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Clinical Guidelines: a NICE Way to Introduce Cost-effectiveness Considerations?

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Background to NICE's clinical guidelines programme

The clinical guidelines programme is one of several operated by the National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK). Others include the programmes on technology appraisal, public health, social care, diagnostics, medical technology (devices) and interventional procedures. One of the distinctive features of the clinical guidelines programme is that it focuses on improving the current standard of care, whereas most of the other programmes focus on assessing new technologies entering the National Health Service (NHS) in the UK.

NICE has a strong commitment to cost-effectiveness. Its procedures state that "Those developing *clinical guidelines, technology appraisals or public health guidance* must take into account the relative costs and benefits of interventions (their 'cost effectiveness') when deciding whether or not to recommend them." (Principle 2, SVJ, NICE 2008). Although "Decisions about whether to recommend interventions should *not be based on evidence of their relative costs and benefits alone*. NICE must consider other factors when developing its guidance, including the need to distribute health resources in the fairest way within society as a whole." (Principle 3).

The clinical guidelines programme was initiated in 2001 and since then more than 200 guidelines have been published. Typically they give broad guidance covering all, or specific, aspects of the diagnosis and management of a particular condition. They also incorporate any relevant technology appraisals or interventional procedure guidance that NICE has already produced for the condition concerned. Unlike NICE's technology appraisals, the clinical guidelines are not mandatory for the NHS, but often they form the basis of the development of standards to evaluate clinical practice.

A key feature of the guidelines programme is that NICE shares the 'ownership' of the programme with the various 'Royal Colleges' of medicine, which are the central clinical associations in the UK. Historically, the national collaborating centres producing the guidelines have been located in the various royal colleges, although the guidelines are produced according to a template devised by NICE. Topics for guidelines are selected based on the need to develop quality standards and assigned to the various collaborating centres. A scoping exercise is then undertaken, with consultation with interested parties, including professional societies, the NHS and the Department (ministry) of Health and, if relevant, technology manufacturers. Then a Guideline Development Group (GDG) is appointed, comprising relevant clinical experts and patient/carer representatives. The GDG is provided with technical support, including expertise in systematic reviews and health economics. A critical feature of the process is to identify a number of 'Key Clinical Questions', which form the basis for the systematic reviews of existing evidence on effectiveness and cost-effectiveness, plus any *de novo* economic analysis in situations where relevant cost-effectiveness evidence is absent or inadequate. Typically, the GDG meets 12 times over a period of up to 2 years. At each meeting, the GDG reviews and discusses the clinical and economic evidence pertaining to 1-3 of the key clinical questions.

Once completed, the guideline is circulated for extensive consultation and is then revised prior to sign-off by NICE. Several documents are produced, the main one being a summary of the recommendations, the 'NICE guideline'. In addition, interested individuals can also obtain the 'Full guideline', or, in the newer guidelines, a range of documents which give details of the evidence and analyses used to support the recommendations. There is also a non-technical version, called 'Information for the Public', which can be helpful for patients and their families. NICE also supports the implementation of the guideline with a number of tools and resources for the NHS, the most important ones being a 'Baseline assessment tool' and a 'Costing statement', which helps health authorities estimate the likely financial impact of adopting the recommendations in the guideline. The current list of published guidelines, plus those in development, can be accessed via the NICE website (http://www.nice.org.uk). The earlier guidelines are called 'Clinical

Guidelines', the more recent ones are called 'NICE Guidelines'. (http://www.nice.org.uk/guidance/published?type=cg)

Advantages of the Clinical Guidelines Programme

NICE's clinical guidelines are probably not as widely known as its technology appraisals, which sometimes attract attention because they imply rationing or restrictions on the availability of new treatments and procedures. However, the guidelines do have a number of important advantages. First, since the operation of the programme is shared with the medical profession, it represents an important collaboration aimed at improving the standard of care in the NHS. Thereby, it is more likely that clinical opinion leaders will be willing and able to help in encouraging the adoption of recommendations. Secondly, the guidelines provide an opportunity to review all aspects of the care pathway, rather than focussing only on the adoption of a new technology. Thirdly, the guidelines offer the potential to discuss disinvestment (in practices and procedures) as well as new investment.

A common criticism made of technology assessment by health care decision-makers is that it often only offers advice on how to spend resources on new technologies and rarely discusses how those resources can be found, especially in situations (like that faced by the NHS in the UK) of having a fixed budget. During the production of a guideline, the GDG often discusses practices or procedures that may be discontinued because they are of limited use, or can be streamlined because they are currently being applied in an inefficient manner. Some these suggestions are included in the list 'Do not dos' published on the NICE website (http://www.nice.org.uk/search?q=Do+not+dos).

Contributions of economic analyses

As mentioned above, the role of the health economist supporting the GDG is to undertake systematic reviews of the economic evaluation literature relevant to each of the key clinical questions and, if necessary, conduct a *de novo* economic analysis. Table 1 details the economic analyses conducted for the guidelines published from 1

January to 31 August 2015. It is the expectation that normally 1-2 new economic analyses will be required per guideline. It can be seen that *de novo* analyses were conducted to help answer at least one of the key clinical questions for all but one of the guidelines over the period considered here. Some of the analyses were merely costing studies, or adaptations of existing economic analysis, but the majority employed a decision-analytic model and are comparable to the analyses carried out in the context of NICE's technology appraisals.

Table 1 Examples of *De Novo* Economic Analyses in NICE Clinical Guidelines (about here)

The economic analyses can support the guidelines in a number of ways. In the case of lipid modification (CG 181) an economic analysis was conducted to support the recommendation that a high intensity statin (eg atorvastatin 20mg daily) should be offered for the primary prevention of CVD to people who have a 10% or greater 10-year risk of developing CVD. It was thought that this recommendation might be controversial, given the high number of individuals who would be brought into therapy and the likely budget impact. Extensive cost-effectiveness modelling provided a robust defence of the recommendation on economic grounds.

In the case of bladder cancer (NG 2), NICE was aware that this is one of the most expensive cancers to manage, so economic considerations were potentially important. In this case two economic analyses we carried out. The first compared a single instillation of chemotherapy immediately after transurethral resection of bladder cancer tumours versus no chemotherapy. The study showed that chemotherapy was highly cost-effective in all risk groups. The second analysis assessed the cost-effectiveness of reduced follow-up and or using newer tests and procedures compared with current practice. It was found that reducing cystoscopic follow-up was cost-effective in low and intermediate risk patients.

Therefore, taken together these economic analyses addressed both the potential for investment in therapy, as well as potential disinvestment. From time to time NICE has produced lists of items of its guidance that have the potential for cost reductions (https://www.nice.org.uk/about/what-we-do/into-practice/cost-saving-guidance). Table 2 gives some examples of the possibilities for cost reductions relating to clinical guidelines. This list is based on costing work undertaken at the time the guidance is published and covers all clinical guidelines from January 2005. (Some of the earlier guidelines on the list have since been updated and are no longer current.) All guidance that was considered to deliver a net saving has been identified. There may be elements of other guidelines that will deliver savings, but in some circumstances fully implementing the guidance requires investment. These figures are estimates only and not to be taken as NICE's view of desirable, maximum or minimum figures, but are useful to provide a sense of the scale of savings achievable. Also, these 'savings' are *potential* savings only. In many cases actions will be required to realize them. NICE encourages users of the costing templates to modify the assumptions used in the templates to more accurately reflect local circumstances.

Table 2 Examples of potential cost reductions resulting from NICE clinical guidelines (about here)

Challenges and issues for further discussion

Despite the attractions of introducing cost-effectiveness considerations into NICE clinical guidelines, many challenges remain. First, some economists have argued that, compared with NICE's technology appraisal programme, the influence of economics has been lower, owing to the joint ownership of the programme with royal colleges. For example, Wailoo et al (2004) argued that NICE gudelines should be subjected to independent appraisal like the technologies considered in NICE's technology assessment programme, since the cost-effectiveness of some clinical procedures might not be sufficiently scrutinized. Littlejohns et al (2004) acknowledged this concern and pointed to the inevitable tension between advising on the quality of care that individual patients could expect, whilst recognizing the

broader public health objectives of equity, fairness and efficiency. They argued that economists should be more involved in the guidelines development process.

Secondly, the potential impact of economics can be lessened owing to the lack of time available to undertake *de novo* analyses. On occasions, the precise topics for the economic analyses have been identified rather late in the guideline development process. If, as is often the case, the existing economics literature does not provide enough to answer the question being proposed, then the necessary *de novo* analysis can be a little rushed. Thirdly, since the implementation of the recommendations from clinical guidelines is not mandatory on the NHS, it is possible that they may not be fully implemented. NICE does encourage implementation through the development of quality standards based on the recommendations, although ultimately implementation can only be achieved by winning over hearts and minds. To the extent that some recommendations are not implemented, this is likely to dilute the impact of guidelines on improving efficiency.

Over time, the acceptability, prominence and quality of economic analyses in guidelines has increased, as evidenced by the list of economic analyses given in Table 1. In addition, the number of key clinical questions examined in each guideline has been reduced, from 20+ to around 10-15. This has partly been achieved because the topics in the more recent guidelines have been narrower in scope, seldom covering the full clinical pathway of a given disease, as was the case in many of the earlier guidelines. Also, the key clinical questions are being identified earlier in the guideline development process, thereby giving the economist more time to conduct analyses if these are needed. Finally, NICE has invested in the production of resources and tools to facilitate the implementation of guidelines, but it is difficult to obtain accurate evidence on the extent of implementation.

Conclusions

NICE's clinical guideline programme compliments the Institute's other programmes of work, which mainly address new heath technologies. Clinical guidelines offer the possibility of prioritizing topics for clinical and economic assessment based on the

consideration of the whole clinical pathway. Opportunities for disinvestment can be considered alongside possibilities for additional investment. However, the guideline development programme needs to be adequately resourced, including the provision of health economists' time to undertake the necessary literature reviews and *de novo* analyses that are usually required. Although issues in the development and use of clinical guidelines is likely to vary by jurisdiction, NICE's experience indicates that it is both feasible and useful to incorporate economic considerations.

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Table 1 Examples of *De Novo* Economic Analyses in NICE Clinical Guidelines (1 January-31 August, 2015)

Guideline	Topics Studied
Gastro-oesophageal reflux disease: children and young people (NG1)	Changes to feeding in infants Antacids/alginates Medical management approaches Fundoplication surgery Enteral tube feeding
Bladder cancer (NG 2)	Single instillation of chemotherapy immediately after transurethral resection of bladder cancer tumours versus no chemotherapy Reduced follow-up and/or using newer tests and procedures compared with current practice
Diabetes in pregnancy (NG 3)	Self management programmes in women with diabetes planning a pregnancy Screening, diagnosis and treatment for gestational diabetes Sceening for congenital cardiac malformations
Medicines optimization (NG 5)	Medicine review cost analysis
Challenging behavior and learning difficulties (NG 11)	Parent training for the management of behavior that challenges Psychosocial, pharmacological and combined interventions for the management of sleep problems Antipsychotics for the management of behaviout that challenges
Violence and aggression (NG 10)	None
Anaemia management in people with chronic kidney disease (NG 8)	Diagnostic tests for predicting response to iron therapy

Examples of *De Novo* Economic Analyses in NICE Clinical Guidelines

(Continued)

Guideline	Topics Studied
Bronchiolitis in children (NG 9)	Bronchodilators, corticosteroids and in combination Costs of CPAP and high flow oxygen Costs of giving intravenous fluids or nasogastric hydration Hypertonic saline versus normal saline
Suspected cancer: recognition and referral (NG 12)	Tests to diagnose colorectal cancer for patients aged 40 years and over with a change in bowel habit
Melanoma: assessment and management (NG 14)	Sentinel node biopsy alongside wide excision versus wide excision only (stage IA to IIC) Alternative follow-up strategies in high risk cutaneous melanoma
Diabetes (type 1 and type 2 in children and young people) (NG 18)	Multiple daily injections compared to mixed insulin injections Different frequencies of capillary blood glucose monitoring Blood ketone monitoring compared to urine ketone monitoring
Type 1 diabetes in adults (NG 17)	Long acting insulins and once versus twice daily insulin HbA1c threshold to reduce the risk of complications Continuous glucose monitoring versus standard monitoring of blood glucose

Table 2 Examples of potential cost reductions resulting from NICE clinical guidelines

Source: National Institute for Health and Care Excellence (2015) Cost saving guidance. www.nice.org.uk/about/what-we-do/into-practice/cost-saving-guidance. (Accessed 3 September 2015)

Guidance Number	Short title	Why does this guidance save money?	Estimated saving per 100,000 (£)
CG34	Hypertension (partial update of CG18)	The recommendations update previous guidance on prescribing drugs for hypertension. Following the revised recommendations will cost more in drugs, but this is far outweighed by the predicted number of cardiovascular events (heart attacks and strokes) that will be avoided if hypertension is better controlled.	-446,627
CG30	Long-acting reversible contraception	The recommendations relate to offering women seeking contraception an informed choice and access to long-acting reversible methods. These methods are more reliable than the oral contraceptive pill, where user-error often results in unplanned pregnancy. The additional cost of providing these methods is more than offset by the costs of unplanned pregnancies (reduced terminations or reduced births).	-214,681
CG127	Hypertension (update)	Following an initial investment in home blood pressure equipment monitoring, in future years, as more people benefit from more accurate diagnoses using ambulatory blood pressure monitoring, a cumulative effect of people not being on antihypertensive drugs starts to be seen. Savings from reduced treatment costs (because of not providing treatment for people who are not truly hypertensive) will start to outweigh the additional costs of diagnoses from year 3.	-20,464
CG108	Chronic heart failure (partial update)	Implementing the recommendations are anticiapted to result in greater costs for diagnosing and monitoring patients with CHF at an earlier stage, and increased costs for rehab. However this is more than offset by anticipated reductions in acute admissions in this patient group that have frequent readmissions.	-19,000
CG115	Alcohol dependence and harmful alcohol use	The guideline is one of three pieces of NICE guidance addressing alcohol-related problems and should be read in conjunction with PH24 and CG100. It is anticipated that implementing this guidance will lead to additional costs due to increasing the proportion of people with mild alcohol dependence receiving psychological interventions and increasing the number of people with moderate and severe dependence receiving medication to prevent relapse following successful withdrawal. These costs are likely to be offset by a reduction in the number of people who are dependent on alcohol, a reduction in the number of people who relapse following successful withdrawal and savings due to people being offered an intensive community programme , rather than residential rehabilitation.	-18,600
CG107	Hypertensive disorders during pregnancy	Increased costs for greater use of aspirin and monitoring of proteinuria are considered to be more than offset by reductions in adverse outcomes with increased costs for treating pre-eclampsia, pre-term deliveries and babies needed special care.	-15,300
NG2	Bladder cancer: diagnosis and management	Savings could arise from a reduction in the number of people with low risk non-muscle-invasive bladder cancer receiving follow-up cytoscopies in secondary care after 12 months. There could be increased drug costs of giving people suspected of low or intermediate risk non-muscle invasive bladder cancer a single dose of intravesical mitomycin C given at the same time as TURBT.	-11,500

CG81	Breast cancer (Advanced)	One of the recommendations in this guidance recommended a change to current practice relating to patients receiving trastuzumab for advanced breast cancer. It is recommended that treatment is discontinued if the disease progresses outside of the central nervous system. It was considered that 50% of women taking trastuzumab and where the disease progresses outside of the central nervous system currently continue to take trastuzumab. In addition to quantified savings relating to trastuzumab we anticipate a reduction in hospital admissions as a result of improved treatment of patients with bone netastases. Bone metastases account for over a third of all nights in hospital in advanced breast cancer care.	-9,690
CG75	Metastatic spinal cord compression	Implementing the guidelines is anticipated to increase surgery for the prevention and treatment of MSCC at a cost of £14 million. This is more than offset by the reduced care costs for the increased periods that patients keep the ability to remain mobile. The cost difference per patient per day between those able to walk, and those that are immobile is £180, some of which is social care costs. Based on those patients expected to be discharged home and cared for in the community a national saving of £17.5 million was estimated.	-8,974
CG69	Respiratory tract infection in Primary Care	The use of a no prescribing, or delayed prescribing policy for a number of conditions (detailed in the guideline) is anticipated to lead to a reduction in antibiotic prescribing of £3.7 million nationally. Additionaly there may be benefits, that it is not possible to quantify, arising from reduced use leading to less antibiotic resistance and reduced adverse events associated with antibiotic use.	-7,299
CG33	Tuberculosis	The majority of the savings arising from changes recommended in the BCG vaccination programme in children between 10-15 year old. In addition we anticipate reduced costs of treating active infection through better identification leading to reduced transmission.	-7,239
CG40	Urinary incontinence	We anticipated a reduction in the cost of urodynamic investigations that would be carried out before conservative treatment or surgery.	-6,506
CG58	Prostate cancer	A number of recommendations relating to whether or not to biopsy, when to offer active surveillence and use of hormonal treatments are predicted to save money. These savings are offset by increased use of radical external beam radiotherapy.	-5,396
CG54	Urinary tract infection in children	A change in the cost of urine collection is estimated to cost £2.9 million, which is offset by anticipated reduction in numbers of referrals and imaging procedures of £5.0 million.	-4,210
CG80	Breast cancer (early)	Recommendations relating to pre-treatment ultrasound evaluation of the axilla is considered to avoid additional surgery if nodal disease is identified before initial surgery.	-2,698

CG99	Constipation in children and young people	The recommendations are anticipated to increase prescribing costs, but lead to fewer outpatient attendances and inpatient admissions.	-2,020
CG64	Prophylaxis for Infective Endocarditis	It is anticipated that a reduction in prophylactic antibiotic prescribing will lead to reduced expenditure. In addition to the quantified savings in antibiotics savings from reduced adverse effects of antibiotics such as anaphylaxis and antibiotic resistance will occur.	-1,411
CG60	Surgical management of OME	The recommendations are anticipated to result in a reduction of adenoidectomies and in antibiotic prescribing for OME.	-776
CG100	Alcohol use disorders - physical complications	Implementing the guidance is anticipated to require investment in alcohol specialist professionals (£5.9 million) and an increase in assessment and surgery for chronic alcohol related pancreatitis (£1 million). However, this is more than offset by an anticipated reduction due to symptom-triggered drug treatment for withdrawal (saving £7.1 million)	assess locally
CG37	Postnatal care	The annual costs have been found to vary from an initial cost of £6.8 million to a potential saving of £1.1 million, due to the effect of increasing savings and reducing training costs over time. The savings arise from a reduction in the incidence of childhood disease due to the protective effects of breastfeeding assuming following the recommendations will lead to an increase in the numbers of mothers who breastfeed. (see also PH11 Public health guidance on maternal and child nutrition)	per average unit experiencing 2534 births p.a. net savings range £5000-£9000