outh African Medico-Legal Association (SAMLA) CONFERENCE 2026

Accountability in the Health Sector: Governance, Reporting and Patient Safety

Dr Siphiwe Mndaweni
Chief Executive Officer

OHSC
Office of Health Standards Compliance
Ensuring quality and safety in health care

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Outline

Accountability, Governance and Reporting in the Healthcare Sector:

1. Why does this conversation matter?
2. Why patient safety makes accountability matter?
3. The Accountability Continuum
4. Regulatory entities in quality and safety:
5. Office of Health Standards Compliance (OHSC) and Health Ombud
6. Regulatory Architecture
7. Conclusion

Background: Accountability in the Healthcare Sector

- **Accountability, Governance, Reporting and Patient Safety**

- Accountability in healthcare is the responsibility of all healthcare professionals and organisations to maintain ethical standards, follow rules and take ownership of patient safety and the quality of care

<u>Key Elements of Accountability</u>

Ownership: Taking full ownership of your choices, actions and outcomes

Transparency: Being open about your decisions, actions and outcomes

Answerability: Duty to report at various levels and the public

Why Does This Conversation Matter? 1

Healthcare is increasingly dependent on:

- Digital clinical decision –support systems
- Artificial intelligence
- Electronic Health records
- Automated diagnostic and laboratory systems
- Electronic prescribing
- Digital monitoring and surveillance
- Telemedicine
- Automated administrative and clinical workflows

Yet technology does not eliminate human responsibility

- Instead, it creates new questions……..

“Who is accountable when technology (AI) is applied, and there is subsequent harm?”

Is it?

- Healthcare professional?
- Health Establishment?
- Institution's governance structures?
- The regulator?
- Technology developer?
- System administrator?
- Or multiple actors simultaneously?

Key Reasons Why Governance Matters 1

- Governance in patient safety matters -------- it shifts healthcare from a reactive, blame-heavy response to errors------- into a proactive, systems-based culture that prevents harm, ensures accountability, and continuously improves care
- **Shifts Focus from Individual Blame to System Learning:**

✓ Instead of punishing healthcare workers for honest mistakes, governance fosters a **restorative "just culture“**

- **Fosters Openness and Staff Psychological Safety:**

✓ Good governance builds an environment where *clinical and non-clinical staff* feel safe to speak up, report near-misses, and voice concerns without fear of retribution

✓ It investigates *why* a system, design, or process failed, so the same error does not happen again

- **Proactive Risk Management:**

✓ Moves organizations beyond simply reacting to adverse events to structured oversight that uses incident reporting, risk registers, and audits to identify and fix vulnerabilities before they harm a patient

- **Standardization and Equity of Care:**

✓ Establishes clear, evidence-based clinical guidelines and protocols to reduce unjustifiable variations in how care is delivered across different clinical service areas or facilities

Key Reasons Why Governance Matters 2

- **Engages Patients and Families:**

✓ Integrates the patient perspective into care design, policy-making, complaint reviews, and shared decision-making

✓ Treats patients as active partners rather than passive recipients

- **Builds Institutional Trust and Lowers Costs:**

✓ Prevent medical errors and patient harm

✓ Improves clinical outcomes

✓ Reduces costly legal and medical complications

✓ Restores community confidence in the healthcare system

THE ACCOUNTABILITY CONTINUUM [1]

- Accountability in healthcare is a continuum that extends from prevention to response, learning and improvement

- **It begins before harm occurs** — through good governance, clear responsibilities, appropriate standards, risk identification, adequate resources and effective safeguards

- The continuum moves from individual accountability >>> to collective and >>> organisational accountability
- Recognising that patient safety is influenced by the actions of individuals, teams and the systems in which they work

THE ACCOUNTABILITY CONTINUUM 2

1. Individual Accountability In Healthcare

Healthcare professionals and staff are personally answerable for their professional actions, ethical decisions, gross negligence and non-compliance with reasonable safety rules and norms and standards.

Key Elements

Professional competence status

Ethical and legal duty towards patient care

Duty to report mistakes and near misses



"To err is human"

"It was not my fault"



THE ACCOUNTABILITY CONTINUUM 3

2. Organisational Accountability In Healthcare

Organisational accountability in healthcare refers to the obligation of health systems, hospitals and governing bodies to allocate adequate resources, uphold ethical and clinical standards, and to take responsibility for quality healthcare, safety and patient outcomes.

When a patient is harmed, accountability cannot end with identifying the person who made the error

Vicarious liability

Is a legal rule that holds one person or organisation liable for the harmful, reckless, or unlawful actions of another person.

We must ask more difficult questions:

- ✓ *Did the system make it possible or allow that error to reach the patient?*
- ✓ *Were there safeguards that should have prevented harm?*
- ✓ *Were the risks known, reported and acted upon?*

To Err Is Human: Building a Safer Health System
Institute of Medicine (IOM). (2000)

Patient Safety Central to Accountability and Governance [1]

When a patient is harmed, part of accountability……..

IT MUST

- Examine the systems and conditions that contributed to the harm

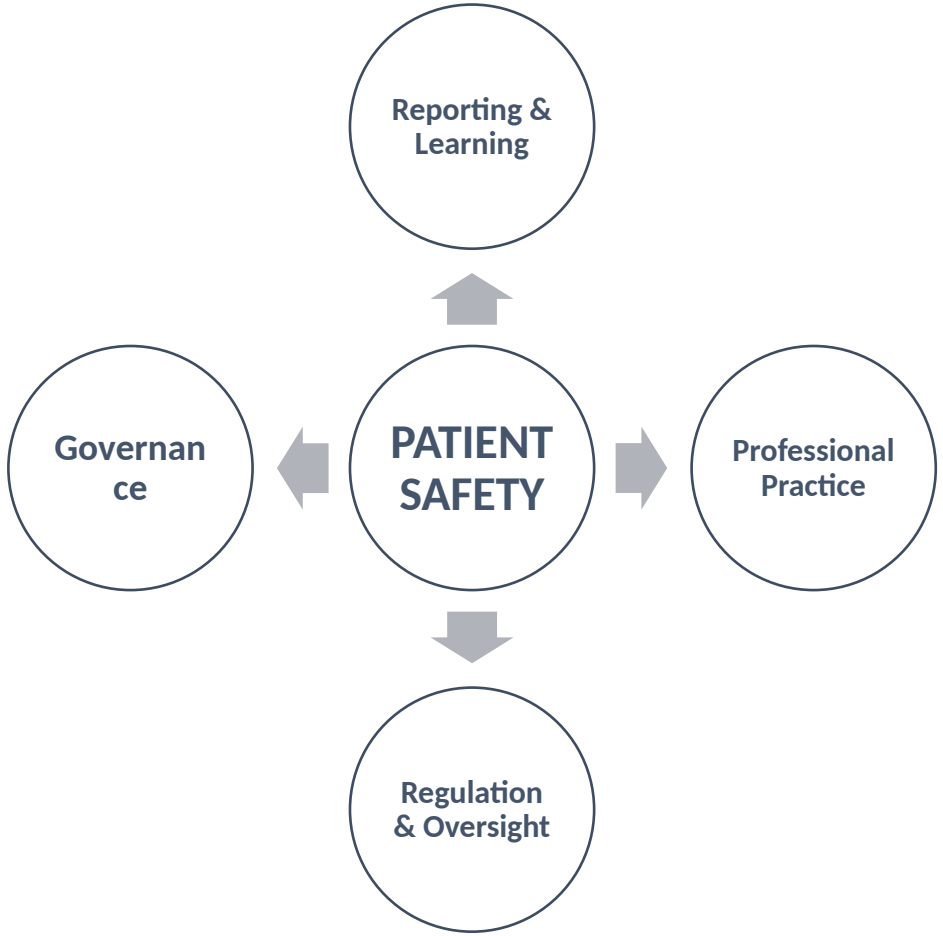
- Accountability must lead to corrective action and learning:—

✓address the root causes,

✓strengthen safeguards and

✓monitor whether interventions are effective in preventing recurrence

Patient Safety Central to Accountability and Governance [2]



Patient safety depends on governance, clear standards, reliable reporting, timely action and learning

- **Governance** establishes the structures, responsibilities and oversight required to promote safe care
- **Professional Practice** Individual/ Collective accountability operates within the governance environment of the health system
- **Reporting** converts events, risks and patient experiences into evidence for governance and action
- **Regulation** should identify risk, require corrective action and support safer systems

Accountability is the thread connecting governance, reporting and patient safety

REPORTING AS A GOVERNANCE AND ACCOUNTABILITY MECHANISM

Reporting is a fundamental accountability mechanism ***because it transforms incidents, risks and patient experiences into evidence that can be acted upon***

Effective reporting ensures that ***what is known does not remain merely documented, but triggers appropriate action, oversight, learning and improvement***

Reporting sources that enable accountability

Incidents and near misses

Early Warning System / Risk indicators

Inspection and audit evidence

Complaints and patient voice

Patient safety, Quality and outcome data

Leadership and governance reporting

Triangulate → verify → prioritise → assign → act → follow up → learn

LEADING WITH ACCOUNTABILITY

Leaders in the Healthcare sector can take a proactive approach and create a culture of accountability in individuals and their teams.

This approach will help team members to assume responsibility for their role in achieving a shared goal.

Steps to leading with greater accountability:

Be intentional: Set clear expectations, and do not assume that everyone knows what is expected of them regarding quality care, patient safety and performance

Monitor Progress: Leaders should monitor the progress of individuals and teams and provide timely feedback, identify and mitigate any challenges

Have accountability conversations: It is critical to identify and address issues that may compromise the quality of patient care

Role of the Regulatory Body: OFFICE OF HEALTH STANDARDS COMPLIANCE (OHSC)

- The OHSC is an independent healthcare regulator -- mandate is to protect and promote the health and safety of users of health services in public and private health establishments. Established under the National Health Act of 2013

- **OHSC Regulatory Role: (Section 79 of the National Health Act, 2013)**
  1) Advise the Minister on health norms and standards
  2) Conduct inspections – assessments against norms and standards for quality and patient safety
  3) Take enforcement actions for non–compliant health establishments
  4) Monitor indicators of risk and breaches in the norms and standards
  5) Investigate complaints through the Office of the Health Ombud
  6) Recommend compliance interventions to relevant health departments.
  7) Publish information on standards; recommend quality systems improvements
  8) Maintain activity records

"OHSC creates an environment that promotes safe and quality healthcare"

REGULATORY ARCHITECTURE

The OHSC creates a direct line from evidence, reporting to consequence

- The OHSC monitors and enforces compliance by health establishments with the norms and standards prescribed by the Minister (NHA s 78).
- The Norms and Standards Regulations applicable to different categories of health establishments (February 2018) set out what is measured.
- **The Compliance Status Framework** classifies each inspected establishment as compliant or non-compliant; compliant establishments are certified, non-compliant establishments receive a **Compliance Notice.**
- **Certificate of Compliance** from OHSC – compliance with minimum quality safety standards and a precondition for accreditation by the NHI Fund. (NHI Act s 39(2)(b):
- Compliance Notices enables, suspension or revocation of a certificate, and referral to the relevant authority where responses are inadequate or absent. Section 82A



WHAT THIS MEANS FOR HEALTH FACILITIES:
Every inspection finding has a defined consequence pathway and a defined route back to compliance.

OHSC REGULATORY PATHWAY: FROM REGULATORY INTELLIGENCE TO SAFER HEALTHCARE

The OHSC operates primarily at the health-system and health-establishment level, rather than determining individual liability



NORMS & STANDARDS

Regulatory Requirements

INSPECTIONS

- Evidence of compliance / non-compliance

REGULATORY INTELLIGENCE

- Complaints
- Early Warning System
- Incident trends

Risk Identification & Risk Assessment

Regulatory Response

CERTIFICATION

ENFORCEMENT

Corrective Action

Monitoring & Follow-up

EWS RISK MONITORING

- Emerging risks & trends identified

COMPLAINTS HANDLING

- Recurring /systematic issues identified

Risk Escalation & Targeted Response

Quality Improvement

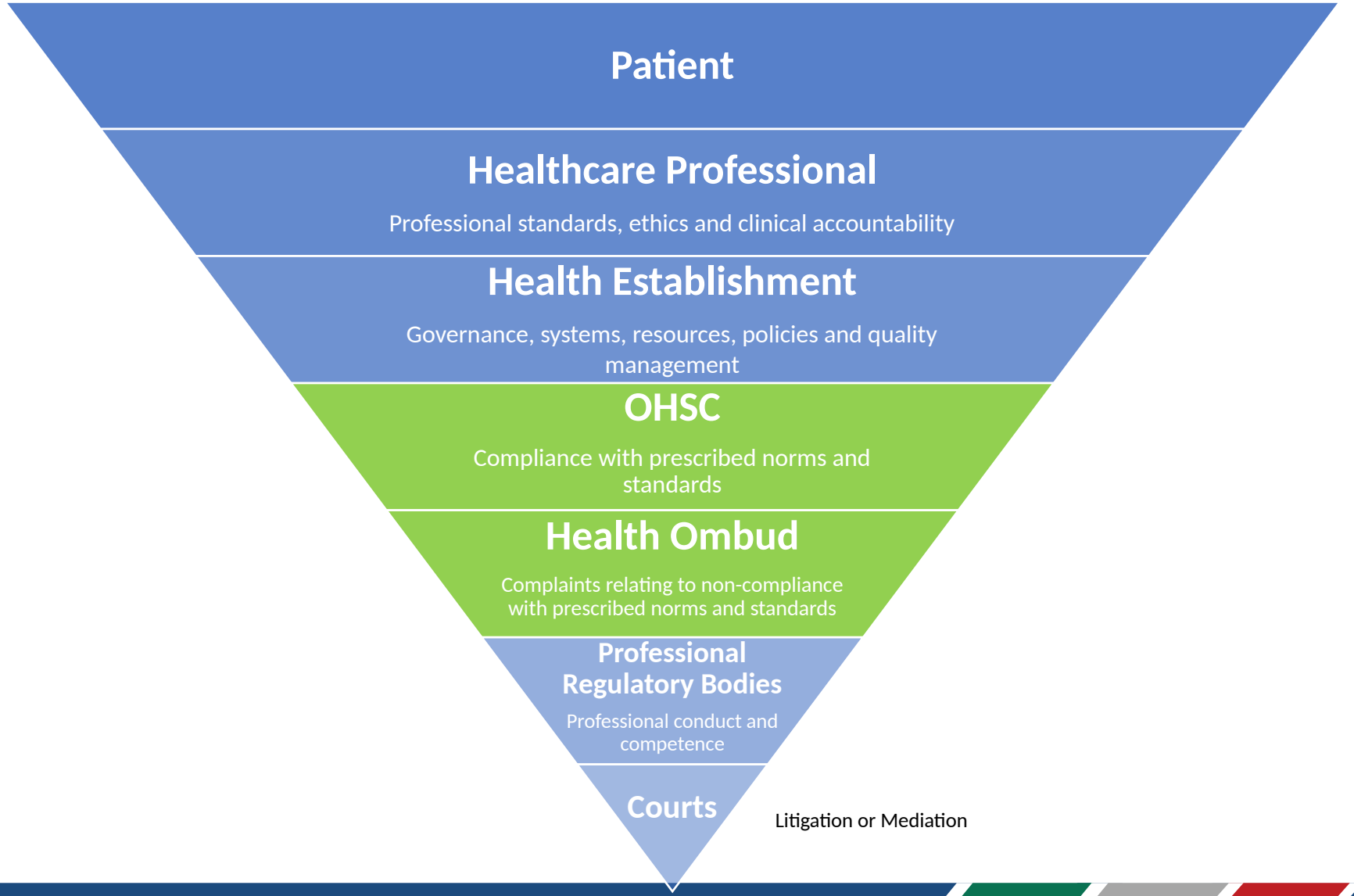
Continuous Regulatory Learning

Safer Healthcare

REGULATORY ARCHITECTURE AROUND PATENT SAFETY

The Regulatory Architecture around Patient Safety

- The patient is situated within several accountability systems



FROM NON-COMPLIANCE TO CONTINUOUS IMPROVEMENT

1

OHSC ENFORCEMENT:

- Enforcement actions --- The OHSC may take against a person in charge of a health establishment which fails to comply with regulated norms and standards
- Non-compliance -- Where prescribed standards are breached, becomes a matter of regulatory accountability, with potential consequences for the health establishment, the persons responsible
- The National Health Act implores the OHSC to adopt a progressive approach in its enforcement of compliance and to consider the nature, extent, gravity and severity of the contravention in relation to patient safety

FROM NON-COMPLIANCE TO CONTINUOUS IMPROVEMENT 2

- In accordance with the National Health Act, the following are listed as possible **enforcement actions:**

  - **Issue a written warning** to achieve compliance within a set period in the manner prescribed.
  - **Require a written response** from the health establishment regarding the continued non-compliance.
  - **Recommend to the relevant authority** any appropriate and suitable action to be undertaken, including the institution of disciplinary proceedings against persons responsible for the non-compliance or continued non-compliance.
  - **Revoke the Certificate of Compliance**
  - **Recommend to the Minister temporary or permanent closure** of the health establishment or part thereof that constitutes a serious risk to public health or health service users.
  - **Impose upon that health establishment a fine** as determined by the Minister in the Gazette from time to time; or
  - **Refer the matter** to the National Prosecuting Authority for prosecution.

INSPECTIONS: NATIONAL PICTURE 2025/26

The OHSC inspected 975 establishments, 791 and complied, 184 non-compliant FY 2025/6

CPUBLIC AND PRIVATE INSPECTION, FY 2025//26

762	**Public establishments** 696 clinics, 7 CHCs, 43 DH 10 RH, 6 TH, 213 GPs
213	**Private establishments** General Practices
33	**Re-inspections** All public
906	**Certified** 1,012 routine, 361 after re-inspection
14	**Written warnings** persistently non-compliant

WHAT THIS MEANS: Most certified health establishments (HEs) were clinics. Some HEs needed a second visit. Compliance does not end with the first inspection --- Continuous Quality Improvement through Self-Assessments

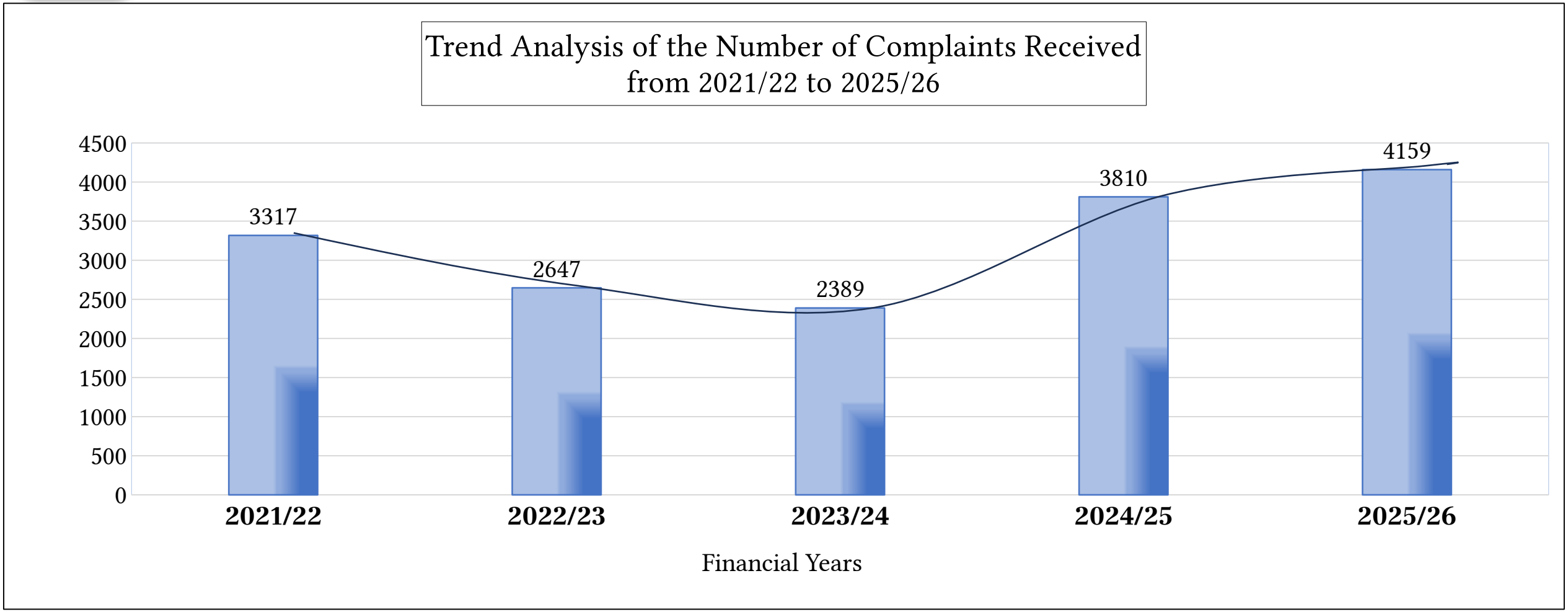
ROLE OF THE HEALTH OMBUD

The Health Ombud – From Complaint to Systemic Accountability

- The Health Ombud is empowered in terms of section 81A(1) of the National Health Amendment Act of 2013 to consider, investigate and dispose of complaints relating to non-compliance with prescribed norms and standards in a procedurally fair, economical, and expeditious manner.

  - Investigates individual and systemic failures
  - Provides an independent investigation mechanism
  - Provides a patient-centred accountability mechanism
  - Refer healthcare professionals to regulatory body, where applicable
  - Identifies recurring governance and quality problems
  - Make recommendations to prevent future medical errors and complaints
  - Monitor implementation of recommendations to strengthen the healthcare system
  - Generates learning for prevention, policy and regulatory action

COMPLAINTS TRENDS (FY 2021/ 22 – FY 2025/26)



Cases received by the Health Ombud increased in the FY 2024/25 and 2025/26.

CONCLUDING REMARKS 1

- Safe healthcare requires more than competent professionals;

It requires:

- Safe and conducive environment
- Effective safeguards against medical errors
- Adequate medical and human resources
- Effective governance and compliance
- Reliable technology and support
- Robust regulation and enforcement
- Valid measurement tools
- Proportionate accountability
- A learning culture

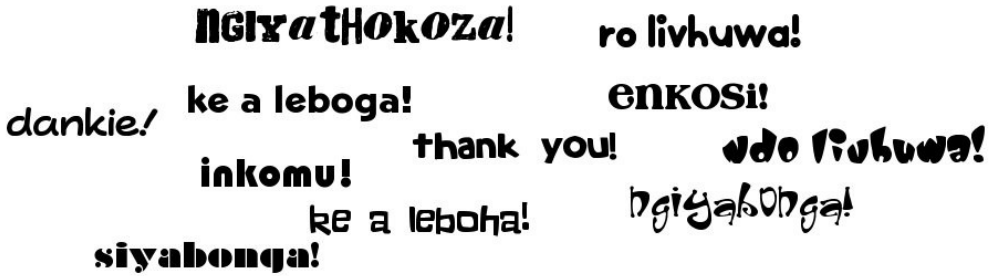
CONCLUDING REMARKS 2

For the OHSC, inspections and enforcement are not the endpoint of regulation

But rather

- ✓ components of a broader accountability cycle in which inspection evidence, complaints, Early Warning System indicators identify patient safety risks and regulatory mechanisms that compel corrective action

The ultimate objective remains the prevention of avoidable harm, the protection of users of health services, and the improvement of quality in services rendered and patient safety.



OHSC

Office of Health Standards Compliance

Ensuring quality and safety in health care

www.ohsc.org.za

+27 (0)12 942 7700