

## Regional quality assessment in perinatal care

Gunilla Lindmark<sup>a,\*</sup>, Jens Langhoff-Roos<sup>b</sup>

<sup>a</sup>Department of Women's and Children's Health, Section for International Maternal and Child Health, Uppsala University, Uppsala, Sweden

<sup>b</sup>Department of Obstetrics and Gynaecology, Rigshospitalet, University hospital of Copenhagen, Denmark

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**Summary** Quality assessment is essential in every sector of health care and, in modern regionalized perinatal care, continuous data should be collected at all levels to give a stable basis for this activity. The discussion of definitions and choice of indicators is in itself an activity that will increase awareness of quality. Modern computer facilities will simplify data storage and analysis, but do not change the need to use a limited number of well-validated and appropriate variables.

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Evaluating the quality of perinatal care at a regional level means assessing the total sum of the resources used, the activities performed and their results in the area (region) that is served by the regional perinatal centre. Since regional quality assessment thus needs contribution and collaboration from all levels of care, it must be part of, and integrated into, the whole system from a structural as well as a functional perspective.

It is generally acknowledged that quality assessment should be part of a continuous process of improving health care and, thus, the concepts of quality assurance and quality improvement have been preferred. For such a process to be possible in a regional context, good communication and collaboration must be present. It is also essential that health workers at all levels feel themselves to be subjects and part of the process and not as objects of scrutiny or criticism.

### Models of quality assessment

For regional quality assessment in perinatal care the model of Donabedian,<sup>1,2</sup> is relatively easy to

apply, since its components—Structure, Process and Outcome—can be well defined within perinatal care. We will, therefore, mainly use this model, although other models for describing the process of quality assessment are possible. Thus e.g. the theory of 'knowledge for improvement' suggested by Deming<sup>3</sup> has the advantage of emphasizing the system in which individual caregivers are working and the importance of the interaction between people in the system.

### Definition of quality

To define quality as the extent to which the care is meeting the expectations and needs of the patient is attractive and implies that outcomes other than the strictly medical ones must also be considered. However, the expectations placed on the health care do not come only from the patient but also from society and from the agencies that cover the cost of the care. Therefore, not only individual but also public health outcomes must be considered and the effective use of available resources will therefore be a quality aspect of great interest. When comparisons of quality of perinatal care are performed, it is common to relate this to indicators of outcome or process only and not to mention indicators of structural input. It will become increasingly important to also define quality as

\* Corresponding author: Dr G. Lindmark, Uppsala University, Section for International Maternal and Child Health, Department of Women's and Children's Health, Uppsala, Sweden. Tel.: +46-18-611-5-998

E-mail addresses: gunilla.lindmark@kbh.uu.se (G. Lindmark), jlr@rh.dk (J. Langhoff-Roos).

cost-effectiveness, especially if the ambition is to offer universal high-quality care to all mothers and newborns.

## Indicators of quality

Quality assessment needs appropriate indicators and data must be collected both at the regional and local level.

Decisions on the best indicators must consider not only their relevance for the assessment of the objectives of the care, but also their feasibility. For an indicator to be useful it must be constructed from data that are possible to collect with the available resources and both these variables and the indicator itself must be clearly defined. The usefulness of quality indicators for comparisons over time or between regions depends on agreement on these definitions and continuous data collection by all the participating health facilities.

Quality assessment of the *structure* of care includes organization, resources, qualifications of staff and availability of structured and adequate programmes of care. The *process* or utilization of resources in the provision of health care can be assessed so that each activity for screening, prevention, diagnosis or therapy is correctly applied and used for the intended or appropriate purpose. Assessment of process quality should ascertain that the care is carried out according to evidence-based guidelines or recommendations.

In perinatal care the *result* of the healthcare process had traditionally been most often discussed in terms of mortality and morbidity. Nowadays, patient satisfaction and the provision of relevant and reliable information are products of care that are generally considered to be just as important, not only in cases with perinatal complications but also in the majority of cases in which, from a strictly medical perspective, everything is normal.

These quality indicators are useful for constructive discussions about the content and quality of perinatal health care. The variations in outcome are not related to physical resources in a simplified way, but must be discussed in the wider context of attitudes, practices and training of health staff at all levels. Assessment of the results of care should not be limited to intermediate variables such as the results of tests or examinations, but should focus on direct patient-related indicators of quality of life. In perinatal care, it is common that the gold standard of a screening procedure or an intervention during pregnancy is not a parameter that is directly related to the actual health outcome of a mother or infant but is the result of another test or examina-

tion. Variables that are indirectly related to health outcome could be useful, however, if there is a direct relationship with short- and long-term morbidity. An example is low birth weight and, to some extent, a low Apgar score.

## Data collection

Since quality assessment includes both the standard of care in all cases as well as less common adverse events, variables and indicators must include both information about all mothers and newborns and special information in selected cases of specific interest. The data collection system must, therefore, include both routine registration of basic characteristics and more complicated events.

Existing routinely collected data, e.g. from medical birth registers should be used whenever possible in order to limit resources needed.<sup>4</sup> Studies have shown that the quality of routine data in maternity services can be adequate for quality control.<sup>5</sup>

In some countries, routine data may be retrieved from clinical information systems in hospitals or primary care centres or from civil registers of births and deaths. In the Scandinavian countries, national Medical Birth Registers provide important information. In many countries, routine surveys of reproductive health outcomes performed at regular intervals and data from routine follow-ups in child healthcare may be used for quality assessment purposes. However, register data and standard data collected without a specific purpose or unrelated to specific quality improvement activities may be of questionable validity. Registers may also be unreliable regarding causes of death, diagnoses of complications or autopsy data. Terms such as hypoxia, placental dysfunction or pre-eclampsia are frequently used without clear and uniform definitions of these variables.

For comparisons, not only of trends over time in one specific region but also between regions or using the data compiled for international comparisons, it is essential that all variables are defined according to international standards.

Definitions of basic concepts such as perinatal mortality, gestational age and diagnoses describing maternal and infant condition must be uniform. It is particularly important that the lowest birth weight and gestational age classes are included, because of their high risk of mortality and morbidity.

The patient record is an important quality instrument if it is standardized and contains specific and well defined data. It is nowadays often in computer format and can be used directly to produce data for

**Table 1** Analyses of indicators is limited by the mode of data collection

Aggregated data	Frequencies and proportions of single indicators Stratification of single indicators by other indicators in predefined tables
Anonymized case-based data	Frequencies and proportions of single indicators and combinations of indicators Stratification of single or combined indicators by any collected variable Multivariate analyses
Case-based data with identity numbers	Frequencies and proportions of single indicators and combinations of indicators Stratification of single or combined indicators by any variable Multivariate analyses Quantitative and qualitative audit by case notes

special purposes. However, there must be specific definitions for registration to make a variable useful for quality assessment. All data that are the result of a subjective interpretation are also less reliable than absolute values of test results.

For many aspects of quality, specific surveys and interviews, as well as observations of the process of care, are valuable, but cannot be routinely used since they are more resource demanding and also require training of the performer together with some degree of skill. Such projects are also difficult to carry out in different types of facilities within a region.

### Validity of data

The most common problem in the initial discussions about choice of indicators is that the difficulties of performing continuous data collection in routine care over long periods of time are underestimated. The validity of the data registration must therefore be given attention before the data registration begins as well as regularly over time.

In order to secure valid registration of indicators it is important that health personnel are provided with regular and immediate feedback based on registered data, and that regular proper validation based on internal registry analyses and external studies based on case notes are performed.

The validation of reported indicators depends on whether the data are aggregated, anonymized case-based, or case-based linked to a personal identifier (ID) (Table 1). At an aggregated level validation may be achieved by logic checks for outliers, at a case-based level by logic checks for relationships between indicators (such as compatibility—caesarean section versus sphincter rupture), whereas at a case-based level where case notes are traceable a proper external validation may be carried out.

### Regional/international examples of sets of indicators for quality assessment

The first efforts to develop indicators for the comparison of clinical quality in obstetric and perinatal care were usually related to process indicators of procedures in the health care, and the results of the care were often also recorded as proportions of cases subjected to various interventions. Clinical quality indicators for monitoring results have been developed by the American College of Obstetrics and Gynaecology.<sup>6</sup> The OBSQUID project, coordinated by WHO EURO, listed eight maternal and 13 fetal indicators for the quality of perinatal care.<sup>7</sup> This list, however, includes not only severe complications and the need for medical interventions that are directly related to procedures which are known to vary considerably between clinicians and institutions, but also such variables as previous preterm delivery, which are maternal characteristics rather than being related to quality of care in the current pregnancy.

Several national and international agencies and scientific societies (Table 2) have developed other lists of essential quality indicators for maternal and perinatal care.

A recent European collaborative effort, PERI-STAT, which is part of the European Commission's Health Monitoring Programme, has developed indicators of perinatal health for health professionals, policy makers, researchers and health service users who wish to monitor and evaluate perinatal health. The aim of this project, which included 13 countries, was to facilitate monitoring and comparison by harmonizing indicator definitions and encouraging the collection of comparable data based on the following priorities:

- Assessment of maternal and infant mortality and morbidity associated with events in the perinatal period.

**Table 2** Indicators currently reported at International/European level

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WHO (World Health Organisation) Europe—(Health For All)  
 OECD (Organisation for Economic Cooperation and Development)  
 EUROSTAT

Recommendations by international organisations/international collaborations  
 WHO—OBSQUID (Obstetrical Quality Indicators and Data collection), April 1997 (21 essential+10 desirable)  
 WHO—Reproductive Health Working Group (17 indicators)  
 WHO—The Perinatal Care Task Force  
 EUROCAT (European surveillance of congenital anomalies)  
 SCPE (Surveillance of Cerebral Palsy in Europe)  
 OECD—'Health Outcomes in OECD countries: a framework of health indicators for outcome-oriented policymaking'  
 EAPM (European Association of Perinatal Medicine)—Perinatal Audit Working Group (10 maternal and 8 fetal/infant audit topics)  
 FIGO (International Federation of Gynecology and Obstetrics)—Perinatal health indicators (15 data items, about 20 indicators)  
 EUROPET (European project on perinatal transports)—only general health indicators presented  
 The EVALUATION Project (USAID)—'Indicators for Reproductive Health Program Evaluation'

Consultation with other Health Monitoring Programme projects  
 REPROSTAT (Project to develop indicators of reproductive health in the EU)—Indicators to measure reproductive and sexual health  
 ECHI—European Community Health Indicators  
 The CHILD project—Indicators to measure children's health  
 EU Working group on socio-economic inequalities in health

Recommendations from countries/groups of countries on perinatal health  
 Nordic Obstetric and Gynaecology Association (12 indicators)  
 Canada—'Perinatal Health Indicators for Canada' (43 indicators+9, of which 24 are collected regularly)  
 Denmark (10 indicators)  
 France—Evaluation tools for perinatal health networks  
 Germany (10 quality indicators)  
 Italy (perinatal, indicators for audit)  
 Italy (child health indicators—35 indicators in 17 key areas)  
 Spain (indicators for hospital based information systems)  
 UK—National Centre for Health Outcomes Development (NCHOD)—Health indicators for normal pregnancy.  
 UK—RCOG (Royal College of Obstetrics and Gynaecology) Audit Unit working party to suggest a list of 'indicators of quality of care' (11 indicators).  
 UK—National Health Service (NHS) performance indicators  
 USA—Federal Interagency Forum on Child and Family Statistics (24 key indicators of the well-being of children+8 contextual measures)  
 Australia—Department of Human Services Victoria, Centre for the Study of Mothers' and Children's Health, the Health Issues Centre—'Measuring Maternity Care: A set of performance indicators' 2001.

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- Description of the evolution of risk factors for perinatal health outcomes in the population of childbearing women, including demographic, socio-economic and behavioural characteristics.
- Monitoring of the use and consequences of medical technology in the care of women and infants during pregnancy, delivery and the postpartum period.

In 2003, a list of recommended indicators was published on the internet (Table 3) together with the figures for year 2000 from most of the participating countries.<sup>8</sup>

This project tried to overcome some of the difficulties involved in finding variables and indicators that can be collected at regional level in a large number of countries. Many of the indicators of long-term maternal or infant morbidity that

were considered to be very important for quality assessment, turned out to be impossible to define in a consistent way and/or impossible to collect without special surveys. The general conclusion of experiences in regional data collection so far is that it is necessary to limit the number of indicators and that more specific outcomes must be the subjects of research projects.

### Comparisons of quality through analysis of indicators

Differences in quality indicators are usually interpreted as mainly related to the care itself, but it is important to also consider differences in the population. Even when comparing geographically defined (area-based) populations, differences in maternal characteristics such as parity, multiple

**Table 3** PERISTAT working list of indicators

Category	Core	Recommended	Future development
Neonatal health	Foetal mortality rate Neonatal mortality rate Infant mortality rate. Distribution of birth weight Distribution of gestational age	Prevalence of congenital anomalies. Distribution of Apgar score at 5 min	Causes of perinatal death Prevalence of cerebral palsy. Prevalence of hypoxic-ischemic encephalopathy
Maternal health	Maternal mortality ratio	Maternal mortality by cause of death. Severe maternal morbidity. Prevalence of trauma to the perineum	Prevalence of faecal incontinence
Population characteristics or risk factors	Multiple birth rate by number of foetuses. Distribution of maternal age. Distribution of parity	Percent of women who smoke during pregnancy. Distribution of mothers' education	Distribution of mothers' country of origin
Health care services	Distribution of births by mode of delivery	Percent of all pregnancies following fertility treatment. Distribution of timing of 1st prenatal visit. Distribution of births by mode of onset of labour. Distribution of place of birth. Percent of infants breast-feeding at birth. Percent of very preterm births delivered in units without a NICU (Neonatal Intensive Care Unit)	Indicator of support to women. Indicator of maternal satisfaction

pregnancy, preterm birth rate etc will influence the rates of interventions and outcome. Differences in social and economic conditions may be even more important for outcomes, but can be much more difficult to assess in a reliable way.

If comparisons are made between regions, it is important to ensure that all cases from the region are considered, including also those who may be referred to highly specialized centres e.g. for malformations or fetal medicine.

Analyses also depend on the level at which data are reported (Table 1). Aggregated data merely provide a basis for frequencies and predefined tables, whereas case-based data allow ad hoc analyses involving all of the variables or indicators recorded.

When data are reported at a case-based level regional differences may be adjusted by multivariate analyses. This is often used in epidemiological analyses for a scientific purpose. Multivariate analyses have the advantages that adjustments may be made in a model that considers several variables/risk factors, finally producing a single odds ratio with confidence intervals. The disadvantage is that the procedure is not easy to explain to clinicians and the analysis is often perceived as something happening in a black box.

Another way to adjust for differences in maternal characteristics is to apply 'standard populations'. One of the first standard populations used in perinatal quality assessment was the 'standard primipara'.<sup>9</sup> The standard primipara is a 20–35 year old parturient without pregnancy complications, admitted in spontaneous labour at term with vertex presentation. This is only one of several possible standard populations that adjust for clinically relevant preconditions, and—not least—reflect the risk of interventions and complications that may be used for informed choice when mode of delivery is discussed.

Recently, Robson has proposed a structure of mutually exclusive standard populations that constitute the whole population.<sup>10</sup> In this way the variables primi/multiparity, preterm/term, vertex/breech-transverse, singleton/multiple pregnancy and elective delivery (induction of labour/caesarean section) have been used to define standard populations.

These standard populations have been generally accepted for the interpretation of medical birth statistics in Denmark at a regional and national level (see [www.dsog.dk](http://www.dsog.dk)) and have been found to be useful for midwives and obstetricians as a basis for discussions on quality improvement issues.<sup>11</sup>

**Table 4** The Nordic-Baltic Perinatal Death Classification

There are 13 mutually exclusive groups	
I	Fetal malformation
II	Antenatal death. Single growth restricted fetus $\geq 28$ weeks of gestation
III	Antenatal death. Single fetus $\geq 28$ weeks of gestation
IV	Antenatal death. Before 28 weeks of gestation
V	Antenatal death. Multiple pregnancy
VI	Intra-partum death. After admission. $\geq 28$ weeks of gestation
VII	Intra-partum death. After admission. Before 28 weeks of gestation
VIII	Neonatal death. 28-33 weeks of gestation. Apgar score $>6$ after 5 min
IX	Neonatal death. 28-33 weeks of gestation. Apgar score $<7$ after 5 min
X	Neonatal death. $>33$ weeks of gestation. Apgar score $>6$ after 5 min
XI	Neonatal death. $>33$ weeks of gestation. Apgar score $<7$ after 5 min
XII	Neonatal death. Before 28 weeks of gestation
XIII	Unclassified

## Audit of perinatal deaths at a regional level

### Classification of perinatal deaths

The intention of perinatal audit is to judge the quality of care. Most perinatal audit activities have focused on perinatal death, which is the most important adverse fetal outcome to be avoided. However, perinatal deaths are heterogeneous and chains of events and causes of death differ widely. Clearly, some deaths are potentially more avoidable than others. A perinatal death classification that stratifies the perinatal deaths into appropriate groups, with the aim of quality improvement, including qualitative analyses by audit and comparison between regions may be helpful as a basic tool. It should rely on simple, routinely recorded variables for allocation into mutually exclusive groups, which should be associated with specific areas for healthcare interventions.

In a recent investigation that analyzed the differences in perinatal mortality rate between Denmark and Sweden, a new perinatal death classification was proposed in order to categorize the perinatal deaths into relevant groups for further qualitative audit. This classification was discussed and evaluated at a Nordic Baltic collaborative workshop with obstetricians, pediatricians and perinatal epidemiologists. The final classification system was named the Nordic-Baltic Perinatal Death Classification (Table 4).<sup>12</sup> Perinatal deaths with fetal malformations were placed in a separate category and, subsequently, the rest were categorized by time of death (before, during or after delivery), gestational age, Apgar score, plurality and birth weight (considering intrauterine growth restriction (IUGR)) in mutually exclusive groups.

### Qualitative audit

Applying the Nordic-Baltic Perinatal Death Classification, a panel from Denmark and Sweden found that there were significantly more intra-partum deaths of non-malformed infants in Denmark than in Sweden. By subsequent qualitative audit on case notes blinded by nationality, a panel of Nordic obstetricians concluded that there was more insufficient care and a higher rate of potentially avoidable deaths among the Danish cases. It was proposed that a cardiotocographic (CTG) recording should be done on admission and that swifter intervention during delivery should be implemented in Denmark.<sup>13</sup>

### Register-based sub-analysis

When comparing Lithuania with the Nordic countries, the doubled perinatal mortality in Lithuania was mainly explained by a doubled rate of malformed infants, a threefold increase in intra-partum, and a two-to-fivefold increase in neonatal deaths of non-malformed infants.<sup>14</sup> Since qualitative audit by case notes was not feasible, a register-based sub-analysis of the type of malformation was performed. The higher rate of malformed perinatal deaths was explained by a four times higher mortality from neural tube defects.

### Comparison of clinical guidelines

The Ukraine has a twofold increase in the perinatal mortality rate compared to Denmark,<sup>15</sup> and using the Nordic-Baltic classification this was explained by more antenatal deaths of growth-restricted fetuses, more intra-partum deaths and more neonatal deaths due to asphyxia. When the clinical

guidelines, general use of technology and rates of interventions in the two regions were compared, it was found that vacuum extraction or caesarean section for fetal distress was rarely used in the Ukraine, and the application of a vacuum extractor was even considered to be dangerous to the fetus. This might explain the relatively higher rates of intra-partum deaths and asphyxiated infants that die in the neonatal period.

In the regions of Denmark, Sweden, Lithuania and the Ukraine with widely different perinatal mortality rates singleton antenatal deaths of fetuses with normal birth weight contribute to perinatal mortality to the same extent. These intra-uterine deaths seem to be independent of both population characteristics and level of antenatal care. This observation does not support the hypothesis that an infectious cause, related to socio-economic conditions, is common among these otherwise unexplained stillbirths.

### Perinatal deaths in Europe

In the Euronatal Study, a research project contracted by the European Union for the period 1996–2000, factors related to differences in populations and healthcare were studied to explain the differences in perinatal death rates. To determine whether sub optimal factors were present in the cases of perinatal deaths, a case-based audit was performed, based on samples of perinatal deaths in the period 1995–98 in 10 European regions from Belgium, Denmark, England, Finland, Greece, The Netherlands, Norway, Scotland, Spain and Sweden.<sup>16</sup>

Using the Nordic-Baltic perinatal death classification, the groups of singleton fetal death and intra-partum death, 28 weeks of gestation or more and neonatal deaths in children born after 34 weeks of gestation or more, were identified and audited to see in which group was care and treatment most likely to have a significant impact on the outcome.

The international audit panel consisted of obstetricians, midwives, neonatologists and perinatal epidemiologists from the participating countries. Explicit audit criteria were applied to a narrative summary of each case history. These criteria were primarily based on clear evidence from controlled trials (Cochrane Pregnancy and Childbirth database 1995), secondly on evidence that was not firmly established by trials and, thirdly, by criteria agreed upon by consensus among the panel members as elements of appropriate perinatal care. The elements of care were grouped into antenatal screening, pregnancy complications, labour and delivery and after delivery.

In the 1619 cases of perinatal deaths audited, consensus was reached for 95.3% out of which 46.3% were considered to be potentially avoidable through appropriate medical care. The proportion of perinatal deaths that were considered to be potentially avoidable correlated with the crude perinatal mortality rates of the regions. Thus the Finnish and Swedish regions had the lowest percentages of potentially avoidable deaths (31.9% and 35.7%, respectively). Sub-optimal factors were mostly identified in the antenatal care period, often related to insufficient professional care, with failure to detect severe intrauterine growth retardation being the most prominent factor. Maternal smoking was also a significant sub-optimal factor among potentially avoidable deaths.

### Quality assessment in low-income countries

Perinatal mortality is one of the health indicators that is closely related not only to the socio-economic standard in a country but also to the relative standard of healthcare and the distribution of resources within that country.<sup>17</sup> Quality assessment of care is, therefore, even more important to ensure that available resources are used accurately.

In low-income countries, regions are not always clearly defined and referral systems are often not working even if there is a proposed structure. The most common situation is that the regional centre, with its better resources, is overloaded with fairly normal deliveries whereas the complicated cases may not even reach the first level of care. The denominator for any area-based assessment of outcome is therefore very uncertain and also the process-related indicators will reflect only what happens to a minor part of the obstetric population. Still, there is agreement that, especially in settings with limited resources and large health problems, quality assessment of care is even more important than in affluent regions. It is essential that quality assessment activities in low-income countries are focused and that their results are implemented to improve the quality of care.

The baseline registration of data in low-income countries is usually limited to a delivery book in which all mothers who are coming for delivery are noted. This registration is done on admission and the information about complications and interventions that occur later is usually not complete. Generally, the outcome of the baby is not registered beyond a notation of stillbirth. In uncomplicated cases the neonatal observation time is very short

and can be a few hours. If the newborn baby needs special care, it is separated from the mother and the information is not available in her file.

Therefore, routine registration needs to be improved at several levels before it is valid for regional quality assessment activities. Until then local and focused (successful) quality improvement activities are needed to motivate staff for (future) relevant routine registration.

## Perinatal audit in developing countries

In a Sudanese study, the Nordic-Baltic classification was found to be suitable for audit purposes.<sup>18</sup> The simple principle of stratifying by time of death relies on the fact that in cases where we find that death was potentially avoidable, this would be by intervention (elective delivery, treatment with antibiotics etc) before death occurred.

In a three month period at Omdurman Maternity Hospital where the a perinatal mortality rate was 71/1000, perinatal deaths were categorized using the Nordic-Baltic classification. When compared with the Ukraine and Denmark the excess of perinatal deaths was most predominant in groups of intra-partum deaths and neonatal deaths above 34 weeks.<sup>19</sup> A subsequent interdisciplinary qualitative audit for these cases was found to be useful for constructive discussion, with several specific suggestions for quality improvement in data collection, interdisciplinary collaboration and obstetric and neonatal care.

Implementation of these suggestions, however, may not be straightforward and, as in other countries, the activity has not been properly validated, even if there are reports of successful use in routine care.<sup>20</sup>

## Practice points

- Data collection of indicators of quality should be part of routine clinical care.
- Since modern perinatal care is necessarily regionalized and conducted at several levels, comparisons of quality should not be limited to the local health facility but should relate to the whole obstetric population and to all of the activities in the health care.
- Continuous feedback to staff at all levels involved in the care is essential, not only to ensure quality of data, but above all to achieve the objective of the data collection: an improvement in quality from all perspectives.

## Research agenda

- Many aspects of quality assessment and assurance have not been subject to research.
- The most important issue is probably the identification of factors that facilitate the implementation of the results of specific types of quality assessment activities to improve the quality of care.
- Randomized—or at least properly controlled—trials of different approaches would be important.

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