Institution: The University of Edinburgh

Unit of Assessment: 4

Title of case study: D: The FOOD trials: feeding policies in hospitalised stroke patients influence patient outcomes

1. Summary of the impact (indicative maximum 100 words)

Impact: Health and wellbeing; improvement in mortality and morbidity; changes in policy and guidelines.

Significance: Clinical trial findings have led to 1160 fewer deaths and 780 fewer severely disabled patients each year in the UK; rationalising feeding policies saves over £12M annually.

Beneficiaries: Stroke patients, the NHS and healthcare delivery organisations, the economy.

Attribution: Trials were designed and led by Professor M Dennis, UoE.

Reach: Worldwide: revised national guidelines in UK, Europe, North America, South Africa, Singapore, Australasia.

2. Underpinning research (indicative maximum 500 words)

Professor Martin Dennis (Professor of Stroke Medicine, UoE, 1990–present) demonstrated that stroke patients, of which there are 15 million new cases worldwide per year, are frequently elderly and under-nourished and about half have difficulties with swallowing caused by the stroke. He demonstrated that patients with poor nutrition are about twice as likely to die after stroke as well-nourished patients [3.1]. In the 1990s, surveys of practice indicated wide variations in the use of oral nutritional supplements, and in the timing and type of enteral tube feeding. Small trials and systematic reviews suggested that routine oral supplementation of the hospital diet may improve outcomes among elderly patients admitted to hospital, and that early feeding via percutaneous endoscopic gastrostomy (PEG), rather than a nasogastric tube, results in reduced mortality.

With £940K funding from the NHS Research and Development Health Technology Assessment Programme, the Stroke Association and Chest Heart & Stroke Scotland, Dennis, Professor Charles Warlow (Professor of Neurology, now Emeritus, UoE, 1987–2008), Dr Steff Lewis (Lecturer in Statistics, UoE, 1997–present) and Dr John Forbes (Reader in Health Economics, UoE, 1987–2013) established the Feed Or Ordinary Diet (FOOD) trials - three multicentre randomised controlled trials to evaluate feeding policies in hospitalised stroke patients. Trials 1–3 comprised 4023, 859 and 321 patients from 15, 15 and 11 countries, respectively. The trials ran between 1996 and 2004 and were reported in 2005 and 2006 [3.2–3.4].

Trial 1 compared a normal hospital diet with oral supplementation. The supplemented diet was associated with an absolute reduction in the risk of death of only 0.7% and a 0.7% increased risk of death or poor outcome. The data did not support routine supplementation for unselected stroke patients who are well nourished on admission.

Trial 2 compared early tube feeding with avoiding tube feeding. Early tube feeding was associated with an absolute reduction in the risk of death of 5.8% and a reduction in death or poor outcome of 1.2%. In other words, a policy of early tube feeding may substantially reduce the risk of dying after stroke, and it is very unlikely that the alternative policy of avoiding early tube feeding would significantly improve survival. Improved survival may be at the expense of increasing the proportion of patients surviving with poor outcome. These data might usefully inform the difficult discussions about whether to feed a patient with a severe stroke.

Trial 3 compared PEG with nasogastric tube feeding. PEG was associated with an increase in the

absolute risk of death of 1.0% and an increased risk of death or poor outcome of 7.8%. The data suggested that better functional outcomes result from feeding via nasogastric tube than PEG, although there was no major difference in survival. The data do not support the policy of early initiation of PEG feeding in dysphagic stroke patients that had been promulgated by previous small studies.

3. References to the research (indicative maximum of six references)

3.1 The FOOD Trial Collaboration. Poor nutritional status on admission predicts poor outcomes after stroke: observational data from the FOOD trial. Stroke. 2003;34:1450–6. DOI: 10.1161/01.STR.0000074037.49197.8C.

3.2 The FOOD Trial Collaboration. Routine oral nutritional supplementation for stroke patients in hospital (FOOD): a multicentre randomised controlled trial. Lancet. 2005;365:755–63. DOI: 10.1016/S0140-6736(05)17982-3.

3.3 The FOOD Trial Collaboration. Effect of timing and method of enteral tube feeding for dysphagic stroke patients (FOOD): a multicentre randomised controlled trial. Lancet. 2005;365:764–72. DOI: 10.1016/S0140-6736(05)17983-5.

3.4 Dennis M, Lewis S, Cranswick G, Forbes J, FOOD Trial Collaboration. FOOD: a multicentre randomised trial evaluating feeding policies in patients admitted to hospital with a recent stroke. Health Technol Assess. 2006;10:1–120. DOI: 10.3310/hta10020.

4. Details of the impact (indicative maximum 750 words)

The FOOD trials showed that (i) routine oral supplements had little effect on outcomes, (ii) that in patients who could not swallow, early tube feeding showed a trend towards improved survival, and (iii) that early use of PEG was associated with worse functional outcomes.

Pathways to impact

The trial team conducted a substantial programme of dissemination activities beyond the three primary results publications. These included many local, national and international conference presentations; materials posted on the FOOD website (www.dcn.ed.ac.uk/food/); co-authorship of a Cochrane review and secondary publications; and engagement with guideline committees, including the National Institute for Health and Care Excellence (NICE), Royal College of Physicians and Scottish Intercollegiate Guidelines Network (SIGN).

Impact on public policy

The results of the FOOD trials have had direct implications for the management of at least 100,000 stroke patients admitted to hospital each year in the UK, and many of the 15 million patients with stroke each year worldwide.

The results of the FOOD trials have been used as the basis for national guidelines in the UK, Canada, Italy, Australia, Singapore and South Africa [5.1–5.6].

The third edition of the UK National Clinical Guidelines for Stroke (2008) references the FOOD trials 2 and 3 and recommends that a nasogastric tube is used after 24–48 hours. PEG may be considered within 4 weeks if the patient cannot tolerate nasogastric feeding, but otherwise not until 4 weeks. These guidelines were revised since the first edition on the basis of the FOOD trials data.

Impact on health and welfare

<u>1160 deaths prevented per year</u>

Based on the estimates of effect seen in the FOOD trial 2 (a 5.8% absolute reduction in death at 6 months – 58 deaths avoided/1000 patients) and assumptions based on Dennis' 2003 survey of UK clinicians [3.4], 1160 additional patients would survive compared with a policy of avoiding tube feeding for at least a week, which was common prior to publication of the trials' results.

780 severe disabilities avoided per year
Based on the effect sizes seen in the FOOD trial 3 (7.8% absolute difference in severe disability – 78 severely disabled patients/1000 treated with early PEG) and assumptions based on Dennis' 2003 survey [3.4], 780 patients might avoid poor outcomes (severe disability) in the UK each year by avoiding an early PEG tube insertion, with no effect on survival.

Improved hospital experience for up to 40,000 patients per year
Based on the estimates of effect seen in the FOOD trial 1 and assumptions based on Dennis' 2003 survey [3.4], up to 40,000 patients may now be avoiding unnecessary supplements each year in the UK without a detriment to their clinical outcome. Many of those patients would have found the supplement unpalatable, which would have had a detrimental effect on their hospital experience.

Impact on the economy
As a result of FOOD trial 1, an estimated 40,000 patients in the UK each year will avoid receiving routine oral supplements (£10 per day). Based on an average hospital stay of 25 days, this amounts to a saving to the NHS of £250 per patient and £10M per year.

According to a survey conducted by Dennis in 2003, 84% would, if resources allowed, insert a PEG within the first 4 weeks. Given the prevalence of prolonged dysphagia, this is estimated to translate into 10,000 PEG insertions per year. Avoiding these PEG insertions by using nasogastric tube feeding will save the NHS approximately £2M each year (£200 per PEG insertion).

In addition, the trials' findings suggested that early PEG insertion might increase severe disability (78/1000 patients), resulting in 780 more severely disabled patients per year; the associated costs of this are possibly as much as £40M if the total cost of caring for a severely disabled stroke patient is estimated at about £50K.

5. Sources to corroborate the impact (indicative maximum of 10 references)

5.1 Intercollegiate Stroke Working Party National clinical guideline for stroke, third edition (2008). http://bookshop.rcplondon.ac.uk/contents/6ad05aab-8400-494c-8cf4-9772d1d5301b.pdf. *[UK guidelines.]*

5.2 SIGN Guideline 118 (2010). Management of patients with stroke: rehabilitation, prevention and management of complications, and discharge planning. http://www.sign.ac.uk/pdf/sign118.pdf. *[Scottish guidelines.]*

5.3 Canadian Best Practice statement, fourth edition (2013). http://www.strokebestpractices.ca/index.php/acute-stroke-management/inpatient-management-and-prevention-of-complications-following-acute-stroke-or-tia/. *[Canadian guidelines.]*

5.4 Clinical Guidelines for Stroke Management (2010). http://strokefoundation.com.au/site/media/clinical_guidelines_stroke_managment_2010_interactive.pdf. *[Australian guidelines.]*

5.5 Stroke and Transient Ischaemic Attacks. MOH Clinical Practice Guidelines (2009). http://www.moh.gov.sg/content/dam/moh_web/HPP/Doctors/cpg_medical/current/2009/CPG_Stroke_Booklet.pdf. *[Singaporean guidelines.]*

5.6 South African guideline for management of ischaemic stroke and transient ischaemic attack (2010): A guideline from the South African Stroke Society (SASS) and the SASS Writing Committee. S Afr Med J. 2010;100:750–78. http://www.samj.org.za/index.php/samj/article/viewFile/4422/3005. *[South African guidelines.]*