

# **Internal Audit Step by Step Guide**

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# Contents

1. Introduction
2. Clinical Audit
3. Audit in Blood Centre
4. AIM
5. STEPS
6. Audit in TM
7. Types of Audit
8. Publications
9. Key elements

# Audit

- System of investigation, evaluation & measurement.
- Means of continuous assessment & improvement.
- Based on set guidelines and predescribed method, consists of determining the difference between the directions given and what has actually been done
- All audits are carried out on the basis of a predescribed method.

# Audit (2)

- Audit is a management tool for monitoring quality assurance system.
- Systematic, independent & documented examination to determine whether activities comply with planned and agreed Quality standards.
- Quality improvement (in health care) is a process to improve patient care services for better clinical outcome.
- Audits are valuable with the intent to review thoroughly all the crucial systems within the centre.

# Clinical Audit

The clinical audit consist of measuring a clinical outcome or a process, against well-defined standards set on the principles of evidence based medicine in order to identify the changes needed to improve the quality of care.

# Audit in Blood Centre

- For surveillance and monitoring the quality of blood centre services
- Regular audit needs to be initiated and the results needs to be discussed among the managements, colleagues, and staffs
- Provide a good opportunity for finding strategies in improving services with appropriate and safe use of blood.



# STEPS

- Planning, execution, review with outliers
- Analyze deficiencies (scope of improvement)
- KAPA including training
- Implement actions
- Again review (at said interval)



# STEPS (2)

- Reviewing Quality Control System
- Monitoring Basic facilities
- Checklists to assess laboratory performance on Blood transfusion
- Donor screening
- Checking records
- Reviewing Activities carried out
- Monitoring of Procedural practices
- Monitoring of Blood Transfusion management Activities

The audit should not be confused with data collection activities (i.e. benchmarking) or clinical research. It compares the current practice against well-defined and established standards. The final aim is always improving the care provided to the patient.

# Audit in Transfusion Medicine

- Being separate specialty directs the transfusion services from vein to vein.
- Co-operating strategy required with treating clinicians to provide quality services for patients.
- With specialized procedures practiced : PBSC, Exchange, ABO incompatible transplants, role of TMP is crucial.

# Audit in Transfusion Medicine(2)

- Occur both in the blood centre itself and on the hospital wards and OT.
- Help to focus novel initiatives to reduce wasteful practice.
- Under HTC to regularly monitor the cross-match : transfusion (C:T) ratio.
- Every hospital/blood transfusion center is expected to develop a system of audit that is appropriate to its needs in addition to audit by statutory bodies

# Types of Audit

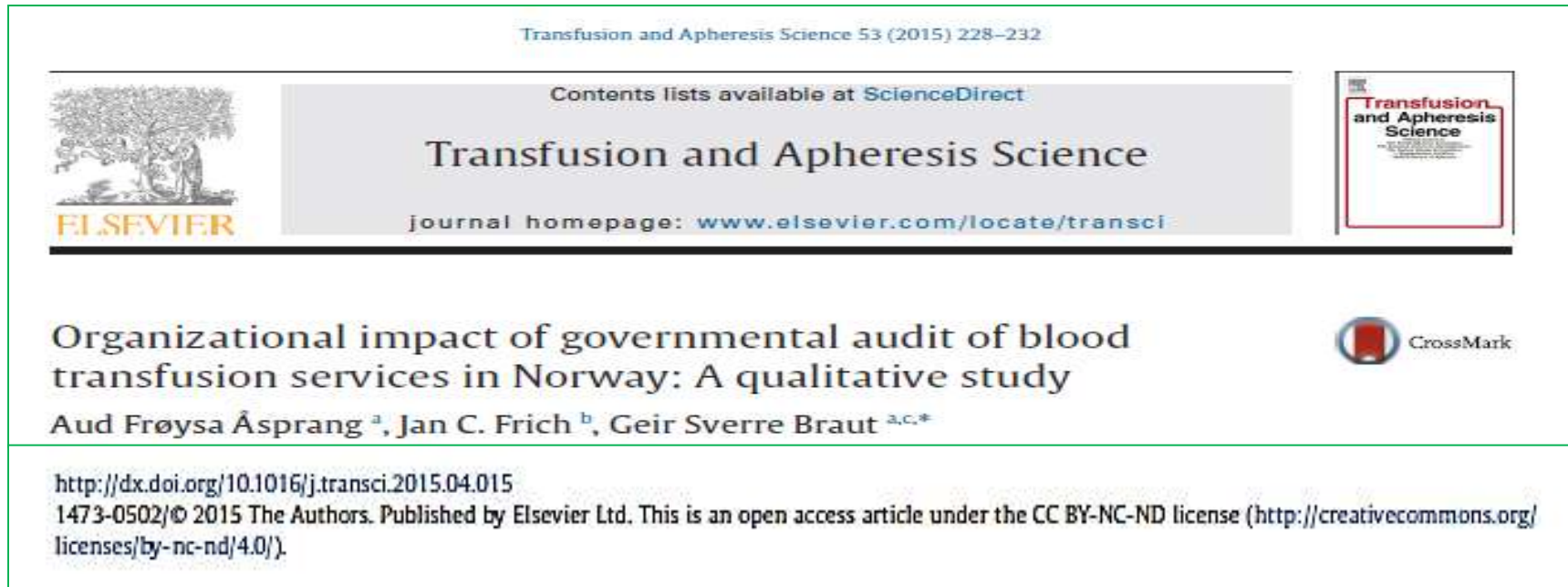
## **Internal audit ( first party)**

- By staff from same organization

## **External audit (third party)**

- Audit by regulatory/ statutory body
- Voluntary AUDIT by organizations : NABH, aaBB, ISO
- Audit by specialized agencies mainly in corporate sectors

# Publication (1)



Audit & continuous publication of results created national awareness about legal standards and common deviations in blood banks.

# Publication (1) contd.

- Quality and safety in health care may be promoted in different ways. Initiatives may be internal and voluntary or forced upon service providers through legal requirements or external audits and inspections
- The audit and the subsequent report and supervisory activities seem to be an important trigger for change.

# Publication (2)

Original Article

## **Audit and education: Role in safe transfusion practice**

Gopal Kumar Patidar, Daljit Kaur<sup>1</sup>

© 2018 Asian Journal of Transfusion Science | Published by Wolters Kluwer - Medknow

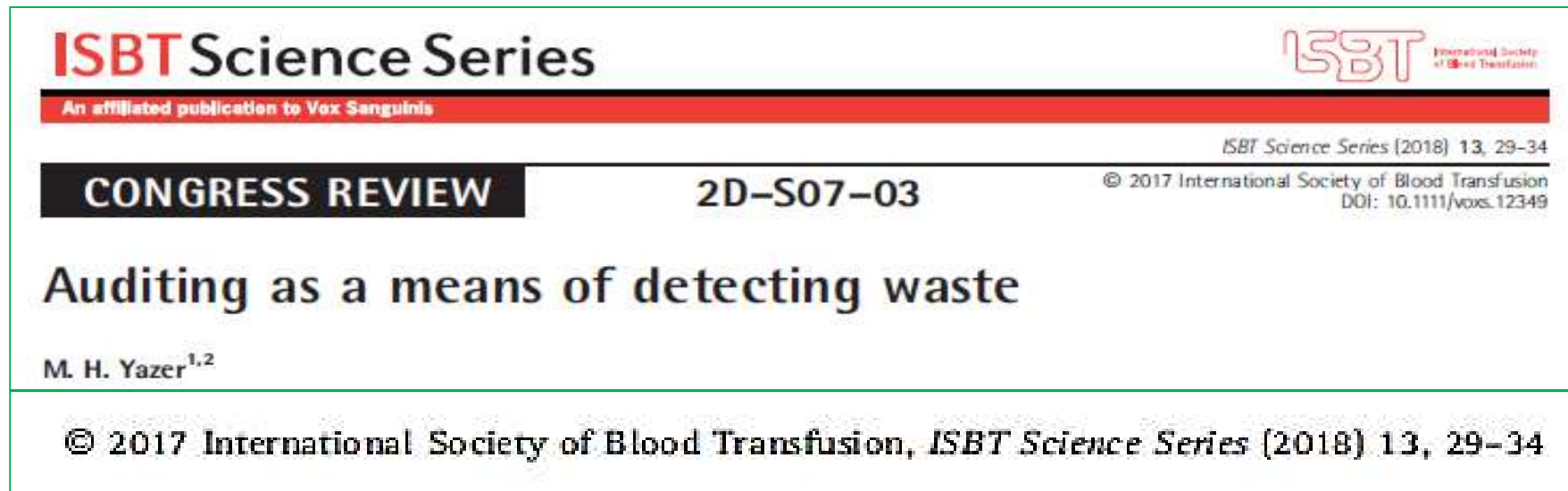
- Evaluated for completeness of the blood request form
- Highly targeted educational program, can improve the clinicians' approach towards transfusion practices.



## Publication (2) contd.

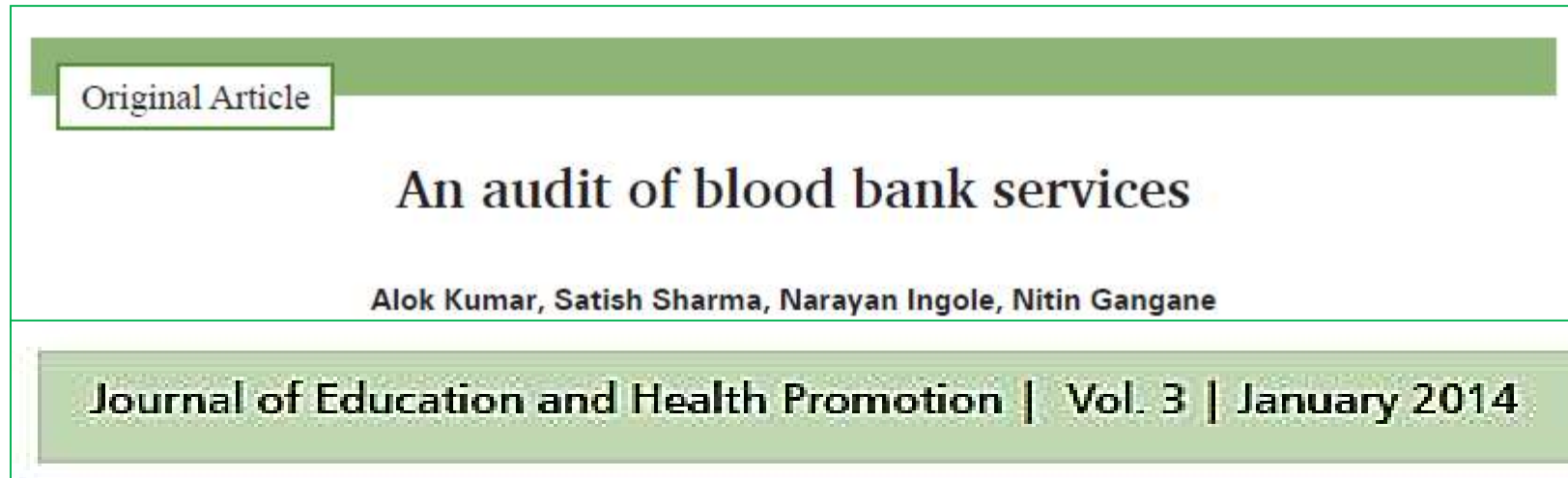
- Physicians underestimate the importance of adequate completion of request forms, which results medical errors or delay in instituting appropriate treatment.
- Prospective auditing of blood request forms and organization of CMEs regarding the transfusion services for the clinicians and staff nurses have major role in improvement for the clinical transfusion practices in the hospitals.
- TMP role should not be limited to role of BCS, while he should participate in the decisions making of transfusion requirements to the patients.

# Publication (3)



Audits are essential to identify wasteful practices  
sources e.g. C/T ratio

# Publication (4)



Audit is a written series of simple, direct questions, which when answered and reviewed, tell whether the laboratory is performing its procedures, activities, and policies correctly and on time.

## Publication (4) contd.

Regular audit of blood bank services needs to be initiated in all blood banks and the results needs to be discussed among the managements, colleagues, and staffs of blood bank. These results will provide a good opportunity for finding strategies in improving the blood bank services with appropriate and safe use of blood.

# Key Elements of Audit Programme

- Written audit protocol
- Audit plan : auditor, auditee
- Audit process : preparation, performance
- Audit report
- Scheduled follow up of audit

# Auditor and Auditee

## **Auditor:**

- Independent from area being audited
- Trained, competent
- Should have knowledge of the section being audited

## **Auditee:**

- HOD / Sr. technician of the section being audited
- Well informed about the working of the area

# Audit Standards

- Audits are performed against standards
- The standards have to be relevant for the organisation and the part of the organisation being audited
- Appropriate BTS standards may include
  - FDA guidelines
  - DGHS guidelines
  - Quality standards such as ISO, NABH, AABB
  - State / Centre guidelines

# Audit Preparation

- Obtain Background Information to review
- Fix date and time
- Prepare a checklist
- Set an agenda
- Team efforts
- Opening / Closing meeting



# Performance (1)

## **Vertical Audit:**

- Follow the flow of work, trace a blood unit from donation to transfusion (Vein to Vein)

## **Horizontal Audit:**

- Review management system
- Review QA system: SOPs , Records
- Review Quality control system:
  - QC results, Equipment maintenance and calibration records (Documents, procedures, equipment)

# Performance (2)

- Teamwork
- Provide feedback during the audit
- Avoid conflicts, no personal opinion
- Non-conformances: if compliance not met with laid down procedures
- Recommendations

# Audit Do's and Don'ts

## DO's

- Make sure that the purpose of the audit is clear
- Be open and polite
- Be constructive
- Thank the staff

## DON'Ts

- Make unnecessary criticism
- Antagonise staff
- Make inappropriate comments
- Use personal beliefs instead of the agreed standards

# Concluding An Audit

**Hold a concluding session with the auditee to**

- Thank the manager and staff
- Reinforce the value of audits and the aim of audit
- Review findings
- Agree findings
- Agree action
- Agree timeframe for action
- Agree re-audit date to check actions
- Guide to close findings (if any)

# Reporting

- Document the audit findings.
- Audit report should include:
  - Findings : Objective, measured agreed standards
  - Summary : of quality status, highlight positive and negative findings
  - Recommendations for corrective action
  - Time frame : for corrective action and follow up
  - Should be shared with the auditee

# Follow up

- Monitor the corrective action that have been planned and the agreed time frame
- Preventive Action Planning : Training etc.
- When the corrective actions have been completed, the audit is complete (All non-conformances closed)
- Re-visit the areas

# Audit Benefits - Outcomes

- Continuous quality improvement.
- Staff motivation.
- More efficient organization operations.
- Better services to patient.
- Confidence and better co-ordination with Clinicians (end blood user) and donors.

# Summary

- Audits are essential to maintain and improve quality.
- Audits must be performed & received as positive events.
- They should be viewed as 'improvement opportunities'.
- Appropriate and relevant standards must be used.
- All staff should become involved and be able to contribute to the audit and its outcome.



Quality is continuous RACE with no  
ends, always AIM high with no  
possibility of look back



**Thank You**