Clinical Audit

Dovepress
open access to scientific and medical research

Open Access Full Text Article

ORIGINAL RESEARCH

Ensuring that mandatory guidance is being correctly implemented – experience of using the NICE technology appraisal audit tool from TA155

This article was published in the following Dove Press journal:
Clinical Audit
31 January 2013
Number of times this article has been viewed

Swathi Panneerselvam
Brigid Ning
Yit C Yang
Nirodhini Narendran

Wolverhampton and Midland Counties Eye Infirmary, Wolverhampton, UK

Background: The National Institute for Clinical Excellence (NICE) Guidance TA155 for the treatment of wet age-related macular degeneration was issued in August 2008. In this work we describe our experience in the application of an audit tool for auditing the implementation of this guidance in our hospital setting and report on the specific and wider aspects of auditing guidance implementation.

Method: Case notes of patients were retrospectively reviewed for compliance to the NICE Guidance TA155, using the audit tool provided, which investigated five domains. A full audit cycle was completed.

Results: Our initial audit failed to reach a satisfactory level of compliance with NICE Guidance TA155 in one domain, which related to dissemination of patient information and documentation of treatment eligibility. To address this issue, we introduced specific changes to our processes, and on reaudit, were able to achieve a satisfactory level of compliance in all criteria.

Conclusion: Audits on implementation of NICE guidance have not been widely reported in the clinical governance literature due to the specific relevance to individual departments. Our experience has demonstrated not only the usefulness of the audit tool in ensuring that our service was in adherence with NICE guidance but also, that as a result of introducing changes to ensure compliance, the quality of service provided to patients was further improved. Implementation of NICE guidance is an intrinsic part of the clinical governance process, and audits on the implementation of NICE guidance are requirements of all service providers, to ensure that there is uniform and systematic uptake of evidence-based medicine throughout the National Health Service.

Keywords: ranibizumab, NICE, TA155, audit

Background

The National Institute of Clinical Excellence (NICE) was established to provide guidance for the National Health Service (NHS) in England, Northern Ireland, and Wales, in three main areas: public health issues, clinical practice guidelines, and technology appraisals of new diagnostic and treatment facilities. The guidance recommendations are provided to clinicians and patients to "diagnose, treat and prevent disease and ill health,"[1] and are based on the highest quality available evidence and as such, are recognized around the world for their excellence.

The technology appraisal by NICE is a rigorous process, taking a minimum 9- to 12-month period of consultation and finally leading to issuance of a Technology Assessment Guidance, intended to offer best clinical practice combined with cost effectiveness. The ideal behind this system is uniform and systematic uptake of

Correspondence: Nirodhini Narendran
Wolverhampton and Midland Counties Eye Infirmary, Wolverhampton Hospitals NHS Trust, Wednesfield Road, West Midlands, WV10 0QP, UK
Tel +44 19 0269 5845
Email niro.narendran@nhs.net

evidence-based medicine and standardized treatment throughout the NHS in England and Wales.[2,3] Acute hospital trusts are actively encouraged to demonstrate that NICE guidance is being implemented and followed. This is one of the many criteria inspected by organizations such as the Care Quality Commission.[4] The implementation of NICE guidance is also underpinned by a document, issued by the Secretary of State in 2004, outlining the legal implications of NICE guidance.[5] Therefore, in every hospital trust, the clinical governance framework ensures the formation of a Guidance Implementation Group to implement new guidance recommendations by NICE and regards audit on implementation as a mandatory requirement of the relevant departments.

In 2008, NICE issued Guidance TA155 on the use of ranibizumab, a biological therapeutic agent targeting vascular endothelial growth factor, for wet age-related macular degeneration (AMD).[6] This particular guidance had a high impact on service delivery for many ophthalmic departments in the UK because of the sudden increase in resources required to deliver intravitreal injections (Figure 1) of a high-cost drug on a frequent basis, to a large number of patients with wet macular degeneration. Nevertheless, once any technology appraisal guidance is released, hospital providers are obliged to commence treatment using the new guidance within 3 months.

In addition to ensuring timely implementation of new guidance, there is also an expectation by NICE that NHS organizations perform audits to ensure that clinical practice and outcomes are in line with guidance.[7] Many hospital departments are very familiar with the process of clinical audit, and good examples of such audits have been acknowledged in the published literature.[8–11] However, when auditing the initial implementation of a new technology for the very first time and without the benefit of prior experience, there is often uncertainty and lack of knowledge. It is therefore useful to have a toolkit containing uniform audit criteria issued with the guidance document, so that all service providers can ensure that there is uniform and systematic uptake of evidence-based medicine throughout the NHS (this is also essential for the purposes of benchmarking).

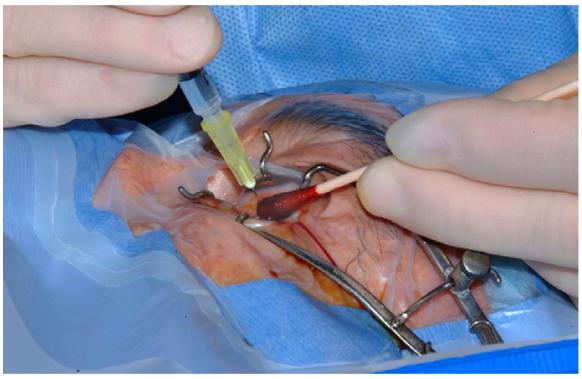

Figure 1 Color photograph showing the intravitreal injection procedure.

In this report, we describe our experience of conducting an audit and the use of the audit support tool issued by NICE for the audit of TA155 implementation, in our hospital trust.[12] The results and also the lessons learned from our audit process, together with our expressed views on the importance and the value of performing such audits of service implementation using a standard tool, should be of interest to other health care professionals in facilitating a smooth, purposeful, and rewarding experience in the performance of similar audits.

Methods

TA155 was implemented in our hospital trust on December 1, 2009. We selected a 4-month period from January 2, 2011 to April 30, 2011 for audit and obtained a list of all 65 patients who fulfilled the criterion of having had at least one intravitreal injection of ranibizumab for wet AMD during this period; as pegaptanib (Macugen®), also licensed for use in wet AMD, was never used in our department, these patients would have only received ranibizumab therapy. From this master list, 30 patients were selected randomly and independently by the hospital's audit and clinical governance department, for detailed audit using the audit tool. This process of selecting a random batch of case notes adhered to the hospital's approved policy and accepted methodology for representative audit to ensure lack of bias in audit case selection. The staff involved in this process were external to the ophthalmology department. Case notes were retrospectively reviewed by junior medical staff (BN and SP), for adherence to all criteria in the audit tool (listed in Table 1). The percentages of patients that satisfied each criterion were determined. The local standard of 75% to 100% compliance for all criteria was imposed prior to commencement of data collection. In the event of failure to meet these standards, it was agreed that reaudit and attempt to close the audit loop would take place following implementation of any necessary changes, within a 6-month period.

A full version of the audit tool can be viewed by using the following link on a web browser: http://www.nice.org.uk/nicemedia/live/12057/41926/41926.doc.[12] Essentially, the audit tool consisted of questions to evaluate compliance with aspects of NICE Guidance TA155 implementation, based on

Table 1 Percentage of patient processes compliant on Criteria 1 to 5 on first and second audit loops

Criteria domain	Criteria	First audit† % compliant, actual (expected)	Reaudit‡ % compliant, actual (expected)
Patient-centered care	1.1. Patient offered evidence-based written information about their illness or condition	10 (>75)*	87.5 (>75)
	1.2. Patient offered evidence-based written information about the treatment and care	10 (>75)*	87.5 (>75)
	1.3. Patient offered evidence-based written information about: "Understanding NICE guidance"	0 (>75)*	87.5 (>75)
	1.4. Patient offered evidence-based written information about the service provider	0 (>75)*	87.5 (>75)
Treatment	2.1. Visual acuity is between 6/12 and 6/96 in treated eye	76.7 (>75)	87.5 (>75)
	2.2. There is no permanent structural damage to the central fovea	60 (>75)*	75 (>75)
	2.3. Lesion size is ≤12 disc areas in treated eye	0 (>75)*	75 (>75)
	2.4. There is evidence of recent presumed progression	70 (>75)*	100 (>75)
	2.5. Treated eye is receiving ranibizumab	100 (>75)	100 (>75)
	2.6. Cost of >14 injections met	100 (>75)	100 (>75)
Follow up	3.1. Was an adequate response to ranibizumab maintained	100 (>75)	100 (>75)
	3.2. Ranibizumab discontinued if persistent visual loss	n/a	n/a
Pegaptanib use	4.1. Is the patient being treated with pegaptanib	0 (0)	0 (0)
	5.1. Was the patient treated with pegaptanib before the publication of the guidance	n/a	n/a
	5.2. Was the patient given the option to continue therapy until they and their clinicians considered it appropriate to stop	n/a	n/a

Notes: †n = 30, ‡n = 24; *below standard.
Abbreviations: NICE, National Institute of Clinical Excellence; n/a, not available.

the five criteria shown in Table 1. Criterion 1 related to patient-centered care, and the remainder contained the treatment criteria. Criterion 2 had six subfields which included four eligibility criteria (2.1–2.4) and two treatment criteria (2.5–2.6). Criterion 3 assessed treatment response to ranibizumab, and Criteria 4 and 5 were largely inapplicable, as they were concerned with use of the alternative agent, pegaptanib (which was used in some departments in UK but not in our department, prior to release of NICE guidance on ranibizumab).

Results

Our initial audit failed to reach a satisfactory level of compliance with NICE Guidance TA155. The specific criteria that were substandard related to dissemination of patient information (only 0%–10% compliant in Criteria 1.1–1.4) and documentation of disease and disease progression (only 0%–70% compliant in criteria 2.2–2.4). We were compliant with TA155 to a high standard (76.7%–100%) in all other domains and criteria.

Following the initial audit, we implemented changes in the areas that were deficient. Firstly, standard patient information leaflets were produced by the senior nurses and doctors involved in the diagnosis and management of patients with AMD. Once hospital trust approval of the information leaflets was granted, these were distributed to all new patients. Secondly, preprinted sticky labels were developed, to be used in patient notes at the commencement of therapy. These labels would indicate that (1) information leaflets had been given to patients; (2) the eligibility criteria had been checked and found to be fulfilled; and (3) there was documentation of disease and disease progression. The costs for these were borne by the directorate budget, and all doctors seeing new patients were informed of the changes, which were welcomed as a further improvement to patient care. By educating all staff to use the eligibility stickers and providing another level of check at the secretarial level, we were able to effectively achieve and maintain compliance in previously deficient areas.

After implementation of these measures, a reaudit was performed on a different subset of new patients entering the treatment program over a 3-month period between July and September 2011. The same process of random selection of audit cases was used, but for this shorter audit period, a smaller sample of 24 patients was selected by external staff from the hospital's clinical governance department. Following this, we were able to show satisfactory compliance with all criteria in the audit tool and were able to close the audit loop. The actual and expected levels of compliance in

each criterion in the initial audit and the reaudit are shown in Table 1.

Discussion

In this report we have described our approach to auditing the implementation of a completely new service in our hospital department. The findings of the audits showed how certain deficiencies in implementation were resolved following specific changes in practice and how it was possible to close the loop satisfactorily after a reaudit. In addition to reporting the mechanistic aspects of the audit and reaudit process, it may be useful to discuss some of our views and experiences gained from the exercise of auditing service implementation of a new service recommended by NICE guidance.

Successful implementation of NICE guidance provides care to patients that is in line with the best available evidence of clinical and cost effectiveness. The provision of an audit support tool for each guidance document, based on the key recommendations of the guidance, is valuable in allowing service providers to assess whether the guidance is being implemented correctly. This work provides evidence that audit tools provided by NICE can be readily used and can improve practice.

In its document "How to Put NICE Guidance into Practice,"[13] NICE has identified the clinical governance system as the main structure to ensuring the implementation of new technology according to the guidelines set out by NICE. We have found the aforementioned document to be useful in highlighting the principles of implementation in clinical governance terms but also, the practical issues that providers face when setting out to implement new technology or to audit the implementation. For instance, it describes the personnel who should be involved in the implementation team, including a lay member (thus helping to facilitate the formation of a multidisciplinary team, which ensures a smooth implementation and subsequent smooth audit), and also the range of tools that can be accessed. In our case, we were initially unaware of this guide and subsequently found deficiencies in our implementation that had to be corrected and reaudited. It would seem this document is not widely circulated and may not be familiar to clinicians performing audit, such as ourselves. The improvement in adherence to the criteria set in the audit tool was likely to be attributable solely to the negative findings of the audit exercise, as the audit tool highlighted shortfalls in implementing certain aspects of the service, eg, patient information sheet provision, which was unlikely to have been picked up without such an audit tool.

In this exercise, we have performed a basic audit according to NICE guidance on the implementation of a new technology. By performing this audit we achieved an important milestone in the history of any service delivery program, and by completing our audit loop, we were able to reassure our patients, Governance Committee, and Commissioners that a new and expensive technology was being delivered according to NICE Guidance TA155, within our organization. We did not perform benchmarking to determine how well our level of implementation compared with the progress made by other organizations – we had a robust audit tool and were able to show compliance at a high level in all the relevant audit domains, and benchmarking ourselves against other organizations may not have been very useful. In general, failure to comply on reaudit might have indicated difficult standards to comply with, and in these situations, benchmarking with other organizations would have then been helpful.

It is important to note that audit of NICE guidance implementation can be performed at any time after implementation. We performed our audit nearly 2 years after establishing a service. An earlier audit would have made it easier to alter our processes to achieve full compliance and also would have given benefit earlier to patients, in the areas which were not initially compliant.

In performing this particular audit, we have learned to appreciate some important general aspects of auditing the implementation of NICE guidance, which should be of benefit to share with other health professionals faced with similar audits. Using the audit tool to plan the audit was a good way to review the important aspects of NICE guidance. It was valuable to realize that NICE technology appraisals give not only guidance on which technology or therapeutic drug to use but also, guidance on patient selection, eligibility criteria, patient information, and measurement of clinical outcomes. All these aspects of the audit tool can help improve the overall service as well as provide audit evidence of compliance with NICE guidance in the fullest sense.

In addition, we learned why audit of NICE guidance implementation should be a high priority for hospital providers hoping to comply with NHS standards on clinical governance. NICE guidance describes a lengthy and thorough process and is issued for technologies that are costly and important to a large group of patients. A high standard of compliance means that the processes are in place for service delivery to all patients to whom the guidance applies. In order to maintain high levels of compliance, it is important to continually monitor performance, and we do intend to

perform reaudit of the implementation criteria on a regular basis. Auditing the processes (rather than the outcomes) is a more direct way of showing that all eligible patients are being exposed to the technology and that there is a uniform delivery of service. This is quite different from the more common types of audit or clinical benchmarking, which are concerned mainly with clinical outcomes and comparison against accepted benchmarks.

In summary, we have described the approach and findings of an audit of the implementation of Guidance TA155, issued by NICE in 2008, for the treatment of wet AMD, with ranibizumab. Such information should be useful for NICE, to ensure the successful dissemination of its guidance, and should also serve to encourage the use of the standard toolkit provided within the NICE guidance document. This particular audit on service implementation was a new and positive experience for our department, and we have written this report to express our views and highlight the value of conducting such audits to improve service provision to our patients.

Authors' contributions

SP and BN were involved with data collection for the audit. NN and YY directed the conduct of the audit and drafted the manuscript. All authors read and approved the final manuscript.

Disclosure

The authors report no conflicts of interest in this work.

References

1. About NICE [webpage on the Internet]. What we do. National Institute for Health and Clinical Excellence; 2012. Available from: http://www.nice.org.uk/aboutnice/whatwed/what_we_do.jsp. Accessed January 10, 2013.
2. Rodgers AT. The National Institute for Clinical Excellence (NICE). *Ann Rheum Dis.* 2002;61 Suppl 2:ii92–ii95.
3. National Institute of Clinical Excellence. *Principles for Best Practice in Clinical Audit*. Abingdon: Radcliffe Medical Press; 2002. Available from: http://www.nice.org.uk/media/796/23/bestpracticeclinicalaudit.pdf. Accessed December 28, 2012.
4. nice.org.uk [home page on the Internet]. NICE and the Care Quality Commission (CQC). CQC essential standards and NICE Quality Standards. National Institute of Clinical Excellence; [updated October 28, 2011]. Available from: http://www.nice.org.uk/usingguidance/benefitsofimplementation/carequalitycommission/carequalitycommission.jsp. Accessed December 3, 2012.
5. nice.org.uk [home page on the Internet]. Meeting legal requirements. National Institute of Clinical Excellence; [updated August 13, 2010]. Available from: http://www.nice.org.uk/usingguidance/benefitsofimplementation/meetinglegalrequirements/meeting_legal_requirements.jsp. Accessed December 3, 2012.
6. National Institute of Clinical Excellence. *Ranibizumab and Pegaptanib for the Treatment of Age-Related Macular Degeneration*. London: National Institute of Clinical Excellence; 2008. Available from: http://www.nice.org.uk/nicemedia/pdf/TA155guidance.pdf. Accessed December 3, 2012.
7. dh.gov.uk [home page on the Internet]. Standards for better health. Department of Health; 2004 [updated April 3, 2006]. Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4086665. Accessed December 3, 2012.
8. Brockbank K, Snoxall S, Beaumont A, et al. Implementing a venous thromboembolism (VTE) prevention strategy. *Clinical Governance: An International Journal*. 2010;15(1):19–28.
9. Campbell A, Reilly D. Are head injury guidelines being met? *Clinical Governance: An International Journal*. 2005;10(1):57–58.
10. Ozbilen M, Cottrell D. Compliance with NICE guidance: concurrent use of different antipsychotic drugs. *Clinical Governance: An International Journal*. 2007;12(2):118–121.
11. Penney GC, Pearson D. A national audit to monitor and promote the uptake of clinical guidelines on the management of diabetes in pregnancy. *Clinical Governance: An International Journal*. 2000;5(1):28–34.
12. National Institute of Clinical Excellence. *Macular Degeneration (Age-Related) – Ranibizumab and Pegaptanib: Audit Support*. London: National Institute of Clinical Excellence; 2008. Available from: http://guidance.nice.org.uk/TA155/AuditSupport/doc/English. Accessed December 3, 2012.
13. National Institute of Clinical Excellence. *How to Put NICE Guidance into Practice: A Guide to Implementation for Organisations*. London: National Institute of Clinical Excellence; [interim version pre-2011]. Available from: http://www.nice.org.uk/media/5F7/3B/HowToPutNICEGuidanceIntoPractice.pdf. Accessed December 3, 2012.