NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

DECODE decision support system for the identification of dementia

1 Technology

1.1 Description of the technology

The DEmentia identification COmputerized DEcision (DECODE) software is a clinical decision support system designed to help identify people that are most likely to benefit from a full dementia assessment. The system uses predictive modelling to estimate the probability of dementia in a given patient, based on clinical information obtained in non-specialist settings. The estimated probability is then provided to the clinician along with suggestions to support clinical decision making, such as whether a full dementia assessment is appropriate. The company claims that DECODE can more accurately identify dementia than brief cognitive assessments and has the potential to reduce waiting lists, reduce the cost per diagnosis, and prevent unnecessary testing and distress in cognitively healthy patients.

The system considers a range of relevant dementia predictors used in primary care to estimate the probability of dementia. It combines relevant information from the patient's clinical history with informant concerns and cognitive assessment scores to produce a personalised probability for each patient, by applying differential weighting. Some of the clinical information is populated automatically from the patient's medical notes while the remainder is entered by the clinician. The predictive algorithms included in the tool have been developed and validated using large population-based cohorts of adults.

The system is intended for use in both primary and secondary care. In primary care, the clinician completes the DECODE assessment within the GP clinical

records system (SystemOne and EMIS). A standalone web-based version of the software is available for use in secondary care memory clinics to triage patients who have been referred from primary care without the use of DECODE or for those referred via non-GP settings.

For the Evidence Standards Framework for digital health technologies, DECODE is classified as a tier 3b calculate technology.

1.2 Regulatory status

DECODE has not yet received a CE mark. The product is currently undergoing regulatory approval for use in the UK.

1.3 Relevant diseases and conditions

DECODE is intended for use in adults with suspected dementia, to identify those who are most likely to benefit from a full dementia assessment.

Dementia is a clinical syndrome caused by a progressive decline in brain function, severe enough to interfere with daily life. This includes problems with memory, communication and language, the ability to focus and pay attention, reasoning and judgment, and visual perception. The main types of dementia include Alzheimer's (accounting for up to 80% of all cases), vascular dementia, dementia with Lewy bodies and frontotemporal dementia (Alzheimer's Association, 2019). Many types of dementia are progressive and can eventually lead to loss of independence, which may severely affect the quality of life of those with dementia. In the later stages of dementia, people are likely to need constant care and attention from family members and / or carers. According to Alzheimer's research UK, there are around 700,000 informal carers of people living with dementia in the UK (Alzheimer's research UK, 2014). Many people in the later stages of dementia will also have behavioural and psychological symptoms. Changes in behaviour may include distress or agitation, aggression, hallucinations and delusions, repetitive behaviour and sleep disturbances (Alzheimer's society, 2019). This may negatively impact on the physical and emotional wellbeing of family members and carers.

According to a report published by Alzheimer's Society, around 850,000 people in the UK are living with dementia and 7.1% of all people over the age of 65 have the condition (Alzheimer's Society, 2014). It was found that the prevalence of dementia is rising with increasing life expectancy. It is projected that by 2051 there will be around 2 million people in the UK with the condition. Dementia has a huge economic impact, with an annual cost to the UK of around £26 billion (Alzheimer's Society, 2014). It is the leading cause of death in the UK, accounting for 1 in every 8 deaths (12.8%) in 2018 (Office for National Statistics, 2019). Age is the biggest risk factor for dementia; 2% of people aged between 65 to 69 have dementia and this increases to 20% for people aged between 85 to 89 (Alzheimer's Research UK, 2019). Women are more likely than men to develop dementia in their lifetimes, mainly because of the longer life expectancy for women. It is estimated that 65% of all people living with dementia are women, while 35% are men (Alzheimer's Research UK, 2019). Identifying people with dementia is clinically challenging, particularly in the early stages, meaning many people with dementia are likely to remain undiagnosed. Diagnosis rates are known to vary by geographical location across the UK and by age. In England, 2018 diagnosis rates were 67.8% for people over 65 and 40.7% for people under 65 (Alzheimer's Research UK, 2019).

1.4 Current management

The NICE guideline on dementia provides recommendations on the assessment and diagnosis of the condition.

An initial assessment is usually done in a non-specialist centre. The guideline recommends taking a history from the person with suspected dementia during the initial assessment as well as from someone who knows the person well (such as a family member), if possible. This includes obtaining details of cognitive, behavioural and psychological symptoms, and the impact these have on daily living. The guideline recommends using a structured instrument, such as the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) or the Functional Activities Questionnaire (FAQ), for the assessment of informant-reported cognitive concerns.

If dementia is still suspected after initial assessment, a physical examination should be done as well as appropriate blood and urine tests to exclude reversible causes of cognitive decline. A structured brief cognitive assessment is also recommended, using validated instruments such as the 10-point cognitive screener (10-CS), the 6-item cognitive impairment test (6CIT), the 6-item screener, the Memory Impairment Screen (MIS) and the Mini-CogTest Your Memory (TYM). According to the guideline, dementia should not be ruled out at initial assessment solely because a person has a normal score on a cognitive instrument. Patients should be referred to a specialist dementia diagnostic service (such as such as a memory clinic or community old age psychiatry service) for a full dementia assessment if dementia is still suspected.

Specialist assessment in secondary care involves a neurological examination and testing for cognitive decline. Structural imaging may be offered to rule out reversible causes of cognitive decline and to assist with subtype diagnosis. Further tests to help diagnose a dementia subtype are recommended only if this information and diagnosis would change clinical management of the condition.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Greater accuracy in detecting dementia, particularly mild and early cases
- Improvements in the referral pathway for patients with dementia, enabling earlier diagnosis and access to dementia services
- Reduction in unnecessary testing and distress in people with a very low likelihood of dementia, as well as more timely testing for alternative diagnoses

The benefits to the health and social care system claimed by the company are:

- Reduction in the number of referrals to secondary care memory clinics for specialist assessment
- Improvement in memory clinic waiting times
- Release of resource and reduction in the overall cost per diagnosis
- Improvement in dementia diagnostic rates

2 Statement of the decision problem

Population	Adults with suspected dementia who are receiving initial assessment in primary care or who have been referred to secondary care for dementia assessment
Intervention	Triaging of patients with the DECODE decision support tool
Comparator(s)	Triaging of patients without the use of DECODE decision support tool
Outcomes	The outcome measures to consider include: • Memory clinic referral waiting times • Number of referrals to memory clinics • Number of specialist assessments done • Time to confirmed diagnosis (for both dementia and non-dementia cases) • Time to first access to dementia services • Total number of dementia diagnoses • Overall dementia diagnostic rates • Diagnostic rates of non-dementia conditions • Healthcare professional acceptability and feasibility, including training requirements • Patient satisfaction • Health-related quality of life of patients and carers
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	• Adults with suspected dementia receiving initial assessment in primary care • Adults with suspected dementia referred to secondary care memory clinics • Severity of dementia - mild, moderate or severe
Special considerations, including those related to equality	Some of the information used by DECODE is taken from the GP clinical records. There may be special considerations when using the technology for people whose GP records are lacking data or are incorrect. Consideration should be given to the potential for DECODE to improve dementia triaging for people with a disability. Disability is a protected characteristic under the Equality Act.

Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No
	Age is the biggest risk factor for dementia. Women are more likely than men to develop dementia in their lifetime. People with learning disabilities or those with a severe hearing or sight impairment may need special arrangements when being triaged for dementia. People with dementia may be considered as having a disability because the condition can have a substantial and long-term impact on their ability to do normal day to day activities. Age, sex and disability are all protected characteristics under the Equality Act 2010.	
Any other special considerations	Not applicable	

3 Related NICE guidance

Published

- Dementia: assessment, management and support for people living with dementia and their carers. NICE clinical guideline NG97 (2018).
- Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease. NICE technology appraisal guidance TA217 (2018).
- Dementia, disability and frailty in later life – mid-life approaches to delay or prevent onset. NICE interventional procedure guidance NG16 (2015).

Under development

NICE is developing the following guidance (details available from www.nice.org.uk):

- Dementia (non-Alzheimer) - new pharmaceutical treatments. NICE technology appraisal guidance. Publication expected TBC.

4 External organisations

4.1 Professional organisations

The following societies have been alerted to the availability of the draft scope for comment:

- Royal College of General Practitioners
- Royal College of Physicians
- Royal College of Psychiatrists
- Royal College of Nursing (RCN)
- The Neurological Alliance
- Institute of Neurology
- Primary Care Neurology Society
- Association of British Neurologists
- British Neuropathological Society
- British Neuropsychiatry Association
- Dementia & Neurodegenerative Diseases Research Network
- British Geriatrics Society
- British Psychological Society
- Association of British Neurologists
- British Neuropathological Society
- Institute of Psychiatry

4.2 Patient organisations

NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Age UK
- Alzheimer's Research UK
- Alzheimer's Society
- Dementia Action Alliance
- Dementia UK

- Life Story Network
- Young Dementia UK