



THE UNIVERSITY *of* EDINBURGH



SCOTTISH COLLABORATION FOR PUBLIC HEALTH RESEARCH AND POLICY (SCPHRP) RESEARCH METHODS SEMINAR SERIES

Seminar No.3: 28 March 2023

A background image showing a close-up of a clock face with a blue semi-transparent overlay. The text 'Clinical Audit: Application of its concepts in public health settings' is written in white on the blue overlay.

Clinical Audit: Application of its concepts in public health settings

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Outline of the presentation

Clinical governance

What is a clinical audit and definition

Audit Vs research

Importance of audit

Audit cycle

Selecting a topic, criteria and standards

Stages of a clinical audit

Example of application of its concepts in public health settings

Exercise

Objective

- To be able to carry out audit projects to improve quality of care offered to patients/community

What is clinical governance?

‘Clinical governance is the system through which organizations are **accountable** for **continuously** improving the quality of their services and **safeguarding** high standards of care by creating an environment in which clinical excellence will flourish’

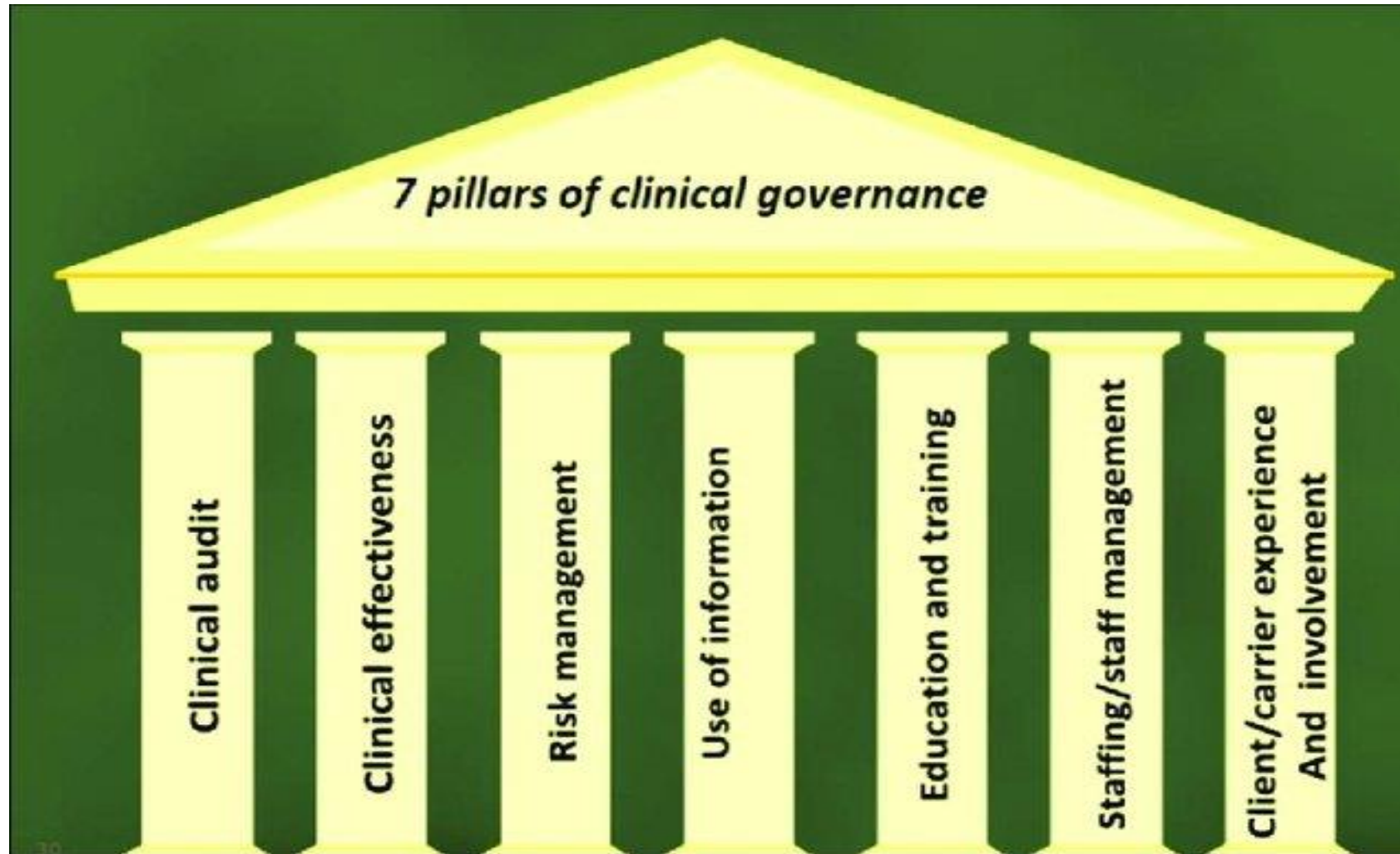
“clinical governance is a way of making sure that everyone who passes through health system is well cared for”

or

System that enable staff to work in the best possible way

+

Staff performing to the highest possible standards



Seven pillars of clinical governance based on the NHS approach

Source: Dehghanian, Danoosh, Peigham Heydarpoor, Nona Attaran, and Mohammad Hossein Khoshnevisan. "Clinical governance in general dental practice." *Journal of International Oral Health* 11, no. 3 (2019): 107

Clinical audit definitions

Clinical audit is a **quality improvement process** that seeks to improve patient care and outcomes through systematically reviewing of care against explicit criteria and the implementation of change.

Aspects of the **structure, processes, and outcomes** of care are selected and systematically evaluated against explicit criteria.

Where indicated, changes are implemented at an individual, team, or service level, and further monitoring is used to confirm improvement in healthcare delivery.

In simple language- Clinical Audit.....

- Clinical audit is a method used to improve quality of patient care in a wide variety of topics.
- It assesses whether **current clinical practice** meets the **expected level of performance** and if it doesn't, take measures to achieve the expected standards

Audit Vs. Research

| | Research | Clinical audit |
|----------------------|---|--|
| Aim | To establish what is the best or most effective practice | To closely evaluate local practice against standard practice |
| Asks | What is right thing to do? | Are we doing right thing? Are we doing what we think we are? |
| Results are compared | With a hypothesis or prediction | With standards that define good practices |
| Knowledge | Aims to add new knowledge to the large body of published research knowledge | Provides knowledge primarily about service being audited |

Audit Vs. Research

| | Research | Clinical audit |
|------------------------|---|---|
| Methods used | Methods of data collection and analysis are often similar. Descriptive studies-prospective or retrospective commonly are used | |
| Implication of results | The results have implication for the whole field of healthcare and often beyond | The results mainly have implications only for the service being audited |
| Reports | Results are reported publicly, and the research is open to scrutiny | Results are often only reported locally, and identity of the clinician is protected |
| Afterwards | Other people will repeat the research to test or add to the strength of the result or to challenge the hypothesis | Practice is changed and then the audit repeated in the same way to see if changes had desired effect. |

Audit Vs. Research

- Audit seeks to determine that we are doing what we should be doing
 - Eg. How many post MI patients receive
 - Coronary revascularization within 30, 90 and 150 minutes
 - secondary prophylaxis with antiplatelets, betablocker, statin, and ACEI
- Research seeks to determine the right thing to do
 - After MI, how soon should revascularization be done?
 - Prophylaxis with antiplatelets, betablocker, statins, and ACEI – Do they improve outcomes ?

Importance of clinical audit

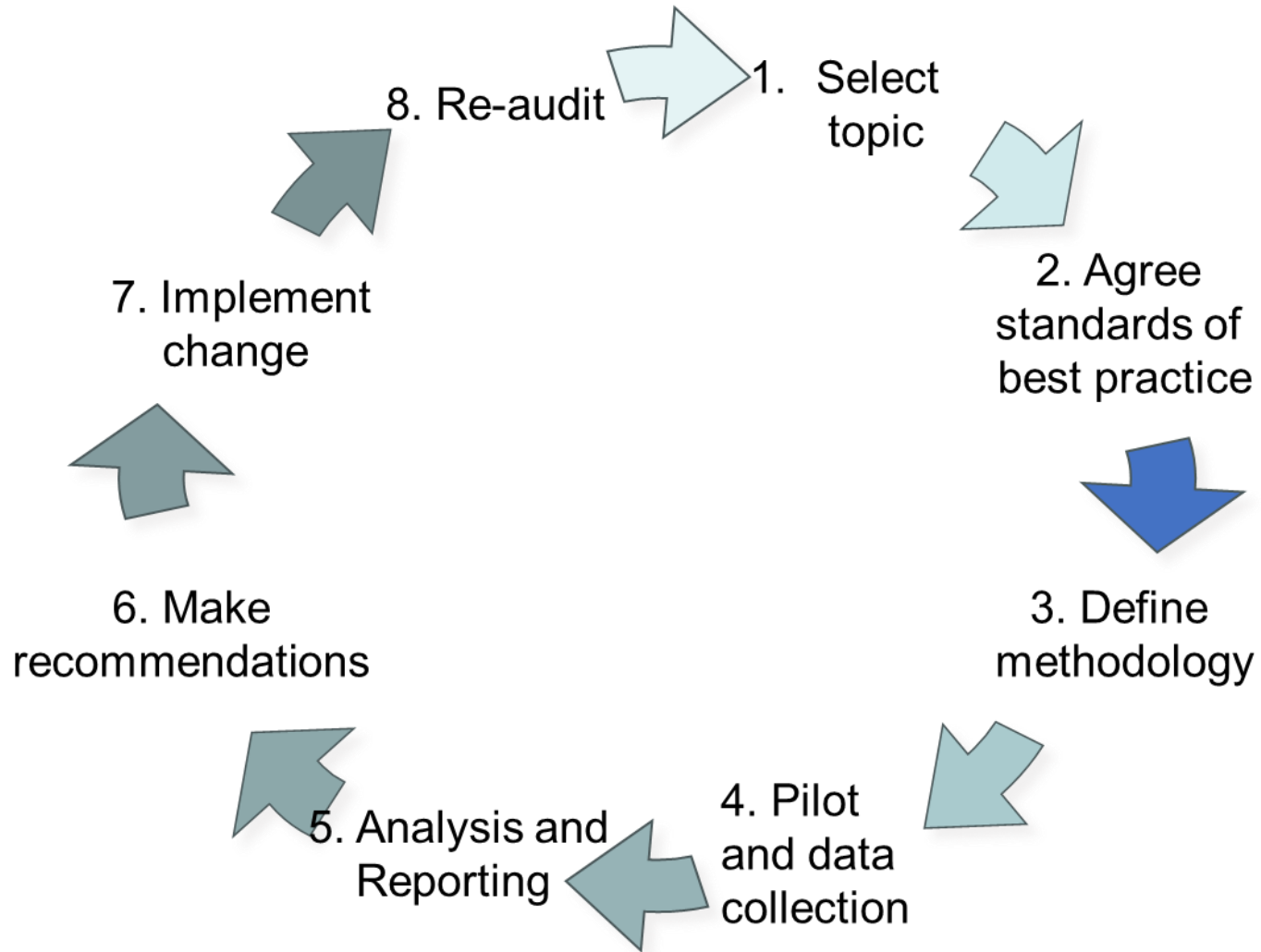
- Society increasingly questions quality of care
- Audit is one way in which the trust and respect can be maintained in an increasingly critical environment.
- Audit can demonstrate the efforts made by dedicated staff to deliver high-quality care to all their patients.
- Clinical audit is increasingly seen as an essential component of professional practice
- Professional bodies, regulators, and governments are giving emphasis and leadership to clinical audit
- Best hospitals are judged on results of clinical audits
- At interviews, participation in audits questioned.

Clinical audit: why bother?

BMJ -
2009

- Clinical audit is usually itemized in the appraisal of consultants.
 - Junior doctors will often have it as a requirement
 - The clinician may be aware of a standard and ask the question whether his department delivers it.
 - A perception that there is a problem with quality.
 - a new benchmark may have been made available
 - Clinical and operational standards are repetitively externally measured
- Robert Ghosh *Chairman* Clinical Audit and Effectiveness Committee

Audit cycle



Stages of audit cycle

- stage 1 - preparing for audit
- stage 2 - define standards and criteria
- stage 3 - measuring level of performance
- stage 4 - making improvements
- Stage 5: sustaining improvement

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Stage by stage approach

Stage 1 - Preparing for audit

- Good preparation is crucial to the success of an audit project.
- Two broad areas of preparation must be addressed
 - ▣ Project management, including topic selection, planning and resources, and communication
 - ▣ Project methodology, including design, data issues, implementability, and the provision of support for local improvement.

Preparing for audit - five elements

1. Involving users (include patients, and carers and those who represent their interests) in the process
2. Topic selection
3. Defining the purpose of the audit
4. Providing the necessary structures
5. Identifying the skills and people needed to carry out the audit, training staff and encouraging them to participate.

Involving users (ie. patients etc)

- The concerns of users can be identified using
 - ▣ Letters containing comments or complaints
 - ▣ Critical incident reports
 - ▣ Individual patients stories or feedback from focus groups
 - ▣ Direct observation of care and conversations.
- The most common method of involving users in clinical audit is the satisfaction survey.

Selecting a topic.....

- Be prioritized to accommodate organizational, local and national agendas whilst avoiding duplication of effort
- Evidence for poor Quality practices/Areas with variations in practice
- Clinical guidelines / Protocols
- Claims / litigation
- Trends from effectiveness data / clinical/quality indicators
- Mortality / morbidity data
- Critical event/ adverse events
- Concernes via complaints, Survey, lettres, focus groups, patient stories
- Findings from inspections, supervisions and investigations
- Re-audit requirements

Selecting a topic

- How to prioritise and select clinical topics ? – ask
 - Is the topic involve high cost, volume, or risk to staff or users?
 - Is there evidence of a serious quality problem, for example patient complaints or high complication rates?
 - Is good evidence available to inform standards, for example systematic reviews or national clinical guidelines?
 - Is the problem concerned amenable to change?
 - Is there potential for involvement in a national audit project?
 - Is the topic pertinent to national policy initiatives?
 - Is the topic a priority for the organisation?
 - Eg. Is it a clinical indicator recently introduced to hospitals in SL through Directorate HQS
 - Eg. door to needle time, medication errors reported

Defining objectives in audit

- Verbs used in defining the objectives (aims of the audit)

-to improve

- to ensure

-To increase

-to enhance

- to change.

- Examples

- to increase the proportion of patients with hypertension whose blood pressure is controlled

- to improve the blood transfusion processes

- to ensure that every infant has access to immunisation against TB, diphtheria, tetanus, pertussis, polio, by 6 months

- to increase medication errors reported and preventive action taken

Stage 2- Defining standards, criteria and targets

Standard = Criterion + Target

- Criterion = (Statement what is being measured) + (Yard stick)
- Target = (% to be achieved)

Developing valid standards

- Once a topic has been chosen, valid standards must be selected. For standards to be valid and lead to improvements in care, they need to be:
 - ▣ based on evidence
 - ▣ related to important aspects of care and measurable.
- Developing such standards can be time-consuming and requires considerable expertise.
- An alternative is to use criteria developed based on evidence, and grading them on strength of evidence.
- Clinical guidelines may give audit criteria and standards

Developing valid standards

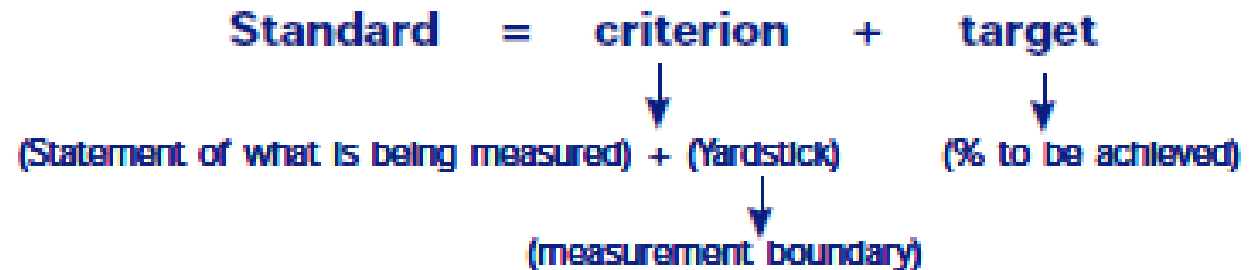
- guidelines can be used to develop criteria and standards
- As the development of good-quality guidelines depends on review of research evidence, the criteria in such guidelines are likely to be valid.
 - NICE and SIGN guidelines on management of MI gives several key points that could be used for developing criteria
 - JNC guidelines from USA on hypertension
- Criteria for the audit of treatment of diseases can be developed from available highest level of evidence e.g., systematic reviews.

SMART standards

- When writing standards they should always be SMART
- Specific – clear, understandable
- Measurable
- Achievable
- Relevant – to the aims of the audit
- Theoretically sound – based on current research

Stage 2- Defining standards, criteria and targets

- All standard statements should contain a criterion and a target
 - After MI patients should receive aspirin, beta blockers, statins ACE inhibitors and Clopidogrel in > 80% patients (NSF UK audit standard)
 - The patients receiving thrombolytics within 30 minutes of arrival at hospital after MI, in England should be 75% or more
- A standard is



Defining criteria and targets

A criterion

- forms the main body of the standard
- is a clear and precise statement of care
- uses words/phrases which mean that it is measurable
- indicates the boundaries of the measurement (e.g. a time frame and who it involves) known as a yardstick

A Target

- A target is expressed as a percentage and defines the level of performance considered acceptable, in relation to the chosen criterion

Setting targets

- The percentage of events that should comply with the criterion
- Targets should be set at realistic and attainable levels, while not being set too low.
 - The patients receiving thrombolytics within 30 minutes of arrival at hospital after MI, in England should be 75% or more
- When setting targets the factors to be considered
 - clinical importance
 - practicability
 - acceptability

Stage 2- Defining criteria -ctd

- Criteria are classified into those concerned with
 - ▣ structure (what you need eg. number of staff, equipment ...)
 - ▣ process (what you do eg. Monitoring therapy, choice of drugs..)
 - ▣ outcome of care(what you expect eg. level of BP ,mortality).
- Categorising the criteria helps to identify problems in structure and process if an outcome is not achieved

Implicit and explicit criteria

Explicit criteria

- these are based on evidence/ published data (e.g. Evidence based BP targets)
- Explicit criteria are preferred as they are more reliable and valid

What are Implicit criteria

- These are criteria recommended/ implied by senior clinicians, based on their experience for judgement of care
- Used in the absence of explicit criteria
- For example, implicit criteria might be used in a case-note review of patients who have experienced adverse outcomes

Selecting an Audit Sample

- The sample is representative of the target population and to collect data which is fit for purpose
 - Inclusion criteria
 - Identify a target population to whom a clinical guideline is intended to apply
 - Exclusion criteria
 - Define areas outside the remit of the clinical guideline
- An audit usually involves a defined group of people who share certain characteristics such as the same medical condition or having received the same type of treatment.
- For most audits a 'snapshot' sample will be sufficient – this should be small enough to allow rapid data collection but large enough to represent the audit population

Types of data collection

- Usually quantitative data (e. g. counting how many times certain things were done and how often) and linking it to standards of best practice.
- Be necessary to collect some qualitative data, for example to establish why standards were not met or to capture patients' subjective experiences.

Stage 3- measuring level of performance

- clinical records are frequently used for data but often incomplete.
- The collection of data from several sources can help
- A carefully developed data collection tool (eg. Questionnaire) is recommended.
- Training data collectors can improve data consistency.
- If routinely collected data are available, they may be appropriate for use in audit.

Data analysis

- The type of analysis should be identified early
- The analysis can range from a simple calculation of percentages, to sophisticated statistical techniques.
- Simple methods are preferable; simple enough for everyone in the care process to understand
- If samples were not used, statistical tests are not necessary.
- If samples have been taken, the most appropriate calculation to perform is confidence intervals

Presentation of data

- just as the analysis should be as simple as possible, the findings should be presented simply and clearly.
- Bar charts have become the most common format, but the numbers should be available in separate tables rather than presenting the charts alone.

Table 4 Use of secondary prevention medication for patients with a final diagnosis of acute coronary syndrome

| | ACEI | β Blocker | Statin | Aspirin |
|--------------------------------|--------------------------|-------------------------|---------------------------|------------------------|
| 2000-1 | 12336/19757 (62.4%) | 13568/17782 (76.3%) | 13678/196432 (69.6%) | 18722/20954 (89.3%) |
| 2001-2 | 34215/49007 (69.8%) | 33745/41744 (80.8%) | 38802/49486 (78.4%) | 46037/50793 (90.6%) |
| 2002-3 | 44507/61472 (72.4%) | 42401/51353 (82.6%) | 52078/62164 (83.8%) | 56695/62876 (90.2%) |
| Difference (percentage points) | 10 | 6.3 | 14.2 | 0.9 |
| 95% CI 2000-1 and 2002-3 | 9.2 to 10.7, p<0.0001 | 5.6 to 7.0, p<0.0001 | 13.4 to 14.8, p<0.0001 | 0.3 to 1.3, p<0.001 |

ACEI, angiotensin converting enzyme inhibitor.

Ethics

- May not be needed to submit to a Research Ethics Committee for ethical approval.
- However, clinical audit must always be conducted within an ethical framework.



Stage 4: making improvements

- It is necessary to understand why problems identified through clinical audit exist and require change.
- Clinical audit data can show what the problems have been, but understanding why they have occurred is not always straightforward.
- Root cause analysis techniques are used in healthcare to investigate adverse incidents but those same techniques can be used in clinical audit to reveal the underlying failures that need to be addressed to bring about improvement

Stage 4: making improvements

- Root cause analysis techniques that can be used at clinical audit are:
 - Brainstorming (structured and unstructured)
 - Brainwriting
 - Cause and effect (e.g. fishbone)
 - Change analysis
 - Five whys
 - Mapping tools: narrative chronology, timelines and time person grids
 - Nominal group technique
 - Pareto analysis
 - Process mapping

Stage 4: making improvements

- A systematic approach to implementation is effective.
- includes identification , and the use of a variety of specific methods.
- Teams undertaking audit that are appropriately supported can identify potential barriers and develop practical implementation plans.
- Avoid relying on feedback of audit results alone as the method of implementing change

Stage 4: making improvements- ctd

- Use of multifaceted interventions is more likely to be effective in changing performance
- The dissemination of guidelines alone has little effect unless accompanied by the use of additional implementation methods
- Interactive educational interventions and/or professional reminders, decision support and system changes can sometimes be effective.

Stage 5: sustaining improvement

- Improvements in care implemented as a part of clinical audit must be monitored, evaluated, sustained, and reinforced in a supportive environment
- Although improving performance is the primary goal of audit, sustaining that improvement is also essential.
- Plans to change professional practice should include
 - ▣ Monitoring and evaluating changes
 - ▣ maintaining and reinforcing the change

Stage 5: sustaining improvement

- Collecting data for a second time, after changes is necessary to both assess and maintain the improvements.
- The same method of sample selection, information collection, and analysis should be used to ensure that data are valid and comparable with each other.
- Rapid-cycle data collection may be appropriate, in which only absolutely essential data are collected from small samples
- If performance targets have not been reached during implementation, modifications to the plan or additional interventions will be needed.

Audit proposal

- Project title
- Background / rationale
- Aims & Objectives
- Method
 - Clinical Audit Standards
 - Study design
 - Study setting
 - Study period
 - Study population with
.....eligibility criteria
- Method contd..
 - Study instrument
 - Data collection
 - Data analysis
 - Ethics
 -

Audit Report

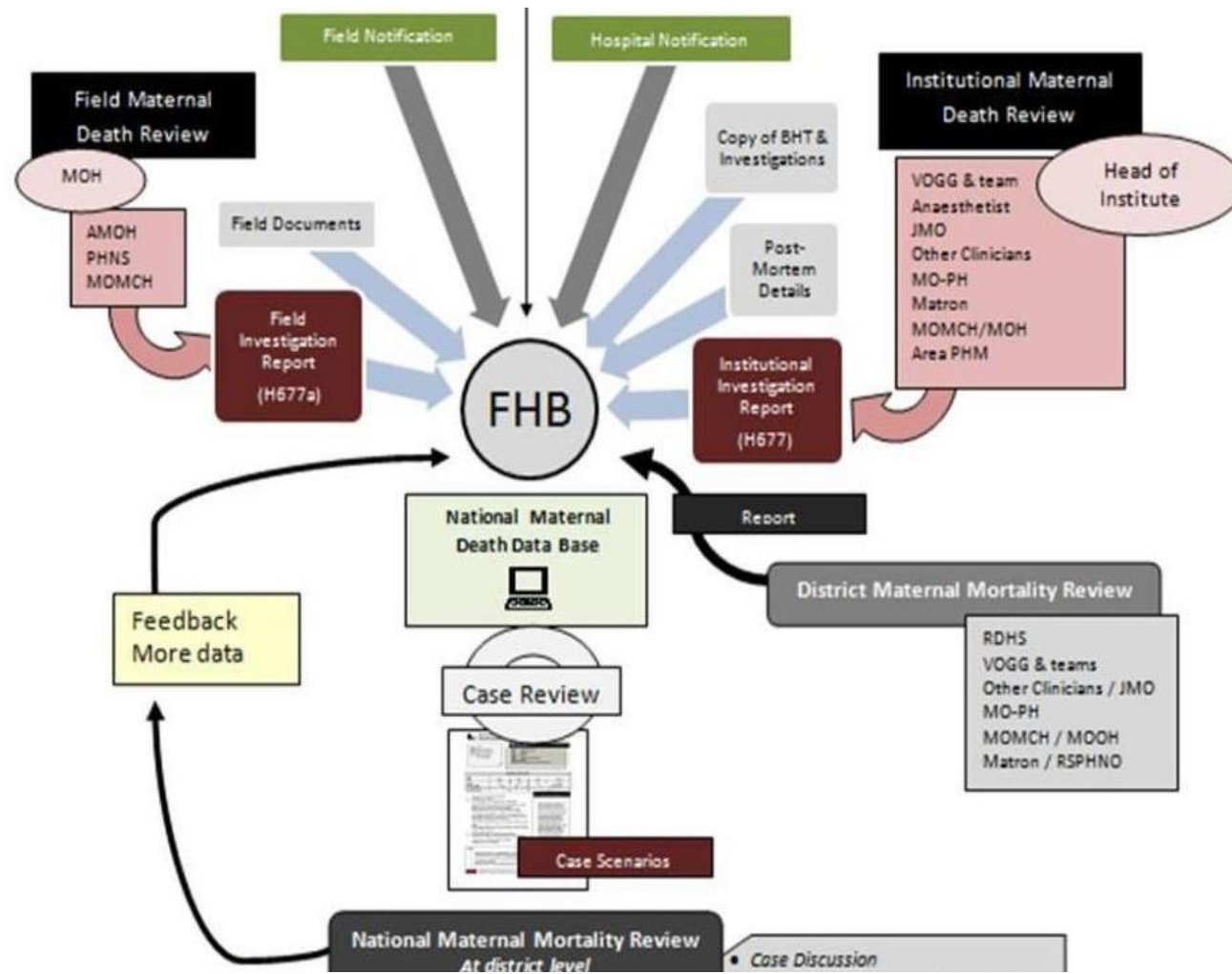
- Title of the report
- Information regarding audit
- Background & Aim
- Standard
- Methodology
- Results
- Conclusion/ Discussion
- Recommendations & quality improvement plan
- References

The Report clearly identify

- Areas for improvement, for example, unrecorded practice, practice not occurring, poor levels of service user satisfaction.
- Causes, for example, poor documentation, inadequate staffing, training and practice issues.
- Needed improvements, for example, the introduction of a structured assessment pro-forma for service users with asthma so that all relevant service user data and examination findings are checked.
- Information explaining why some cases do not meet the required standards.
- Relevant, meaningful and useful information that will help to identify and address issues arising from the audit



Application of its
concepts in Public
Health Settings



Maternal Death Surveillance & Response System – Sri Lanka

Source: Guidelines for Hospital & Filed Healthcare Workers

Verbal autopsy (community level)

– A field investigation is carried out by all the relevant field healthcare workers as a method of finding medical causes of death and ascertaining personal, family and community factors that may have contributed to the death in women who died both in a health institute and outside of a medical facility



Facility-based MDR

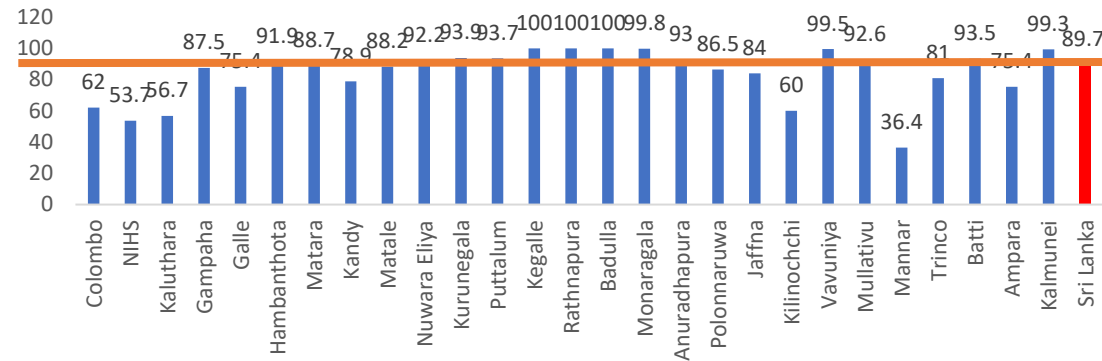
– An institutional maternal death review is conducted as an in-depth investigation of the causes and circumstances surrounding maternal deaths occurring in health facilities with the participation of all the health care workers (Obstetricians, Anesthetists, Physicians, other medical officers, nursing officers and paramedics) involved in the management of the deceased woman. Forensic Pathologist who conducted the post-mortem and public health workers from the mother's residential area also participate at this review meeting.



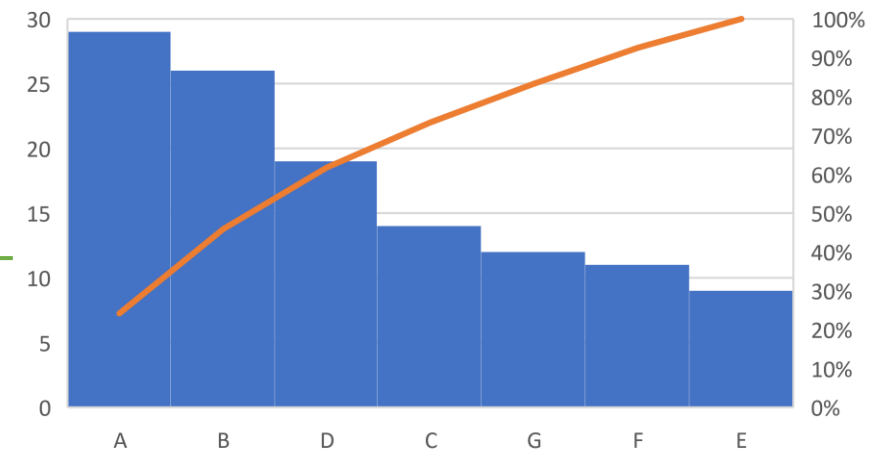
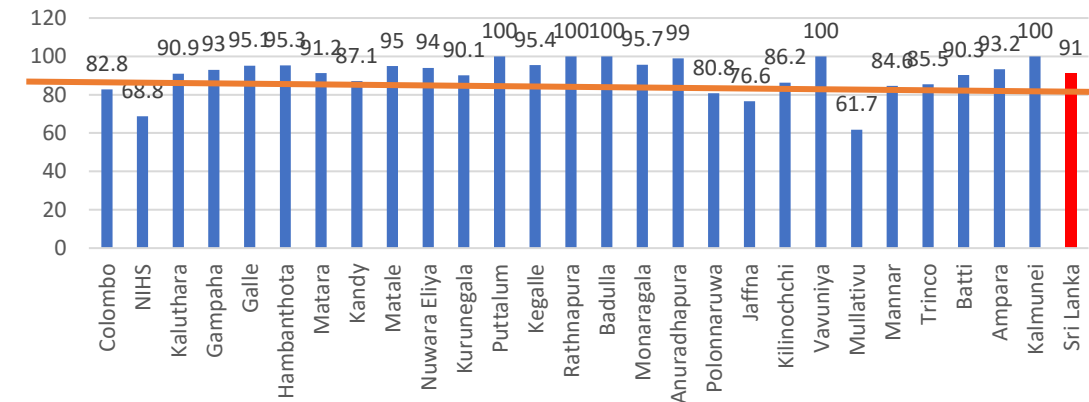
Clinical audit – A modified clinical audit process is adopted at the national maternal mortality review with the participation of multitude of experts (Obstetricians, Anesthetists, Physicians, Forensic Pathologists, Health Administrators, Community Physicians etc.) as a quality improvement process. This is conducted as a systematic evaluation of care against standard protocols already available at local level with due consideration to available facilities.

Audit on assessment of 10 year-CVD risk of Healthy Lifestyle Center attendees aged 35 years or older at District/National level in Sri Lanka

Audit



Re-audit



References

Wilson, Jo. "Clinical governance." *British Journal of Nursing* 7, no. 16 (1998): 987-988.

Healthcare Quality Improvement Partnership, and Nancy Dixon. *Ethics and Clinical Audit and Quality Improvement (QI): a guide for NHS organisations*. HQIP, 2011.

Smith, Richard. "Audit and research." *BMJ: British Medical Journal* 305, no. 6859 (1992): 905

Paton, James Y., Rita Ranmal, Jan Dudley, and RCPCH Clinical Standards Committee. "Clinical audit: still an important tool for improving healthcare." *Archives of Disease in Childhood-Education and Practice* 100, no. 2 (2015): 83-88.

Esposito, Pasquale, and Antonio Dal Canton. "Clinical audit, a valuable tool to improve quality of care: General methodology and applications in nephrology." *World journal of nephrology* 3, no. 4 (2014): 249.

Boughey, Chrissie, and Sioux McKenna. "Analysing an audit cycle: A critical realist account." *Studies in Higher Education* 42, no. 6 (2017): 963-975

Gnanalingham, Janaki, Muhuntha G. Gnanalingham, and Kanna K. Gnanalingham. "An audit of audits: are we completing the cycle?." *Journal of the Royal Society of Medicine* 94, no. 6 (2001): 288-289.

Copeland, Graham. "A practical handbook for clinical audit." London: Clinical Governance Support Team, Department of Health Publications (2005).

Roycroft, Matthew. "Clinical audit of healthcare." *Pathy's Principles and Practice of Geriatric Medicine* 2 (2022): 1543-1551.

Pathmanathan, Indra, and Jerker Liljestrand, eds. *Investing in maternal health: learning from Malaysia and Sri Lanka*. World Bank Publications, 2003.

Maternal Death Surveillance & Response System – Sri Lanka, Guidelines for Hospital & Filed Healthcare Workers

Wijesinghe, P. S., Kapila Jayaratne, and Dimuth Peiris. "National maternal death surveillance and response: Sri Lankan scenario." (2019).

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Thank you



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SCOTTISH COLLABORATION FOR PUBLIC HEALTH AND POLICY (SCPHRP) RESEARCH METHODS SEMINAR SERIES

Seminar No.4: 18 April 2023 @Forrest Hill Room 3.D02 & online



Using the 6SQiD intervention development framework



Jillian Manner
Final year PhD student,
HiSS