THE HUMAN FACTOR IN MEDICAL ERROR

Ethics, Accountability and the Law Beyond Technology

Validated Guidelines that Contribute to the Prevention of Malpractice Litigation in Nursing Practice in South Africa

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PRESENTATION LAYOUT

- Introduction
- The development of validated guidelines
- Research evidence to practice: Development of validated guidelines
- Guideline development process
- Group Development Group
- Validation process
- Validated guidelines
- Conclusion

INTRODUCTION (Cont.)

- Healthcare is increasingly digital, but care remains fundamentally human.
- Patient safety depends on clinical judgement, ethical decisions, communication and competence.
- Adverse events often emerge when human actions interact with weaknesses in the system.
- The key question: not only who made the error, but what contributed and how can recurrence be prevented?

INTRODUCTION (Cont.)

- Despite the legislative and regulatory measures, medical and nursing errors continue to occur, highlighting the gap between established legal standards and their effective implementation in clinical practice.
- National Health Act 61 of 2003: Provides a framework for equitable access to healthcare, quality service delivery and the protection of patients' rights.

Key legislative and regulatory frameworks

Constitution of the Republic of South Africa: Guarantees fundamental rights, including access to healthcare and human dignity.

Key legislative and regulatory frameworks (Cont.)

- Regulation 767 (Acts or Omissions) as promulgated through the Nursing Act 33 of 2005: Establishes professional accountability for improper or disgraceful conduct.
- Regulation R2127 (Scope of Nursing Practice): Defines the scope of nursing practice and guides nurses and midwives in performing authorised professional duties.

Research Evidence leading to the development of validated guidelines

- The main study “Retrospective Audit Analysis of Malpractice Litigation Cases in Nursing Practice in South Africa” in which malpractice litigation in Nursing practice was investigated in South Africa was conducted to identify factors contributing to malpractice litigation
- An audit of 325 litigation study bundles from both the public and private healthcare sectors was undertaken.
- Four principle types were identified: Clinical management, Human behaviour, Administration and Organization

Research Evidence leading to the Development and Validation of Guidelines (Cont.)

The development and validation of guidelines aimed at preventing malpractice litigation in nursing practice using the Delphi technique were based on the principle types as identified in the research, specifically Clinical management, Human behaviour, Administration and Organization. A systematic validation process was followed (Stellenberg, Gcawu and Whittaker, 2020).

Guideline Development process

- Guided by the WHO guideline development process.
- **Informed by**:
  - Main study findings.
  - Literature review.
  - Theoretical framework.
  - Safety Assessment Code (SAC).
  - Nursing process

Guideline Development Group (GDG)

- **Principal Investigator and PhD supervisor**: Expert witness in malpractice litigation, specialising in quality and safe patient care.
- **PhD Co-supervisor**: Expert in quality assurance.
- **Biostatistician**: Co-investigator in the main study.
- **PhD Student**: Sub-investigator in the main study and Chairperson of the GDG.

Validation Process: Delphi Method

- The guidelines were validated through a two-round Delphi technique to obtain expert consensus, refined to ensure clarity and relevance.
- **Round 1: Initial Validation**
  - Questionnaires were sent to N= 82 experts, with N=60 (73.1%) response rate .
  - Experts rated the proposed guidelines and provided comments.
  - Two draft guidelines were removed for failing to achieve the 80% consensus threshold and receiving substantial negative feedback.

Validation Process: Delphi Method (Cont.)

- **Round 2: Revalidation and Refinement**
  - Questionnaires were sent to the 60 Round 1 participants, with N=36 (60%). responding
  - Experts reviewed the revised guidelines and recommended rephrasing selected statements to improve clarity.

Results of the Validation Process

- A total of 144 guidelines were validated.
- 127 validated guidelines (88.2%) achieved 100% consensus.
- 17 validated guidelines (11.8%) achieved 96–97% consensus.
- All 144 validated guidelines therefore achieved ≥96% consensus, confirming a high level of expert agreement.

Validated Guidelines

- The final 144 validated guidelines were organised according to the principal incident types associated with adverse events
- **The validated guidelines were classified into three main areas:** clinical management, human behavior and organisational factors.
- Administrative and organisational factors were consolidated under the organisational category

Validated Guidelines (Cont.)

A. Clinical Management — 63 Validated guidelines

- These validated guidelines focus on ensuring that nurses consistently follow the nursing process when providing patient care in healthcare establishments.
- Emphasis is placed on interpreting clinical information, recognising and responding to clinical manifestations, and interpreting relevant test results.

B. Human Behaviour — 14 Validated guidelines

- These guidelines address human behavioural factors through staff motivation, support, coaching and mentoring to promote safe nursing practice.

Validated Guidelines (Cont.)

C. Organisational- 67 Guidelines

These guidelines are based on good governance, effective and efficient leadership and management divided into five areas:

- Nursing Leadership, Administration and Management
- Mentoring and Coaching
- Operational Management
- Continuing Professional Development
- Monitoring and evaluation

Clinical Management Validated Guidelines structured around the Nursing Process

The guidelines were structured around the five stages of the nursing process, providing a systematic approach to prevent malpractice litigation in nursing practice:

- **Assessment** – Collect and analyse relevant subjective and objective information, including patient observations, clinical findings and investigation results.
- **Nursing Diagnosis** – Analyse the assessment findings and identify actual or potential patient problems.
- **Planning** — set individualised goals, expected outcomes and appropriate interventions.
- **Implementation** — provide care within competence and scope, using protocols and clinical guidance.
- **Evaluation** — monitor response, reassess and revise the plan when needs or outcomes change.

Across every phase: clear, timely documentation and effective handover support continuity of care

Human Behaviour Validated Guidelines

- Promote ethical conduct, honesty, transparency, professional values and motivation.
- Build a just culture: encourage reporting, learning and corrective action without fear or victimisation.
- Address conditions that affect practice: workload, staffing pressures, overtime and workplace conflict.
- Provide staff support through coaching, counseling, debriefing, recognition and opportunities to raise concerns.

Organisational Factor Validated Guidelines: divided into five areas

- **Nursing Leadership, Administration and Management: N=20 guidelines:** Effective leadership, collaboration, governance, planning and resource management.
- **Mentoring and Coaching: N=4 guidelines**: Staff supervision, support, orientation and induction.
- **Operational Management: N=13 guidelines**: Effective implementation of institutional and ward/unit operational plans.
- **Continuing Professional Development (CPD)**: **N=19 guidelines**: Staff development and implementation of structured professional development programmes.
- **Monitoring and evaluation: N=11 guidelines:** audit practice, review incidents and feedback, and act on findings.

Conclusion

- The ultimate purpose of preventing malpractice litigation is to prevent avoidable harm, protect human dignity and save lives.
- The impact of guidelines depends on consistent implementation, competent healthcare professionals and accountable leadership.
- Healthcare institutions must ensure that appropriately qualified and trained professionals provide care, particularly in high-risk areas, in accordance with their scope of practice.

Conclusion (Con.)

- Our responsibility goes beyond identifying errors.
- It requires us to address the conditions that contribute to them, strengthen accountability and promote a culture of patient safety.
- As we embrace technology, let us remember that no technology can replace sound clinical judgement, professional competence, ethical responsibility and human compassion

Conclusion (Cont.)

- Ultimately, our greatest achievement is not avoiding litigation, but preventing harm, saving lives and ensuring that every patient receives safe, dignified and quality care.

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THANK YOU

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