality Standards:**

  Osteoporosis (2017). Quality standard 149.