NICE advice

HealthVCF for detecting vertebral compression fractures on CT scans

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is HealthVCF. It is used for opportunistically detecting spinal bone (vertebrae) fractures on routine abdominal and chest CT scans.
- The **innovative aspects** are that the technology provides automated information to support radiologists to detect vertebral fractures.
- The intended **place in therapy** would be to support radiologists in secondary care when they are reviewing routine chest and abdominal CT scans. The UK National Screening Committee notes that looking for vertebral compression fractures in people who have not asked for advice on this may be seen as asymptomatic screening and the harms and benefits of such screening has not been evaluated.
- The **main points from the evidence** summarised in this briefing are from 2 retrospective clinical validity cohort studies including 48,434 people with abdominal or chest CT images. An abstract reported that HealthVCF is more effective at

detecting vertebral compression fractures than routine reporting.

- **Key uncertainties** around the evidence are that only 1 of the studies used the commercially available technology alone. This study was reported in abstract form only with limited information. None of the studies report the effect of HealthVCF on patient outcomes or clinical management.
- The **cost** of HealthVCF ranges from £38,000 to £90,000 every year, depending on the total number of scans done at the clinical site using the technology. This is an add on to standard care.

The technology

HealthVCF (Zebra Medical Vision [Zebra-Med]) is software that uses artificial intelligence (AI) to detect moderate-to-severe vertebral compression fractures from CT scans of the chest or abdomen. The AI solution does not distinguish between acute and chronic fractures, but both would be detected by the software. HealthVCF forms part of a wider Bone Health Solution offered by the company. The company states that the Bone Health Solution, which is in development, will include CT predictors of fracture such as bone mineral density. This briefing is focused on HealthVCF, which is currently the only commercially available component of the Bone Health Solution.

CT scans are sent automatically by picture archiving communication systems (PACS) to the Zebra-Med imaging analytics engine (server). Once received, the HealthVCF AI-based algorithm analyses the scans for vertebral compression fractures. Algorithm results are displayed in the Zebra Insight window, the technology's user interface, which automatically appears inside the PACS viewer used to view CT scan images.

According to the company, the software can be configured into 2 distinct modes:

- Direct to radiologist at point of reporting. In this mode, the radiologist is alerted to suspected positive findings in the scan at the time of reading a case and writing the radiology report. This is done through a pop-up alert window when the CT image is opened, which provides images of the detected fracture. The radiologist can confirm or refute the findings and enter locally agreed text into the radiology report. A list of radiologist-approved fractures is auto populated into Zebra Insight, which can then be reviewed and followed up by fracture liaison services (FLS).
- Direct to FLS. In this mode, eligible scans are analysed by the algorithm and a list of

scans with suspected positive findings are sent directly to the FLS team through the Zebra Insights desktop application. The findings can then be reviewed and validated by a specially trained FLS team, with the support of a radiologist.

The company states that on completion of the analysis, the CT images are deleted from the Zebra-Med server. The algorithm results are stored and are accessible to the radiologist in the Zebra Insight window within the PACS workstation.

The company states that Zebra Medical Vision is compliant with General Data Protection Regulations and has the organisational and technical measures in place to fulfil its fundamental requirements.

Innovations

HealthVCF is designed to detect and alert radiologists of suspected vertebral compression fractures in people who are having chest or abdomen CT scans for other indications. The company claims that using HealthVCF allows radiologists to increase reporting of primary fractures in people with osteoporosis. These people can then be referred for fracture prevention care before they have a more serious fracture, such as a hip fracture.

Current care pathway

Vertebral compression fractures can be caused by trauma, cancer, or osteoporosis. Most vertebral compression fractures are identified incidentally when found on chest and abdominal X-ray or CT images taken for other indications.

Osteoporosis is an asymptomatic condition that weakens bone strength, making them fragile and more likely to break. It develops slowly over several years and is often only diagnosed when a fall or sudden impact causes a bone to fracture. The most common injuries in people with osteoporosis are fractures of the wrist, hip, or vertebrae.

NICE's guideline on osteoporosis: assessing the risk of fragility fracture recommends that women aged over 65 and men over 75 should be assessed for fracture risk. People under 65 should also be considered for assessment of fracture risk if they have risk factors such as a history of falls, a previous fragility fracture, or current use of oral or systemic glucocorticoids. Methods of risk assessment includes using tools such as the FRAX tool or the QFracture risk calculator. If a person's risk is high enough that intervention is considered, then bone mineral density (BMD) is measured using a dual

X-ray absorptiometry scan (DXA) and a person's risk score is recalculated using the FRAX tool with BMD.

Treatment for osteoporosis involves treating and preventing fractures and using medicines to strengthen bones. People that have been diagnosed with osteoporosis are referred to fracture liaison services (FLS). FLS are coordinator-based health programmes designed to prevent secondary fractures in people with osteoporosis. Some FLS also offer screening programmes which involve screening for wrist or vertebral fractures in people that are suspected of having osteoporosis.

Population, setting and intended user

HealthVCF is intended as a tool to opportunistically detect vertebral compression fractures from chest or abdomen CT scans in people aged over 50. It would be used by radiologists in secondary care settings to support their review of chest and abdominal CT scans by providing additional information to support detection and treatment planning. HealthVCF may also be used by radiologists who work at an FLS centre who want to systematically enrol people onto a fracture prevention program.

The UK National Screening Committee states that looking for vertebral compression fractures in chest or abdomen CT scans in people who have not asked for advice on these fractures is close to asymptomatic screening. It notes that not everyone will benefit from the knowledge or the treatment of detected fractures. There may also be additional resource needs including more diagnostic and follow-up tests and using staff and healthcare funds that could be used elsewhere.

Costs

Technology costs

Zebra-Med provides the technology with a yearly license fee based on the annual volume of the site (total number of scans done at the clinical site). The solution can be sold under the Bone Health AI Solution package. Prices range from £38,000 to £90,000 every year, depending on the volume of scans done at the site using the technology.

The company states that installation of HealthVCF is done through integration with the PACS and that once it is installed other options can be added without additional technical

work. Zebra-Med's imaging analytics engine can be installed as an on-premises or cloud-based service. The cost of the technology covers training provided by the company.

Costs of standard care

Fracture risk assessment tools such as FRAX or QFracture are available free of charge. The average cost of a DXA scan is £72 (RD50Z; NHS reference costs 2019/20).

The average cost of a CT scan in adults can range from £83 to £115 (NHS reference costs 2019/20). Screening for fracture risk using CT scans is not currently recommended. CT scans would not be done as part of the current osteoporosis care pathway but for a different medical reason.

Resource consequences

The technology would be used alongside standard care and would cost more than using standard care alone. There may be costs savings if the device results in early detection of and improved management of fractures or fracture risk in people with osteoporosis. There is no published evidence to support this.

The company states that they provide a one-day training session for radiologists and IT administrators, which is included in the cost of the software.

Regulatory information

HealthVCF is a class IIa medical device.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Vertebral compression fractures are common in people with cancer and osteoporosis. Osteoporosis is more common in older people and women. Age and gender are protected characteristics under the Equality Act 2010. People with cancer are also protected under

the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement for medtech innovation briefings. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology.

Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

There were 2 studies identified by the literature search that are summarised in this briefing. They include 48,434 people aged 50 and over with abdominal or chest CT images.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The evidence base is limited. Currently there are only 2 published studies on the use of the HealthVCF AI algorithm: 1 full-text publication and 1 conference abstract. Both are retrospective clinical validity cohort studies that report on the performance of the AI algorithm in either detecting vertebral compression fractures or predicting fracture risk (with 2 other products in development). None of the studies report the effect of using the AI technology on patient outcomes or clinical management outcomes.

Only 1 of the studies used the commercially available software (HealthVCF) alone to incidentally detect vertebral compression fractures (Gunasingham et al. 2020). This study reported the specificity and sensitivity of the algorithm in detecting fractures from previous CT scan images, using expert radiologist review as a reference standard. The study reported a specificity of 94% and a sensitivity of 59%. The sensitivity of routine reporting (that is, whether fracture risk had been noted in the original reports of the CT scans) was reported to be 38%. Results were reported in a conference abstract only,

which lacked sufficient methodological detail to fully assess the study.

The other study used HealthVCF with 2 other in-development products to predict fracture risk (Bone Health Solution). In Dagan et al. (2020), the Bone Health Solution algorithm was developed and used to predict fracture risk based on historic data from previous chest or abdominal CT scans of 48,227 people aged 50 to 90. Predictions were then compared with outcomes of major osteoporotic fractures over a 5-year follow-up period. Study results report non-inferior performance to FRAX without bone density (FRAXnb) in predicting both major osteoporotic fracture and hip fracture risk. Results reported that Bone Health Solution algorithm could predict major osteoporotic fractures with 66.5% sensitivity and 64.7% specificity, and hip fractures with 92.6% sensitivity and 36.9% specificity.

There is limited evidence on HealthVCF for detecting spinal bone fractures on CT scans. The evidence base would benefit from further evidence using prospective data collection to fully establish the real-world clinical performance of the HealthVCF AI algorithm. Ideally this evidence would be UK-based. Also, studies evaluating the effect of using the technology on patient outcomes and changes in clinical management would be useful, such as referrals to osteoporotic care.

Dagan et al. (2020)

Study size, design and location

Retrospective clinical validity cohort study assessing HealthVCF with 2 other in-development algorithms (for CT-derived simulated DXA T-scores and evaluated lumbar trabecular density), in predicting 5-year fracture risk. The study was done in Israel and included 48,227 people aged 50 to 90 who had previously had abdomen or chest CT scan as of 2012. Predictions based on historic CT data were compared with outcomes of hip fractures and major osteoporotic fractures during the 5-year follow-up period (2012 to 2017). The prediction performance of the algorithm, alone and with FRAXnb, was compared with that of FRAXnb.

Intervention and comparator

Intervention – HealthVCF with 2 other in-development algorithms (for CT-derived simulated DXA T-scores and evaluated lumbar trabecular density), alone and in combination with FRAXnb.

Comparator – FRAXnb.

Key outcomes

The area under the curve (AUC), sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) measures of the intervention for predicting major osteoporotic fractures were 70.9%, 66.5%, 64.7%, 18.4% and 94.2%, respectively (at a cut-off of 10.3 absolute risk). They were 76%, 92.6%, 36.9%, 5.7% and 99.2%, respectively for predicting hip fractures (at a cut-off of 1.7 absolute risk). The study reported that the intervention had comparable discriminatory performance to FRAXnb, both for major osteoporotic fractures (AUC +1.9%, sensitivity +2.4%, PPV +0.7%) and hip fractures (AUC +0.9%, sensitivity +1.5%, PPV +0.1%). The study reported that when the intervention was used with FRAXnb, the combined prediction tool further improved predictive performance for major osteoporotic fractures (AUC +3.2%, sensitivity +3.3%, PPV +0.9%) and hip fractures (AUC +2.1%, sensitivity +1.5%, PPV +0.1%) compared with FRAXnb alone.

Strengths and limitations

The study included a large population and used data from a large healthcare organisation across multiple centres. Prediction performance was compared with that of FRAXnb, a tool with accepted clinical utility used routinely in NHS practice. Only 5.2% of the potential study population aged 50 to 90 had a relevant CT scan available for analysis. The study population had relatively older ages; a higher proportion of men; and higher rates of previous major osteoporotic fracture, secondary osteoporosis, and glucocorticoids use compared with the baseline population without a CT scan. Scans that were technically inadequate for interpretation by the intervention were excluded from the analysis, but details of how inadequacy was determined was not clearly stated. The technology used in this study comprises HealthVCF with 2 other products that are in development and not yet commercially available. The study was funded by the company.

Gunasingham et al. (2020)

Study size, design and location

A retrospective clinical validity cohort study assessing sensitivity and specificity of HealthVCF for detecting incidental vertebral compression fractures in 207 people over 50 with abdominal or chest CT scans compared with routine reporting in Australia
(104 people with abdominal CT scans and 103 people with chest CT scans).

Intervention and comparator

Intervention – HealthVCF.

Comparator – routine reporting (that is, whether fracture risk had been noted in the original reports of the CT scans).

Reference standard – expert radiologist review.

Key outcomes

The expert radiologist reported the prevalence of vertebral fractures to be 16.5%. The sensitivity of HealthVCF in detecting vertebral fractures was 59% with a specificity of 94%. The PPV was 67% with a NPV of 92%. The sensitivity of routine reporting was 38%.

Strengths and limitations

The study reports appropriate diagnostic outcome measures, a relevant comparator, and the care setting and application of the technology is comparable to the UK. The expert radiologist was blind to the routine report and algorithm findings. The study is reported as an abstract and methodological detail is limited.

Sustainability

The company states that the technology is environmentally friendly because it is a software. The company claims the technology will reduce the use of consumables because of the reduced need for further examinations. There is no published evidence to support these claims.

Recent and ongoing studies

No ongoing studies identified.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not

represent NICE's view.

One expert was familiar with the technology and had examined its technical specifications for a planned clinical effectiveness study. Two experts were familiar with the diagnosis of vertebral fractures using CT chest and abdominal images but had not used the technology.

Level of innovation

Two experts felt that using artificial intelligence (AI) to identify vertebral fractures is novel. One considered the technology to be a minor variation on standard care because they felt that radiologists are more than capable of identifying vertebral fractures on CT scans without using the technology. All experts noted that these types of fractures are often missed, overlooked, or not reported by radiologists. One of the reasons given for this was that vertebral fractures are often not linked to the main clinical issues the reporting radiologists have been asked to consider. Two of the experts identified an alternative competing AI technology. The remaining expert was not aware of any specific competing products but noted that the number of AI technologies in radiology is increasing and it is likely that other products will provide a similar function.

Potential patient impact

Earlier detection of incidental fractures was highlighted by experts as a benefit of the technology, leading to earlier diagnosis of osteoporosis or reduced bone mineral density, more timely clinical management, and reduced risk of future fractures. One expert said all patients having CT scans may benefit because some of the common clinical reasons for having a CT scan (such as malignancies, liver diseases, chronic cardiac and respiratory conditions or their treatments) are also risk factors for osteoporosis. Another said that patients over 55 having routine CT examinations of the chest, abdomen, and pelvis would benefit most from the technology. The remaining expert also agreed that older people are more likely to benefit from the technology than younger people because of the higher prevalence of vertebral fractures.

Potential system impact

Increased identification of patients with osteoporosis and reduced numbers of future fractures was highlighted by experts as being a potential benefit to the healthcare system.

One expert noted that spinal and hip fractures cost the NHS more than £5 million and that the technology could help reduce GP and hospital visits and the numbers of acute hip operations needed.

One expert felt that although adopting the technology would incur a small initial investment, this is likely to be offset in the long-term with savings from fewer primary care and hospital visits, and a decrease in the number of hospital admissions and surgical episodes. One said that adopting the technology would increase costs in the short term and that the cost benefits from reduced future hip fractures would not be seen for several years. One of the experts said that the technology could be cost saving compared with standard care.

Experts highlighted that using the technology would involve more radiologist time to review the reports and it would also increase the referral rates to bone health teams. One noted that an increased need for radiologist time could affect waiting times for reports to be issued. One noted that fracture liaison services would need additional resources to manage increased patient numbers and there would be an increased cost associated with treating patients with osteoporosis.

One expert said that minimal radiologist training (10 to 20 minutes) would be needed, as well as local PACS support training. Another agreed that minimal training would be needed but noted the potential need for radiology information systems integration update training. The expert also noted that the on-premises service needs a small computer server so an area in server rooms with intranet and power connections may be needed.

General comments

The experts said that the technology is not widely used across the NHS. Only 1 NHS trust was identified by experts as using the technology in clinical practice. Data security, availability of IT resources and limits on trust expenditure were identified as potential issues that could prevent adoption. One expert stated that robust quality assurance and accompanying governance structure will need to be in place before adopting these types of technology. One expert noted that the performance of the technology (sensitivity of 59%) appears lower than would be expected for an AI trained to recognise only 1 pathology. They also said that understanding how the AI is predicting future fracture risk from the CT data is important and that this is currently unclear.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Shouvik Saha, consultant radiologist, Royal Wolverhampton NHS Trust, did not declare any interests.
- Richard W Whitehouse, consultant musculoskeletal radiologist, Manchester University Hospitals NHS foundation trust, did not declare any interests.
- Dr Jozsef Illes, consultant radiologist, Dorset County Hospital NHS foundation trust, did not declare any interests.

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