

## What's the evidence that NICE guidance has been implemented? Results from a national evaluation using time series analysis, audit of patients' notes, and interviews

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### Abstract

**Objectives** To assess the extent and pattern of implementation of guidance issued by the National Institute for Clinical Excellence (NICE).

**Design** Interrupted time series analysis, review of case notes, survey, and interviews.

**Setting** Acute and primary care trusts in England and Wales.

**Participants** All primary care prescribing, hospital pharmacies; a random sample of 20 acute trusts, 17 mental health trusts, and 21 primary care trusts; and senior clinicians and managers from five acute trusts.

**Main outcome measures** Rates of prescribing and use of procedures and medical devices relative to evidence based guidance.

**Results** 6308 usable patient audit forms were returned. Implementation of NICE guidance varied by trust and by topic. Prescribing of some taxanes for cancer ( $P < 0.002$ ) and orlistat for obesity ( $P < 0.001$ ) significantly increased in line with guidance. Prescribing of drugs for Alzheimer's disease and prophylactic extraction of wisdom teeth showed trends consistent with, but not obviously a consequence of, the guidance. Prescribing practice often did not accord with the details of the guidance. No change was apparent in the use of hearing aids, hip prostheses, implantable cardioverter defibrillators, laparoscopic hernia repair, and laparoscopic colorectal cancer surgery after NICE guidance had been issued.

**Conclusions** Implementation of NICE guidance has been variable. Guidance seems more likely to be adopted when there is strong professional support, a stable and convincing evidence base, and no increased or unfunded costs, in organisations that have established good systems for tracking guidance implementation and where the professionals involved are not isolated. Guidance needs to be clear and reflect the clinical context.

### Introduction

The National Institute for Clinical Excellence (NICE), aims to improve standards of care for patients and reduce inequalities in access to innovative treatments.<sup>1</sup>

It is hoped that guidance from NICE will lead to the rapid and systematic uptake of evidence based medicine into routine practice. This paper presents the results of a national evaluation examining the pattern of implementation of NICE guidance by healthcare organisations (see [www.nice.org.uk](http://www.nice.org.uk)).

### Methods

We assessed the response of the NHS to 12 pieces of "tracer" NICE guidance. By October 2001, 22 sets of guidance were eligible for inclusion (see [bmj.com](http://bmj.com)). We audited 11 (50%), chosen to reflect a range of drugs, devices, and procedures; different care settings; and cost consequences. Some included clear stopping messages (removal of wisdom teeth, laparoscopic surgery for colorectal cancer); some fairly clear messages to use a technology (implantable cardioverter defibrillators, hearing aids); and other complex messages regarding appropriate use (hip prostheses, taxanes for breast cancer, orlistat for obesity).

The research consisted of three phases, each one using a different method of data collection to answer different but complementary questions.

#### Phase I

We analysed routine national or regional data and national surveys to assess the extent to which practice changed after publication of the tracer guidance. We used data from the NHS Prescription Pricing Authority, which covers all of England, to explore trends in primary care prescribing. We used hospital episode statistics data (covering England and Wales) to assess the trends in use of invasive procedures. We accessed or collected other sources of national and regional data where these two sources did not have relevant or adequate data (see [bmj.com](http://bmj.com)).

We used interrupted time series analysis to assess if the pattern of practice had changed after NICE guidance.<sup>2</sup> We used an autoregressive integrated mov-

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The interview schedule for clinicians is on [bmj.com](http://bmj.com)



This is the abridged version; the full version is on [bmj.com](http://bmj.com)

ing average (ARIMA) model with dummy variables to examine the impact of publication on the growth rate and the average rate of use (constant parameter) of a technology once any growth rate had been removed.<sup>3</sup>

### Phase II

To assess whether the guidance was being implemented properly, we selected a random sample of 20 (out of 221) acute trusts and their associated mental health hospitals and 21 (out of 303) primary care trusts (within which we selected a stratified random sample of five practices), from which we reviewed 50 relevant case notes for each of eight guidance topics. The resulting trusts reflected a good cross selection of geographical spread and size.

Local audit staff extracted data from patients' records. Usable audit forms for 6308 patients were returned. We calculated the proportion of cases conforming to the NICE guidance for each healthcare organisation in the sample at two periods of time and estimated the overall average.

### Phase III

We surveyed the chief executives, leads of clinical governance, and leads of clinical specialties of the 20 acute trusts that participated in the audit of patients' notes (65% response rate for chief executive officers (13 out of 20) and 57% overall (68 out of 120)) to assess their handling of NICE guidance. We conducted semistructured interviews to access professional and managerial perspectives on our quantitative findings and, in particular, to explore the response to the NICE guidance.

We purposively selected five acute trusts that returned positive consent forms, to represent differing degrees of implementation of guidance (see phase II). In each trust we approached the chief executive, medical director, and lead clinicians for the guidance topic. We supplemented a common interview schedule (see [bmj.com](http://bmj.com)) by interview questions based on findings from the audit. We recorded and transcribed interviews where possible or returned notes to the interviewee for checking.

Data analysis was concurrent, and clear thematic categories were developed by two researchers independently. Differences were reconciled by discussion. We used analytic matrices to examine differences between trusts and across sets of guidance.

## Results

### Wisdom teeth extraction

National data indicate a sharp decline in the number of extractions between 1995 and 2001 (fig 1). Although these fell in the year in which the guidance had been published (March 2000), we found no evidence of a change in the downward trend in extractions ( $-8.9$  extractions per month, 95% confidence interval  $-57.5$  to  $39.6$ ). More than 90% of extractions were compliant with the guidance. Survey respondents indicated that compliance was high because the costs of implementation were low, involved a single specialty service, and had professional support and a strong evidence base.

### Hip prostheses

The guidance recommended the use of prostheses with a demonstrable replacement rate of 10% or less, at

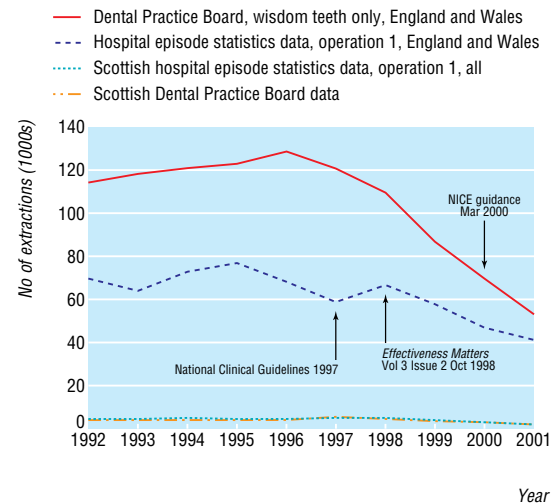


Fig 1 Wisdom teeth extraction activity, 1992-2001

10 years, or a minimum of three years, provided that the performance of the prostheses is consistent with the 10 year benchmark. The guidance did not specify which prostheses met the benchmark.

Use of more than 50 different prostheses was documented in the Trent and Wales register over the period 1998-2002 (see [bmj.com](http://bmj.com) for details of the register). Of the single prostheses, 69% (3671) met the 10 year benchmarks and 81% (4327) met the three year benchmark, proportions that had been declining over recent years. There is some evidence that the decline in 10 year benchmarked prostheses may have stabilised slightly after guidance. We observed similar results from the audit of patients' notes. Surgeons thought that the guidance did not adequately acknowledge the complexity of hip surgery.

### Taxanes for breast and ovarian cancer

We obtained usable data on taxanes from 24 hospital pharmacies (including nine cancer centres). We found a significant increase in the use of docetaxel and paclitaxel of 1112 (95% confidence interval 530 to 2222,  $P < 0.001$ ) patient months and 3.7 (1.1 to 7.8,  $P < 0.002$ ) patient months, respectively, but no evidence of a change in the growth rate in the use of gemcitabine (0.5% per month,  $-36.2\%$  to  $37.2\%$ ) or vinorelbine ( $-1.0$  patient months,  $-3.3$  to  $1.3$ ). This is unlikely to be due to lack of statistical power.

Of the 707 patients identified as receiving taxanes for breast cancer, all but one were receiving this appropriately. Interviewees acknowledged that the NICE guidance had made funding easier to obtain. Of the 520 women with ovarian cancer for whom we have data, only 33% (166) were recorded as having been prescribed paclitaxel. However, oncologists believed that the guidance had overstated the effectiveness of taxanes in ovarian cancer. NICE subsequently amended its guidance.

### Implantable cardioverter defibrillators

Although the number of implantable cardioverter defibrillators implanted has risen, we found no evidence of a significant change after NICE guidance had been published (fig 2). This may reflect the high costs of implantable cardioverter defibrillators, at

around £20 000 (\$36 000; €29 000) per device, competition for resources with other interventional procedures in cardiology, and scarcity of skills in electrophysiology.<sup>4</sup>

### Hearing aids

All audiology departments surveyed had undertaken an immediate audit of their service against the guidance requirements. However the range of analogue hearing aids offered does not seem to have been extended. Funding was described in the interviews as a major impediment. The guidance was issued at the same time as the Department of Health implemented a series of pilots of digital hearing aids, which cut across the guidance on analogue aids, which was subsequently withdrawn.

### Laparoscopic surgery for primary inguinal hernia repair and colorectal cancer

Only 4% of primary inguinal hernia repairs in England and Wales were undertaken laparoscopically (contrary to NICE guidance), and this did not change after the guidance (0.3 monthly increase in hernia repairs, 95% confidence interval - 5.48 to 6.08).

Although hospital episode statistics data for the 19 trusts that returned audit forms also showed 96% compliance, our audit of 545 repairs of primary unilateral hernias indicated only 65% compliance, indicating that coding of hospital episode statistics data may be unreliable. However, both national and audit data agreed that most laparoscopic procedures were concentrated in a few trusts, and that did not change over time.

Interviews showed that some local expert surgeons had the support of managers and commissioners to continue the use of laparoscopic surgery for primary repair. It was also claimed that patients often requested laparoscopic procedures.

The percentage of cases of colorectal cancer treated with laparoscopic surgery remained unchanged, at around 0.1% from 1998 to 2001.

### Zanamivir for influenza

National prescribing data show little inappropriate prescribing of zanamivir in the absence of high levels of flu; prescriptions remained very low, at 499 in 2001, 190 in 2002, and 124 in 2003.

### Orlistat for obesity

We found a significant increase in the average monthly prescribing of orlistat after the guidance had been

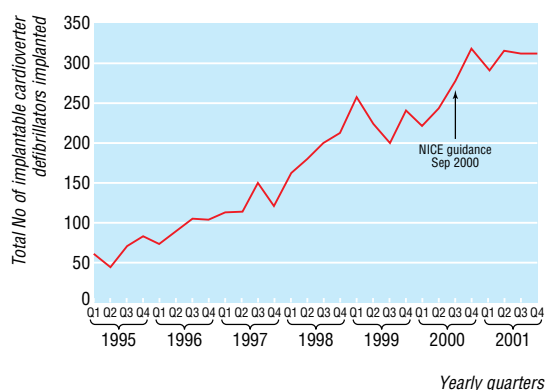


Fig 2 Total number of implantable cardioverter defibrillators implanted by quarter, 1995-2001

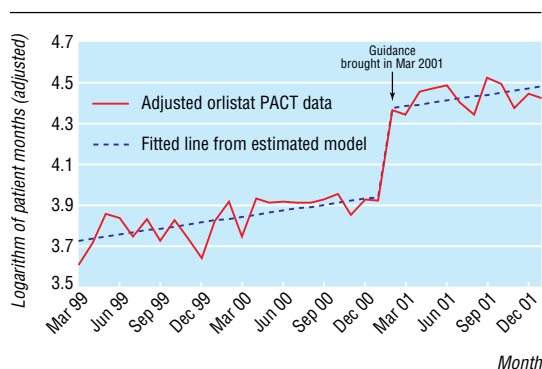


Fig 3 Use of orlistat in the community

published (22 per month, 95% confidence interval 15.9 to 27.8,  $P < 0.001$ ; fig 3). Health authorities increased their use of orlistat, standardised by age, in the year after NICE guidance had been issued by about eight patient months per 1000 people aged 18-75 years. The variation in use, as measured by the coefficient of variation, fell from 0.4 in 2000-1 to 0.3 in 2001-2.

In the 689 primary care patients for whom we have a record we found evidence that the drug was not being prescribed in accordance with guidance. Only in 12% of cases ( $n = 83$ ) were there data showing compliance in each of the three key areas of age, body mass index, and weight loss. However, the recording of patient information was poor. The rise in prescribing of orlistat therefore does not necessarily imply a rise in appropriate prescribing.

### Drugs for Alzheimer's disease

Total use grew logarithmically since February 1999. Taking this into account, the growth rate at the time of publication of guidance (- 1.4% per month, 95% confidence interval - 4% to 1.2%) did not increase significantly. However an increase in trend occurred shortly before the guidance was formally issued. Variability between health authorities decreased; the coefficient of variation fell from 1.1 to 0.97.

Based on the audit data from 583 usable forms, compliance with the five recommendations in the guidance at first prescription varies between 52% and 85% for mental health organisations and 21% and 46% in primary care. Compliance with the recommendations at follow up is low.

## Discussion

### Principal findings

The evidence that NICE guidance has made a difference either to the quality of care or to variations in practice is mixed. Use of orlistat and taxanes grew rapidly after NICE guidance had been published, and uptake of drugs to treat Alzheimer's disease also increased, although this slightly preceded the release of that guidance. The guidance for wisdom teeth was published during a long downward trend in the extraction rate and did not have a discernable additional effect. The guidance for hips in general showed no effect. We found no evidence of a change in the number of implantable cardioverter defibrillators used, the numbers of inguinal hernias or colorectal cancers treated laparoscopically, or expansion in the range of

**Box 1: Features of trusts consistent with high compliance**

- Commitment to managing process of implementing guidance
- Identification of lead clinician at point of NICE announcement of topic for review
- Proactive assessment of local costs and implications of implementation
- Responsibility for funding and implementation vested in locality-wide group
- Strong clinical governance function appropriately resourced
- Culture of consensus
- Recognition of legitimacy of NICE
- Involvement of clinicians in guideline process
- Financial stability
- Expectation that compliance is mandatory, subject to identification of funding
- Targeted audit of areas of non-compliance

hearing aids made available. In some cases audit showed that clinical practice was highly compliant with the indications for treatment laid out in the guidance (for example, wisdom teeth and the use of taxanes for breast cancer), but compliance was low for some (such as orlistat) and more variable for others. Some trusts seemed to exhibit more consistent compliance than others across a range of guidance (box 1).

**Strengths and weaknesses of the study**

In a retrospective observational study we cannot fully assess the impact of NICE guidance because of the absence of the counterfactual and because NICE guidance is just one factor influencing professional practice. We can only observe whether clinical practice is consistent with the guidance. This research was based on a large data gathering exercise, and although data taken from national routine hospital and primary care are complete, those obtained from hospital pharmacies were less so. Where data were recorded, the audits allowed us to assess more reliably details of practice. The interviews were useful in highlighting the managerial, financial and clinical perspectives on implementation.

**Meaning of the study**

The establishment of NICE as a mechanism for institutionalising evidence based health care was a unique initiative. However, it is not sufficient for rapid and uni-

**Box 2: Factors influencing adoption of innovation (after Rogers<sup>7</sup>)**

- Perceived attributes and consequences of adoption (for example, relative advantage, complexity, observability)
- Type of innovation decision (optional, collective authority)
- Communication channels (for example, media, interpersonal, professional)
- Nature of the social system (norms, degree of interconnectedness of networks, concentration of opinion leaders)
- Extent of promotion efforts by agents of change

**What is already known about this topic**

Research on the implementation of guideline implementation has been summarised, but its relevance to this unique national initiative was unknown

The implementation of NICE guidance has not been evaluated overall. Previous work has been limited to single health technologies

**What this study adds**

Some clinical practice has changed in line with NICE guidance, in particular around prescribing (for example taxanes and orlistat)

Other technologies have been adopted in line with NICE guidance but continued pre-existing practice patterns

There is evidence that NICE guidance has been less influential in surgical procedures and use of medical devices

Routine data are not sufficient to assess compliance with guidance; this needs review of case notes

NICE guidance seems to have had an uneven impact on the uptake of evidence based medicine. This impact is likely to be greater if more effort is devoted to clarity of the guidance and its relevance to practice; adequate funding provision; getting professional support; and encouraging healthcare organisations to set up formal mechanisms for handling guidance

versal implementation of evidence based health care. This is unsurprising; NICE guidance is being issued at a time of great change in the NHS. Change is also dependent on the actions of groups of professionals and individual clinicians<sup>5</sup> working in complex health care organisations containing strong professional bureaucracies<sup>6</sup> and is complicated by the increasing importance of networks that span several organisations.

The adoption of guidance is likely to depend on several factors (box 2) (see [bmj.com](http://bmj.com)).<sup>7,8</sup> In areas where practitioners and managers see advantages to adoption, where the value is hardly disputed (clear evidence), and where there is professional endorsement (taxanes for breast cancer, wisdom teeth extraction, and orlistat for obesity) practice has changed relatively fast. Marketing activity by the pharmaceutical industry should not be overlooked as a possible explanation for the apparent increased uptake of drugs over devices and changes in surgical behaviour.

If evidence has been disputed, or the costs not covered by increased income, adoption is more variable. Where practice is complex and also depends on an interaction with a practitioner's skills (such as with hip replacements), research to understand the clinical context of practice may have helped to produce more influential guidance. Adoption may also be influenced by whether decisions rest with an individual or requires team or organisational agreement.

The extent to which trusts are prepared for NICE guidance and have put in place structures and processes to manage their implementation was variable.

The degree of active promotion by NICE is likely to have some impact on adoption, although probably not directly proportional to the effort invested. The greatest effect is likely when opinion leaders including the professional bodies and associations adopt and promote the guidance.

### Conclusions

Implementation of NICE guidance is likely to be improved if it is clear and based on an understanding of clinical practice, if the evidence is strong and relatively stable, if adequate funding is available, and if the guidance is supported and disseminated by professional bodies. Trusts should institute strong supportive internal systems for handling guidance and gathering data on implementation.

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Competing interests: NC was a member of the NICE Appraisals Committee between 1999 and 2002. KL, PW, DW, and JM work for York Health Economics Consortium, which undertakes work for a range of pharmaceutical companies, the Department of Health, and the NHS and has undertaken a cost-effectiveness study for Guidant, which manufactures implantable cardioverter defibrillators. This study was submitted to NICE as part of the assessment process.

Ethical approval: North West Multicentre Research Ethics Committee.

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## Commentary: Is NICE delivering the goods?

Nick Freemantle

Those of us concerned with the ability of organisations such as the National Institute for Clinical Excellence (NICE) to influence clinical practice in line with their guidance will read this paper with great interest.<sup>1</sup> But what conclusions can we draw from it? If NICE was an unqualified success, clinical practice in the NHS would reflect its guidance—so use of implantable cardioverter defibrillators would have gone up smartly, laparoscopic hernia repair would have stopped, and so on. This was demonstrably not the case.

In contrast with randomised controlled trials, where the intervention is under the control of the investigator, the quasi-experimental method necessarily used by the authors is weak in attributing cause and effect. So we cannot even conclude that changes that occurred apparently in line with the NICE guidance were actually caused by it, either in part or in whole.

Some may find it surprising that prescribing of (two of four) taxanes for cancer, and of orlistat for obesity were the only topics out of 12 surveyed where significant changes in the rate of use occurred after NICE guidance. Given that the manufacturers of these products are also very interested in increasing prescribing, and from informal accounts have worked hard to increase sales, it seems a big step to presume that changing use at around that time was caused by the guidance. Indeed, it would be much more convincing if there was evidence that practice had changed after publication of NICE guidance in the counterfactual direction to that which would result from market-

ing activity. Without such evidence many will remain, correctly, sceptical as to whether there is any real return from the substantial efforts and resources that go into producing NICE guidance.

NICE has recently woken up to the potential problems regarding the implementation of its guidance in the NHS and is appointing a board level “implementation tsar.”<sup>2</sup> That person’s task may seem unenviable— influencing clinical practice seems much more difficult than merely issuing edicts. Indeed, as A H Weiler reputedly said, “Nothing is impossible for the man who doesn’t have to do it himself.” Achieving real change in clinical practice is clearly a necessary part of the remit of NICE. Without this vital step, the resources currently used to support the NICE enterprise would be better spent on care for patients. Other regulatory structures, such as the pharmaceutical benefits scheme in Australia, which limits access to reimbursement in the health service to pharmaceuticals that are judged to be good value for money, seem much more effective in achieving real change, and there is a lot to learn from the experience in other health systems.<sup>3</sup> So, rather than give up on the task of modernising the way the NHS uses healthcare interventions, we should look at a variety of ways to make NICE more effective.<sup>4</sup>

As he left the *BMJ*, Richard Smith ably appraised the performance of NICE in a sentence or two, questioning in particular the extent to which NICE dealt with rationing and the breadth of clinical practice,

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