



HQIP

Healthcare Quality
Improvement Partnership

Guide to Working with Industry on Clinical Audit

**HQIP in collaboration with the Cambridge Institute
for Research, Education and Management (CiREM)**

Clinical audit tool to promote quality for better health services

Contents

1	Introduction	1
1.1	Who this guide is for	1
1.2	Why these issues will continue to be significant	1
1.3	The implications for clinical audit teams and clinicians	2
2	Background	3
3	Principles	5
3.1	Patient benefit	5
3.2	Data protection	5
3.3	Equality and diversity	5
3.4	Transparency	5
3.5	Cost neutral	6
3.6	Probity	6
4	Approaches to development of joint working	6
4.1	Code of conduct	6
4.2	Ethical and probity review of proposed projects	7
4.2.1	Ethical issues	7
4.2.2	Probity review	7
4.3	Making commercial interest work in supporting clinical audit in NHS organisations	9
5	Template	10
6	Summary	13
7	Resources	13
8	References	15
	Acknowledgements	16
	Appendix 1. Examples of income-generation schemes	17
	Appendix 2. Summary of code of conduct for non-NHS staff	18

1 Introduction

1.1 Who this guide is for

This guide is for clinical audit departments in NHS organisations considering working with external, i.e. non-NHS, organisations in respect of clinical audit. For the purpose of this guide, these organisations can include the pharmaceutical industry, manufacturers of specific equipment and devices, and other consultancy and commercial organisations.

There is increasing interest from such organisations in becoming involved in service development and clinical audit. This guidance offers advice on how and when it may be appropriate for clinical audit departments and clinicians to work with these non-NHS organisations on clinical audits and the safeguards and standards that need to be in place.

The guide is intended to inform, standardise and develop the interface between NHS organisations and non-NHS organisations in relation to clinical audit activities. It will provide insight as to the concerns and issues that may arise when clinical audits are undertaken across healthcare organisational boundaries and/or by an independent organisation.

The principles contained in this guide also may be applicable to non-NHS organisations.

1.2 Why these issues will continue to be significant

The NHS is and will be for the foreseeable future under sustained pressure to bring about greater productivity within a performance framework of continuous quality improvement with the likelihood of significantly reduced resources. Although quality is likely to remain a highly significant driver in the NHS, improvements in the quality and safety of patient care have to be achieved in a context of no increases in available funding.

The *NHS Plan*¹ recognises the benefits that can come from constructive engagement with organisations outside of the health sector, particularly in areas covered by National Service Frameworks. By constructing the right partnerships, the NHS can harness the capacity of private and voluntary providers to treat more NHS patients.

Building on the Government's firm commitment to create an innovative health service, England's ten Strategic Health Authorities (SHAs) received £2 million in 2009 and £5 million in each of the following four years to support frontline NHS staff in developing innovative ideas. The funding was to be invested directly in projects on the ground and at regional level to speed up the time it takes for innovative solutions to get from idea to NHS practice. This initiative is aimed at benefiting patients directly and increasing the quality of the care. Clinical audits can play a vital part in demonstrating innovation in services for patient benefit. Although the continuation of this funding cannot be confirmed at the time this guide is published, the funding illustrates a theme of investment in innovative practice.

Commercial and other organisations outside the NHS are aware that there are emerging opportunities for them to support and develop the delivery of NHS services, including suggesting how efficiencies and innovation can be attained and how the quality of clinical care can be improved with their help. Commercial interests will inevitably see funding, if it remains available for innovation, and the current climate, as opportunities for partnership.

A philosophy of developing appropriate partnerships to help achieve high quality patient care could further enhance the objectives of a patient-centred NHS. Increasingly, commercial companies are moving to a mature and developed approach. However, such proposed partnerships need to be managed in an effective and efficient way.

Commercial companies are seeking to be involved in clinical audit because they want to be involved as partners in the development of care and they wish to offer their support through partnership and collaboration. However, when commercial companies are involved in assessments of specific care or treatment provided, there may be a perception that their primary purpose is to promote their commercial interests.

Clinical audit is an objective process that is based on professional standards. However, it can offer opportunities for commercial organisations to show that adherence to a specific form of intervention or practice, expressed in a standard used in an audit, is associated with the use of a specific technology or pharmaceutical product or use of a procedure that involves a product that a commercial company sells. In one way, a clinical audit can use professionally verified, perhaps NICE-approved, standards. In another way, the audit may be perceived and actually may be shaped, by image or design, by commercial interests. An example illustrating possible motives is in the box.

Possible motives to be aware of from commercial organisations in sponsorship—An example

Pharmaceutical products, including a generic drug or group of drugs, may be recommended in guidance as the optimum treatment for a specific condition. A clinical audit may seek to measure compliance with the guidance; therefore, adherence to the guidance could increase uptake of that drug or group of drugs.

A pharmaceutical company that manufactures a form of the drug will want to see the company's drug prescribed. If the company is involved in a clinical audit on the specific condition, the wording of the standards used in the audit could mention a specific commercial name instead of the generic drug name, thus communicating to clinicians that they should use the company's drug.

Increased usage of the generic form of the drug may itself be seen as valuable to a commercial organisation. The audit may offer a springboard for sales. However, a company's further interest is in ensuring that its form of the drug is most widely used. The company, therefore, may wish to ensure adherence to the guideline because it is in its commercial interest, as well as being recommended practice.

1.3 The implications for clinical audit teams and clinicians

Those managing clinical audits need to reassure themselves, their management and their patients that the process is not being used, overtly or covertly, to offer commercial advantage to any specific company or intervention, and that the findings are not being distorted or objectivity compromised by the nature of the relationship with a commercial entity. Processes need to be followed in collaborations with commercial companies on clinical audits to offer assurance to third parties and to regulate the relationship between commercial providers and the NHS. Most commercial companies would wish their participation to be informed by the same safeguards. This guide describes the policy background on why collaborations can be encouraged where appropriate safeguards are in place and how these safeguards can be implemented.

The NHS, particularly clinicians and those working in research and development, have had experience of the benefits that can be gained through working with a wide range of external organisations. However, for many staff who work in clinical audit, the concept of engaging with and developing a partnership with non-NHS organisations can be both challenging and increase the prospect of risk. The guide addresses these concerns.

The guidance aims to be:

- **sound**—based on good evidence of current and potential development
- **realistic**—accurately reflect what is achievable for patient benefit
- **enabling**—by providing a framework for working with industry on clinical audit.

2 Background

This section describes some of the areas in which the NHS has successfully developed commercial relationships (income generation, sponsorship and joint working) with external organisations.

The NHS is the largest health organisation in Europe and it is recognised by the World Health Organisation as delivering one of the best health services in the world. As described in the White paper, *Our health, our care, our say: a new direction for community services*,² the strategic shift in services from secondary to primary care encompasses NHS partnerships with relevant organisations such as the pharmaceutical industry as one of a range of options available to meet the needs of patients and achieve clinical excellence. The Government's priorities and planning framework³ treats health and social care as one system, with shared-lead priorities in which both health and social care organisations have a distinct and major contribution to make. Joint working and engagement are essential, especially in delivering National Service Frameworks and intermediate care, and improving services for vulnerable people and those with long term conditions.

An underlying principle for partnership working is that the arrangements must bring benefits to patients. The NHS and potential external partners share a common agenda to improve patient outcomes through high quality and cost effective treatment or services and management.

The Government set out a policy that aimed to encourage government departments, agencies and non-departmental public bodies to make better use of their assets (e.g. clinical services, buildings, and educational resources) by engaging with appropriate commercial services. This policy is set out in the HM Treasury document, *Selling into Wider Markets: A Policy Note for Public Bodies*, issued in December 2002.⁴

Income generation powers enable NHS organisations that abide by specific rules to raise additional income for health services from marketing any spare capacity resulting from a non-core function or from exploiting intellectual property rights. A recent publication on income generation⁵ provided a broad range of activities (see appendix 1). There is no mention of clinical audit per se in the publication. However, clinical audit activities would have a 'natural fit' with at least three of the eleven examples of income generation schemes. Clinical audit data represent a potentially valuable source of clinical data that could be of value to external companies as long as the right safeguards and protections are in place.

For many years, commercial companies, in particular, the pharmaceutical industry, have demonstrated their commitment to improvements in patient care in a variety of ways, for example, by providing medical and educational goods and services and unrestricted educational grants. More recently, however, the NHS and the pharmaceutical industry have been seeking to extend the nature of these relationships in order to develop higher quality care for patients and improve mutual understanding and trust. For example, joint working projects are taking place in some parts of the UK, but this experience is by no means universal.⁶

Commercial sponsorship has provided an additional source of funding for the NHS. The NHS document, *Commercial Sponsorship—Ethical Standards in the NHS*⁷ requires strategic health authorities, provider trusts, primary care trusts and independent contractors to develop local arrangements in relation to commercial sponsorship within a national framework. It is recognised that there can be mutual benefit in sponsorship arrangements with organisations external to the NHS, but only if these are agreed within a framework with the necessary safeguards and checks. Accepting sponsorship from organisations whose primary aim is to make profits or that campaign for a particular interest group has raised concerns in the past that the quality of patient care may be compromised through such arrangements. Priorities may be distorted by sponsorship agreements, which look attractive in one part of the NHS, but may lead to increased costs or poorer care of patients in other parts of the service.

The Department of Health published joint working guidance in March 2008,⁸ confirming the Government's wish to see a closer and more mature working relationship between the NHS and industry and this was emphasised further in the *Next Stage Review—High Quality Care for All*.⁹

We will involve the industry systematically to support better forward planning and to develop ways of measuring the uptake of clinically and cost effective medicines once introduced. (3.51)

We want to foster a pioneering health service that makes best use of the talents of NHS staff, the higher education sector and industry. International evidence from continental Europe, North America and the Far East has demonstrated that patients benefit by bringing together the talents of different sectors. Their skills are harnessed in developing pioneering treatments and service models for patients. (4.42)

By Spring 2009, each PCT will publish its strategic plan, setting out a five-year plan for improving the health of people locally. These plans will put into practice the evidence-based pathways of care at the heart of each region's vision. They will show a strong emphasis on partnership working between PCTs, local authorities and other partners (public, private and third sector – including social enterprise) to ensure that local health and wellbeing needs are better understood and addressed. (8.5)

However, for partnership working to be sustainable in the longer term, it needs to bring benefits to both the NHS organisation and the industry partner, such as cost effective use of NHS resources and increase in commercial or organisational value respectively.

Joint working is a relatively new concept in the NHS and differs from the traditional practice of sponsorship. In sponsorship arrangements, commercial companies simply provide funds for a specific event or work programme. Joint working can be defined as 'situations where, for the benefit of patients, NHS and industry organisations pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery'.⁸

In joint working, goals are agreed jointly by the NHS organisation and company, in the interest of patients, and shared throughout the project. A joint working agreement is drawn up and management arrangements made with participation from both parties in an open and transparent manner. For many organisations, joint working still represents a new way of working. It requires a different mindset from sponsorship and a collaborative approach. However, where the potential for vested interest is guarded against and **both NHS and commercial processes are put in place** to manage joint projects, there is real opportunity for additional value for patients.

3 Principles

The following principles are presented as a framework upon which any policy on clinical audit working with non-NHS organisations should be based.

3.1 Patient benefit

Whatever the work, project and type of agreement entered into, it should be based on informed decision on what is of benefit to patients. There should be no interference with normal provision of clinical care.

3.2 Data protection

Information governance¹⁰ is a framework for handling personal information in a confidential and secure manner to appropriate ethical and quality standards. It sits alongside research and integrated governance and brings together all the requirements, standards and best practice that apply to the handling of personal information. Robust information governance working practices give patients and clients confidence that their personal health information will not be disclosed or used inappropriately.

3.3 Equality and diversity

A culture and advice ethos should be adopted that gives due consideration to the appropriate representation of gender, disability, or particular ethnic or social groups in samples designed for clinical audits, depending on the nature of the project(s).

All dealings with external commercial partners should comply with the relevant organisational policies.

3.4 Transparency

For joint working to be sustainable in the longer term, it should bring benefits to both the NHS organisation and the external partner, such as cost effective use of NHS resources and increase in shareholder value respectively. The anticipated benefits should be clearly stated and understood at the outset of the project. NHS organisations should be clear as to what resources will be assigned to joint working. To be consistent with existent NHS policies, due consideration should be accorded to legitimate commercial sensitivities of commercial partners.

3.5 Cost neutral

As a minimum, NHS organisations should not run at a loss as a result of any joint commercial activity; other non-financial gains to the NHS and to patient care should be taken into account.

3.6 Probity

All NHS staff should be aware of probity issues in relation to working with commercial companies. Staff should be able to differentiate among the many forms of sponsorship (e.g. educational resources) and other forms of relationship building. Social scientists caution that acceptance of a gift, even one of minor value, obligates the recipient to reciprocate in a like manner.¹¹⁻¹²

A key risk to be aware of is the distortion of findings of clinical audits carried out in partnership with industry through compromised design of audits. A badly designed clinical audit that has a risk of becoming in practice a market review of one specific commercial product needs to be carefully considered and an audit must be designed to prevent this possibility. An audit that cannot clearly demonstrate that it is free from either obvious or inadvertent bias toward a specific product or company or an approach to treatment favoured by one specific commercial organisation would fail any probity test. There is risk that clinical audits could be rendered unusable where there was apparent suggestion of vested interest; skewed interpretation of results; design bias; topic, intervention or product selection; or governance that suggested lack of separation between the commercial funding body and the work involved. The credibility and profile of the NHS organisation could be severely compromised if these factors are not taken into account.

4 Approaches to development of joint working

4.1 Code of conduct

Staff working in the NHS should follow existing organisational codes of conduct. Clinical audit staff should seek to ensure that all non-NHS staff are made aware of such codes in any proposed development work. Expectations of conduct for NHS staff not covered by a code of conduct are in the box.

Code of conduct for NHS staff not covered by a code of conduct

NHS staff who are not covered by a code of conduct are expected to:

- act impartially in all their work
- assess the nature of all gifts, benefits, hospitality or sponsorship of any kind
- declare and register gifts, benefits, or sponsorship of any kind
- declare and record financial or personal interest
- brief senior management on any breach of conduct
- do not further private interests or those of others in the provision of care
- monitor and assess the promotion of commercial products or services
- beware of bias generated through sponsorship
- maintain professional independence or judgement.

Further guidance for staff on ethical standards regarding code of conduct in relation to sponsorship has been published (see annex A).⁷

4.2 Ethical and probity review of proposed projects

4.2.1 Ethical issues

HQIP has published separate general guidance and on ethics in clinical audit.¹³ The guide includes guidance on systems of ethical review of clinical audits and how and where proposed audits should be assessed for their ethical dimension. In considering joint work with external organisations, specific ethical issues may arise that may not be covered in standard ethics assessments. These issues are comparable to procurement and concern influencing decisions, which should be subject to the same level of scrutiny as procurement in order to assure fairness. The principles enshrined in standard policies for accepting sponsorship from commercial organisations should apply here. Good practical examples of such approaches are set out by the Department of Health⁷ and in Wales.¹⁴

One area of concern under ethics is the level of sensitivity and competence of honorary contract staff to undertake roles in the NHS that involve highly sensitive or complex clinical audits. Formal induction and education and training are critical for a risk managed and ethically sound project (see appendix 2).

There should be a clear statement of what the intended benefits and anticipated risks are in any partnership concerning a clinical audit. These statements should be backed up by relevant evidence and information. There also should be clear statements by both the NHS organisation and the commercial organisation on both organisations' commitments to evaluate the project to determine if, in time, the project achieved the stated benefits, and if not, why not.

4.2.2 Probity review

In this section, probity means the moral validity of the process involved, that is, does it contravene or compromise essential principles and values. Clinical audit staff and clinicians need to assess the risk of the issues identified in section 3.6 in planning any clinical audit, including the following:

- Has the clinical audit topic been objectively chosen because of clinical factors that can be objectively justified, even if it has been suggested by a commercial entity? (See the example in the box below.)
- If a topic has been suggested by one or more commercial organisations, what is the motivation of any commercial partner?
- Does the audit arise from a commercial interest of any clinician or other NHS employee?
- Are the standards used in the audit based on independent guidelines, not supplied by industry, and selected objectively?
- Is the proposed activity an audit according to the indicators for quality in clinical audit set out in HQIP's guidance, *Criteria and Indicators for Best Practice in Clinical Audit*?¹⁵ Is it simply a data collection exercise?
- Even if clinically justified and derived from professionally assured guidelines, will the audit offer market advantage to a specific market sector or single provider?

- Is the reason for the audit going ahead not simply that the commercial organisation is paying for it? (See the box below.)
- Will funding be provided through a group of organisations acting together, a trade organisation or from a single company?
- Is commercial funding subject to restrictive criteria?
- Is the proposed governance structure balanced with commercial interests not dominating?
- Are there any proposed restrictions on ownership of audit results and will dissemination be subject to agreed processes and usage agreements? (See the example on the next page about why agreement on handling results is important.)
- Will the audit through design favour specific commercial organisations or lead to significant increases in costs through changed treatment that will benefit a commercial partner? Are there ways of avoiding this, for example, through cheaper generic drug prescribing?

How sponsorship might 'skew' the choice of a clinical audit topic—An example

Company X offers sponsorship for a clinical audit on a drug used in management of a long-term condition in primary care. The drug offers the potential of stabilising the condition and thereby preventing readmission. It is suggested that the audit may demonstrate that adherence to the recommended drug regimen will prevent readmission and save money.

Does the audit really add useful information and does it comprehensively review the issues involved? Is the programme being skewed towards the pharmaceutical aspects of treatment simply because funding is available? Is the drug really the main prevention of readmission or are other factors equally or more important? Are the more critical issues to do with prescriber awareness, practice team training and expertise, patient co-morbidities or use of correct diagnostic procedures? Is the drug prescription really the factor that prevents readmission or is it social and nursing support at home?

Application of these processes (evaluative judgements) within the context of broader ethical considerations by competent clinical staff using a systematic process should ensure the following:

- Any clinical audit project being carried out with industry can be safely entered into.
- The results of the clinical audit project can be presented in such a way that there is openness about the involvement of the company and transparency about the nature of the involvement.

Assurance needs to be given that the clinical audit project has not been compromised in any way. Both the commercial company and the NHS organisation must be able to provide this assurance to all its stakeholders—patients, management and clinicians.

Why agreements on handling clinical audit results are important—An example

Clinical audit results can be capable of different interpretations. In the previous example, a guideline recommended a particular drug or group of drugs. If the audit is undertaken, results could show that there is greater adherence to the guideline following the completion of the audit.

According to the research that underpinned the guideline, this change in practice should mean that treatment outcomes improve. However, the audit may not necessarily have been designed to show this. Unless such data were collected, the audit does not show this. Accordingly, the audit report should not speculate on possible outcomes unless they can be proven. Any partners to the audit must not overstate the significance of the audit findings. For example, company literature should not state: “audit trials conducted in NHS Trust X showed that compliance with guideline Y led to better patient outcomes”.

4.3 Making commercial interest work in supporting clinical audit in NHS organisations

It is perfectly possible, through the application of these procedures, for audits to be built around the interests of a commercial organisation and yet allow for broader consideration of factors beyond the interest of the commercial organisation to be considered, such as benefits to a patient group or to the NHS organisation. Discussion and dialogue could enable the commitment of the pharmaceutical company, for example, to support an audit that also looked at non-pharmaceutical factors alongside the specific interests of the commercial organisation. This can ensure that the interest and commitment of commercial organisations, and their specific commercial interests in the sales of their products, can be used appropriately to support clinical audits that meet ethical and probity needs of NHS providers. This match ensures that effective partnerships can be achieved in line with the spirit of cooperation described in this guide.

Hallmarks of a mature relationship of sponsorship of clinical audit

Commercial sponsorship of a clinical audit should be consistent with the following ideas:

- Organised through a trade body for an industry, not a specific company
- Meets criteria for best practice in audit
- Has clinical relevance
- Covers wider aspects of care beyond products, drugs or devices
- Provides patient benefit
- Is used appropriately and results are not overstated
- Is governed by professional interests
- Does not directly further the interests of one commercial supplier against rivals or generic products.

5 Template

This section includes sample checklists and templates to enable the principles described above to provide a systematic approach to assurance. The following template gives an overview of the main actions to take in order to achieve the desired outcomes in a possible collaboration with a commercial organisation on a clinical audit, including a systematic approach to assurance of the integrity of the work.

Area	Action	Outcomes
Pre-project planning stage		
Definition of audit topic	<p>Clinicians and managers identify areas of possible audit, including consideration of suggestions from commercial partners.</p> <p>Suitable guidelines and standards exist.</p>	<p>The audit topic is agreed and confidence in the value of the audit project is achieved across multiple stakeholders.</p>
Ethics and probity assessment	<p>Ethical and probity concerns are raised and reviewed.</p>	<p>Any concerns of vested interest are recognised and safeguards are put in place, for example, a bid is rejected or designed appropriately.</p>
Awareness at organisational level	<p>Meetings are held with relevant sections in the NHS organisation, for example:</p> <ul style="list-style-type: none"> • Research and development • Governance (patient safety) • Laboratory services • Medicines • Management • Pharmacy services • Contracting or commissioning leads • IT services • Press and publicity. 	<p>There is clear management understanding of any risk.</p> <p>Point(s) of contact are established within the clinical audit department.</p> <p>There is a proactive response to an opportunity.</p> <p>There is alignment with the strategic priorities of the organisation and a balance in the audit programme as a whole.</p>
Technical support identified	<p>Identify and use existing skills and expertise of the organisation, including:</p> <ul style="list-style-type: none"> • Appraisal of external documents • Appraisal of formal external contracts • Appraisal of prior external intellectual property. <p>Use or adapt existing policies:</p> <ul style="list-style-type: none"> • Clinical governance • Ethics • Information governance • Intellectual property. 	<p>Risk management is in place for the work.</p> <p>There is an assessment of contractual obligations and value.</p> <p>There is an assessment of the potential value of the proposed development.</p>

Area	Action	Outcomes
<p>Patient perspective</p>	<p>Data protection issues are assessed, including:</p> <ul style="list-style-type: none"> • Access to data • Portable data • Transmission of data • Patient identification issues. <p>The Caldicott Guardian is informed and briefed as to the nature of the project.</p> <p>Benefits are clear, explicit and transparent.</p> <p>Risk checks are carried out:</p> <ul style="list-style-type: none"> • Criminal Records Bureau • Independent Safeguarding Authority • Vetting & Barring assessment. <p>Interest from patient and/or lay groups is elicited.</p> <p>The use of a patient leaflet is considered.</p>	<p>Patient safety is assured.</p> <p>Formal consent is obtained from patients as needed.</p> <p>All project staff (having access to data/patients) have honorary contract status if needed.</p> <p>There is an expectation of benefit.</p> <p>All data are encrypted to NHS standards.</p> <p>There is an informed commercial development.</p> <p>There is a forum to air any ethical concerns.</p>
<p>Project implementation stage</p>		
<p>Project oversight</p>	<p>Nominated leads for the NHS and commercial organisation(s) are appointed.</p> <p>Clear objectives, 'investment' and time periods are set.</p> <p>A governance group is agreed on the following:</p> <ul style="list-style-type: none"> • Ownership of data • Usage of data • Control of outputs • Branding of outputs. <p>Outputs are defined.</p> <p>Funding arrangements are agreed.</p> <p>The timetable for the work is agreed.</p> <p>Roles and participants are agreed.</p>	<p>Communication channels are established with the commercial organisation(s).</p> <p>There is shared project management.</p> <p>Accountability is assured and roles are clear and can be justified.</p> <p>Planned dissemination and promotion systems are in place to avoid future disagreement.</p>

Area	Action	Outcomes
Monitoring, review and evaluation stage		
Outputs	<p>An audit action plan is produced and a change monitoring programme is in place.</p> <p>Repeat data collection for the audit is planned and carried out.</p> <p>Preliminary and final reports are issued.</p> <p>The report process provides for:</p> <ul style="list-style-type: none"> • Agreed sign-off procedures • Joint responsibility for accountability • Due weighting to contributions and acknowledgements. 	<p>New systems and procedures are in place.</p> <p>Increased productivity through greater efficiency and effectiveness) is achieved.</p> <p>An example of innovation is available.</p> <p>Better clinical care and patient satisfaction has been demonstrated.</p> <p>Commercial partner(s) profile, growth and sales are established.</p>
Promotion	<p>Dissemination is carried out.</p> <ul style="list-style-type: none"> • Agreed reference to partnership and rules on rights of release and handling • Shared databases • Agreed timings. 	<p>The audience understands the role of the commercial organisation in the process.</p> <p>Data are not misused.</p> <p>Processes and systems are in place for further development and innovation.</p>

Each of the areas in the table can be used to create a checklist that a clinical audit department could use to assure itself that due diligence had been carried out.

Two areas are of note: The need for a Criminal Records Bureau check and the emerging vetting and barring scheme will be of particular importance for individuals that are granted an honorary contract for the duration of the project.

NHS staff that started work after 2002 should have a Criminal Records Bureau (CRB) check. All new members of staff joining an NHS organisation are CRB checked. A standard check is normally done for administrative staff and an enhanced check is made for people working in those roles that may have contact with children or vulnerable adults, such as nurses, porters, physiotherapists, etc. An enhanced CRB check is generally done for all new staff working in a women and children's division.

The new Vetting and Barring (V&B) system introduced on 12 October 2009¹⁶ is designed to offer a more stream-lined system of workplace vetting for those working with children and vulnerable adults and will build on the existing work of the CRB. As an employer, an NHS organisation will have to ensure that there is V&B registration for all existing and new staff.

6 Summary

This report highlights the current opportunity and need in relation to further development of working with industry, including on clinical audit. The opportunity is represented by calls for innovation in the healthcare sector while confronting the need for greater productivity and quality within constrained resources. However, working with industry on clinical audits needs to be addressed with proper consideration of risk.

Discussions with clinicians and clinical audit staff found that although developments of this nature were 'work in progress', there was a clear perception that it would result in patient benefit and benefit clinical audit staff in terms of professional development.

The principles described in this guide give a **sound** basis for work leading to approaches to further development of partnership projects on clinical audit. Examples of codes of conduct and critical appraisal of ethical concerns are provided.

The template provides a **realistic** action framework.

As the healthcare system engages a greater range of service providers (notably voluntary agencies and social enterprise companies), the opportunity to engage in a different way of working with these new providers will emerge.

Clinical audit staff may perceive that this emerging area of work is difficult and risk laden. The guide addresses the main concerns and provides a risk-managed **enabled** method for engaging positively with industry.

7 Resources

Medicines, Pharmacy and Industry Group, Department of Health. *Best practice guidance for joint working between the NHS and the pharmaceutical industry*. London: Department of Health; February 2008.

This guidance encourages NHS organisations and staff to consider joint working as a realistic option for the delivery of high-quality healthcare and informs and advises NHS staff of their main responsibilities when entering into considering joint working arrangements with the pharmaceutical industry.

Link: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082569.pdf

Standards of Business Conduct for NHS Staff, 1993

This circular on *Standards of Business Conduct for NHS Staff* (HSG(93)5) describes the general standards that should be maintained by staff working in the NHS.

Link: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4065045.pdf

The New NHS: Modern, Dependable, 1997

The New NHS: Modern, Dependable requires the various parts of the NHS to work together and in collaboration with other agencies to improve the health of the population they serve and the health services provided for that population.

Link:http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008869

Commercial Sponsorship — Ethical Standards for the NHS, 2000

The purpose of this guidance is to emphasise to NHS bodies and primary care contractors that their staff are accountable for achieving the best possible health care within the resources available. It advises them to consider fully the implications of a proposed sponsorship arrangement before entering into any arrangement.

Link:http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005135

Confidentiality: NHS Code of Practice, 2003

The NHS Confidentiality Code of Practice is a guide to required practice for those who work in or under contract to NHS organisations concerning confidentiality and patient's consent to use their health records. It replaces previous guidance. The code is a key component of information governance arrangements for the NHS.

Link:http://www.dh.gov.uk/en/Policyandguidance/Informationpolicy/Patientconfidentialityandcaldicottguardians/DH_4100550

Our Health, our Care, our Say, 2006

The Our Health, our Care, our Say sets out a vision to provide people with good quality social care and NHS services in the communities where they live. This paper will change the way services are provided, placing greater choice and control in the hands of the people who use them. Social care services are also changing to give service users more independence, choice and control.

Link:http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_4127552

Code of Conduct: Code of Accountability in the NHS, 2nd revised, 2004.

This code focuses on the three crucial public service values that must underpin the work of the health service: accountability, probity and openness.

Link:www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4116282.pdf

Medicines (Advertising) Regulations, 1994

This regulation concerns advertising and promotion of medicinal products to health professionals and to the public. Guidance on interpretation can be found in the MHRA Blue Guide, *Advertising and Promotion of Medicines in the UK*.

Link: http://www.opsi.gov.uk/SI/si1994/Uksi_19941932_en_1.htm

The ABPI Code of Practice for the Pharmaceutical Industry, 2006

The ABPI Code of Practice for the Pharmaceutical Industry is designed to ensure a professional, responsible and ethical approach to the promotion of prescription medicines in the UK through a self-regulatory system.

Link: http://www.abpi.org.uk/links/assoc/PMCPA/pmpca_code2006.pdf

8 References

1. Department of Health. *The NHS Plan: a plan for investment, a plan for reform*. Norwich: HMSO; July 2000. Available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4002960. Last accessed 13 July 2010.
2. Secretary of State for Health. *Our health, our care, our say: a new direction for community services*. Norwich: HMSO, November 2006. Available at: www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4127465.pdf. Last accessed 12 July 2010.
3. *Operational Plans 2008/09–2010/11. National Planning Guidance and “vital signs”*. London: Department of Health, 31 January 2008. Available at: www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082560.pdf. Last accessed 12 July 2010.
4. Enterprise and Growth Unit. *Selling into Wider Markets: A Policy Note for Public Bodies*. London: HM Treasury, December 2002. Available at: www.hm-treasury.gov.uk/d/New_WM_Guidance.pdf. Last accessed 12 July 2010.
5. Department of Health. *National Health Service income generation—Best practice: Revised guidance on income generation in the NHS*. London: Department of Health; 1 February 2006. Available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4130667. Last accessed 13 July 2010.
6. *ABPI Guidance notes on joint working between pharmaceutical companies and the NHS and others for the benefit of patients*. London: Association of the British Pharmaceutical Industry; March 2009.
7. Department of Health. *Commercial Sponsorship—Ethical Standards in the NHS*. London: Department of Health; November 2000. Available at: www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4076078.pdf. Last accessed 13 July 2010.
8. Department of Health, Association of the British Pharmaceutical Industry. *Moving beyond sponsorship—Joint working between the NHS and Pharmaceutical Industry*. London: Department of Health, March 2008. Available from: www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082853.pdf. Last accessed 13 July 2010.
9. Department of Health. *High Quality Care for All. NHS Next Stage Review Final Report*. London: TSO; 30 June 2008. Available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085825. Last accessed 13 July 2010.
10. Harrison W, Sharp H. *An Information Governance Guide for Clinical Audit*. London: Healthcare Quality Improvement Partnership; 2009. Available from: www.hqip.org.uk/information-governance-guide-for-clinical-audit/ Last accessed 13 July 2010.
11. Dana J, Lowenstein G. A social science perspective on gifts to physicians from industry. *JAMA* 2003;290(2):252–5.
12. Katz D, Caplan AL, Merz JF. All gifts large and small: toward an understanding of the ethics of pharmaceutical industry gift giving. *Am J Bioeth* 2003;3(3):39–46.
13. Dixon N. *Ethics and Clinical Audit and Quality Improvement—A Guide for NHS Organisations*. London: Healthcare Quality Improvement Partnership; 2009. Available at: www.hqip.org.uk/assets/Downloads/Ethics-and-Clinical-Audit-and-Quality-Improvement-Guide.pdf. Last accessed 13 July 2010.
14. NHS Industry Forum. *Guidance for partnership working between NHS organisations, primary care contractors, the pharmaceutical industry and the allied commercial sector in Wales*. NHS Wales; August 2004. Available at: [www.wales.nhs.uk/sites3/Documents/371/WHC\(2005\)16-Partnershipdocument.pdf](http://www.wales.nhs.uk/sites3/Documents/371/WHC(2005)16-Partnershipdocument.pdf). Last accessed 13 July 2010.
15. *Criteria and Indicators of Best Practice in Clinical Audit*. London: Healthcare Quality Improvement Partnership; 2009. Available at: www.hqip.org.uk/assets/Downloads/Criteria-and-indicators-of-best-practice-in-clinical-audit.pdf. Last accessed 13 July 2010.
16. Vetting and Barring Scheme Guidance. Independent Safeguarding Authority. Available at: www.isa.gov.org.uk/Default.aspx?page=402. Last accessed 13 July 2010.

Acknowledgements

HQIP and The Cambridge Institute for Research, Education & Management acknowledge the time and assistance given in producing this guidance by the following individuals and organisations.

Martin Anderson, Association of British Pharmaceutical Industry

Annie Cooper, NHS East of England

Shelagh Goddard, Basingstoke and North Hampshire NHS Foundation Trust

Joanne Colgan, West Middlesex University Hospital

Anne Fairbairn, Ashton, Leigh and Wigan Primary Care Trust

Mike Francis, South Devon Healthcare NHS Foundation Trust

Jim Gardner, North Lancashire Teaching Primary Care Trust

Paul Griffiths, Sheffield Teaching Hospitals NHS Foundation Trust

Carol Heesom-Duff, Cambridge University Hospital NHS Foundation Trust

Robert Holmes, Eli Lilly and Company

Claire Housden, Roche

Wendy LeFort, NHS Cambridgeshire

Anita Maudsley, The Hillingdon Hospital NHS Trust

Saifee Mullahitha, The Christie Hospital NHS Foundation Trust

Mohammad Badran, Mid Essex Hospital Services NHS Trust

Sonia Renwick, The Royal Free Hampstead NHS Trust

Wendy Stephens, County Durham Primary Care Trust

Jane Whittome, Guy's and St Thomas' NHS Foundation Trust

Robert Winder, BioIndustry Association

Eleanor Thomas, HQIP

Mandy Smith, HQIP

Liz Smith, HQIP

Appendix 1. Examples of income-generation schemes from *National Health Service Income Generation—Best practice: Revised guidance on income generation in the NHS*, Department of Health, February 2006

- Amenity beds charges for certain patient services
- Financial services
- Hearing aids
- Intellectual property and the use of companies
- Land and property development
- NHS Plus
- Occupational therapy activities
- Patient transport services
- Research and development
- Telephone services
- Training courses

Appendix 2. Summary of code of conduct for non-NHS staff from *Commercial Sponsorship—Ethical Standards for the NHS, Department of Health, 2000*

Staff working in the NHS should follow existing organisational codes of conduct. Staff should seek to ensure that independent contractors are made aware of such codes.

Staff who are not covered by such a code are expected to:

- act impartially in all their work
- refuse gifts, benefits, hospitality or sponsorship of any kind which might reasonably be seen to compromise their personal judgement or integrity, and to avoid seeking to exert influence to obtain preferential consideration. All such gifts should be returned and hospitality refused.
- declare and register gifts, benefits, or sponsorship of any kind, in accordance with time limits agreed locally, whether refused or accepted
- declare and record financial or personal interest (e.g. company shares, research grant) in any organisation with which they have to deal, and be prepared to withdraw from those dealings if required, thereby ensuring that their professional judgement is not influenced by such considerations
- make it a matter of policy that offers of sponsorship that could possibly breach the Code be reported to appropriate governing board
- not misuse their official position or information acquired in the course of their official duties, to further their private interests or those of others
- ensure professional registration (if applicable) and/or status are not used in the promotion of commercial products or services
- beware of bias generated through sponsorship, where this might impinge on professional judgement and impartiality
- neither agree to practise under any conditions which compromise professional independence or judgement, nor impose such conditions on other professionals.