HQIP

Healthcare Quality Improvement Partnership

Criteria and indicators of best practice in clinical audit

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"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."

Burgess R (ed). New Principles of Best Practice in Clinical Audit,Radcliffe,2011

Introduction

The purpose of this guidance is to define the markers or indicators of good quality clinical audit, at both national and local level, conducted by both individuals and more commonly, by teams. The guidance takes into account the views of those active in clinical audit at all levels - clinicians, managers and clinical audit specialists.

In producing this guidance HQIP looked to set an agreed, definitive, widely consulted, consensus standard for clinical audit quality which could then be used in other processes. These may include: revalidation of individual professionals; the allocation of funding for clinical audit; the offer of support, such as from clinical audit departments, for clinical audits proposed by provider teams; the accreditation or kite marking of clinical audits and clinical audit departments; the performance management of clinical audit teams; the commissioning of services; and regulation and performance management of healthcare.

The aims of the process were to be inclusive, by engaging people (including patients) from a range of disciplines, roles, and locations, as well as experience and orientation and use of clinical audit; to draw from the history and experience of clinical audit over the last forty years, starting from accepted and agreed definitions instead of re-inventing terminology; and be thorough and extensive, by consulting widely and in phases at greater levels of detail, which allowed participants to reflect on their original views given the subsequent contributions of others and re-contribute.

Process

This list of criteria has been derived from these stages:

a. An identification of a wide number of pre-existent but recent definitional lists of quality indicators for clinical audit from the international literature.

b. From these, a synthesis document incorporating common elements was compiled and used as the basis for consultation.

c. A series of focus groups conducted after open invite with those who run national clinical audits and work locally on clinical audit including methodologists, clinicians, managers and clinical audit staff, as well as representatives from professional bodies for several disciplines. These were held across England and involved 65 people.

d. Further focus groups of patients with experience of involvement in clinical audit on a range of conditions.

e. Two workshops at the HQIP national conference of local clinical audit practitioners (a further 60 people).

f. Wide email consultation with HQIP's list of contacts, which reflects the groups listed above; a total of 250 participants.

g. Further consultation with the National Clinical Audit Advisory Group.

h. Revalidation workshops that have discussed these criteria as a tool in the revalidation process, including members of the Academy of Medical Royal Colleges.

i. A final email consultation with all the above with the updated version.

Outcomes

These processes have led to the following key headings being identified below, with definitional expansion in each case as to what the heading means, derived from the views expressed in focus group work and the broader consultation.

The consistent consensus view was that good clinical audit has to have four essential stages of activity to be considered high quality.

The stages are:

Quality in clinical audit is then further defined by detailed indicators or markers under each heading, set out below.

These stages, and the definitional markers of quality within them, are common to both national and local clinical audit work, although some of the emphasis will as of necessity be different.

Following the Criteria

Given this diversity, not every criterion or indicator will apply to every clinical audit project undertaken by every speciality, nor will they be relevant for consideration of clinical audit products in all of the processes outlined above. The list given here represents a 'gold standard' that would apply to an ideal clinical audit project. In the circumstance that a criterion or indicator cannot be applied, the reason should be followed and omissions made with exception and explanation.

The criteria have been designed to apply in principle to all types of clinical audit - outcome, process and input, at the local, regional and national level, and against clinical audits carried out by all professional disciplines; although inevitably some criteria are more applicable to one setting or another, or will need adaptation to specific settings.

Additional guidance for those applying these criteria in some specific settings will be developed as part of further HQIP workstreams.

Criteria and indicators of best practice in clinical audit

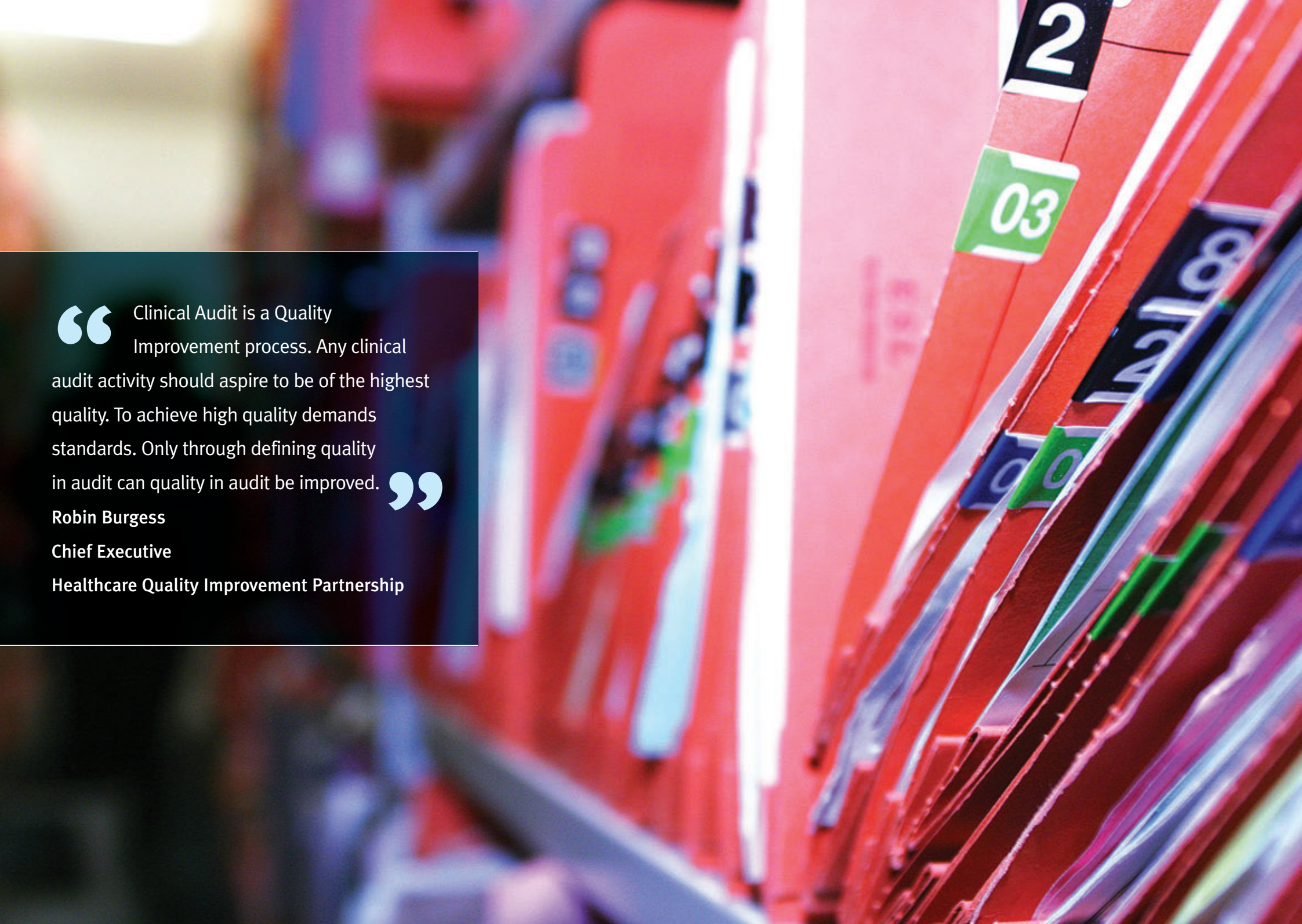
	Criteria		Key indicators	Remarks
STAGE 1: PREPARATION AND PLANNING (INCLUDING FOR RE-AUDIT)				
1	**The topic for the clinical audit is a priority.**	1.1	The clinical audit topic reflects a local service, speciality or national priority which merits evaluation and where care could be improved or refined through clinical audit.	Some topics will be maintenance clinical audits.
		1.2	The key stakeholders, both clinical and non-clinical, agree that the clinical audit topic is a priority.	Stakeholders may include providers, commissioners, non-clinical managers, trust boards (or equivalents), clinicians, staff, patients/service users and national organisations representing both clinicians and patients/users.
2	**The clinical audit measures against standards.**	2.1	The clinical audit standards are based upon the best available evidence.	For example; NICE guidelines (or equivalent), National Service Frameworks, national guidelines etc. A literature source to identify suitable standards may be appropriate. If there is no other evidence, the standards should be developed through an appropriate process; for example a properly designed consensus exercise. Some national clinical audit will have a role in defining or refining standards.
		2.2	The clinical audit standards are referenced back to their source and an explanation of this link is provided.	

	Criteria	Key indicators	Remarks
		2.3 The clinical audit standards are agreed and signed off by the clinical audit team and by those clinicians, clinical governance teams and patients to whose practice they relate.	
		2.4 The clinical audit standards are expressed in a form that enables measurement.	For example, the standards are expressed as criteria that are "SMART-compatible"; that is - Specific, Measurable, Achievable, Relevant and Theoretically sound. ('T' can also refer to Timely, which is also appropriate but needs to be in keeping with a scientific process)
3	The organisation enables the conduct of the clinical audit.	3.1 A written plan describes the structures and processes necessary to support the clinical audit.	This includes a statement about who provides the leadership, the composition of the clinical audit project team, the frequency of meetings, how commitment from the key clinical and non-clinical stakeholders will be secured and a communications plan which includes the production of a comprehensive clinical audit report and to disseminate the findings.
		3.2 Staff have time to participate fully in the clinical audit.	As far as possible, clinical audit work should be embedded into the routine work of clinicians. If clinicians will be required to give time over and above normal practice, this must be identified at the outset of the clinical audit, and all relevant clinicians given protected time to participate.

Criteria		Key indicators		Remarks
		3.3	The organisation provides the administrative and other practical support required to conduct the clinical audit.	When necessary this should be provided by experienced clinical audit support staff.
		3.4	Any necessary training to conduct the clinical audit is identified and provided.	Managers need to accept reasonable training requirements to support effective delivery of clinical audit programmes
		3.5	Any financial costs associated with running the clinical audit are identified and met.	
4	The clinical audit engages with clinical and non-clinical stakeholders.	4.1	Where possible, clinical audit should review the practice of all clinical disciplines in the service unit or team whose work is relevant to the audit topic area.	Most healthcare practice happens in teams with various disciplines and the clinical audit should cover the whole team rather than the practice of individual disciplines within the team.

Criteria	Key indicators	Remarks
	4.2 Those clinicians with senior responsibility for the area of healthcare being audited show commitment to the clinical audit and provide the necessary leadership.	
	4.3 There is ownership of clinical audit findings at the most senior management level. Responsibility to enact change resulting from a clinical audit is accepted by those with power to implement change.	This commitment should be at Board level and, if appropriate, should involve commissioning organisations as well as providers.
	4.4 The roles of stakeholders, and their accountability, are defined clearly from the outset and are in the clinical audit plan.	
	4.5 All relevant stakeholders are involved from the beginning of the clinical audit cycle through to completion.	
	4.6 Active communication with stakeholders is maintained throughout the clinical audit process.	

Criteria		Key indicators		Remarks
5	Patients or their representatives are involved in the clinical audit if appropriate	5.1	The patient group to whom the clinical audit standards apply is clearly defined.	
		5.2	The clinical audit standards take full account of patient priorities and patient-defined outcomes.	For example, the clinical audit incorporates Patient Reported Outcome Measures (PROMS).
		5.3	Patients/carers are recognised as key stakeholders in the clinical audit process.	If appropriate and feasible, patient representatives and relevant patient organisations are involved in clinical audit governance, treated as stakeholders, and where appropriate, in all stages of the clinical audit cycle as equal members of the clinical audit team.
		5.4	Patients who are members of the clinical audit team are fully informed about what is expected from them in terms of participation, commitment and workload.	Not all patients and/or patient organisations will be members of the clinical audit team but, as relevant stakeholders, should still be kept informed and engaged.
		5.5	If required, patients who are members of the clinical audit team are given basic clinical audit training to enable them to contribute effectively to the clinical audit process.	
		5.6	Patients are kept informed throughout the clinical audit process about timescales, progress, results and actions.	All communications should use plain English avoiding the use of jargon and acronyms.



> Clinical Audit is a Quality Improvement process. Any clinical audit activity should aspire to be of the highest quality. To achieve high quality demands standards. Only through defining quality in audit can quality in audit be improved.

Robin Burgess
Chief Executive
Healthcare Quality Improvement Partnership

Criteria		Key indicators		Remarks
STAGE 2: MEASURING PERFORMANCE				
6	**The clinical audit method is described in a written protocol.**	6.1	The timetable for the clinical audit is described; including timescales for completion and re-audit, where necessary.	
		6.2	The protocol describes the methodology and data collection process in detail.	
		6.3	Systematic consideration is given to ethics, data confidentiality and consent issues, and Caldicott principles are applied.	Clinical audits should not require approval from a research ethics committee but still have ethical issues to address, for example maintaining confidentiality and obtaining process consent.
		6.4	The methods used in the audit are recorded so that re-audit can be undertaken later in the clinical audit cycle.	
7	**The target sample should be appropriate to generate meaningful results**	7.1	If a sample of the population is to be audited then the method for sampling is that which is best suited to measuring performance against the standards and, as best as possible, scientifically reliable.	Those planning the clinical audit should consider seeking statistical advice about how to ensure that the sample is adequately significant, representative, clinically relevant, unbiased etc.

Criteria		Key indicators		Remarks
		7.2	The sample size is sufficient to generate meaningful results.	Those planning the clinical audit should consider seeking statistical advice about sample size relevant to a given topic.
		7.3	When necessary, the sample allows for adjustment for case mix.	Those planning the clinical audit should consider seeking statistical advice about casemix adjustment.
8	The data collection process is robust.	8.1	The clinical audit utilises pre-existing data sets where possible.	Those planning the clinical audit should consult with appropriate advisors to identify any relevant data sets, but these should be used with caution dependent on their reliability.
		8.2	The data collection tool(s) and process have been validated.	This might include undertaking simple statistical tests on the data collection tools to examine their reliability and accuracy in practice, or by using data collection tools that have already been proven for this type of clinical audit.
		8.3	The data collection process aims to ensure complete capture of data.	This should demonstrate full case ascertainment and full completion of each case within the clinical audit. Any excluded data should be explained.

Criteria		Key indicators		Remarks
9	The data are analysed and the results reported in a way that maximises the impact of the clinical audit.	9.1	Data are analysed, and feedback of the results is given, so that the momentum of the clinical audit is maintained in line with the agreed timetable.	
		9.2	Results of the clinical audit are presented in the most appropriate manner for each potential audience to ensure the audit results stimulate and support action planning.	For example; the use of accessible graphics.
		9.3	The results are communicated effectively to all key stakeholders, including to patients.	Through presentations at meetings; in written reports; posters etc, in such a form as to be easily understood.
STAGE 3: IMPLEMENTING CHANGE				
10	An action plan is developed and implemented to take forward any recommendations made.	10.1	The clinical audit results are channelled into a plan which both sets out the areas needing attention and where there is good compliance; recommends the actions required to address the identified issues and sets out how these will be carried through.	Recommended actions should be targeted at service, team, managerial or organisational level, where possible. Local teams will need to devise their own action plans in relation to the results of national clinical audits.

Criteria	Key indicators	Remarks
	10.2 The action plan has the agreement of all or the majority of stakeholders involved in the clinical audit process; including managers who may have to commit resources to the changes, and patients whose care they will affect.	Any barriers to implementing change are identified in the plan and action is taken to address them. A suitable risk management strategy will need to be incorporated into the plan.
	10.3 The plan identifies who is responsible for taking which actions and by when, and when achievement of actions will be reviewed.	
	10.4 The plan identifies any financial or other resource implications associated with the recommended actions.	Managers need to be involved from the start to ensure that any resource requirements are anticipated.
	10.5 The results and the following action plan is communicated and distributed widely and effectively, including to managers and patients.	There should be a clear pathway through which the clinical audit results are reviewed by the immediate clinical team and their patients, and by the senior management team responsible.
	10.6 Implementation of the action is closely monitored and progress regularly communicated to stakeholders. Those with responsibility oversee and drive the implementation of the action plan and its subsequent follow up.	Timetables for implementation need to be set.

Criteria		Key indicators	Remarks
STAGE 4: SUSTAINING IMPROVEMENT (INCLUDING RE-AUDIT)			
11	**The clinical audit is a cyclical process that demonstrates that improvement has been achieved and sustained.**	11.1 The topic is re-audited to complete the clinical audit cycle, where necessary.	Re-audit can measure continuing compliance with the clinical audit standards; confirm that recommendations arising from the initial audit have been implemented, or measure that good practice has been maintained. In some cases, re-audit may not be necessary or possible; for example if all standards are met in the first clinical audit; or there has been a significant structural change.
		11.2 Where recommended action has not been achieved in full the topic is re-audited at agreed intervals.	
		11.3 The results of re-audit are recorded and disseminated appropriately, including to patients.	Clinical audits, which demonstrate both compliance and non-compliance, should be widely shared and made widely available.

> The principal purpose of professionally led quality improvement work is to engage front-line clinicians in a robust process to improve the quality of local services....
> The taxpayer has a legitimate expectation that the information is used to maximum effect. In this era of transparent accountability, this includes its use to enable patients to make better informed choices.

Doctor Paul Lelliott

Chairman, HQIP

The role of the clinical professions in the regulation of healthcare in England: walking the tightrope, 2009

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