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NICE implementation

— overcoming the barriers

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NHS organisations now have to demonstrate their commitment to implementing NICE guidance. This article describes changes to the way NICE guidance is funded, strategies for improving implementation and the implications for foundation trusts

The National Institute for Health and Clinical Excellence was created in 1999 to promote high clinical standards in health care and to encourage equitable health care provision across England and Wales, thus bringing postcode prescribing to an end. NICE aims to achieve this using technology appraisals and clinical guidelines which are evidence-based and take cost-effectiveness into account. NICE also issues guidance on interventional procedures from a safety and efficacy perspective. Between 15 and 20 technology appraisals and approximately 10 clinical guidelines are issued per year.

As a general principle, the NHS is required to fund NICE technology appraisals within three months of publication, including staffing and ancillary costs. This target can be extended where significant capital investment is required, or staff training and significant changes in service delivery are needed. A target has not been set for the implementation of clinical guidelines with the exception of the guidelines for fertility treatment.

Standards for better health

NHS organisations will now have to demonstrate their commitment to the implementation of NICE guidance, as out-

lined in “Standards for better health”¹ and subsequently through the Healthcare Commission’s annual health check.² The standards relating to NICE implementation are:

- **Core standard (C5)** Health care organisations should ensure that “they conform to NICE technology appraisals and, where it is available, take into account nationally agreed guidance when planning and delivering treatment and care”.
- **Developmental standard (D2)** Health care organisations should ensure that “patients receive effective treatment and care that conforms to nationally agreed best practice, particularly as defined in national service frameworks, NICE guidance, national plans and agreed national plans on service delivery”.

These measures are intended to ensure that NHS bodies conform to national guidance and to reduce the incidence of postcode prescribing and health inequalities. Where organisations fail to meet the standards set out and fail to have robust systems in place for implementing NICE guidance, this will be reflected in the trust’s annual health check rating which replaces the previous star rating exercise.

Payment by results

The introduction of a tariff-based “payment by results” system for most acute trust activity

should simplify the process for funding NICE guidance.³ The costs associated with NICE guidance are reflected within the tariff price. Since funding is theoretically available through the tariff, commissioners, usually primary care trusts, should ensure that the trusts providing patient care implement the guidance in a timely manner. The main complication in this model is that the tariff is historically based and then adjusted to reflect expected changes. For example, the 2005/06 tariff is based on 2003/04 reference costs, uplifted for expected cost pressures such as NICE guidance, inflation and pay awards. The accuracy of the tariff is therefore dependent on the accuracy of those assumptions.

The level of payment by results implementation is dependent upon the status of the provider trust — either foundation or non-foundation — and also upon local agreement between commissioners and providers. For foundation trusts tariff income in 2005/06 is received for all elective, emergency, outpatient and accident and emergency activity. For non-foundation trusts only elective work is mandated to be funded through payment by results for 2005/06, although the other areas are optional, based on local agreement. From 2006/07 all elective, emergency, outpatient, accident and emergency and critical care activity for all acute provider trusts will be funded through this method.

Where a tariff-based payment by results system is not operational the costs of the NICE guidance within trusts will have to be

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negotiated through the local delivery plan process with their host PCTs. In this instance, competing demands on PCT resources come to the fore.

Within the 2005/06 national tariff there are a number of specific exclusions relating to high-cost medicines, a number of which have been through the NICE process. Medicines such as anti-tumour necrosis factor alpha therapies (infliximab and etanercept) prescribed for rheumatoid arthritis are currently excluded. One of the reasons for this is that the cost of the drugs is disproportionately high in comparison to the value of the tariff for an outpatient or day case procedure. In these instances the local PCT will have to decide, in conjunction with the trust, the level of funding available for these treatments. This may be in the form of an overall pot of money within which the trust should manage the demand, or it may be on a patient basis, whereby the trust invoices the PCT for the costs of each patient.

The risk, that is, the consequences of a financial overspend beyond the confines of the agreed "pot", lies with the trust in the first instance, and with the PCT in the second instance, unless the number of patients the trust is allowed to treat is capped. Further exclusions from the tariff for high-cost medicines are likely to be announced by the end of the year. It is essential that both commissioner and provider engage in horizon scanning activities and keep funding aside for any expected changes. In this way NICE guidance that becomes active within a financial year can be managed both clinically and financially.

It is clear that the current system can still lead to postcode prescribing where commissioning and finance decisions have to be made within finite resources. Although the tariff-based system passes the risks and responsibilities on to provider trusts, there are still significant costs associated with NICE guidance which require commissioning decisions.

— Audit Commission report

The Audit Commission report: "Managing the financial implications of NICE guidance", published last September by the commission and NICE, is derived from data obtained from questionnaires and site visits to NHS trusts across 10 strategic health authorities. The report covers the implementation of technology appraisals and clinical guidelines, but not interventional procedures.

The commission reports that the target for implementation of guidance is not always met, particularly where technology appraisals involve high implementation costs, expensive drugs or medical devices. Clinical guidelines were found to be less likely to be implemented quickly, primarily

because of the complexities of managing change across primary and secondary care boundaries and the requirement to adapt locally designed care pathways.

There are many reasons why NHS organisations do not implement NICE guidance quickly but the reason is primarily cost. PCTs are not allocated funds that are specifically ring-fenced for implementing NICE guidance but receive funding within their overall financial allocation. As a consequence, the costs of implementing NICE guidance are one of many competing demands on PCT resources.

The Audit Commission report provides some useful commentary around financial management. It says that the key steps that should be taken include:

- An assessment of compliance with current and imminent guidance
- Verification of the position of NICE guidance within and outside the tariff
- Development of business cases to support NICE guidance where appropriate and subsequent clarification of funding availability to support that guidance
- Incorporating guidance into business plans and providing appropriate budgetary support
- Monitoring the implementation of NICE guidance and the financial implications
- Inclusion of horizon scanning of NICE guidance into financial planning templates
- An estimate of any financial risks (overspends) from the implementation of NICE guidance

The report found that the most significant weakness in funding NICE guidance was in local financial arrangements. Key findings included that only 26 per cent of organisations undertook regular horizon scanning exercises to forecast financial pressures arising from new guidance. Exercises to forecast the financial implications in terms of savings for NICE guidance were carried out by approximately a third of respondents, while around three-quarters identified potential costs. However, the report found that the quality of these costing exercises tended to be less robust than the ideal.

Again, cost templates developed by NICE were used in the minority of cases and financial planning and budget setting were not routinely inclusive of NICE guidance. Furthermore, less than a quarter of organisations produced an action plan for NICE guidance and business planning was uncommon. If trusts fail to plan financially it is clear that the ability to determine whether they can or cannot afford the impact of NICE guidance is limited.

— Barriers to implementation

The report states that a number of barriers to implementation of both NICE guidance and guidance in general have been widely reported. The report's findings cite lack of interest, money, resources, time, resistance to change, too much change and, in some cases, lack of knowledge that guidance exists as the most common perceived barriers. However, the findings suggest that where planning is robust for the implementation of guidance, lack of funding was not the greatest barrier to implementation. In these cases, the greatest barriers were a lack of understanding of the total cost of implementing guidance and differences in the interpretation of funding required, including ancillary costs.

— Improving implementation

From a financial perspective, all new guidance and reviews of guidance issued after January 2006 will have a cost template associated with them. The report suggests that a business case template needs to be designed which includes start up as well as ongoing costs. The report makes a number of suggestions as to the way forward, such as using cost and business planning templates, taking into account the assumptions made by NICE in its model, and using clinical and financial expertise at a local level. Once these processes have been completed, local negotiation needs to take place to decide how the costs of implementation will be met.

Clearly, these negotiations will be smoother and more positive where local relationships between NHS organisations are good. However, this is not always the case, particularly where conflicts arise between foundation trusts and PCTs. The report suggests that the organisations comprising the local health economy should work together through partnership and clinical networks. From a clinical perspective, the chances of successful implementation are increased by the presence of a "champion", usually a clinician, who develops a business case as part of a local delivery plan.

Once an agreement has been reached over the implementation of NICE guidance, the costs associated with that guidance should appear in the financial plan and the annual budget. The Audit Commission report found that 35 per cent of respondents failed to budget for a single piece of NICE guidance in the past three years.

A decision also needs to be made whether to retain funding within a NICE reserve or "slush fund", or to devolve the funds to the services providing the services. The Audit Commission found that, when organisations run out of funds, most of them reallocate funds from other areas to support NICE guidance, some reallocate between funding streams for NICE guidance, and others stop

funding once that limit is reached. The report suggests that where there is a reserve or central budget, funds should be transferred to services to ensure that guidance can be linked in with clinical practice and monitored accordingly. However, the report also suggests that the budget should be allocated in such a way as to allow monitoring and identification of where that money has gone and is important in the development of an audit trail. Where savings are expected as a result of NICE guidance, expenditure should be monitored to ensure that those savings are realised.

Monitoring the implementation of NICE has clinical, audit and financial strands. Where organisations decide not to implement NICE guidance, an exception report should be logged within the Healthcare Commission's performance assessment standards.² At the Countess of Chester NHS Foundation Trust, this is monitored using the CIRIS web-based database,⁴ which allows exception reports and evidence of compliance to be recorded on an ongoing basis. A relevant committee should acknowledge NICE guidance that has not been implemented on the PCT and trust risk register, together with a plan for how the guidance will be implemented and how the risks of non-implementation will be monitored. PCTs paying for NICE-related tariffs should ensure that guidance is being adhered to within that tariff. Expenditure on NICE guidance should be monitored and tracked in comparison with that forecast at the outset and appropriate action taken where necessary, including monetary forecasting for the following financial year.

Pharmacy finally gets a mention in the last few pages of the report but, regrettably, the report focuses solely on the financial impact of NICE rather than pharmacy contributions to medicines management and quality of care. Expenditure on medicines is already routinely monitored by pharmacy and finance staff and, as such, monitoring expenditure on NICE-approved medicines already takes place. However, there are problems with this. Where drugs are approved for a specific indication, monitoring of the clinical activity that those medicines are used to support is essential to ensure that the process

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The site also contains advice to contributors to *Hospital Pharmacist*, and information on subscribing to the journal.

is followed correctly. The report describes prescribing protocols and audit against those protocols so that the drugs are only prescribed for particular conditions in accordance with NICE guidance. However, there needs to be provision to monitor expenditure where the drugs are prescribed for non-NICE conditions. Electronic prescribing and other IT developments may account for this in the future.

Foundation trust implications

With regard to payment by results, the Audit Commission report provides reassurance about the role of NICE guidance within the tariff. However, negotiation over medicines outside the tariff remains an issue. If all NICE therapy is eventually put into the tariff, this may improve access to medicines for patients affected by that guidance, but may place even more financial pressure on PCTs. This could ultimately mean that services to patients are cut in other areas. This removes some elements of local choice about funding that both the introduction of PCTs and practice-based commissioning were intended to develop.

The report acknowledges that the implementation of all guidance may not be possible due to challenging demands on local funding and that funds are limited, but the risk of this is best managed through local financial management planning. However, the report does not significantly cover what the challenges might be. Given the recent explosion of biotechnology and other high-tech and, subsequently, expensive medicines available now or due to be launched in the near future, there are going to be some difficult choices for trusts to make.

Expenditure on NICE technology appraisals has risen from less than £200m in 2000 to in excess of £800m in 2005. Since NICE funding is included in the general allocation of money to the PCT, it is generally difficult to identify how much money has been provided specifically to fund individual technology appraisals. Greater transparency over the amount of funding available from the general allocation would help commissioners to identify funds available and work within them.

Patient awareness of NICE guidance is also growing. The recent publicity over the availability of trastuzumab (Herceptin), even before it has been formally reviewed by NICE, has raised awareness of patients to the existence of high tech and high cost medicines that could be life saving or life changing, and that the threat of legal action might improve their chances of receiving these medicines. Patient and professional groups are reviewing the prescribing of products that should be prescribed under NICE guidance but may not be. Although NICE cannot produce guidance on the use of trastuzumab in patients with early breast

cancer until it is licensed for this indication, Health Secretary Patricia Hewitt is reported to have said that NHS trusts have a statutory duty to provide the drugs for people who would potentially benefit from them, and lack of funding is not an acceptable excuse.

The competing pressures on finances referred to in the report will continue to grow and, as a result, ensuring the availability of funding to support NICE will become even more difficult. Another problem is the explosion of information to support the use of medicines with the result that, once guidance is published, it rapidly becomes out of date and may be superseded by other guidelines.

In addition, new agents may be marketed with significant advantages or offering reasonable alternatives to agents that have been included in guidance. There may be some reluctance for trusts to fund other guidelines or new agents, regardless of their place in therapy, because funding may be directed to towards the implementation of NICE guidance instead, for political or performance management reasons, rather than with consideration of patient care.

Another problem with the current system is that the two models for financial risk referred to in the report create an opportunity for conflict between commissioners and providers. Both organisations are likely to be under considerable financial pressure, and to agree to own financial risk from the implementation of NICE guidance is a significant challenge that can lead to difficult negotiations.

Conclusion

In conclusion, the Audit Commission report will come as welcome and timely support to organisations that are seeking to tighten their approach to the implementation of NICE guidance in a more structured manner. With regard to performance management targets set out in "Standards for better health" and the annual health check, the report sends out a clear message that a great deal of work is required to meet the targets set out by NICE guidance, but that this can be achieved through careful planning and use of supporting material. The funding and co-ordination of staff devoted to monitoring and managing NICE implementation also requires some consideration.

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Correction

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