An evaluation of the impact of NICE guidance on GP prescribing

Bernard Wathen and Tara Dean

SUMMARY

Background: One of the aims of the National Institute for Clinical Excellence (NICE) is to promote faster access to the best treatments. However, there is no published research on the impact that NICE guidance has had on prescribing decisions.

Aims: To explore the attitudes of general practitioners (GPs) to NICE guidance and to investigate any changes in prescribing patterns.

Design: Descriptive cross-sectional study.

Setting: North Devon Primary Care Trust.

Method: Five technology appraisals most likely to impact on GP prescribing were investigated. Prescribing analysis and cost (PACT) data were analysed for changes in prescribing patterns before and after the publication of each technology appraisal. A postal questionnaire, developed from semi-structured interviews, was sent to all GPs within a single primary care trust (PCT) to explore factors that were encouraging or discouraging adherence to NICE guidance.

Results: PACT data showed that there was an increase in the prescribing of the drugs studied immediately after NICE guidance, with the exception of zanamivir (Relenza® [GlaxoSmithKline]); only one zanamivir inhaler was prescribed during the study period. Although there was an increase in the prescribing of maintenance doses of proton pump inhibitors, there was also an increase in treatment doses. Eighty-one (82.7%) questionnaires were completed and returned. In general, there was a balance between the factors that encouraged and those that discouraged adherence. The main exception was zanamivir, where factors that discouraged adherence greatly exceeded factors that encouraged adherence.

Conclusions: This study showed that NICE guidance in isolation had little impact on GP prescribing. Where the guidance coincided with information from other sources, or personal experience, there was some evidence that technology appraisals triggered an increase in prescribing, but that this was not always sustained. The recommendations of NICE concerning zanamivir were universally rejected and there was evidence that this had undermined confidence in NICE recommendations in general.

Keywords: clinical practice guidlines; prescriptions, drug; primary health care; technology assessment.

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Introduction

THE National Institute of Clinical Excellence (NICE) was set up in April 1999 to provide patients, health professionals, and the public with guidance on best practice.[1] NICE aimed to promote faster access to the best treatments and to end 'postcode prescribing'.[2] As a part of its remit, NICE produces technology appraisals that give guidance on the use of both individual and groups of drugs. However, it relies mainly on a strategy of dissemination of printed guidelines direct to doctors.

Building on previous work by Grimshaw and Russell,[3] the NHS Centre for Reviews and Dissemination issued an *Effective Health Care* bulletin on the implementation of clinical practice guidelines.[4] It concluded that, 'Although some interventions based on the more passive reception of information (e.g. mailing to relevant groups) have been shown to influence professional awareness and knowledge of guidelines they are usually insufficient to change professional behaviour by themselves'. In 1999, the Cochrane organisation investigated the effect of printed educational materials to improve professional behaviour.[5] Their systematic review found that 'printed educational materials alone appear to have, at best, only a small impact on practice' and that 'rapid and substantial changes in practice appear unlikely to be achieved from this approach'. Given NICE's high profile, and the amount of money that has been invested in it by the government, would their technology appraisals prove more successful?

A comprehensive search of electronic databases, including EMBASE and MEDLINE, and manual searching failed to locate any published research evaluating the impact of NICE guidance on prescribing. This study aimed to identify key issues and concerns expressed by general practitioners (GPs) working within one primary care trust (PCT) with regards to NICE guidance, alongside an analysis of prescribing patterns within the PCT.

Method

The target population for this study was the 102 GPs working within the North Devon PCT. Five NICE technology appraisals, which had the potential to impact on GP prescribing, were selected for the study. These represented a broad range of therapeutic areas, and included both new classes of medication and established drugs.

The overall methodology underpinning this study was descriptive cross-sectional. The research was conducted in three distinct phases involving three types of data collection tools.

Phase I — semi-structured interviews

This phase of the study involved interviewing a broad range of GPs, purposefully selected to include: male and

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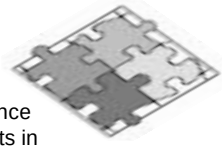

What do we know?

The National Institute of Clinical Excellence (NICE) aims to change prescribing habits in order to end postcode prescribing and to promote best treatments. However, it relies mainly on direct mailing in order to inform healthcare professionals of its decisions. Previous research has indicated that this strategy alone is usually insufficient to change professional behaviour.

What does this paper add?

No previous research could be located on this topic. This study evaluated changes in prescribing within a single primary care trust before and after the introduction of five NICE technology appraisals. In addition, it explored the factors that were encouraging and discouraging doctors from following the recommendations contained within NICE guidance.

female doctors, dispensing and non-dispensing practices, experienced and recently qualified doctors, and large and small practices. The doctors were notified of the five technology appraisals to be discussed prior to the interview. A manual categorisation of the transcripts of the interviews was carried out to identify themes that had encouraged and discouraged the GPs from adhering to the recommendations of each technology appraisal. Three encouraging themes and three discouraging themes were incorporated into the design of a postal questionnaire.

Phase II — postal questionnaire

The questionnaire was sent to 98 GPs who had worked in the North Devon area for the previous 12 months (two had retired within the past year and two had taken sabbatical leave). The questionnaire listed the number and title of each of the chosen NICE technology appraisals and a summary of the main conclusions. An example for one technology appraisal is shown in Box 1.

The doctors were invited to indicate the factors that encouraged or discouraged them from following the recommendations of each technology appraisal and also to add their own comments.

Phase III — a before-and-after study of PACT data

This phase of the project involved collecting prescribing analysis and cost (PACT) data for the North Devon PCT, for 6 months before and 12 months after the introduction of each technology appraisal. Data from the month that the NICE technology appraisal was introduced were treated as transitional and were excluded from subsequent analyses. Six months was considered to be a practical period of time to elucidate the underlying trends in prescribing before and after the introduction of NICE guidance. Data were collected for a further 6 months to allow for any seasonal effects. There were no changes in prices during the study periods so cost was an accurate indicator of the amount of drug prescribed.

With zanamivir (Relenza® [GlaxoSmithKline]), data were collected between October and March, the periods when influenza was most likely to be present in the community, for 3 consecutive years.

Guideline no. 22: The use of orlistat in the treatment of obesity in adults. March 2001.

Promoted the prescribing of orlistat for obese patients who could demonstrate the loss of at least 2.5 kg in weight by dietary control or physical activity alone.

Box 1. An example of the questionnaire listing for a NICE technology appraisal.

Results

Semi-structured interviews (phase I)

All of the twelve doctors contacted agreed to be interviewed. The first interview was recorded on 27 November 2001 and the last on 20 February 2002. The average length of interview was 2599 words (range = 1169–4700 words) and lasted on average 25.8 minutes (range = 9–35 minutes). The doctors had a mean of 12.0 years experience as GPs (range = 1–30 years).

Questionnaires

Of the 98 questionnaires sent out, a total of 81 (82.7%) were completed and returned. Sixty-six (67.3%) after the first posting, 12 (12.2%) after a first reminder, and three (3.1%) after a second reminder. From 11 (47.8%) of the practices there was a 100% response rate and from two (8.7%) there was a zero response.

PACT data

PACT data is shown in Tables 1 and 2.

NICE technology appraisal no. 7: proton pump inhibitors (PPIs).[6] Doctors identified a greater number of factors that encouraged adherence to the guideline (E-factors), than factors that discouraged adherence (D-factors) (60.5% versus 45.7%, respectively, $P < 0.005$). The most common E-factor was 'cost savings' (81.5%), followed by 'previous successes at lowering doses' (56.8%), and finally 'pressure from local pharmaceutical advisers' (43.2%). The most common D-factor was 'resistance from patients' (56.8%), followed by 'previous failures at lowering doses of PPIs' (50.6%), and finally 'concerns over deterioration in patient's symptoms' (29.6%).

Two-thirds of doctors interviewed mentioned that reducing the strength of PPI doses was their current practice before NICE guidance, and this was also the most frequent comment added to the questionnaire:

> '*The guidelines reinforced my practice rather than changed it.*' (Interview 4.)

> '*I don't think it changed what I do much, so NICE were a little behind the times with this one.*' (Interview 10.)

NICE technology appraisal no. 9: rosiglitazone (Avandia® [SmithKline Beecham]).[7] Doctors identified a greater number of D-factors, 50.2% versus E-factors, 20.6% ($P < 0.001$). The most common D-factor was 'still a black triangle drug' (63.0%), followed by 'concerns over adverse effects' (45.7%), and finally 'cost' (42.0%).

Table 1. Cost of drugs prescribed in the North Devon Primary Care Trust before and after the introduction of relevant NICE guidance.

NICE guidance number and drug(s)	Mean cost of drugs prescribed 6 months pre-NICE guidance (£/month)	Mean cost of drugs prescribed 2–6 months post-NICE guidance (£/month)	Mean cost of drugs prescribed 7–12 months post-NICE guidance (£/month)
No. 7: proton pump inhibitors (high doses)	43 476	44 908	47 460
No. 7: proton pump inhibitors (low doses)	30 234	32 628	34 372
No. 9: rosiglitazone	0	977	2449
No. 22: orlistat	586	2651	3334
No. 27: Cox II inhibitors	9177	13 194	16 854

Table 2. Rate of change in spend on drugs prescribed in the North Devon Primary Care Trust before and after the introduction of relevant NICE guidance.

NICE guidance number and drug(s)	Change in spend on drugs prescribed 6 months pre-NICE guidance (£/month)	Change in spend on drugs prescribed 2–6 months post-NICE guidance (£/month)	Change in spend on drugs prescribed 7–12 months post-NICE guidance (£/month)
No. 7: proton pump inhibitors (high doses)	216	1168	600
No. 7: proton pump inhibitors (low doses)	922	843	616
No. 9: rosiglitazone	0	362	217
No. 22: orlistat	22	420	-122
No. 27: Cox II inhibitors	346	724	974

The most common E-factor was 'avoids the need for insulin injection' (34.6%), followed by 'clarification of which patient should be prescribed a glitazone' (21.0%), and finally 'recommended by local consultants' (6.2%).

Concern over the safety of the glitazones, a new class of drugs that still carried a 'black triangle' (indicating that the Committee on Safety of Medicines and the Medicines and Healthcare Products Regulatory Agency were still intensively monitoring the product for safety), was the main factor for the reluctance to prescribe rosiglitazone. There was mention, during the interviews, that the first member of this class of drugs, troglitazone, was withdrawn from the market because of a possible link with hepatic toxicity:

'*Then there's that worry about liver disease.*' (Interview 9.)

'*Particularly* [of concern] *since troglitazone was withdrawn at high speed.*' (Interview 11.)

The most common comment was that GPs considered that the drugs were not living up to expectations:

'*Not that effective.*' (Questionnaire.)

'*Word on the street locally is that you still end up referring them for insulin in a few months time when it hasn't worked.*' (Interview 8.)

NICE technology appraisal no. 15: zanamivir (Relenza).[8] A large number of D-factors (73.7%) were chosen but very few E-factors (2.1%), $P < 0.001$. The most common D-factor was 'not convinced of the effectiveness of Relenza' (80.2%), followed by 'flu vaccination is a better option' (71.6%), closely followed by 'cost' (69.1%). Only two of the E-factors were chosen 'only option for at-risk patients' (3.7%) and 'clarifies which patient should be prescribed Relenza' (2.5%). No doctor felt pressurised by patients to prescribe Relenza.

The PACT data supports the doctors' lack of belief in the conclusions of this technology appraisal. During the three 6-month periods studied, only one Relenza inhaler was prescribed.

Two main reasons emerged as to why GPs had so strongly failed to follow the recommendations of this guideline. The first was that the majority of doctors (80.2%) disagreed with NICE that this was an effective treatment:

'*I'm not entirely convinced of its clinical benefits.*' (Interview 1.)

'*Because a lot of data on it, I think, is not that convincing.*' (Interview 11.)

Secondly, doctors felt that it was impossible to follow the guidelines in practice. There were difficulties in identifying true influenza and seeing patients within the first 36 hours of onset of symptoms:

'*The NICE guidelines are unworkable, if you've got to present within 36 hours.*' (Interview 6.)

'*Most people around here wouldn't contact us until they'd had it for a couple of days.*' (Interview 10.)

Doctors were also concerned over the cost of the drug and felt that money would be better spent on extending the vaccination programme:

'*I mean it's the flu jabs that are much more valuable and that's what the government ought to be putting the money into.*' (Interview 11.)

As well as unanimously rejecting NICE's conclusions concerning this specific technology appraisal, this study found some evidence that it had damaged doctors' belief in the NICE process as a whole and its independence:

'*With Relenza, what planet are they* [NICE] *actually operating from? And that's what makes you feel "how can I trust the other guidelines?*"' (Interview 2.)

'[It] *makes you think of NICE not being independent at all, because it's government funded.*' (Interview 5.)

NICE technology appraisal no. 22: orlistat (Xenical® [Roche]).[9] Doctors identified a greater number of D-factors, 50.6% versus E-factors, 41.6% ($P < 0.05$). The most common D-factor was 'cost' (58.2%), followed by 'concerns about adverse effects' (54.3%), and finally 'previous failures with other anti-obesity drugs' (39.5%). The E-factors were relatively evenly selected, 'pressure from patients' (42.0%), 'clarification of which patient should be prescribed orlistat' (42.0%), and 'support for patients' (40.7%).

Doctors reported that they had received pressure from patients to prescribe the drug and wanted to support their efforts to lose weight. The guideline was helpful in negotiations between doctor and patient to identify which patients were eligible for drug treatment:

'*That's really helpful because you can actually prevent people coming and saying they want the drug, but without making the effort to change their diets.*' (Interview 11.)

'*I think it's helpful to have one document to see if you meet the criteria. It backs up what we are saying to people; there is a national guideline that makes it clear what should happen.*' (Interview 12.)

However, there were concerns over side effects:

'[It] *did OK for a short while then* [patients] *had terrible side effects with it*.' (Interview 12.)

'*Side effects have made these patients stop* [taking] *the drug.*' (Questionnaire.)

The most frequent comment added to the questionnaire concerned the practicalities of prescribing the drug. Patients had to demonstrate a weight loss of 2.5 kg before starting on orlistat. Either they could not achieve this:

'*None of my patients* [were] *able to lose the 2.5 kg first — catch 22.*' (Questionnaire.)

'No one has come back after having lost 2.5 kg in 1 month.' (Questionnaire.)

Or if they could lose weight without drug therapy, it would be a better option to continue without it:

'*If you can lose the weight by diet and physical activity, why not carry on like that?*' (Questionnaire.)

'*Patients who have lost weight with diet and exercise do not need drugs.*' (Questionnaire.)

NICE technology appraisal no. 27: cyclo-oxygenase (Cox) II inhibitors.[10] Doctors identified a greater number of D-factors, 63.4% versus E-factors, 51.0% ($P < 0.01$). The most common D-factor was 'concerns that Cox IIs may not prove to be as safe as first thought' (77.7%), followed by 'cost' (64.2%), and finally 'still black triangle drugs' (48.1%). The most common E-factor was 'previous experience of adverse effects with older non-steroidal anti-inflammatory drugs (NSAIDS)' (67.9%), followed by 'clarifies which patients should be prescribed a Cox II' (42.0%), and finally 'medicolegal concerns' (40.7%).

The main drive encouraging prescribing was previous experience of patients developing serious adverse effects while taking the traditional anti-inflammatory drugs:

'*There's so much evidence to show that it's so much a safer drug that anybody on long-term non-steroidals should probably be switched.*' (Interview 7.)

'*One feels much easier prescribing a drug with less side effects than others, it's nice to use a drug that's safer.*' (Interview 8.)

However, a large proportion of doctors (77.7%) are concerned that the Cox II inhibitors may not prove to be as safe as first reported:

'*One of my patients was admitted with haematemesis and melaena who'd been on rofecoxib, so they are not that safe.*' (Interview 11.)

One further general point to emerge from the interviews was that NICE is not operating in isolation. Doctors receive advice from a number of resources locally:

'*My plan of action has been based upon* Drug Talk [a locally produced newsletter] *and from our pharmaceutical advisor and the shared care guidelines.*' (Interview 4.)

and nationally:

'*You've got* Drugs and Therapeutics Bulletin *and the* Effective Health Care *bulletin, that are quite good.*' (Interview 9.)

and from representatives of the pharmaceutical industry:

'*I saw the rep last week and my perception is that he's right.*' (Interview 6.)

Discussion

Previous work has shown that the dissemination of guidelines by post has not been successful in bringing about change. Would guidance from NICE prove more successful? This study assessed the impact of five NICE technology appraisals on the prescribing patterns of a local community

of GPs. This study attempted to demonstrate, not only whether or not there had been a change in prescribing behaviour post-NICE guidance, but also what factors were encouraging or discouraging change.

PACT data are readily available and give a comprehensive indication of the quantity of drugs prescribed by GPs (or more accurately, dispensed to patients). However, the nature of PACT data is such that it is hard to draw any firm conclusions. At best, they give an accurate reflection of current prescribing. For all of the drugs studied, there was an increase in prescribing after the publication of the relevant NICE technology appraisal, however, a better indication of the possible direction of future prescribing might be given by the rate of increase (or decrease) in prescribing.

Prescribing of rosiglitazone and orlistat was relatively low and could be a reflection of the prescribing habits of only a small number of GPs. There was increase in the rate of prescribing of both drugs immediately post-NICE, but this then tailed off. Further data are required to confirm this. Doctors' comments suggest that a possible explanation for the decline in rosiglitazone prescribing was that the drug was not living up to expectations, and in the case of orlistat, there were concerns over its adverse effects.

With Cox II inhibitors there was an increase in the rate of prescribing immediately post-NICE and the rate continued to increase 6 months later. This is despite the fact that more GPs identified with factors that were discouraging adherence to the NICE technology appraisal. Previous experience of adverse effects with non-selective NSAIDs troubled over two-thirds of doctors in this study, although this was balanced by concerns that the Cox II selective NSAIDs may not prove to be as safe as first thought.

With one group of established drugs, the PPIs, there was no evidence that the technology appraisal had produced the desired effect. Although the amount of maintenance doses increased, so did the amount of treatment doses. The general feeling was that the advice given merely reinforced established practice. Transferring patients to the lowest effective dose was something that GPs were already doing. This was the only technology appraisal studied that was predicted to produce cost savings in the drug budget, but this study showed that no savings accrued.

With the final drug studied, zanamivir, the recommendations of the technology appraisal were found to have been universally rejected by the GPs. Although the threshold of 50 cases of influenza-like illness per week per 100 000 of the population had been exceeded in each of the study periods, only one inhaler had been prescribed. Not only was NICE's advice rejected for this technology appraisal, but there was some evidence that this had reduced faith in the whole NICE process.

NICE does not operate in isolation. GPs receive advice and information from a number of sources, both locally and nationally. Representatives of the pharmaceutical industry tend to become more active following the publication of a 'favourable' NICE technology appraisal. Our overall finding was that NICE guidance taken in isolation had little impact on GP prescribing. Where the guidance coincided with information from other sources or personal experience, there was some evidence that technology appraisals triggered an increase in prescribing, but that this was not always sustained. Where there was conflict in advice from other sources, or if it was considered dated, NICE guidance had no perceivable impact on prescribing.

A recent World Health Organisation report was generally favourable to the NICE appraisal process.[11] However, two of its main criticisms were that there was a conflict between transparency and confidentiality, and that budget impact was not part of the remit of NICE in its guidance development. If these two criticisms are addressed by NICE, perhaps GPs' confidence in NICE will grow and its technology appraisals will have a greater impact.

References

1. National Institute for Clinical Excellence: About NICE — Background. http://www.nice.org.uk/cat.asp?c=137 (accessed 5 Jan 2004).
2. National Institute for Clinical Excellence: About NICE — Why has NICE been set up? http://www.nice.org.uk/article.asp?a=256 (accessed 5 Jan 2004).
3. Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet* 1993; **342:** 1317-1322.
4. NHS Centre for Reviews and Dissemination. Implementing clinical practice guidelines. *Effective Health Care* 1994; **1(8):** 1-12.
5. Freemantle N, Harvey EL, Wolf F, *et al*. Printed educational materials: effects on professional practice and health care outcomes. In: Cochrane Collaboration. *Cochrane Library*. Issue 2. Oxford: Update Software, 2000. [Currently withdrawn by the Cochrane editorial group.]
6. National Institute for Clinical Excellence. *Technology appraisal guidance no. 7. Guidance on the use of proton pump inhibitors in the treatment of dyspepsia*. London: National Institute for Clinical Excellence, 2000. http://www.nice.org.uk/pdf/proton.pdf (accessed 18 Dec 2003).
7. National Institute for Clinical Excellence. *Technology appraisal no. 9. Guidance on rosiglitazone for type 2 diabetes mellitus.* London: National Institute for Clinical Excellence, 2000. http://www.nice.org.uk/pdf/rosiglitazoneguidance.pdf (accessed 18 Dec 2003).
8. National Institute for Clinical Excellence. *Technology appraisal guidance no. 15. Guidance on the use of zanamivir (Relenza) in the treatment of influenza.* London: National Institute for Clinical Excellence, 2000. [Obsolete, replaced by no. 58.] http://www.nice.org.uk/cat.asp?c=426 (accessed 18 Dec 2003).
9. National Institute for Clinical Excellence. *Technology appraisal guidance no. 22. Guidance on the use of orlistat for the treatment of obesity in adults*. London: National Institute for Clinical Excellence, 2001. http://www.nice.org.uk/pdf/orlistatguidance.pdf (accessed 18 Dec 2003).
10. National Institute for Clinical Excellence. *Technology appraisal guidance no. 27. Guidance on cyclo-oxygenase (Cox) II selective inhibitors, celecoxib, rofecoxib, meloxicam and etodolac for osteoarthritis and rheumatoid arthritis.* London: National Institute for Clinical Excellence, 2001. http://www.nice.org.uk/pdf/coxiifullguidance.pdf (accessed 18 Dec 2003).
11. Hill S, Garattine S, van Loenhout J, *et al. Technology Appraisal Programme of the National Institute of Clinical Excellence — A review by WHO*. Geneva: World Health Organisation, 2003. http://www.nice.org.uk/pdf/boardmeeting/brdsep03itemtabled.pdf (accessed 18 Dec 2003).

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