Treatment of irritable bowel syndrome in primary care

Ispaghula, antispasmodics, and peppermint oil should be considered

RESEARCH, p 1388

Roger Jones professor, Department of General Practice and Primary Care, King's College London, London SE11 6SP
roger.jones@kcl.ac.uk

Competing interests: None declared.

Provenance and peer review: Commissioned; not externally peer reviewed.

Cite this as: *BMJ* 2008;337:a2213
doi: 10.1136/bmj.a2213

Irritable bowel syndrome is a common condition with a community prevalence of 10-15% of the general population.[1 2] The annual incidence in primary care is around 0.8%, and the prevalence of patients diagnosed in primary care is about 3-4%.[3] The disorder is difficult to treat, hence the wide range of treatments used—dietary exclusion, fibre supplements, and probiotics; antispasmodic drugs, antidiarrhoeal agents, and laxatives; antidepressants, hypnotherapy, and cognitive behavioural therapy. This unusual spectrum of drug and non-drug treatments also highlights our ignorance about the cause of the condition. In the linked systematic review, Ford and colleagues summarise the effects of three different agents—fibre, antispasmodic drugs, and peppermint oil—in people with the syndrome.[4]

In the 1990s a range of new agents acting on 5-hydroxy-tryptamine type 3 and type 4 receptors in the enteric nervous system held considerable therapeutic promise. Most of them, however, failed to find a place in the routine drug treatment of irritable bowel syndrome because of lack of efficacy, serious adverse effects, or both. These disappointments added to the general scepticism about treating the syndrome with drugs, which is compounded by the high placebo response seen in therapeutic trials.

Such reservations are reflected in the neutral treatment advice given to patients by the American Gastroenterology Association,[5] and the qualified suggestions for drug treatment given by CORE—the UK digestive diseases charity[6]—and the British Society for Gastroenterology.[1] Complementary and alternative approaches feature strongly in the recently published National Institute for Health and Clinical Excellence (NICE) guidelines,[7] with cognitive behavioural therapy and hypnotherapy suggested if symptoms persist beyond 12 months.

Ford and colleagues' systematic review and meta-analysis includes data on more than 2500 patients with irritable bowel syndrome.[4] At first glance their conclusions look like good news for patients (and prescribers), with numbers needed to treat (NNTs) for fibre, antispasmodics, and peppermint oil of 11.5, 5, and 2.5, respectively. However, as always, the devil is in the detail.

Although the trials of fibre show an overall benefit, analysis of the effect of different kinds of fibre shows that bran is not effective and that only ispaghula significantly reduces symptoms (NNT 6). However, the effect is no longer significant when only the highest quality studies are analysed. Nevertheless, these findings add support to NICE guidance,[7] which advises against the use of insoluble fibre (such as bran) and recommends the use of soluble fibre (such as ispaghula).

The analysis of antispasmodic agents includes studies on a dozen different agents, with the most impressive therapeutic effects being shown for otilonium, cimetropium, hyoscine, and pinaverium. There was some evidence of publication bias, and the authors expressed reservations about the strength of their conclusions for otilonium and cimetropium because of heterogeneity between trials. The best evidence of efficacy was for hyoscine. Hyoscine butylbromide is an antimuscarinic agent extracted from the cork wood tree. It is not widely used in primary care in the United Kingdom at present—10 times more prescriptions are written for mebeverine than for hyoscine.[8] Hyoscine is available without prescription from pharmacists in many countries, including the UK and United States.

Peppermint oil, which is also available without prescription, seems to be the most promising agent—NNT 2.5—although this figure was based on only four trials of fewer than 400 patients in total. However, secondary analysis of the three highest quality of these trials showed a similar treatment effect, with little heterogeneity between trials. None of these agents had significant adverse effects.

Limitations of the meta-analysis include the lack of information on the subtype of irritable bowel syndrome (constipation predominant, diarrhoea predominant, or alternating pattern), drug dosage, and patterns of administration. The analysis provides no guidance on patient selection for particular agents on the basis, for example, of demographic factors, disease subtype, or clinical history, which limits the implementation of the findings.

It may be a little premature to follow the authors' recommendation that national guidelines should be updated to include therapeutic guidance on these agents, but the results should reawaken an interest in the pharmacotherapy of irritable bowel syndrome and stimulate further research. Trials should have sufficient power and patients be better characterised so that predictors of response to treatment can be identified. There may also be a place for "N of 1 trials" in individual patients to determine individual therapeutic responses.[9] None of these data, of course, invalidate the importance

of making a "holistic" diagnosis in irritable bowel syndrome—that takes into account physical, psychological, and social factors—and of planning an integrated approach to treatment, which deals with all of these factors.[10]

1 Spiller R, Aziz Q, Creed F, Emmanuel A, Houghton L, Hungin P, et al. Guidelines on the irritable bowel syndrome: mechanisms and practical management. *Gut* 2007;56:1770-98.
2 Hungin AP, Chang L, Locke GR, Dennis EH, Barghout V. Irritable bowel syndrome in the United States: prevalence, symptoms patterns and impact. *Aliment Pharmacol Ther* 2005;21:1365-75.
3 Jones R, Latinovic R, Charlton J, Gulliford M. Physical and psychological co-morbidity in irritable bowel syndrome: a matched cohort study using the general practice research database. *Aliment Pharmacol Ther* 2006;24:879-86.
4 Ford AC, Talley NJ, Spiegel BMR, Foxx-Orenstein AE, Schiller L, Quigley EMM, et al. Efficacy of fibre, antispasmodics, and peppermint oil in irritable bowel syndrome: systematic review and meta-analysis. *BMJ* 2008;337:a2313.
5 American Gastroenterology Association. *Irritable bowel syndrome*. 2008. www.gastro.org/wmspage.cfm?parm1=4032.
6 CORE. *Irritable bowel syndrome*. 2008. www.corecharity.org.uk/content/view/107/22/1/1/.
7 Dalrymple J, Bullock I. Diagnosis and management of irritable bowel syndrome in adults in primary care: summary of NICE guidance. *BMJ* 2008;336:556-8.
8 NHS Health and Social Care Information Centre. *Prescription cost analysis England 2005*. 2006. www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescribing/prescription-cost-analysis-2005.
9 Madhok V, Fahey T. N-of-1 trials: an opportunity to tailor treatment in individual patients. *Br J Gen Pract* 2005;512:172.
10 Jones R. An integrated approach to the management of IBS. *Nat Clin Pract Gastroenterol Hepatol* 2007;4:354-5.

Cardiovascular disease and cancer in very old age

Risk seems to plateau, but other causes of death are poorly defined

RESEARCH, p 1400

Timo E Strandberg professor of geriatrics, Department of Health Sciences/Geriatrics, University of Oulu, and Unit of General Practice, Oulu University Hospital, FIN-90014 Oulu, Finland
timo.strandberg@oulu.fi

Competing interests: None declared.
Provenance and peer review: Commissioned; not externally peer reviewed.
Cite this as: *BMJ* 2008;337:a2521
doi: 10.1136/bmj.a2521

Death in young or middle aged people usually has a single, well defined cause, whereas cause of death in older people is often poorly defined. The multifaceted nature of the association between death and disability is gradually being realised.[1] An older person may have a sudden cardiac death or succumb to rapidly advancing cancer, but a more common scenario is a fluctuating worsening of health towards death—for example, because of heart failure. Another pattern—gradual loss of life force—is seen especially in frail, institutionalised patients.

In the linked study, Driver and colleagues analysed the effect of increasing age on the most important causes of death in developed societies: cardiovascular diseases and cancer.[2] The study assesses the interaction between age and the main causes of death in 22 048 male doctors aged 40-84 in the United States. The most intriguing results are those in men aged 80-90, in whom the residual lifetime risk of cancer and cardiovascular diseases seems to plateau, even decrease. The lifetime risk of cancer was 45.1% (95% confidence interval 43.8 to 46.3) at age 40 and 9.6% (7.2 to 11.9) at age 90. The lifetime risk of major cardiovascular disease was 34.8% (33.1 to 36.5) at age 40 and 16.7% (12.9 to 20.6) at age 90. The findings seem to contradict the widespread belief that these diseases increase in ageing societies and substantially drain health services.

The results are a reminder of the many paradoxes in health, disease, and death of very old people. For example, a recent study of Danish nonagenarians and centenarians showed that although the individual risk of disability rose with age, disability in the population was not increased during the ninth decade of life.[3] This is because nonagenarians with the most disability at any timepoint are more likely to die sooner, and therefore the burden of disability in the cohort remains constant over time.

Old age leads to a selected population of people who for some reason have not died earlier—often because of a combination of lack of risk factors (for example, hypertension, dyslipidaemia, diabetes, smoking), presence of protective factors (resistance to oxidative stress, longevity genes), and good luck. But because everybody dies eventually, various causes of death compete in old people, leading to further paradoxes. For example, if you don't live to be old, you are spared from dementia. So from a tongue in cheek perspective, smoking could be recommended for the prevention of dementia, because it would prevent people from reaching the age when dementia usually develops. A similarly foolish argument is that prevention of cardiovascular disease is not worth while, because people who avoid such diseases will get cancer instead. Many people would prefer to prevent cardiovascular death at 50 even if they might then get cancer at 80.

But if the oldest doctors have a reduced risk of death from cardiovascular causes and cancer, what do they die of—dementia, accidents, or "old age"? The present study does not answer this question. Dementia is an accepted diagnosis, but is it acceptable to attribute death to frailty or old age? Although geriatricians have defended older people's right to receive a proper diagnosis, a recent study showed that the amount of poorly defined diagnoses in acutely ill patients increased by 91% between 1995 and 2003, with the greatest increase in those aged 65 and over.[4]

Clues about causes of death may come from studies on centenarians.[5] Epidemiological studies have shown that only a minority of centenarians have been healthy all their lives—most of them have either survived chronic disease, or delayed it.[6] Dementia is a common ailment in the oldest people,[7] and predisposes to death by several mechanisms, but cognitive decline is not necessarily communicated in death certificates. Frailty is also common in men over 80,[8] and predisposes to death, but it is probably seldom

recorded as a cause of death. Should we use these diagnoses in death certificates more often?

The death of extremely old people over 110—"supercentenarians"—is a case of its own. Examination of a 115 year old Dutch woman showed that it is possible to live very long with hardly any atherosclerosis and neurodegeneration.[9] She eventually died of cancer, but in other supercentenarians a specific form of cardiac amyloidosis[10] has been argued to be an important cause of death.[5]

Driver and colleagues' results do not rule out cardiovascular disease and cancer as important causes of death in very old people, but the probability of developing these diseases seems to diminish if they have been avoided for a long time. Vascular pathology may nevertheless underlie many geriatric syndromes—including frailty and falls—through white matter lesions in the brain.[11] This is the masked, long term dimension of vascular risk factors such as hypertension, which we should more effectively be able to prevent or postpone in the future. However, the cancers that were reduced in older doctors in Driver and colleagues' study were the types that can be detected by screening. Would less competition from cardiovascular disease and frailty give these cancers time to manifest clinically? Only time will tell. But we may be spared from pondering these complexities—with the prevalence of obesity and diabetes increasing, cardiovascular disease will probably remain an important determinant of potentially declining life expectancies.[12]

1 Lunney JR, Lynn J, Foley DJ, Lipson S, Guralnik J. Patterns of functional decline at the end of life. *JAMA* 2003;289:2387–92.
2 Driver JA, Djousse L, Logcroscino G, Gaziano JM, Kurth T. Incidence of cardiovascular disease and cancer in very old people: prospective cohort study. *BMJ* 2008;337:a2467.
3 Christensen K, McGue M, Petersen I, Jeune B, Vaupel JW. Exceptional longevity does not result in excessive levels of disability. *Proc Natl Acad Sci* 2008;105:13274-9.
4 Walsh B, Roberts HC, Nicholls PG, Lattimer VA. Trends in hospital inpatient episodes for signs, symptoms and ill-defined conditions: observational study of older people's hospital episodes in England, 1995-2003. *Age Ageing* 2008;37:455-8.
5 Leslie M. Searching for the secrets of the super old. *Science* 2008;321:1764-5.
6 Evert J, Lawler E, Bogan H, Perls T. Morbidity profiles of centenarians: survivors, delayers and escapers. *J Gerontol Biol Sci Med Sci* 2003;58A:232-7.
7 Corrada MM, Brookmeyer R, Berlau D, Paganini-Hill A, Kawas CH. Prevalence of dementia after age 90: results from the 90+ study. *Neurology* 2008;71:337-43.
8 Cawthon PM, Marshall LM, Michael Y, Dam T-T, Ensrud KE, Barrett-Connor E, et al. Frailty in older men: prevalence, progression, and relationship with mortality. *J Amer Geriatr Soc* 2007;55:1216-33.
9 den Dunnen WFA, Brouwer WH, Bijlard E, Kamphuis J, van Linschoten K, Eggens-Meijer, et al. No disease in the brain of a 115-year-old woman. *Neurobiol Aging* 2008;29:1127-32.
10 Tanskanen M, Peuralinna T, Polvikoski T, Notkola IL, Sulkava R, Hardy J, et al. Senile systemic amyloidosis affects 25% of the very aged and associates with genetic variation in alpha2-macroglobulin and tau: a population-based autopsy study. *Ann Med* 2008;40:232-9.
11 Inzitari M, Pozzi C, Rinaldi LA, Masotti G, Marchionni N, Di Bari M. Cognitive and functional impairment in hypertensive brain microangiopathy. *J Neurol Sci* 2007;257:166-73.
12 Olshansky SJ, Passaro DJ, Hershow RC, Layden J, Carnes BA, Brody J, et al. A potential decline in life expectancy in the United States in the 21st century. *N Engl J Med* 2005;352:1138-45.

How should health be defined?

Join a global conversation at blogs.bmj.com/bmj

Alejandro R Jadad professor, Centre for Global eHealth Innovation; Department of Health Policy, Management and Evaluation; Dalla Lana School of Public Health; Faculty of Medicine, University of Toronto; and University Health Network, Toronto, Canada M5G 2C4
ajadad@ehealthinnovation.org
Laura O'Grady postdoctoral fellow, Centre for Global eHealth Innovation; Department of Health Policy, Management and Evaluation; Dalla Lana School of Public Health; Faculty of Medicine, University of Toronto; and University Health Network, Toronto, Canada M5G 2C4

Competing interests: None declared.
Provenance and peer review: Commissioned based on an idea from the authors; not externally peer reviewed.
Cite this as: *BMJ* 2008;337:a2900
doi: 10.1136/bmj.a2900

On 7 April 1948, the member states of the United Nations ratified the creation of the World Health Organization. It was set up with the fundamental objective of "the attainment by all peoples of the highest possible level of health." This lofty goal was coupled with an equally ambitious opening statement that defined health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."[1]

This definition invited nations to expand the conceptual framework of their health systems beyond the traditional boundaries set by the physical condition of individuals and their diseases, and it forced us to pay attention to what we now call social determinants of health. Consequently, WHO challenged political, academic, community, and professional organisations devoted to improving or preserving health to make the scope of their work explicit, including their rationale for allocating resources. This opened the door for public accountability.

But the founding principles of WHO are still unfulfilled because many countries have failed to reduce the staggering numbers of premature deaths or to cope with the onslaught of chronic complex conditions. The Millennium Development Goals, most of which are directly or indirectly related to health, may not be achieved by 2015, as was initially envisioned,[2] and are unlikely to be met in the next two decades.[3] In addition, the ageing population is increasing the prevalence of chronic incurable diseases, which are associated with 60% of deaths worldwide and more than 80% in low to middle income countries.[4]

So what does the future hold? Were the goals set in 1948 too ambitious? Is the concept of health a "deception"?[5] Should we lower or readjust our expectations about our ability to decrease the number of premature deaths and our power to conquer chronic diseases? Is it even possible to reach a basic level of agreement on the meaning of the word health? Is health a construct that can be defined and measured? Can any definition of health be operational?

The biomedical literature is of little help. A search of Medline from 1950 to June 2008—with the terms "World Health Organization", "health", and "definition" (or "defined")—yielded 2081 citations. Of these, only a handful focused specifically on the definition

of health.[6-10] Some of these articles highlight its lack of operational value and the problem created by use of the word "complete." Others declare the definition, which has not been modified since 1948, "simply a bad one."[10 11] More recently, Smith suggested that it is "a ludicrous definition that would leave most of us unhealthy most of the time."[5] Interestingly, a Google search on 23 July 2008 using the terms "health" and "definition", yielded more than 14 million hits, with Wikipedia, not WHO as the top hit.

Witnessing the rapid rise of wikis, blogs, and many other online social networks (such as FaceBook, YouTube, and MySpace), we wonder if we are ready for what has been called the Fifth Estate,[12] a new form of civil society participation, enabled by the growing use of the internet, mobile phones, and related information and communication technologies. This is why we have created a blog on http://blogs.bmj.com/bmj/2008/12/05/alex-jadad-on-defining-health/ that includes the original definition of health as proposed by WHO in 1948, and an invitation to anyone with internet access to comment on it, to challenge it, or to try to enhance it.

In the end, we might conclude that any attempt to define health is futile; that health, like beauty, is in the eye of the beholder; and that a definition cannot capture its complexity. We might need to accept that all we can do is to frame the concept of health through the services that society can afford, and modulate our hopes and expectations with the limited resources available, and common sense.

1 WHO. *Constitution of the World Health Organization.* 2006. www.who.int/governance/eb/who_constitution_en.pdf.
2 United Nations. *The Millennium Development Goals report 2008.* 2008. www.un.org/millenniumgoals/pdf/The%20Millennium%20Development%20Goals%20Report%202008.pdf.
3 Tanne JH. UN global summit disappoints aid groups. *BMJ* 2005;331:651.
4 WHO. *Chronic diseases and health promotion*. 2008. www.who.int/chp/en/.
5 Smith R: *The end of disease and the beginning of health*. BMJ Group blogs. 2008. http://blogs.bmj.com/bmj/2008/07/08/richard-smith-the-end-of-disease-and-the-beginning-of-health/.
6 Breslow L. A quantitative approach to the World Health Organization definition of health: physical, mental and social well-being. *Int J Epidemiol* 1972;1:347-55.
7 Usuda K, Tamashiro H, Kono K. Some discussion on why WHO definition of health has not been revised [In Japanese]. *Jpn J Publ Health* 2000;47:1013-7.
8 Larson JS. The conceptualization of health. *Med Care Res Rev* 1999;56:123-36.
9 Saracci R. The World Health Organization needs to reconsider its definition of health. *BMJ* 1997;314:1409-10.
10 Callahan D. The WHO definition of "health." *Studies/Hastings Center* 1973;1:77-88.
11 WHO. *WHO definition of health*. 2003. www.who.int/about/definition/en/print.html.
12 Dutton WH. *Through the network (of networks)—the fifth estate*. Social Sciences Research Network, 2007. http://ssrn.com/abstract=1134502.

Cryotherapy and high intensity focused ultrasound for prostate cancer

More evidence is needed before they can be recommended for widespread use

Fergus Macbeth director, National Collaborating Centre for Cancer, Cardiff CF10 3AF
Fergus.Macbeth@nccc.wales.nhs.uk
Nathan Bromham researcher, National Collaborating Centre for Cancer, Cardiff CF10 3AF
Robert Kagan emeritus chief of radiation oncology, Southern California Permanente Medical Group, Los Angeles, CA 90027, USA

Competing interests: FM and NB work for the National Collaborating Centre for Cancer which is funded by the National Institute for Health and Clinical Excellence and for whom the systematic review informing this editorial was carried out. The views expressed in this publication are those of the authors and not necessarily those of the institute.
Provenance and peer review: Commissioned; externally peer reviewed.

Cite this as: *BMJ* 2008;337:a2540
doi: 10.1136/bmj.a2540

Men with prostate cancer and their healthcare professionals are faced with several options for treating the primary tumour at the time of diagnosis and any recurrence. Newer treatments such as cryotherapy and high intensity focused ultrasound are available in some centres in the UK and have enthusiastic advocates.

In 2005, the National Institute for Health and Clinical Excellence (NICE) issued guidance on cryotherapy and ultrasound treatment saying that "the current evidence on efficacy and safety" seemed "adequate to support their use" in patients with prostate cancer.[1 2] But in 2008, NICE published clinical guidelines on prostate cancer which stated that these treatments "are not recommended for men with localised prostate cancer other than in the context of controlled clinical trials comparing their use with established interventions."[3] This apparent change of heart caused concern among urologists and even reached the national press.[4] However, the advice was not really inconsistent—NICE deemed these techniques safe and efficacious enough to be used but thought that the evidence on their clinical effectiveness compared with alternatives was insufficient to recommend their routine use in the NHS.

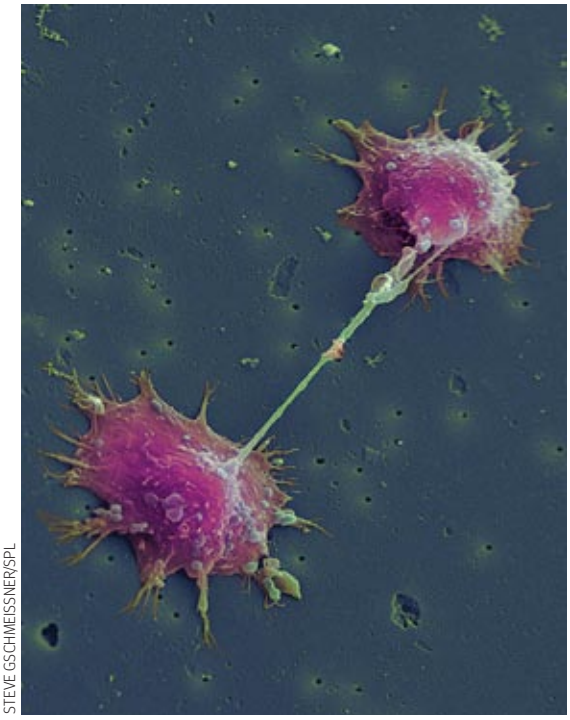
Cryotherapy is increasingly being used in the United States, especially in patients with local recurrence after radiotherapy. High intensity focused ultrasound is not approved for use. The American Urological Association's 2007 clinical guideline on prostate cancer did not include either treatment because of the lack of published evidence.[5] The association published a *Best Practice Statement* on cryotherapy in 2008, however, which acknowledges the lack of comparative data but includes consensus opinion that it is an option for selected patients as primary treatment and on relapse after radical radiotherapy.[6]

The European Association of Urology also published guidelines on prostate cancer in 2007, which are more cautious.[7] Cryotherapy is described as a possible alternative treatment in patients unfit for surgery or in those with a life expectancy of less than 10 years. High intensity focused ultrasound, along with other interventions, is described as still experimental or investigational.

So, what is the current evidence underpinning the 2008 NICE guidelines? No fully published randomised trials are available, and the evidence for both interventions came from reports of case series or observational studies.

Cryotherapy

For cryotherapy, the evidence comprised 16 original publications that studied 2102 men (median study size 85 men, range 48-590) and three systematic reviews.



STEVE GSCHMEISSNER/SPL

Coloured scanning electron micrograph (SEM) of prostate cancer cells in the final stage of cell division (cytokinesis)

Most men had disease confined to the prostate and clinical tumour stage T1-T2, although around 15% had T3 or T4 disease. Reports included men treated with older cryotherapy techniques and more recent third generation machines. Series also differed in the proportion of men treated with neoadjuvant hormonal therapy (0-91%) and those treated with salvage cryotherapy after radiotherapy (0-15%).

Follow-up was relatively short—only two studies (of 130 men) had a median follow-up greater than three years. In these two series, 89-92% of men were alive five years after treatment, with 1-6% having died of prostate cancer during this time. A positive prostate biopsy after cryotherapy was seen in 1.4-28% of men. A year after treatment, 63-75% of men had a prostate specific antigen concentration lower than 1.0 µg/l. Commonly reported complications were impotence (47-100%), stress incontinence (1-19%), and urethral sloughing (4-37%).

High intensity focused ultrasound

For high intensity focused ultrasound the evidence was limited to reports of case series from nine centres where this technique was used as primary treatment; 884 men were studied (median study size 103 men, range 14-271). Clinical tumour stage was T1 or T2 in all men. Treatment included the use of prototype machines and commercially available machines. Some men received ultrasound therapy without transurethral resection of the prostate, and centres differed in their use of hormonal therapy.

Again, the median follow-up was short, less than two years in most cases. No data were available on overall survival or disease specific survival. A positive prostate biopsy after treatment was seen in 6-23% of men, and 16-31% of men had biochemical recurrence within a year of treatment. Commonly reported complications were impotence (20-66%), stress incontinence (with transurethral resection of the prostate 7-9%, without 15-28%), and urinary tract infection (with transurethral resection of the prostate 11-16%, without 48%).

In summary, there is some evidence that these interventions are effective, at least in the short term, but are they more effective than existing surgical treatments or radiotherapy? Adverse effects seem to be high compared with existing treatments, but the rates quoted may be higher than for experienced practitioners using the latest equipment.

How should manufacturers and the research community respond to the lack of randomised evidence? Ideally, large scale randomised trials in men with prostate cancer should be set up to compare treatments either at first diagnosis or at the time of local recurrence. This may be tricky. Urologists using the techniques may be reluctant to take part because of their experience and beliefs. Men may be reluctant to take part in a trial with randomisation. The practical difficulty of such research is illustrated by the early closure of two randomised controlled trials of cryotherapy versus radiotherapy because of failure to recruit.[8 9]

We urgently need to explore alternative ways of investigating the clinical effectiveness of these and other non-drug technologies for which randomised controlled trials may be difficult or impossible. Case-control studies might be feasible but would require a degree of organisation, cooperation, and careful data collection that currently is seen only with the more usual research studies, such as randomised trials. A determined effort and considerable funding may be needed nationally or internationally to make this happen.

1 National Institute for Health and Clinical Excellence. *Cryotherapy for recurrent prostate cancer.* 2005. www.nice.org.uk/guidance/index.jsp?action=byID&o=11084.
2 National Institute for Health and Clinical Excellence. *High-intensity focused ultrasound for prostate cancer.* 2005. www.nice.org.uk/guidance/index.jsp?action=byID&o=11128.
3 National Institute for Health and Clinical Excellence. *Prostate cancer: diagnosis and treatment.* 2008. www.nice.org.uk/guidance/index.jsp?action=byID&o=11924.
4 Donnelly L. NHS U-turn on prostate cancer treatment. *Sunday Telegraph* 16 December 2007. www.telegraph.co.uk/news/main.jhtml?xml=/news/2007/12/16/ncancer116.xml.
5 American Urological Association. *Prostate cancer*. 2007. www.auanet.org/content/guidelines-and-quality-care/clinical-guidelines/main-reports/proscan07/content.pdf.
6 American Urological Association. *Best practice policy statement on cryotherapy for the treatment of localized prostate cancer*. 2008. www.auanet.org/content/guidelines-and-quality-care/clinical-guidelines/main-reports/cryosurgery08.pdf.
7 European Association of Urology. *Guidelines on prostate cancer*. 2007. www.uroweb.org/fileadmin/user_upload/Guidelines/Prostate%20Cancer.pdf.
8 Chin JL, Ng CK, Touma NJ, Pus NJ, Hardie R, Abdelhady M, et al. Randomized trial comparing cryoablation and external beam radiotherapy for T2C-T3B prostate cancer. *Prostate Cancer Prostatic Dis* 2008;11:40-5.
9 Donnelly B, Saliken J, Brasher P, Ernst D, Lau H, Rewcastle J, et al. A randomized trial of external beam radiotherapy versus cryoablation in patients with localized prostate cancer. American Urological Association Annual Meeting, 2007. Abstract 1141. www.abstracts2view.com/aua_archive/view.php?nu=200790792&terms=.

Trading regulations and health foods

New legislation requires evidence for marketed health foods

M E J Lean professor of human nutrition, Faculty of Medicine, University of Glasgow, Division of Developmental Medicine, Glasgow G31 2ER
lean@clinmed.gla.ac.uk

Competing interests: None declared.

Provenance and peer review: Commissioned based on an idea from the author; externally peer reviewed.

Cite this as: *BMJ* 2008;337:a2408
doi: 10.1136/bmj.a2408

The European Union promotes a free market economy in Europe; however, the pursuit of profit sometimes has to be curtailed if consumers are injured or deceived. For example, the unregulated marketing of certain foods may include claims about effects on health that deceive patients. The EU Directive on Unfair Commercial Practices, enforced in the United Kingdom in May 2008,[1] was designed "to plug gaps in existing consumer protection legislation" and "to protect vulnerable consumers who are often the target of unscrupulous traders." It obliges businesses not to mislead consumers,[2] and this includes health claims for services or products.

The distinction between medicines and foods is sometimes unclear when they are marketed for health reasons, and consumers can be misled. Medicines are licensed in Europe only after stringent experimental research to establish safety and efficacy. In the UK, this process is regulated by the Medicines and Healthcare Products Regulatory Agency. Food products marketed for health have largely escaped these controls. The Joint Health Claims Initiative, which was set up in the UK to establish a code of practice for health claims on food, established a process for their evaluation on the basis that similar systematic evidence bases should be required to those for drugs. The EU regulation on nutrition and health claims for foods was adopted in 2006. All claims—such as "low fat," "high fibre," or "helps lower cholesterol"—are required to be clear, accurate, and substantiated, so that only products offering genuine health or nutritional benefits could refer to these claims on their labels.[3]

It is already illegal under food labelling regulations (1996) to claim that food products can treat or prevent disease. However, huge numbers of such claims are still made, particularly for obesity (which is a disease—international classification of diseases, 9th revision code 278).[4] Many such claims are not overt or verbal. Using "implied claims" in brand names, and images on packaging, they are positioned and promoted, by staff or "testimonials" on vendors' websites, in such a way that consumers are likely to be misled. Under the new regulations, products or services that falsely (without substantiation) claim or imply that they can improve health are now clearly illegal. Commercial practices considered unfair in all circumstances are listed. Sponsored "advertorials," the use of images or sounds in editorial material in the media that fail to make their promotional intent explicit to consumers, and misleading allusions to approval or endorsement from professional or public bodies are specifically prohibited.[2]

Misleading marketing is targeted at other vulnerable groups of patients—for example, "diabetic" foods, which do not benefit people with diabetes. However, unscrupulous trading is most commonly linked to obesity. In 2000, $35bn (£22bn; €28bn) was spent in the United States on weight loss products. Many of these products use false and unsubstantiated claims, enticing 7% of the entire population to buy them every year.[5]

Obesity is a serious disease that causes disability and shortens people's lives.[6] Its effect on quality of life is similar to that of rheumatoid arthritis or spinal cord injury,[7] and it has enormous personal, healthcare, and social costs.[8] Avoiding the simple facts that losing body fat requires a lower energy intake than energy expenditure, and that obese people need to consume more calories than if they were thinner are coupled with frequent intentional misreporting[9] and a willingness to spend huge amounts of money on ineffective, non-evidence based, treatments. Of hundreds of products on sale, only appropriately delivered diets and exercise, orlistat, sibutramine, and bariatric surgery are safe, efficacious, and cost effective.[10 11] The remainder should not be marketed until we have evidence for their effectiveness and safety.[4]

With no requirement for research, these products have been hugely profitable. Ironically, well informed public denouncement of these medicines usually leads to increased sales. Products that are investigated by advertising trading standards authorities can disappear and reappear with modified names, or in a different country. Harmonised regulations across member states would help this.

Nothing justifies the commercial exploitation of vulnerable patients with quack medicines. The new regulations provide good legislation to protect vulnerable consumers from misleading "health food" claims. They now need to be enforced proactively to help direct doctors and consumers towards safe, cost effective, and evidence based management of diseases. The regulations may even help with the bigger battle to prevent obesity, by prohibiting advertisements across the EU that encourage children to buy energy-dense products or to pester their parents to buy them.[2]

1 Office of Public Sector Information. *Consumer Protection from Unfair Trading Regulations*. 2008. www.opsi.gov.uk/si/si2008/uksi_20081277_en_5#sch1.
2 Department for Business, Enterprise and Regulatory Reform. *Unfair Commercial Practice Directive*. 2008. www.berr.gov.uk/consumers/buying-selling/ucp/index.html.
3 European Commission. *EU Directive on Health Claims*.http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm.
4 Pittler MH, Ernst E. Dietary supplements for body-weight reduction: a systematic review. *Am J Clin Nutr* 2004;79:529-36.
5 Cleland RL, Gross WC, Koss LD, Daynard M, Muoio KM. *Weight-loss advertising: an analysis of current trends*. Federal Trade Commission, 2002. www.ftc.gov/bcp/reports/weightloss.pdf.
6 Sattar N, Lean MEJ. *ABC of obesity*. Oxford: Blackwell Publishing, 2007.
7 Sullivan M, Karlsson J, Sjostrom L, Backman L, Bengtsson C, Bouchard C, et al. Swedish obese subjects (SOS)—an intervention study of obesity. Baseline evaluation of health and psychosocial functioning in the first 1743 subjects examined. *Int J Obes Relat Metab Disord* 1993;17:503-12.
8 Rissanen AM. The economic and psychosocial consequences of obesity. *Ciba Found Symp* 1996;201:194-201.
9 Lara JJ, Scott JA, Lean MEJ. Intentional mis-reporting of food consumption and its relationship with body mass index and psychological scores in women. *J Hum Nutr Diet* 2004;17:209-18.
10 National Institute for Health and Clinical Excellence. *Rimonabant for the treatment of overweight and obese patients (appraisal consultation document)*. 2007. www.nice.org.uk/guidance/index.jsp?action=article&o=38515.
11 National Institute for Health and Clinical Excellence. *Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children*. 2007. www.nice.org.uk/CG43.