South Africa

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

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health
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Health
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Contents

- Country background
- Definitions and Objectives
- Why develop a patient safety incident (PSI) reporting and learning system?
- Purpose of the PSI reporting and learning system
- How was the PSI reporting and learning system developed?
- What is reported
- Implementation of the PSI reporting and learning system
- Findings
- Way forward

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

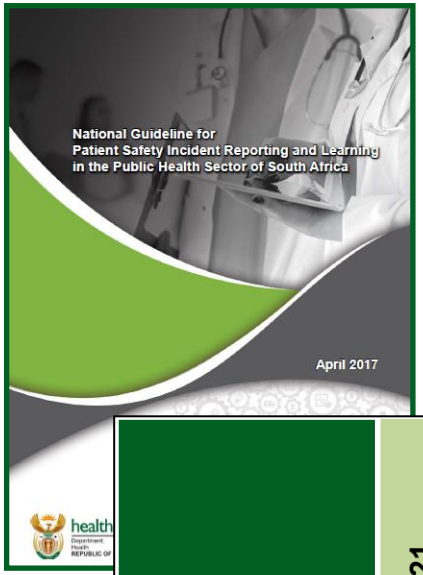
Definition and Objectives

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).
- WHO's ***Global Patient Safety Action Plan 2021-2030*** - contains core and advanced indicators that countries must report on.

Purpose of the PSI reporting and learning

- 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

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Jan 2016: First draft developed – request inputs from provinces

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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

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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 provided technical assistance with development of the first guideline
• Better Health Programme – Mott MacDonald (UK) assisted with the revision

* WHO Conceptual framework for the international classification for patient safety

What is reported (cont.)

- Severity Assessment Code (SAC):

1 Serious	2 Moderate	3 Minor	4 None

- 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

Appendix F: Patient Safety Incident Reporting Form

Section A (notification) - to be completed by the staff who witnessed the incident that occurred. Submit section A and B to next level for notification for SAC 1 incidents

Section B (Account of the event by patient, staff or other witnesses)– to be completed by staff, patients or other that were directly involved while the incident took place

Section C(investigation) - to be comple… incident took place

SECTION A – Notification of …

1. Date of PSI	
3. Event identified by	Reported by health professional

4. Provide a short overview of the…
What happened/went wrong?
What is the initial outcome or harm?

5. Describe immediate actions tak…
What happened to minimise harm?
Who led that action?
What was the outcome of the minimising …

6. Provide a description of commu…
What and how was the incident communic…
What and how was the incident communic…
What and how was the incident escalated to management within the facility? (if appropri…

7. Type of patient safety incident (PSI): Mark with an X (review this once th…

No harm	Near miss

8. SAC rating: Mark with an X	1 Serious	2 Moderate	3 Minor	4 None	9. Date SAC 1 reported to next level		11. No of days to report PSI with SAC = 1	
					10. Time SAC 1 reported to next level			

12. Patient and ward information	
Patient name and surname	
Patient file number	
Patient Id number	
Location (department/ward)	
Age	
Gender	
Final diagnosis	
Number of patients in the ward/head count	
Name of facility patient was referred from (where applicable)	
Name of facility patient was down referred to (where applicable)	

13. Staff witnesses

Compiled by: Designa…

SECTION B- Account of the event by pat…

1. Account by staff, patient or significant other: (…

Account 1:

Account 2:

Compiled by: Designa…

SECTION C – Investigation including classification

1. Classification according to incident type – mark appropriate one with an X

1.Clinical administration	3. Health care-associated infections	5. Blood and blood products	8. Patient Accidents and self-inflicted injury
Medical procedure performed without valid consent	Central line associated Blood Stream Infection	Acute transfusion reactions	Falls – Bedside
Communication/ confidentiality	Non-device related blood line blood infections	Delayed transfusion reactions/ events (including Transfusion Transmitted Infections)	Falls – Toilet/bathroom
Patient incorrectly identified and recorded	Peripheral line blood infection	Errors- wrong blood/ blood products	Falls – Stretcher
Missing patient record	Surgical site infections	**6. Medical device/equipment**	Falls – Therapeutic equipment
Unclear/ ambiguous/ illegible/ incomplete information in patient record	Hospital acquired pneumonia	Not available	Patient injury
	Ventilator associated pneumonia	Failure / malfunction	Self-inflicted injury
2. Clinical process/ procedure	Catheter associated urinary tract infection	Not used correctly	Suicide Attempted suicide
Not performed when indicated	Communicable diseases	Incor…	
Performed on wrong patient	**4. Medication / IV fluids**	**7. E…**	
Clinical procedure errors	Incorrect dispensing	Sexu…	
Surgical procedure errors	Omitted medicine or dose	Sexu…	
Incorrect treatment provided/ clinical decision made	Medicine not available	Physi…	
Clinical assessment error	Adverse drug reaction	Physi…	
Failure to act on test results or report	Incorrect medicine	Explo…	
	Incorrect dose/ strength administered	degra…	
Missed or delayed diagnosis	Incorrect patient	Explo…	
	Incorrect frequency	degra…	
Performed on wrong body part/ site/ side	Incorrect route	Patie…	
Retention of foreign object during surgery	Prescription error	Abso…	
	Incorrect dispensing label		
	Medicine expired		
	Wrong technique		

2. Framework for root cause analysis and implementation of …

a. Contributing factors – Mark with an X

1. Staff	Lack of knowledge of clinical processes/ guidelines/ protocols	Human error- clinical	Human error - Admin / Risky beha…
2. Patient	Behaviour	Communication factor	Condition/ …
3. Work/ environment	Physical environmental / infrastructure	Remote/ long distance from servic…	
4. Organisational/ service	Clinical Protocols/ policies/ procedures not available/ up to date/ approved	Non - Clinical Protocols/ polic… procedures not available/ up date/ approved	

5. External	Natural event or disaster	Equipment, products malfunctioning due to manufacturer's fault	Services, systems and policies of external providers	Delays in emergency medical services transport
6. Other	Not specified in classification 1 to 5			

b. Root cause analysis - These are the most fundamental underlying factors contributing to the incident that can be addressed

Contributing factor	Describe the factor that contributed to the event	Describe the action plan to rectify the identified problem	Person responsible for implementing the action plan	Date for implementation

3. Findings and recommendations of the investigation

What were the key findings (why did the incident occur)?

What are the key recommendations? (Note: Recommendations should address all the root causes and lessons learned, be designed to significantly reduce the likelihood of recurrence and/or severity of outcome; be clear and concise and kept to a minimum wherever possible; be Specific, Measurable, Achievable, Realistic and Timed (SMART) so that changes and improvements can be evaluated; be prioritised wherever possible; be categorised as: those **specific** to the area where the incident happened; those that are **common** only to; the organisation involved; those that are **universal** to all and, as such, have provincial/district significance.)

4. Type of behaviour according to Just Culture: mark with a X | No error | Human error | At–risk behaviour | Reckless behaviour

5. Provide a description of final communication to patient/family (final disclosure)

What and how was the incident communicated with patient? (if appropriate)

What and how was the incident communicated with patient's family? (if appropriate)

6. Date of closure of PSI case	7. No days to close PSI case	8. Type of closure: mark with an X	PSI case concluded	Litigation	Referred to labour relations

9. Patient outcome according to degree of harm: Mark with an X	No harm	Mild	Moderate	Severe	Neonatal trauma	Obstetric trauma	No longer classified as a PSI after investigation
	Child death	Adult death	Neonatal death	Maternal death	Still birth	Deaths due to hospital associated venous thromboembolism	Deaths due to health care associated sepsis	Perioperative death (30 days after surgery)

10. Organisational outcome: Mark with an X	Property damage	Increased length of stay	Admission to special care area (e.g., high care or ICU)	Additional treatment/tests	Additional staff required	Additional equipment required	Media attention
	Formal complaint	Damaged reputation	Legal ramifications	None	Other	No longer classified as a PSI after investigation	

Compiled by: Designation: Signature: Date:

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 meaning 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

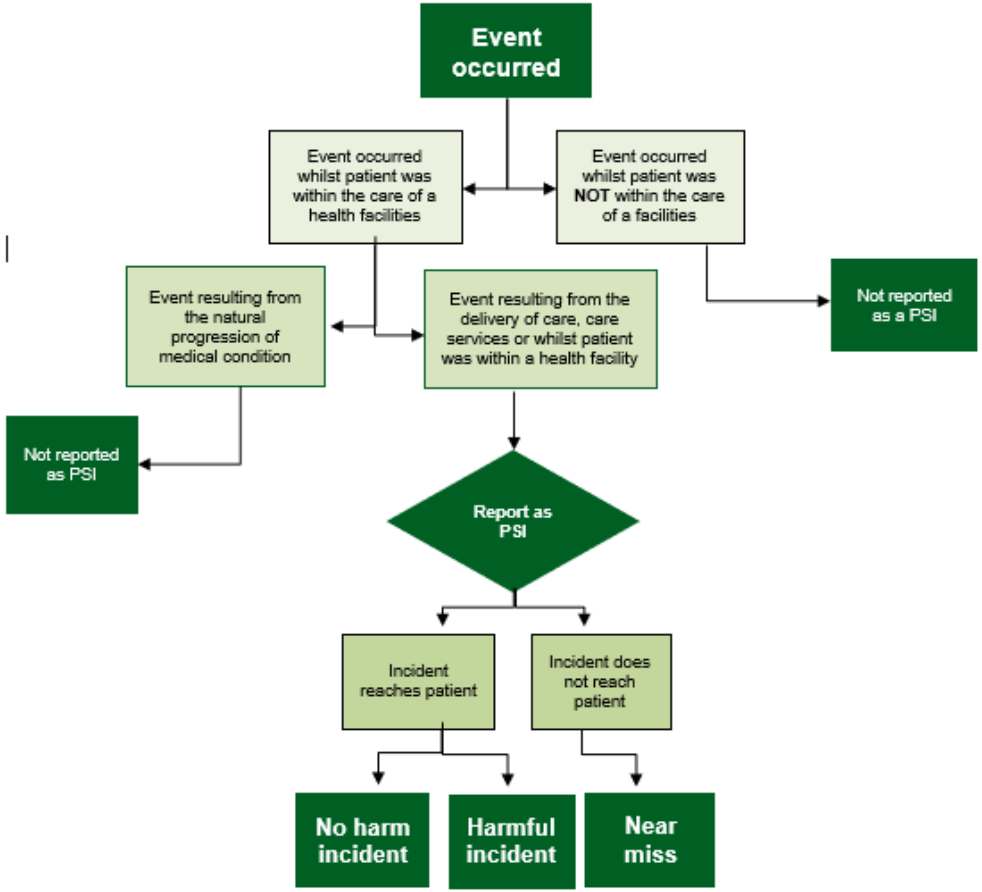
How

- 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 to 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



Algorithm to guide a just assessments of individual acts of staff based on the Just Culture.

United Kingdom National Patient Safety Agency. Sandra Meadows, Karen Baker, Jeremy Butler. The Incident Decision Tree: Guidelines for action following patient safety incidents. Sept 2019.

Start here

1. Deliberate Harm Test
Identify at the earliest possible stage those rare cases where harm was intended

Yes

Were the actions as intended?

No

Yes

Where adverse consequences intended?

No

Yes

- 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

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?

No

Yes

Does the individual have a known medical condition?

Yes

No

- 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

3. Foresight Test
Examines whether protocols and safe working practices were adhered to

Did the individual depart from agreed protocol or safe procedure?

No

Yes

Where the protocols and safe procedures available, workable, intelligible, correct and in routine use?

No

Yes

Is here evidence that the individual took an unacceptable risk?

Yes

No

- Advise individual to consult with Labour Union Rep

Consider:

- Corrective training
- Improved supervision
- OHS referral
- Reasonable adjustment to duties

Highlight any system Failures identified

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

No

Where there any deficiency in training, experience, or supervision?

Yes

No

Were there significant mitigation circumstances?

Yes

No

- Consult with relevant Regulatory Body
- Advise individual to consult with Labour Union Rep

Consider:

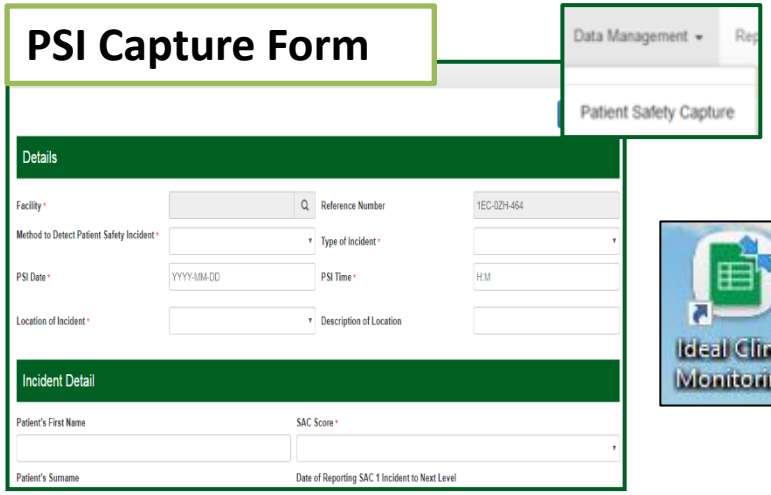
- Referral to disciplinary/Regulatory body
- Reasonable adjustment to duties
- OHS referral
- Suspension

Highlight any system Failures identified

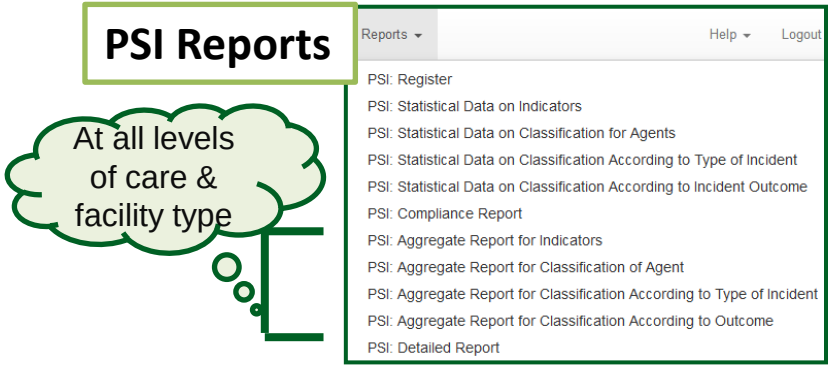
SYSTEM FAILURE

Review system

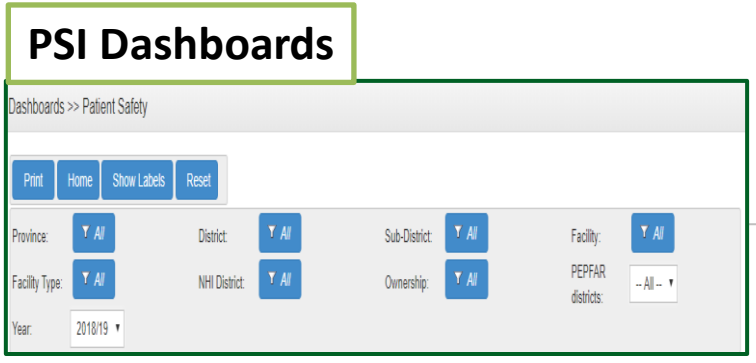
Web-based information system for reporting PSIs



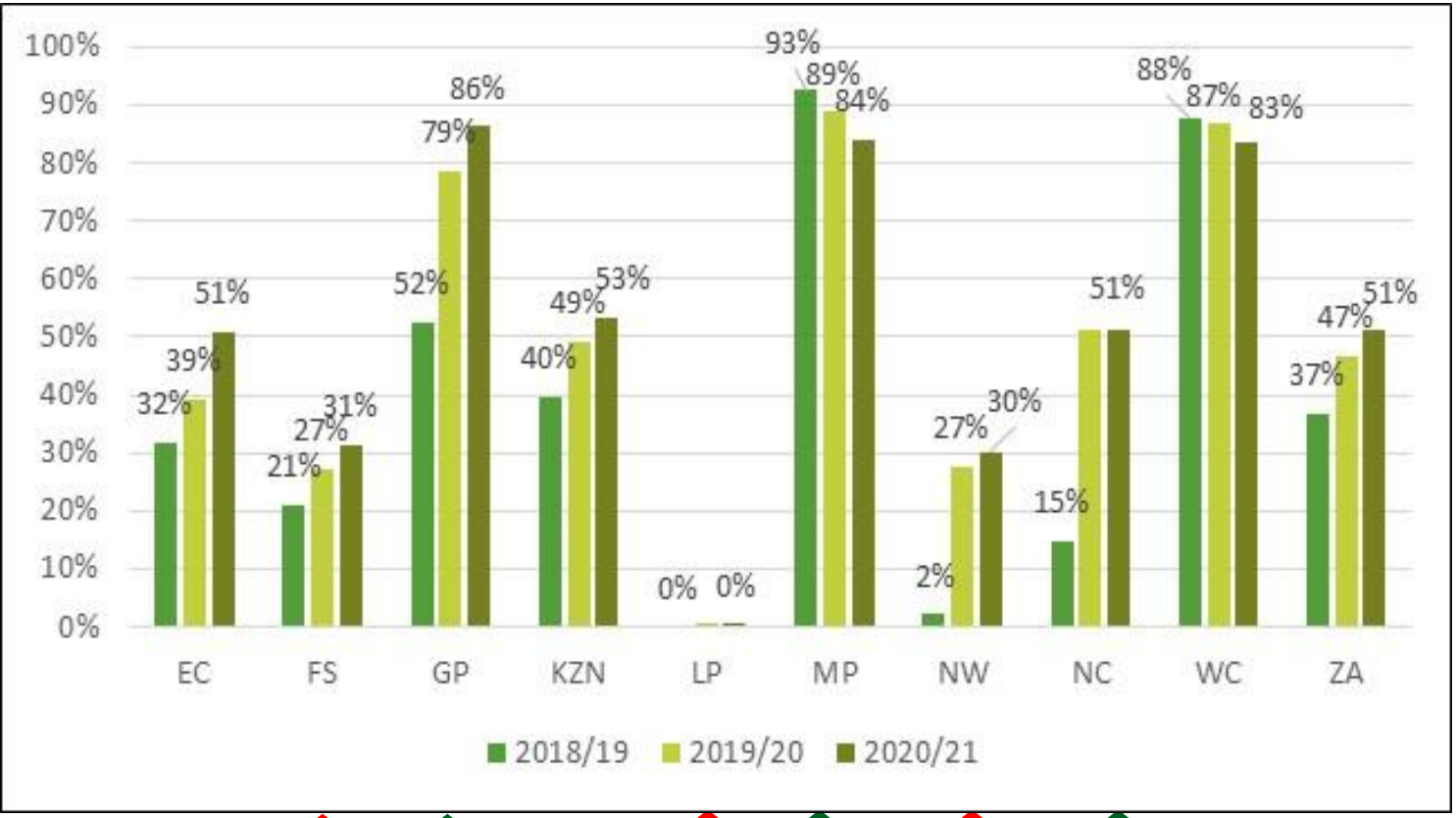
Offline module



13 000 users. Provinces manage their own user accounts

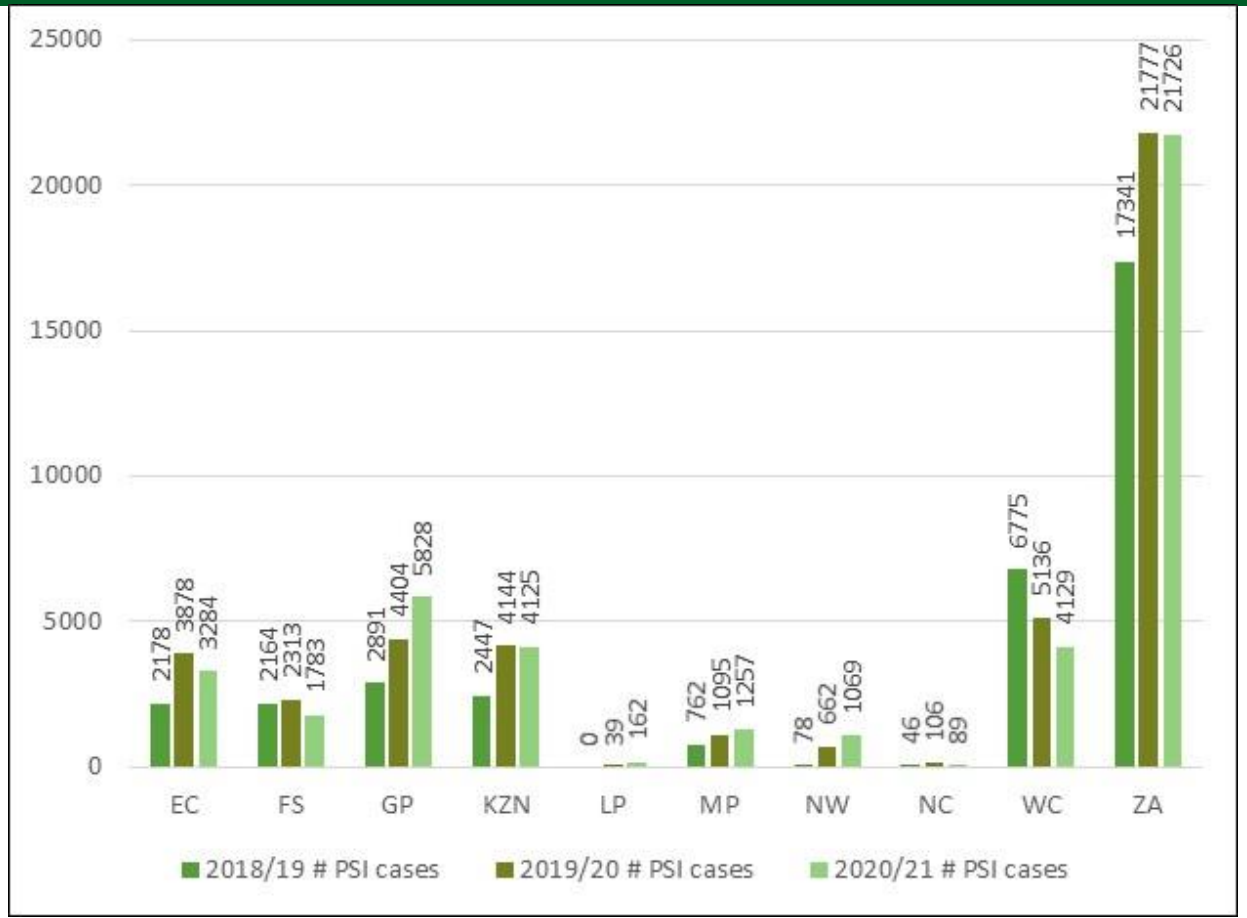


Results at end of 2020/21financial year: Compliance rate per province



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.

END

Thank you

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