Establishing a National Patient Safety Incident Reporting and Learning System for public health facilities in South Africa

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National and geo-economics

- Located at the southern tip of Africa
- National Health Act, No. 61 of 2003
- Ministry of Health – sets policies, monitor implementation. Approval obtained through National Health Council
- 9 provinces (responsible for providing healthcare services, autonomous), sub divided into 52 Districts
- Population of 56 million – 80% of population use public health services
- Total expenditure on Health as a % of Gross Domestic Product (GDP) = 8.8%
- 3 426 Primary Health Care facilities
- 422 hospitals
- 93% of population has access to a health facility within 5km (45 min walk) radius
**Definition of a Patient Safety Incident (PSI)**:
PSI is an unplanned or unintended event or circumstance that could have resulted or did result in harm to a patient while in the care of a health facility. This event is thus not due to the underlying health condition or natural progression of disease. An incident can be a near miss, no harm incident or harmful incident (adverse event).

**Objectives:**
- To set up a national standardised patient safety incident reporting and learning system to give direction to the public health sector of South Africa regarding the management of PSIs.
- Data on the reporting of PSIs will be used to develop national action plan/framework to improve patient safety to ensure that all South Africans receive safe healthcare.
Why develop a reporting and learning system?

First Guideline developed in 2017:
- **No national uniform system** to report patient safety incidents → number and type of PSIs not known → improvement strategies?
- **World Health Organization’s** (WHO) call that all countries should have a national system for PSI reporting and learning.
- Increasing cost of **litigation cases** in health sector - Medico-Legal Summit hosted by the Minister of Health in March 2015. **Recommended** that a uniform National Reporting System be developed.
- **Audits results** from Office of Health Standards Compliance (Regulatory body): 35% compliance for management of PSIs.

Version two approved in 2021. Revision was prompted by two documents:
- 2020/21 **Annual PSI report** that included an analysis of the data reported on the National PSI RLS over a two-year period (2018/19 and 2019/20).
• Create a framework to **guide the implementation of a PSI reporting system** in the public health sector.

• **Standardise** the definitions, classification system, methodology for reporting, investigating and responses to PSIs.

• Ensure that **statistical data on PSIs are readily available** through the web-based information system for planning, decision making, prevent reoccurrence of PSIs (learning) to ensure that **patient safety, quality of care and health outcomes of patients** are improved.

• Inform the development of national and provincial action plan/framework to improve patient safety.

• Ensure **appropriate communication with patients** who have been harmed due to a PSI, including an apology if indicated.
How was the reporting and learning system developed?

- End of 2015: Situational analysis conducted in 9 provinces
- Jan 2016: First draft developed – request inputs from provinces
- May 2016: Inputs reviewed - Finalised the National Guidelines for PSI Reporting and Learning for public health facilities
- Jun to Sept 2016: Presented at various national committees for approval e.g. Managerial, District Health, Hospital, National Health Information System
- Oct 2016: 1st presentation to Technical advisory Committee of the National Health Council – sent back to revise
- March 2017: Approved by National Health Council
What is reported

• Harmful incidents, no harm incidents and near misses

• Uniform Classification system according to WHO’s Minimum Information Model (MIM) for PSI reporting

Classification according to:
✓ Incident identification (patient (age& sex), time, location)
✓ Contributing factor*
✓ Incident type*
✓ Incident outcomes (patient & organization)*
✓ Resulting actions
✓ Reporter
✓ Free text (Summary of PSI & Findings/ recommendations)

* WHO Conceptual framework for the international classification for patient safety

WHO provided technical assistance with development of the first guideline
Better Health Programme – Mott MacDonald (UK) assisted with the revision
What is reported (cont.)

- Severity Assessment Code (SAC):
  
  - Three indicators:
    - ✓ PSI closure rate
    - ✓ SAC 1 reported within 24-hour rate
    - ✓ PSI closure rate within 60 working days
How is recording done

Patient safety incident form
Implementation of the reporting and learning system

Designate a provincial PSI champion in each province

Nov and Dec 2017: Provincial workshops conducted to train staff

Implementation through national, provincial, district and facility Patient Safety Committees

Implementation commenced on 1 April 2018 (beginning of financial year)
Implementation through Patient Safety Committees
Terms of Reference (TOR) for Provincial PS Committee

- Develop a provincial protocol/guideline.
- Monitor that facility/District office’s standard operating procedure (SOP) are aligned.
- Assist health facilities/district offices to mitigate immediate risks.
- Monitor time frame for reporting of Severity Assessment Code (SAC) 1 incidents.
- Review PSI reports for all SAC 1 incidents, investigate further were indicated.
- Monitor SAC 1 incident finalised within 60 days.
- Monitor that recommendations are implemented, prevent reoccurrence.
- Conduct quarterly meetings (attended by hospital and district representatives).
- Analyse (including data quality e.g., is it a PSI, classification done correctly?) and compile reports.
- Submit quarterly statistical reports to the national department (where a national web-based reporting system is not in place).
- Disseminate lessons learned from PSI management/issue alerts.
- Foster a Just Safety culture.
- Implement provincial system-wide initiatives to prevent reoccurrence.
- Provide continuous training of staff/identify training needs.
Implementation through Patient Safety Committees
TOR for Hospital, Community Health Centres, District/Sub-district

- Develop SOP for PSI Reporting and Learning System (aligned with Provincial protocol/guideline).
- Designate staff members to manage PSIs in every unit/ward.
- Monitor adherence to SOP.
- Conduct monthly meetings (can form part of other existing Quality Assurance/Improvement forums).
- Report all SAC 1 incidents within 24 hours to the next level.
- Investigate SAC 1 incidents further were indicated (District offices.)
- Monitor that SAC 1 incidents reports are finalised within 60 working days.
- Monitor implementation of recommendations prevent reoccurrence.
- Analyse (including data quality e.g. is it a PSI, classification done correctly?) and compile monthly/quarterly/annual reports
- Submit monthly statistical reports to next level (where a national web-based reporting system is not in place)
- Disseminate lessons learned
- Create a Just Safety Culture
- Attend Provincial Patient Safety Committee meetings
- Identify training needs/Coordinate continuous training of staff/
Why and how were the revision done in 2021?

Why

• Annual report indicated that analysis of classification does not provide meaningful full aggregated data. Partly because additional sub-classifications were required, and staff did not correctly classify incidents. Category for ‘Other’ for type of PSI constituted 25%.
• Add additional classification to report on WHO indictors in Global Patient Safety Action Plan

How

• Detailed analyses conducted on data that was collected since implementation of the PSI RLS (2 years) – guided revision of classifications.
• Supported by Better Health Programme South Africa - Mott MacDonald (UK offices).
What was revised?

- Classifications revised for:
  - type of PSI,
  - contributing factors,
  - Outcome (patient and organization) and
  - severity assessment code (SAC) - added SAC 4 (no harm)
- PSI definition. The definition was reviewed to ensure that everyone has the same understanding of what a PSI is. A decision tree to guide staff to correctly identify a PSI was added.
- The PSI reporting form:
  - rearranged to allow for a logic flow for collection of information.
  - classifications were updated according to the revised classification
  - prompts were added into some fields to guide staff on the content to be completed for those fields.
- Added an algorithm to guide a just assessments of individual acts of staff based on the Just Culture.
PSI decision tree

Event occurred

- Event occurred whilst patient was within the care of a health facility
  - Event resulting from the natural progression of medical condition
    - Not reported as PSI
  - Event resulting from the delivery of care, care services or whilst patient was within a health facility
    - Report as PSI
      - Incident reaches patient
        - Incident does not reach patient
          - No harm incident
          - Harmful incident
          - Near miss
      - Incident does not reach patient
Algorithm to guide a just assessments of individual acts of staff based on the Just Culture.

1. Deliberate Harm Test
   Identify at the earliest possible stage those rare cases where harm was intended
   - Were the actions as intended?
     - Yes: Continue
     - No: Proceed to Incapacity Test

2. Incapacity Test
   Identify whether ill health or substance abuse caused or contributed to the PSI
   - Does there appear to be evidence of ill health or substance abuse?
     - Yes: Proceed to Foresight Test
     - No: Proceed to Substitution Test

3. Foresight Test
   Examine whether protocols and safe working practices were adhered to
   - Did the individual depart from agreed protocol or safe procedure?
     - Yes: Proceed to Substitution Test
     - No: Proceed to Incapacity Test

4. Substitution Test
   To assess how a peer would have been likely to deal with the situation
   - Would another individual coming from the same professional group, possessing comparable qualifications and experience, behave in the same way in similar circumstance?
     - Yes: Review system
     - No: Proceed to Incapacity Test

- Consult with relevant Regulatory Body
- Advise individual to consult with Labour Union Rep
- Consider: Suspension
- Referral to SAP
- Occupational Health and Safety (OHS) referral
- Highlight any system Failures identified

- Consult with relevant Regulatory Body
- Advise individual to consult with Labour Union Rep
- Consider: OHS referral
- Reasonable adjustment to duties
- Sick leave
- Highlight any system Failures identified

- Advise individual to consult with Labour Union Rep
- Consider: Corrective training
- Improved supervision
- OHS referral
- Reasonable adjustment to duties
- Highlight any system Failures identified

- Consult with relevant Regulatory Body
- Advise individual to consult with Labour Union Rep
- Consider: Referral to disciplinary/Regulatory body
- Reasonable adjustment to duties
- OHS referral
- Suspension
- Highlight any system Failures identified

Web-based information system for reporting PSIs

Used an existing information system

https://www.idealhealthfacility.org.za

13,000 users. Provinces manage their own user accounts

At all levels of care & facility type

PSI Capture Form

Offline module

PSI Reports

PSI Dashboards
Results at end of 2020/21 financial year: Compliance rate per province

Compliance rate provides data on the percentage of facilities that have reported PSI on the web-based information system and is used as a proxy for progress made with implementation of the National Guidelines for PSIs. A health facility is viewed as compliant if they have captured a PSI or a Null Report for the specific month on the web-based information system.
Number of PSI recorded
Conclusion

• Convincing provinces that a national system is needed as some provinces had a well-established reporting system.

• Culture of reporting patient safety incidents (Just Culture).

• Majority (93%) of PSIs reported were reported by health professionals – other methods for detecting PSIs not used. Literature shows that only 7-15% of PSIs are reported by health professionals.

• Data quality – incorrect classification done, and incidents reported that involved standard care. Incident description is poor as well as findings/recommendations.

• Facilities to report on web-based information system - 51% compliance rate

• Compliance exercise vs using data to improve quality of service? – capacity of facilities/district/provinces to analyse, monitor and learn from PSI information.
Way forward

• Continued low compliance rate
  ✓ Presented to the Technical Committee of the National Health Council in October 2019 – Director General: Health requested that provincial heads of health must strive towards better use of the.
  ✓ Annual report shared with Provincial Heads of Departments
• Developed an automated notification system for SAC 1 PSIs – rolled out to other provinces
• Integration of other existing patient safety reporting systems – Pharmacovigilance and maternal, neonatal, child deaths.
• Strengthen facility/district/provincial capacity to analyse PSI data and use data to improve safety.
• Continued training and guidance
• Develop a national patient safety plan/framework using data collected.
Thank you

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