A Guide for Clinical Audit, Research and Service Review

— An educational toolkit designed to help staff differentiate between clinical audit, research and service review activities

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Clinical audit tool to promote quality for better health services

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Contents

1   Overview

1.1   Introduction

The Healthcare Quality Improvement Partnership (HQIP) is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. Our purpose is to promote quality in healthcare, and in particular to increase the impact that clinical audit has on healthcare quality in England and Wales.

Clinical audit is "a quality improvement cycle that involves measurement of the effectiveness of healthcare against agreed and proven standards for high quality, and taking action to bring practice in line with these standards so as to improve the quality of care and health outcomes."[1]

In order to facilitate this, HQIP have funded the development of a number of clinical audit support tools to help local teams deliver local clinical audit activity. They are intended to be used as reference material or toolkits to help with the clinical audit process.

This document should be read in conjunction with the following:

- the separate glossary provided
- other relevant tools produced as part of this collection by HQIP.

1.2   Background

Over the last few years a number of policy initiatives have changed the data collection landscape for those working within the NHS. This has resulted in a need for clearer guidance on how the activities are categorised or defined and, furthermore, on the governance of those activities to ensure rigour and patient safety.

Following publication of the national health research strategy, *Best Research for Best Health,*[2] the National Institute of Health Research (NIHR) was established to carry forward the vision of improving the health and wealth of the nation through research. Also the Tooke report[3] made recommendations to the Chief Medical Officer of England to address possible ways forward to improve clinical effectiveness across the UK. This showed the need for clinical engagement in quality improvement projects to have rigorous methodology and outcome measurements to provide robust data to improve the fidelity of care provided.

The Next Stage Review[4] by Lord Darzi in 2008 built on the progress made in the implementation of the *NHS Plan*[5] and established a vision for the next decade. It identified a role for measuring outcomes as assessed by patients themselves, PROMs (Patient Recorded Outcome Measures)[6] with *High Quality Care for All*[4] further proposing to make self-reported measures a key strategy to secure improvements in the quality of care in the NHS.

1.3   Implications

The result of this changing landscape for clinicians and researchers means that they find themselves having to comply with increasingly complex ethical, legal, clinical and governance requirements. Whilst research activity involving NHS patients (or their tissue or data) and NHS staff which is conducted in NHS premises must comply with research governance requirements,[7] other data collection activities within the clinical effectiveness and quality improvement arena also have governance requirements. Clinical audit, service development and service evaluation activities frequently involve collecting data from patients or staff. Such activities should be managed within appropriate clinical governance systems in the host organisation with due consideration given to ethical and data protection requirements together with public protection and risk management.

Whilst the ability to distinguish between these data collection activities may be straightforward in some cases, in practice there are frequently grey areas where it may be more problematic. Some NHS trusts could decide to treat grey areas as research in order to ensure that all research activity would be managed appropriately. However, this stance could result in an unnecessary management burden and cost to the research and development department. Additionally, there is a risk that an unnecessary administrative burden on the investigator could serve to stifle innovation.

1.4   Purpose of this guide

In order to assist clinicians, managers and researchers to differentiate between research and other data collection activities, an educational toolkit had been developed by Sheffield Teaching Hospitals NHS Foundation Trust. This provides both a decision-making aid for staff together with guidance on ethical principles and governance for all the non-research data collection activities that might be required within the new NHS innovation landscape. The toolkit has been updated and adapted into a guide for national use across all NHS sectors and in all sizes of NHS organisations.

Key points about the toolkit

Why create it?

This toolkit provides guidance to help staff follow established clinical governance practices in respect of data collection activities. Please refer to the diagram on the next page for an overview.

What will it do?

- This toolkit will help staff differentiate between clinical audit, research and service review and therefore enable the proposed data collection activity to be correctly categorised **most of the time** i.e. accepting that no toolkit can be 100% comprehensive.

- Consideration must always be given to the risks of applying an incorrect method of data collection e.g. contravening research governance, the risk of harm to patients, the organisation or staff. Hence, guidance on how to ensure appropriate governance of these data collection activities, including ethical principles to consider, is also provided.

Who is it aimed at?

Staff with a responsibility to lead projects involving data collection as well as those wishing to learn more about such activities.

How to use it to categorise your project

In the first instance, use:

- the flowchart on the next page to gain an overview

- the "Simple Rules" on page 5 to get a reasonable indication of your project type i.e. is it clinical audit, research or service review

- the "Rule in Questions" on pages 6–9 to confirm your project type

- the "Rule in Questions" for Research in Table 3 on page 7 as a final check to ensure your proposed project is **not research**.
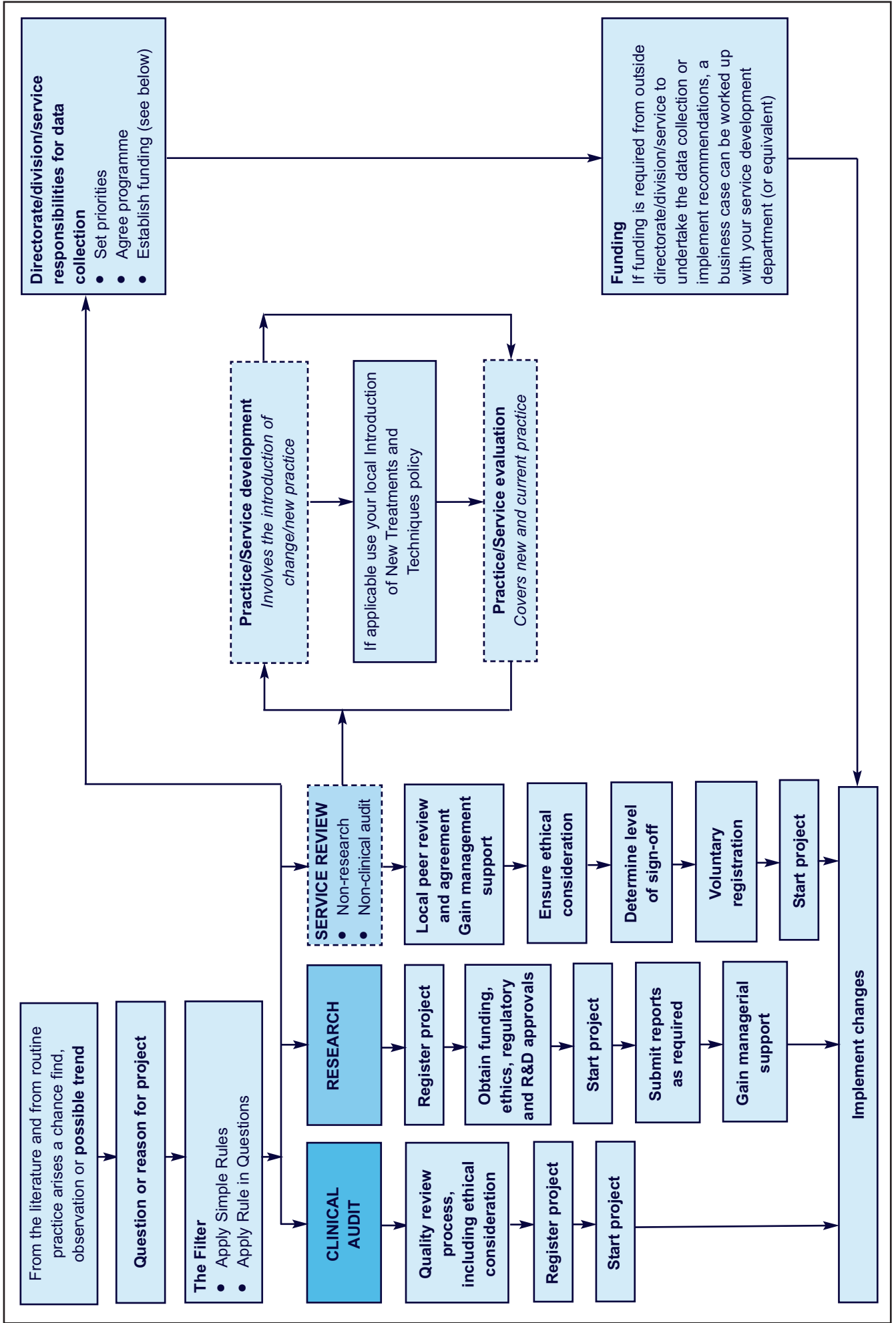
For grey area projects where the toolkit does not provide you with a clear categorisation between these activities, staff are advised to seek assistance from appropriate departments in their organisation. A clinical governance process should exist within these departments to deal with service review grey area projects as well as advise on the steps to ensure due ethical consideration for these activities (also outlined on pages 10–14 of this guide).

Application of this process allows trusts to issue a letter that will enable staff to provide evidence for prospective publishers or any other relevant parties that the project has been classified as service review, risk assessed and confirmation that ethical review has taken place and there are no unresolved issues. Example provided in Appendix 3, pages 27–28.

Changing practice following service review activities

Any proposed changes in practice arising from these activities must be safe, clinically effective, legal and ethical. In general, all proposed changes to practice must consider the clinical impact of the proposed changes and must be set in the context of risk to patients. The final decision to change clinical practice rests with the lead clinician and their team. For additional guidance, please refer to Table 6 on page 11–13 for the ethical principles applicable to clinical audit and service review.

Overview of established clinical governance practices and links in respect of data collection activities

Directorate/division/service responsibilities for data collection
- Set priorities
- Agree programme
- Establish funding (see below)

Funding
If funding is required from outside directorate/division/service to undertake the data collection or implement recommendations, a business case can be worked up with your service development department (or equivalent)

Practice/Service development
Involves the introduction of change/new practice

If applicable use your local Introduction of New Treatments and Techniques policy

Practice/Service evaluation
Covers new and current practice

From the literature and from routine practice arises a chance find, observation or **possible trend**

Question or reason for project

The Filter
- Apply Simple Rules
- Apply Rule in Questions

SERVICE REVIEW
- Non-research
- Non-clinical audit

RESEARCH

CLINICAL AUDIT

Local peer review and agreement Gain management support

Ensure ethical consideration

Determine level of sign-off

Voluntary registration

Start project

Register project

Obtain funding, ethics, regulatory and R&D approvals

Start project

Submit reports as required

Gain managerial support

Quality review process, including ethical consideration

Register project

Start project

Implement changes

2   The Simple Rules

By applying the simple rules below you will get a reasonable indication of the type of data collection activity you want to embark on and whether you need to use a local policy on the introduction of new treatments and techniques.

Table 1. The Simple Rules

Activity		Simple Rule
Clinical audit	1	Measures existing practice against *evidence-based clinical standards* (see section 6.8)
	2	All clinical audit must comply with the *clinical audit governance requirements*
Research	1	Generates new knowledge where there is **no or limited research evidence** available and which has the potential to be *generalisable* or *transferable*
	2	All research must comply with research governance requirements
Service review	1	Incorporates both **service/practice development** and **service/practice evaluation**
	2	**Service/practice development** — introduces a change in service delivery or practice for which there is *evidence* derived from research or from other health/social care settings that have already introduced and evaluated the change. New developments should always be evaluated.
	3	**Service/practice evaluation** evaluates the *effectiveness* or *efficiency* of an existing or new service/practice that is evidence based, with the intention of generating information to inform local decision-making. This type of activity is sometimes referred to as a clinical effectiveness study, baseline audit, activity analysis, organisational audit and *benchmarking.*
	4	All service review activity should comply with clinical governance requirements and follow the ethical principles in Table 6 on pages 11–13.
	5	Service/practice development which is concerned with introducing a new treatment or technique must follow the local policy on introduction of new treatments and techniques as summarised below.
Local policy on introduction of new treatments and techniques		This policy could apply to the introduction of: • a treatment or technique which is understood to be safe and effective but new to your trust • a treatment or technique that is an interventional procedure (as defined by NICE) and has not been used in the NHS before • an existing treatment or technique that is to be adapted for new purposes • a medicine not on the trust formulary or a new indication for an existing formulary medicine.

Note. The terms in bold italic are defined in Section 5, Glossary of terms (see pages 16–18).

3 The Rule In questions

Table 2. Rule In question for clinical audit

	Question	Yes	No	Don't know
2.1	Do you want to measure current practice against *evidence based clinical standards*? This will typically involve measuring both process and outcomes at the same time.			

If you have answered **YES** to question 2.1 then your proposed project is clinical audit. Please follow the established *clinical audit governance requirements* for your organisation.

If you have answered **DON'T KNOW**, seek further advice from appropriate departments in your organisation before proceeding.

If you have answered **NO** to this question, your proposed project **IS NOT** clinical audit. Proceed to either the research or service review questions (Tables 3, 4 and 5).

Note. The terms in bold italic are defined in Section 5, Glossary of terms (see pages 16–18).

Table 3. Rule In questions for research

		Question	Yes	No	Don't know
3.1		Do you want to *investigate* the *effect* of a *new* treatment or technique on patients/ carers?			
3.2		Do you want to *investigate* the *effects* of an existing treatment or technique on a *new* patient/carer group or pathology?			
3.3		Do you want to *investigate* the *correlation* between two treatments/techniques or characteristics?			
3.4		Do you want to **test** a *new* technology or *new* medicine on a patient or their carer?			
3.5		Do you want to **develop** a new technology using NHS staff or facilities?			
3.6		Are you generating or testing a *hypothesis*?			
3.7		Is the new knowledge you are providing *generalisable* or *transferable* to other patients or NHS settings?			
3.8		Do you want to *investigate* a cognitive, physiological, physical/ functional, psychological or social phenomenon of staff, patients or carers where **current evidence** or **knowledge** is lacking?			

If you have answered **YES** to **any** of these questions, your proposed project is research. Please follow your established research governance pathway.

If you are using human tissue from patients/staff in your investigation you must comply with the Human Tissue Act.[8] Please contact your research and development department for advice.

If you have answered **DON'T KNOW** to any of these questions, seek further advice from your research and development department before proceeding. The director of research and development may be the final arbiter in deciding if a project is research.

If you have answered **NO** to **all** of these questions then your proposed project **IS NOT** research. Proceed to either the clinical audit or service review questions (Tables 2, 4 and 5).

Note. The terms in bold italic are defined in Section 5, Glossary of terms (see pages 16–18).

Table 4. Rule In questions for practice/service developments

		Question	Yes	No	Don't know
4.1		Do you want to **introduce** and evaluate a new practice(s) based on *robust published evidence*? For example, evidence-based guidelines or a systematic review			
4.2		Do you want to **introduce** and evaluate a new practice(s) based on evidence of implementation and evaluation in another NHS trust or health/social care setting?			
4.3		Do you want to **introduce** and evaluate a new practice(s) for which there is limited evidence but for which you have completed an *assessment of risks and benefits*?			
4.4		Do you want to **introduce** and evaluate a new outcome measure or assessment tool which is based on *robust published evidence*?			
4.5		Do you want to **introduce** and evaluate a new type of equipment currently licensed in the UK?			

If you have answered **YES** to any of these questions then your proposed project is practice/service development.

But as a final check to ensure your proposed project is **not research,** answer the research questions in Table 3.

To comply with local clinical governance requirements you may need to:

- register your project (further information in Appendix 1, Registration processes, page 25).
- follow ethical principles which are considered best practice (refer to Section 4, Ethical principles applicable to clinical audit and service review, pages 10–14).
- Where appropriate involve **service users** in your practice/service developments.

> **If yes to Q4.1 to Q4.3,** use your local **introduction of new treatments and techniques policy** if your proposed service/practice development relates to the introduction of:
>
> - a treatment or technique that is understood to be safe and effective, but new to your trust
> - a treatment or technique that is an interventional procedure (as defined by NICE) and has not been used in the NHS before
> - an existing treatment or technique that is to be adapted for new purposes
> - a medicine not on your trust formulary or a new indication for an existing formulary medicine.
>
> Your local clinical governance lead/team may provide further advice.

If yes to Q4.5, contact your local medical equipment manager (or equivalent) who will advise on the steps you will need to follow to comply with medical equipment management manual.

If you have answered **DON'T KNOW** seek further advice before proceeding. You could contact one of your key trust departments responsible for supporting clinical effectiveness activities.

If you have answered **NO** to all these questions, your proposed project **IS NOT** a practice/service development. Proceed to either the clinical audit (Table 2), research (Table 3) or service evaluation (Table 5) questions.

Note. The terms in bold italic are defined in Section 5, Glossary of terms (see pages 16–18).

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Table 5. Rule In questions for practice/service evaluation

	Question	Yes	No	Don't Know
5.1	Do you want to *evaluate* the *effectiveness* and or *efficiency* of your *current practice* or service?			
5.2	Do you want to *evaluate* the *effectiveness* and or *efficiency* of an educational programme?			
5.3	Do you want to *compare* the *effectiveness* or *efficiency* of a *new* practice (consistent with *new* practice as described in Table 4 Q4.1–Q4.3) with your *current practice* or service?			
5.4	Do you want to *compare* the *effectiveness* or *efficiency* of your *current practice* against another area of existing practice within your Trust?			
5.5	Do you want to collect and analyse patient/staff/carers data to *evaluate* patterns of activity?			
5.6	Is the purpose of your *evaluation* to provide information of local relevance to inform local decision-making?			
5.7	Will your *evaluation* provide information for making clinical decisions about the care or management of your patient(s)?			

If you have answered **YES** to any of these questions then your proposed project is practice/service evaluation.

If you are using **human tissue** from patients/staff in your project you must comply with the Human Tissue Act.[8] Please contact the research and development department for advice.

To comply with local clinical governance requirements you may need to:

- register your project (further information in Appendix 1, Registration processes, page 25).
- follow ethical principles which are considered best practice (refer to Section 4, Ethical principles applicable to clinical audit and service review, pages 10–14).
- where appropriate involve **service users** in your practice/service evaluation.

> **If yes to Q5.3,** please use your local **introduction of new treatments and techniques policy** if your proposed service/practice development relates to the introduction of:
>
> - a treatment or technique that is understood to be safe and effective, but new to your trust
> - a treatment or technique that is an interventional procedure (as defined by NICE) and has not been used in the NHS before
> - an existing treatment or technique that is to be adapted for new purposes
> - a medicine not on your trust formulary or a new indication for an existing formulary medicine.
>
> Your local clinical governance lead/team may provide further advice.

If you have answered **DON'T KNOW** seek further advice before proceeding. You could contact one of your key trust departments responsible for supporting clinical effectiveness activities.

If you have answered **NO** to all these questions, your proposed project **IS NOT** a practice/service evaluation. Proceed to either the clinical audit (Table 2), research (Table 3) or service development (Table 4) questions.

Note. The terms in bold italic are defined in Section 5, Glossary of terms (see pages 16–18).

4 Clinical governance and project development

4.1 Ethical principles applicable to clinical audit and service review

4.1.1 Introduction

It is important that due ethical consideration is given to all types of projects which involve the collection of data from NHS patients and staff. Under research governance requirements,[6] research projects require formal approval in the form of a favourable ethical opinion from an NHS Research Ethics Committee. There are no such national requirements for clinical audit and service review projects. Approval and oversight of these projects falls within the clinical governance responsibilities of NHS trusts (acute, primary care, mental health, health and social care, ambulance) where the project is undertaken.

Under clinical governance NHS organisations should have ownership and control of clinical audit and service review projects involving their patients, data, staff, equipment or facilities. They should therefore be responsible for considering any ethical implications and for ensuring each project complies with local policy and relevant NHS guidance e.g. confidentiality, consent, data protection, etc. A set of ethical principles (see pages 11–14) have been developed to assist with this process and these are consistent with the principles contained in *Ethics and Clinical Audit and Quality Improvement (QI) – A Guide for NHS Organisations.*[9] Each project will need individual consideration as to which principles are relevant.

It is recommended that staff planning a clinical audit or service review project conduct an initial self-assessment of the project proposal based on their own personal values and with reference to their professional code of practice. The proposal should then be approved through the agreed mechanisms within the host organisation. Individual NHS organisations may have established systems for this purpose. For example, there may be a specific committee established to review and approve clinical audit and service review project proposals or the responsibility may be delegated to individuals within a clinical directorate/ division/service, for example the clinical governance lead. A five–step governance process is included as a model for organisations to use/adapt as appropriate to their local circumstances (page 15).

When a service review project involves an invasive procedure, consideration should be given to ensuring an independent review of the ethical implications is undertaken by an appropriate clinician. Should any matters of a complex or sensitive ethical nature remain unresolved it may be appropriate to seek a specialist opinion, for example from a clinical ethics group (CEG) or the local research ethics committee.

It is recommended that staff gain management support for their proposals before proceeding and committing resources. Once any necessary approvals have been obtained, there may be a requirement to register the project in an appropriate database within the host organisation.

4.1.2 The ethical principles

Along with the rest of this toolkit, the principles on pages 11–14 have been developed to guide staff in planning and undertaking any type of clinical audit or service review project. The principles address the design and conduct of the project; the welfare of participants; and the rights of participants who become involved.

The ethical principles for clinical audit and service review are compatible with the ethical principles that inform professional practice. Therefore, in the same way that a practitioner obtains the consent of a patient before undertaking a clinical procedure, consideration should be given to whether the consent of participants is required for a particular service review project. Similarly, a clinician will weigh up the risks involved in deciding whether or not to use a particular intervention. In service review activity, it is equally important to consider how to minimise any untoward effects, and to identify what could possibly go wrong and what to do if it does. For example, if patients are to be interviewed about their experiences of a particular service, it is important to ensure that questions are phrased in an appropriate manner, and to know how to respond if a patient becomes distressed with the line of questioning.

Consideration of these ethical issues should begin at the same time as the project plan is forming. They cannot be addressed separately or at a later stage in the design of the project. **Not all the principles outlined in Table 6 will apply to every project, but each one should be considered in turn as appropriate.** The suggested indicators have been developed to provide guidance and are not meant to be seen as requirements for every project.

Principles apply equally to clinical audit and service review, but for clinical audit, reference should also be made to *Ethics and Clinical Audit and Quality Improvement (QI) – A Guide for NHS Organisations.*[9]

Table 6. Ethical principles applicable to clinical audit and service review

	Principle	Suggested indicators
1	The aim of the project is justified and compatible with the priorities and requirements of the professional/care group/directorate/division/service/trust, and support exists.	A written protocol/project proposal exists. Evidence of directorate/division/service/trust support exists. A clinical governance lead/clinical audit lead is aware of project. Directorate/division/service-based peer review outcome exists.
2	The proposed project is underpinned by an appropriate evidence base.	Evidence is presented in a written protocol/project proposal. Evidence is sourced in a written protocol/project proposal.
3	The ethical requirements regarding the identification and recruitment of participants are met. Where it is appropriate to gain consent from patients, consideration is given to: - contact - right of equal access - right to refuse - right to withdraw - consent/agreement to take part.	Processes should be in place (and described in the protocol) to address the following issues: - first contact with potential participants - consideration of vulnerability - right to refuse - right to withdraw - process for obtaining consent/agreement where appropriate - justification for not seeking consent with reference to relevant policy or guidance.
4	The roles and responsibilities of any participants (patients/relatives/staff) are agreed between the project lead and relevant participants.	The roles and responsibilities of the participants are outlined in the protocol.

		Principle	Suggested indicators
5		The participant's privacy should be respected and confidentiality should be maintained. See *An Information Governance Guide for Clinical Audit* available from HQIP.	The peer review process should consider compliance with *NHS Code of Confidentiality*, and an opinion from the trust's data protection officer and/or Caldicott guardian should be obtained in sensitive or complex situations.
6		Data collection tools such as interview schedules and questionnaires are appropriately phrased. Where possible, existing validated instruments should be used. See *An Information Governance Guide for Clinical Audit* available from HQIP.	The peer review process should consider the appropriateness of data collection tools.
7		A risk assessment should be conducted to pre-empt what could go wrong and what to do if it does, including disclosure, for example, what to do if the following occurs: • patients reveal information that would indicate clinical need or intervention • malpractice is identified • the project disrupts normal care or routines • non-compliance with policy/guidelines is identified which results in patient care being compromised.	The peer review process should address risks and make recommendations. Evidence of organisational support exists Evidence of adhering to the Trust guidance on disclosure exists.
8		A risk-benefit evaluation should be undertaken to assess the potential burden of harm to participants.	The peer review process should address the likelihood of harm and/or distress.
9		Where a proposal involves an invasive procedure, an independent review of the ethical implications should have been undertaken by an appropriate clinician.	Evidence of independent ethical review by an appropriate clinician exists.
10		Findings are disseminated to/shared with areas of the organisation that will learn from them.	Entry in local project database Project findings disseminated locally, regionally, nationally, for example through newsletters, publications, websites, etc.
11		Participant involvement is accurately presented in reports and shared in a way that is easily understood.	Evidence of patient and public involvement (PPI) input into reports (if relevant) is available.
12		Where appropriate, due consideration has been given to the legal requirements associated with the use of human tissue.	The peer review process should address compliance with the Human Tissue Act 2004. Advice should be sought from the trust's data protection officer where appropriate.
13		Staff should be skilled and competent to undertake project tasks, and should be in receipt of appropriate clinical and/or academic supervision. Necessary skills might include data collection, data analysis, project management, time management, communication, etc.	Project staff CVs Training records Competency assessment records Supervisor's statement

	Principle	Suggested indicators
14	Resources (including time and money) required to complete the project are available and supported by managers/supervisors.	The peer review process should address resource utilisation. Evidence of management support

4.2   Assurance of ethical consideration

It is the responsibility of each organisation to establish local systems for ensuring ethical consideration of all service review projects takes place. In the absence of any formal national guidance/policy framework to govern service review work, the following practical advice has been developed to help frontline staff give due ethical consideration to service review projects.

The three levels of assurance in **sign off** are described below and can be used as follows:

- to register the service review activity
- to comply with governance processes as detailed on page 4 and the 5–Step Governance Process for Service Review Activity on page 15.
- to provide prospective publishers and educational establishments, if required, with evidence that ethical review has been achieved. Refer to Appendix 3 pages 27–28 for a copy of this proforma letter. This letter can also be used to provide evidence that a particular project has been classified locally as service review.

Ideally, the minimum level of assurance sign off for all organisations is level 2, but it may not be feasible as a minimum level for organisations with less well developed clinical governance support mechanisms (see 5–Step Governance Process, page 15).

The results of the risk assessment carried out as part of the ethical review will indicate the necessary level of risk sign off for the project to proceed. Ultimately, this means that if the risk assessment deems the project of very low, low or moderate risk, then sign off at directorate/division/service level would be appropriate. However, if the risk assessment identifies any high or major risks associated with carrying out the project, organisational sign off is required e.g. by the trust executive.

Level 1 assurance — lead clinician/project stakeholder group

The lead clinician and/or the project stakeholder group need to assure themselves their proposed project method is consistent with:

- the ethical principles contained within the toolkit
- their codes of professional conduct
- local directorate/division/service governance systems.

In order to confirm the level of assurance is appropriate for your project, it is recommended that you discuss your proposal with a colleague who has appropriate expertise in the field and/or your line manager. If unable to confidently sign off for Level 1 assurance, you would then need to proceed to the next level.
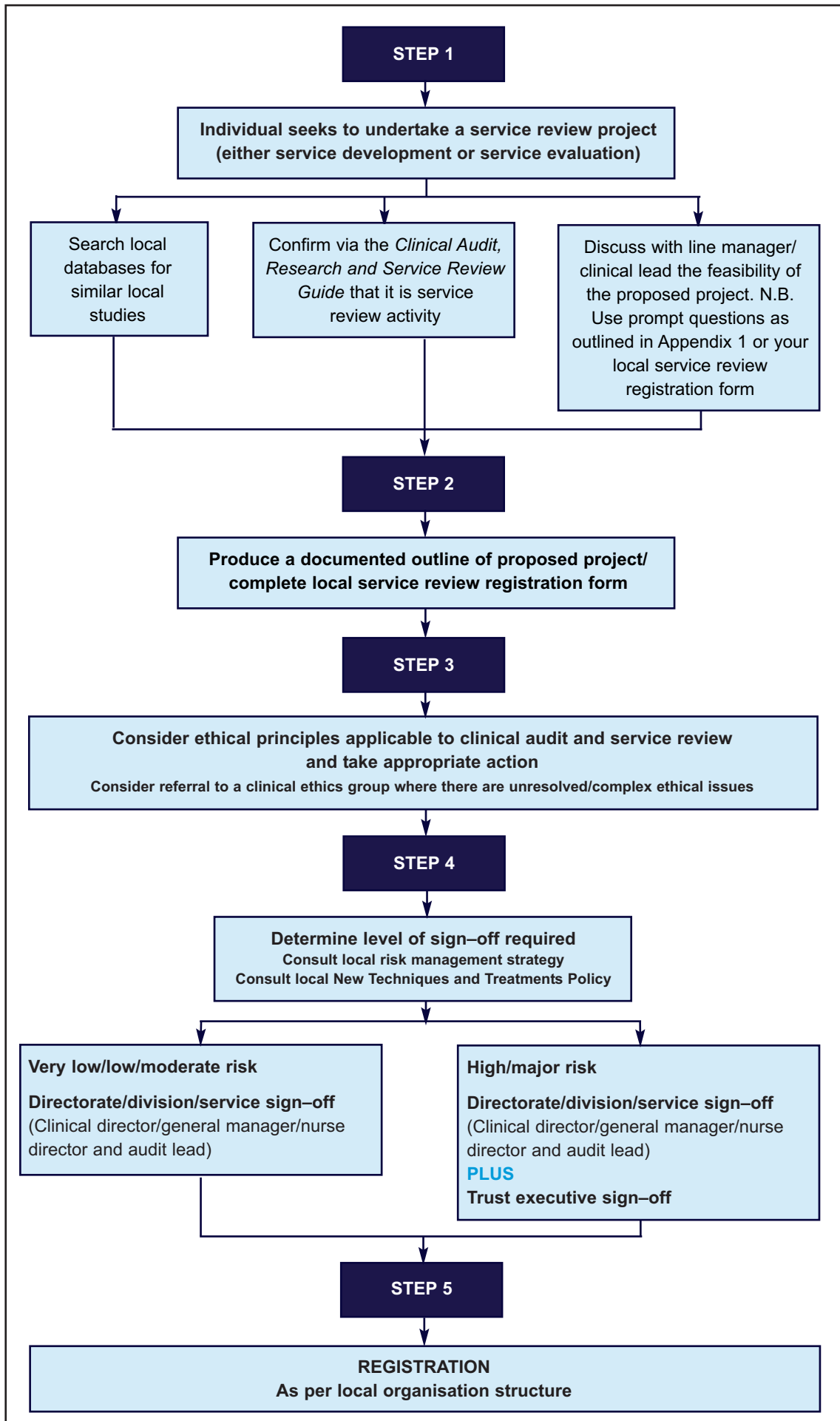
Level 2 assurance — local governance review

Use local directorate/division/service governance systems to reach a final resolution. In some directorates/divisions, there are established peer review groups that staff can take a proposed project to for ethical consideration. For those where no formally established peer review groups exist, the next best thing would be to link with individuals such as the clinical governance lead or the clinical director. If unable to confidently sign off for Level 2 assurance, you would then need to proceed to the next level.

Level 3 assurance — clinical ethics group

In the occasional case, where a favourable ethical opinion cannot be reached within the above two levels, a clinical ethics group (or similar) may be able to provide advice to the directorate/division/service.

5–step governance process for service review activity

STEP 1

Individual seeks to undertake a service review project
(either service development or service evaluation)

Search local databases for similar local studies	Confirm via the *Clinical Audit, Research and Service Review Guide* that it is service review activity	Discuss with line manager/ clinical lead the feasibility of the proposed project. N.B. Use prompt questions as outlined in Appendix 1 or your local service review registration form

STEP 2

Produce a documented outline of proposed project/
complete local service review registration form

STEP 3

Consider ethical principles applicable to clinical audit and service review
and take appropriate action
Consider referral to a clinical ethics group where there are unresolved/complex ethical issues

STEP 4

Determine level of sign–off required
Consult local risk management strategy
Consult local New Techniques and Treatments Policy

Very low/low/moderate risk	High/major risk
Directorate/division/service sign–off (Clinical director/general manager/nurse director and audit lead)	**Directorate/division/service sign–off** (Clinical director/general manager/nurse director and audit lead) **PLUS** **Trust executive sign–off**

STEP 5

REGISTRATION
As per local organisation structure

5   Glossary of terms

Adequate — Where there is sufficient evidence to enable the clinician to make a recommendation about current best practice

Assessment of risks and benefits — The potential risks that individuals or the organisation may experience have been identified and steps have been taken to minimise them. Consideration is then given to justifying the potential risks in terms of the potential benefits of undertaking the service review project.

Benchmarking — The benchmarking process helps practitioners to take a structured approach to sharing and comparing practice, enabling them to identify the best and to develop action plans to remedy poor practice.

Clinical audit — a quality improvement cycle that involves measurement of the effectiveness of healthcare against agreed and proven standards for high quality, and taking action to bring practice in line with these standards so as to improve the quality of care and health outcomes.

Clinical audit governance requirements — A full list of the governance requirements for clinical audit are highlighted in *Principles for Best Practice in Clinical Audit*[1] available at: http://www.nice.org.uk/media/796/23/BestPracticeClinicalAudit.pdf.

Compare — To examine in order to observe a resemblance or difference between results or outcomes

Correlation — To establish a relationship between variables i.e. to **investigate** the **correlation** is where a researcher seeks to provide evidence of a relationship between variables

Current practice — Is an activity, which is "happening now, belonging to the present time", or equipment that is in use now.[10] Current practice can be based on either formal or informal knowledge. **Formal knowledge (external evidence, empirical knowledge)** is knowledge that has been validated by independent scientific scrutiny, for example, textbooks and peer reviewed publications. **Informal knowledge** is knowledge that has **not** been validated by independent scientific scrutiny, for example, unpublished research reports, unpublished reports, conference papers, unpublished but shared experiences,[11] and consensus expert, opinions.

Decision making — Action or change based on observed and documented evidence of benefit

Effect — To establish a causal link between variables; i.e. to **investigate** the **effect** is where a researcher seeks to provide evidence of a causal link between variables by testing a hypothesis

Effective — The capability of producing a result or outcome such as the achievement of a patient's potential for improvement or the prevention of the patient's deterioration

Effectiveness — The ability of the health care practitioner, multidisciplinary team or organisation to produce results or outcome, i.e. the extent to which the recovery potential is achieved

Efficiency — The ability of the health care practitioner, multidisciplinary team or organisation to achieve results or outcome with the minimum use of resources

Evaluation (evaluate) — To ascertain the amount or value or to judge or assess the worth of an existing technology, medicine, practice or intervention

Evidence — "…data on which to base proof or to establish truth or falsehood".[12] Within the health and social care environment this involves the provision of data (i.e. the systematic recording of clinically significant observations of change) on which to base proof of clinical effectiveness. Evidence can be formal or informal. See current practice definition.

Evidence based clinical standards — Define precisely the service/practice we are seeking to provide. The standards can be based on the hierarchy of evidence. Refer to FAQ 6.8 on page 20. For more information about what standards are and how to set them, see *NEW Principles for Best Practice in Clinical Audit*[1].

Generalisable — The ability to infer the findings of a study to a wider population. This can theoretically only occur when the study population is randomised from the wider population. Refer to FAQ 6.17 on page 23 for additional information.

Hypothesis — A tentative explanation for an observation, phenomenon, or scientific problem that can be tested by further investigation. A causal hypothesis is a prediction that a change in one variable (observation or phenomenon), the dependent variable is the result of another variable, the observed independent variable. This investigation of causality requires an experimental design with the hypothesis being tested by statistical methods. Hypotheses can also be developed, supported and refuted from descriptive (quantitative and qualitative) or analytical (experimental or quasi experimental) studies.[13–14]

Investigate — To provide evidence about the existence of a variable or phenomenon e.g. a medical investigation seeks to provide evidence of pathology

Model — A description of practice adequately representing the real thing, which is regarded as excellent and worthy of reproduction

New — Where no current evidence has been published in peer reviewed publications

Outcome measure — A tool that quantifies change in one or more patient characteristics over time. "Measurement transforms certain attributes of the world into numbers, which can be summarised, organised, and analysed by statistical procedures".[15]

Patient Reported Outcome Measures (PROMS) — "PROMs are measures of a patient's health status or health-related quality of life. They are typically short, self-completed questionnaires, which measure the patient's health status or health related quality of life at a single point in time".[6] For more guidance, see: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_092647.

Quantifying evidence — The amount of evidence needs to be quantified a) to be able to judge whether the effect is real or a chance (random) occurrence using probability statistics; b) to be able to establish the internal and external validity of the findings.[16]

Robust published evidence — Includes but is not restricted to research published in peer

reviewed scientific journals, systematic review, meta analyses, and evidence-based guidance such as that produced by NICE

Transferable — The ability to infer similar findings in another comparable population setting rather than in the wider population from which the study population was drawn. Refer to FAQ 6.17 on page 23 for additional information.

6 Frequently asked questions about the toolkit

6.1 Does the Toolkit cover university students?

Yes. Your university supervisor will need to use this toolkit with you to ensure the correct trust governance systems are adhered to. Also, it is important to note that all student projects should have an NHS trust employee as a lead collaborator.

6.2 Is the confirmation accuracy of the toolkit 100%?

Absolutely not.

However, by applying the Simple Rules and Rule In questions to a likely clinical audit project, this should confirm it as clinical audit in the vast majority of cases.

But, given the accepted complexity in differentiating between research and service review in particular, there will always be grey area cases where the toolkit will not be able to provide a clear categorisation between these activities. In these instances, if staff are worried that they may inadvertently be undertaking research, advice must be sought from the local research and development department.

Please note this is a guidance only document. If there is no mandatory registration and approval system for service review activities in your organisation, the final decisions to undertake service review activities should rest with the individual professional.

6.3 How do we deal with grey area cases?

We accept there will be the purists' view that certain service review projects are in fact grey area research, and should therefore be conducted as research. However, the pragmatists accept there will always be grey area cases (evidenced by the continuing global debate on this subject) and therefore believe we cannot conduct everything as research or innovation would grind to a halt.

Therefore, a balance is required between these two viewpoints and final decisions must take account of the following points:

- Accept that this toolkit will enable staff to correctly categorise their data collection activity **most of the time** i.e. accept that no toolkit can be 100% accurate.

- In grey area cases, proceed with caution and be sure any proposed changes in practice are safe, legal and ethical. Consider the risks of applying an incorrect method to the data collection i.e. contravening research governance, any applicable regulations and

legislation, is there a risk of harm to patients, the organisation or staff?

- The risk of getting it wrong can be minimised by peer review, advice from the audit and research departments, Researach Ethics Committee (REC) applying the Section 4, Ethical principles, informed conversations with colleagues and ensuring work is part of directorate/division/service programmes/plans.

6.4 What is the difference between research and the service evaluation described in Q 5.3? (page 9)

Research is about establishing new knowledge, whereas, Q5.3 is about finding out whether local outcomes replicate the research evidence. If they do, then clinicians may want to adopt the new practice; if they don't, then the clinicians may want to reject that practice.

6.5 If I compare two evidence-based treatments is this research or service review?

Imagine you want to compare two current treatments A and B (both evidence based). If you want to establish the "effectiveness" or "efficiency" of the treatments, this is a service review activity. In this situation you are looking at the individual's response to treatment in a real clinical situation. You cannot attribute causality in this situation.

If you want to establish the "effect" of each treatment on the patients this will require randomisation from the patient population, as effect is a term used to describe where there is a causal link between treatments A or B and the patient's outcome. This will then be a research activity where you are investigating the effect of the treatment on a group of patients by testing a hypothesis mathematically to establish the probability of the change being a random event.

If the research project demonstrates that treatment A has a greater effect than treatment B and that this is statistically significant i.e. not a random event but attributable to the treatment given, you would change your practice. To establish this you use inferential statistics to confirm or reject your hypothesis.

6.6 If your service review demonstrates that treatment A is more effective and efficient than treatment B, can you change your practice?

Yes, because the aim of the health care practitioner/medical practitioner and the aim of the organisation is to provide the best patient outcomes with the minimum use of resources. To establish the effectiveness and efficiency of the treatment you would use descriptive statistics. You are providing informal evidence of the most efficient and effective evidence based treatment.

6.7 Can I change practice (e.g. set new standards of care) through service review, clinical audit or as a result of using adequate evidence from elsewhere?

Yes, if the methods used were rigorous and the data collected robust, it is then safe to make such decisions. From a clinical governance perspective, consideration must be given to the clinical impact of the proposed changes and must be set in the context of risk to patients.

The key concerns about making changes to clinical practice focus on whether the proposed change is safe, clinically effective, clinically efficient and all concerned are properly trained, competent and supported, and that the change is properly resourced.

The final decision to change clinical practice rests with the lead clinician and their team i.e. professional accountability.

6.8   Which hierarchy of evidence is applied to the toolkit?

The hierarchy below[16] was adopted for the toolkit.

Type	Strength of evidence
I	Strong evidence from at least one systematic review of multiple well-designed randomised controlled trials
II	Strong evidence from at least one well-designed randomised controlled trial of appropriate size
III	Evidence from well-designed trials without randomisation, single group pre-post, cohort, time series or matched case-controlled studies
IV	Evidence from well-designed non-experimental studies from more than one centre or research group
V	Opinions of respected authorities, based on clinical evidence, descriptive studies or reports of expert committees.

6.9   In the absence of higher levels of evidence, can service review data be used as part of the discussions needed to set local level V standards as per hierarchy of evidence in 6.8 above?

Yes. The ideal scenario would be that:

- The current practice is within a centre of excellence.
- The standards must be set via local consensus.
- Robust service review methodologies are applied to the data collection. Please note the practical reality is that poor methodologies are often applied, leading to the use of unreliable data.

6.10   Can you explain what evidence means in relation to this toolkit?

Evidence can be regarded as *"...data on which to base proof or to establish truth or falsehood"*.[12]

In the health and social care environment this can be translated into the provision of data (i.e. the systematic recording of clinically significant observations of change) on which to base proof of clinical effectiveness. The amount of evidence needs to be quantified in order to be able to judge whether the effect is real or a chance (random) occurrence. In a peer reviewed article of a quantitative research project the criteria used to establish this is based on

probability. This increases the confidence the reader can have about new knowledge of treatment efficiency or disease prognosis. The quality of the study also needs to be established through **critical appraisal**, as a poorly designed project may produce statistically significant results that have limited clinical value. The use of evidence to inform clinical decision-making and clinical practice is based on the synthesis of **informal** and **formal knowledge** (see current practice explanation in glossary of terms on page 16).

There has been considerable debate over the last decade around the small proportion of medical treatments that are based on sound scientific evidence[17–18] and about the wisdom of basing clinical decisions and practice solely on the findings of quantitative research.[19–20]

"…external clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external (formal) evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision."[21]

6.11   When do you use a hypothesis?

Research generates evidence to refute, support or develop a hypothesis. We carry out a test of significance to establish the probability of a "chance" difference between group outcomes. The hypothesis of "no difference" or "no effect" in a population is called the null hypothesis. If there is a significant difference between the groups, the "alternative hypothesis" is supported. This means that the difference detected is not "chance" but attributable to the intervention.

6.12   What is service review?

Service review is defined as an activity undertaken within the organisation that involves service providers, service users or facilities, the purpose of which is to ensure the provision of high quality, effective and efficient care. It incorporates the development and evaluation of practice and services and mostly relies on the use of data contained in current hospital information systems, e.g. patient notes, databases, surveys. It may involve collecting new data.

Service review in the health service can enhance the local knowledge base and improve the quality of local decision-making by critically evaluating service delivery using a number of quality improvement tools.

Service review incorporates both **service/practice development** and **service/practice evaluation.**

6.13   What is the difference between service/practice evaluation and evaluation research?

There is considerable debate as to whether evaluation of initiatives in health care is a separate activity from research or a particular kind of applied research. The toolkit takes the position that some evaluation activities in health care settings constitute research whereas others fall outside the remit of research and are referred to as service/practice evaluation. Evaluation research and service evaluation both require a well thought out design and the collection, analysis and interpretation of data; it can therefore be very difficult to differentiate between these activities. In terms of the toolkit, it is suggested that the two activities may differ in terms of purpose and outcome.

Evaluation research involves the use of systematic rigorous methods with the aim to describe and explain the effects of a new innovation in service delivery and to make generalisations about its worth. As with other forms of research, the intention is to generate new knowledge that has applicability beyond the setting in which the evaluation is undertaken.

Service evaluation also uses systemic rigorous methods to describe and investigate the efficiency of an established service or clinical intervention with the purpose of generating information that is of local significance. The aim of service evaluation is to generate information that can be used to inform local decision-making.

6.14 Why are both words service and practice used in conjunction with development and evaluation?

The reasons both terms are included is as follows:
- Different professional groups are familiar with different terms.
- Both terms are used interchangeably.
- It is important to highlight practice development as a support service within the trust.

6.15 What is the difference between service/practice development and action research?

Action research and service/practice development have in common a concern with developing practice through the implementation of change. Both may use similar systematic processes and methods and it can therefore be difficult to differentiate between these two activities. In terms of the toolkit, it is suggested that the two activities may differ in terms of purpose and outcome. In facilitating change, action research seeks to develop knowledge about the change process and outcomes of the change introduced which may have wider application beyond the particular setting where the research took place.[22] Thus, an important outcome of action research is the contribution to new knowledge. The purpose of practice/service development is to implement change at local level rather than generate knowledge that has wider applicability. Practice development is generally context specific and so it cannot be assumed that practice development initiatives are directly transferable to other settings. Rather, it is important to consider the context into which a successful practice development initiative is being implemented in a new setting.

6.16 Why would I need to use a 'New Techniques and Treatments Policy'?

The purpose of such a policy is to guide you through the clinical and financial governance considerations you will need to take into account prior to a new service development (remember this should involve an element of service evaluation).

6.17   Why is the word transferable used in the toolkit definition of research?

The DH definition of research[7] uses the words "new knowledge that is generalisable". The term generalisable describes the ability to infer findings to the population from which the research subjects were randomised i.e. if another sample were randomly selected from the population the findings would be the same (see Glossary). This term is used when an experimental design has been implemented. In health care research within the NHS there are many other research designs that would provide valuable findings about processes, interventions, attitudes involving patients, carers, staff or technologies. The term used to describe how the findings from these types of research are used is transferable (see Glossary). The DH definition[7] has been further developed in this document to encompass all forms of healthcare research.

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Appendix 1. Registration processes

Clinical audit

It is best practice to register your clinical audit projects and in some trusts this may be mandatory. To do this, you will need to comply with your local policy.

Research

It is mandatory to register your research projects. Please contact your research and development function for advice and guidance.

Service review (development/evaluation)

In some trusts, registration for "service review" projects is not mandatory. However, as best practice, it is recommended that staff should be registering their projects locally with their line manager and/or clinical governance lead. To assist discussions in this registration process, completion of an outline proposal using the following **prompt questions** may help both clinicians and governance leads in thinking through the project and the ethical considerations involved.

Prompt questions:

Project title

What are you trying to achieve?

Rationale for project

Why are you doing it?
Impact on other departments
Assistance from other departments

Planned methodology/design

Assistance required from central departments
Resources required(staffing, non-pay)
Sampling (staff, patients)
Methods (interview, questionnaires, observations, case note analysis)
Consider data collection and entry (with costs associated)
Confidentiality (data protection)
New techniques and treatments
Ethical principles

Implications (i.e. trust–wide or local)

Change
Timescales
Dissemination

Appendix 2. Where to go for help

Within NHS organisations, large and small, there are usually members of staff available to help in taking forward research, clinical audit and service review activities. In the table below are some suggestions as to where you may get that help in advice and support to do the work, gain an ethical opinion where necessary, register their work where applicable and if appropriate be referred to specialist staff. Be aware that the set up of these departments and the assistance they offer may differ across NHS organisations and in some cases may be one department supporting every activity.

	Clinical audit support	Research support	Service review support
Clinical Audit Unit or Clinical Effectiveness Unit or Quality Department	Can offer advice and support in undertaking and registering clinical audit activities		Can offer advice and support in undertaking and registering service review activities
Research and Development Department		Can offer advice and support in undertaking and registering research, ethical approval and registration activities	
Education Department or Training Department			Can offer advice and support in undertaking and registering service review activities or training for improvement or innovative activities
Patient Partnership Department			Can offer advice and support in undertaking service review activities specifically those associated involving patients
Clinical Risk Department or Clinical Governance Department or Healthcare Governance Department			Can offer advice and support in undertaking service review activities specifically those involving risk and governance issues

Appendix 3. Example service review confirmation letter for publication or educational purposes

To whomever this may concern

This letter will help staff provide evidence to prospective publishers or any other relevant parties that the stated project has been classified as service review and that ethical review has been achieved.

Title of project: [insert]

Signature of project lead clinician:

Date: [insert]

Part 1. Evidence this project has been signed off as service review

Please complete the table below.

	Please tick all that apply	**Please print name, sign and date**
1a. Self declared by project lead clinician as service review +/- directorate/division/service clinical governance team		
1b. Signed off by the Research and Development Department		
1c. Signed off by the Clinical Audit/ Effectiveness Department		
1d. Signed off by the Education/Training Department		

If the project materially changes from the original project description represented to the above signatory, it is the responsibility of the project lead clinician to re-present the project for further consideration. This includes self review in the case of 1a above. Any failure to do this is the responsibility of the lead clinician.

Part 2. Evidence that ethical review has been achieved for this project

Please complete the table below.

	Please tick box	Please sign and print name
Level 1 assurance — Lead clinician/project stakeholder group		
Level 2 assurance — Local governance review		Signatory could be chair of relevant directorate peer review group or the clinical governance lead or the clinical director
Level 3 assurance — Local clinical ethics group for difficult to resolve ethical issues		signatory would be chair of local clinical ethics group or their deputy

For any of the above sign-offs, if the project materially changes from the original project description represented to the above signatory, it is the responsibility of the lead clinician to re-present the project for further consideration. Any failure to this is the responsibility of the lead clinician.

Part 3. Evidence that this project has been risk assessed

Please complete the table below.

		Please tick one box	Please print name, sign and date
2a	Very low/low/moderate risk		Signatory could be clinical director/ general manager/nurse director or designate in directorate/division or service
2b	High/major risk		Signatory would be from trust executive

For more information refer to 5–Step Governance Process for Service Review Activity, page 15 and Table 6, point 8, page 12 on Ethical principles applicable to clinical audit and service review.

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