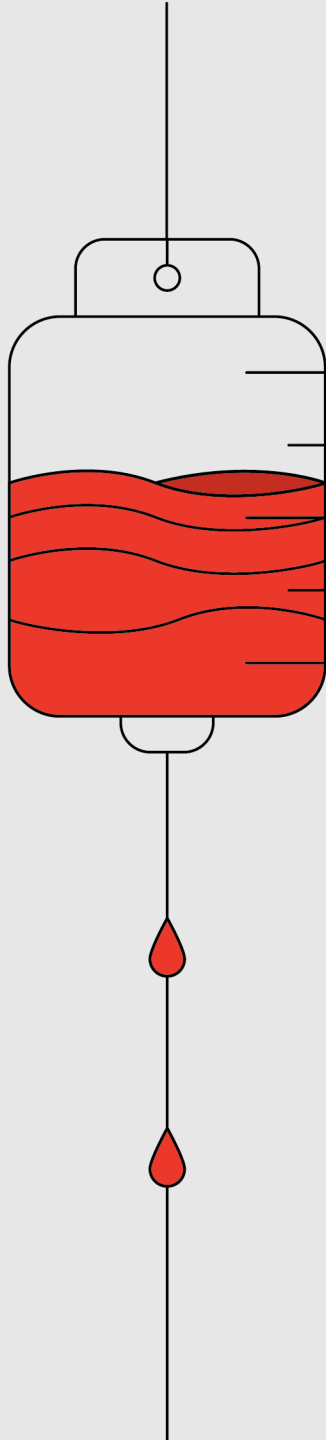




**36th South African
NATIONAL BLOOD
Transfusion Congress**

22 – 25 August 2022 - Durban

SHAPING A SUSTAINABLE FUTURE



Implementation of a Risk-Based Quality Notification system reduced the number of notification –associated disciplinary actions

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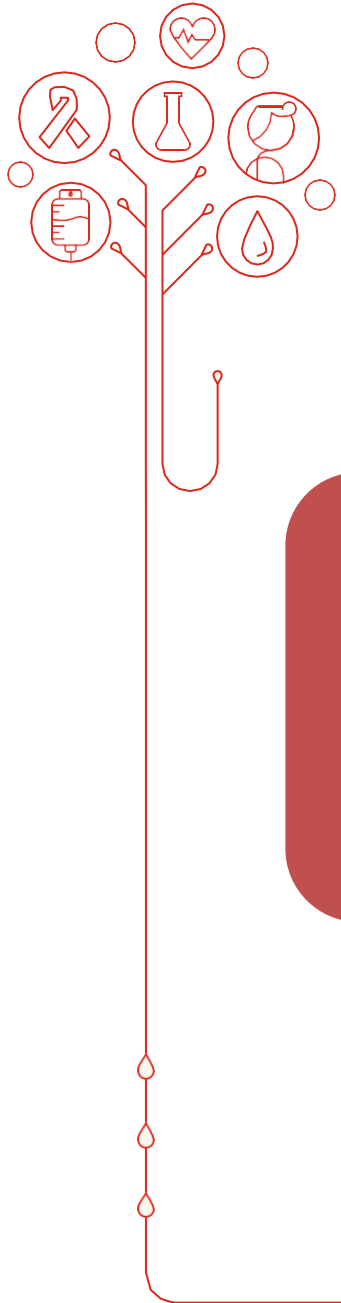
Presenter: Leesha Raman
Quality Assurance Manager
Quality Systems Department



General Information

- SAP tool used as our CAPA system.
- Definitions
 - **Non-Conformance:** a non fulfillment or deviation of a requirement
 - **Notifications:** SAP process to manage non compliances, customer complaints, suggestions, vendor related and product complaints
 - **Disciplinary action:** corrective action in response to employee misconduct, rule violation, or poor performance





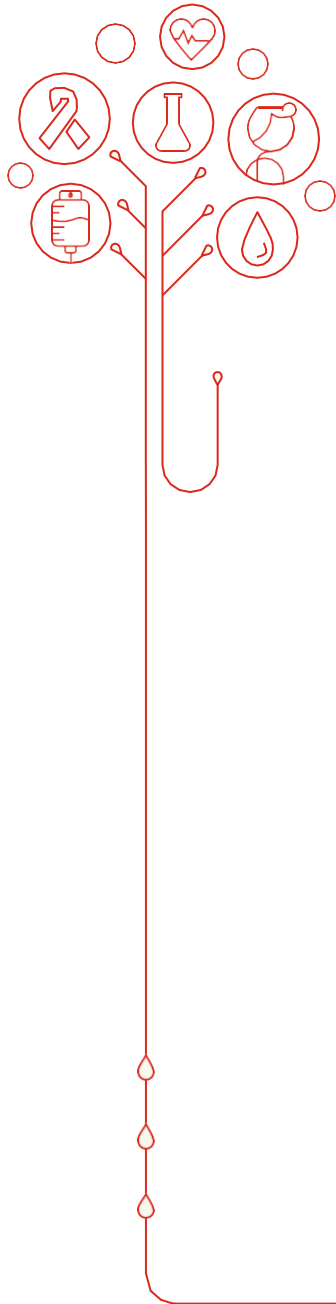
Background



The need to review the notification system was identified.

A review of CAPA systems in use and benchmarking was performed.

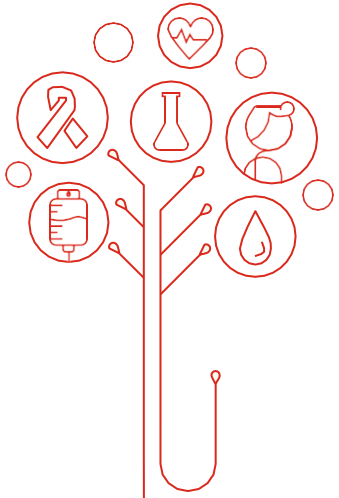
Identified a risk-based approach, as described by the Mayo clinic, and the CLSI



How it works?

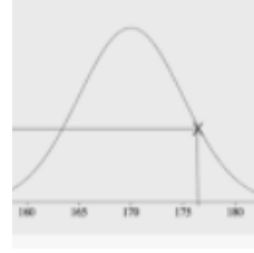
- Assesses the impact of the non-compliance and frequency of occurrence.
- Based on the outcome, time and resources are allocated.
- Therefore the higher the risk the more time and resources will be allocated.





Impact

- Critical
- Major
- Moderate
- Minor
- Insignificant



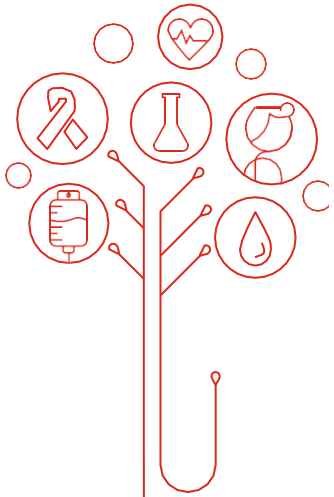
Likelihood

- Almost certain
- Likely
- Possible
- Unlikely
- Rare



Heat Map

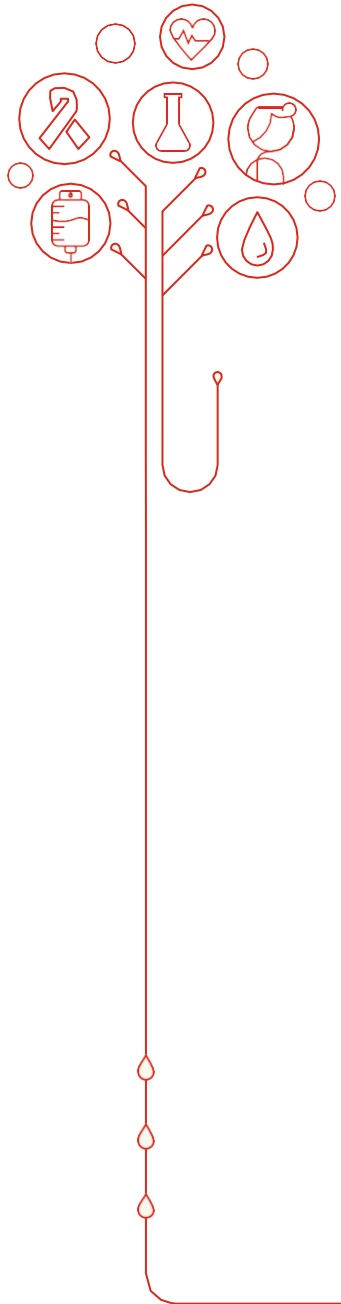
Impact	Critical	95	4.75 Root cause and Corrective action (by Supervisor)	14.25 Root cause and corrective actions (by team)	47.5 Root cause and corrective actions (by multifaceted team)	76 Root cause and corrective actions (by multifaceted team)	94.05 Root cause and corrective actions (by multifaceted team)
	Major	45	2.25 Root cause and Corrective action (by Supervisor)	6.75 Root cause and Corrective action (by Supervisor)	22.5 Root cause and corrective actions (by team)	36 Root cause and corrective actions (by multifaceted team)	44.55 Root cause and corrective actions (by multifaceted team)
	Moderate	25	1.25 Corrective action and monitor (by Supervisor)	3.75 Root cause and Corrective action (by Supervisor)	12.5 Root cause and Corrective action (by Supervisor)	20 Root cause and Corrective action (by team)	24.75 Root cause and Corrective action (by team)
	Minor	10	0.5 Monitor and take action if needed (by Supervisor)	1.5 Corrective action and monitor (by Supervisor)	5 Root cause and Corrective action (by Supervisor)	8 Root cause and Corrective action (by Supervisor)	9.9 Root cause and Corrective action (by Supervisor)
	Insignificant	2	0.1 Monitor and take action if needed (by Supervisor)	0.3 Monitor and take action if needed (by Supervisor)	1 Corrective action and monitor (by Supervisor)	1 Corrective action and monitor (by Supervisor)	2 Corrective action and monitor (by Supervisor)
			0.05	0.15	0.5	0.8	0.99
			Rare	Unlikely	Possible	Likely	Almost Certain
Likelihood							



Priority and Actions



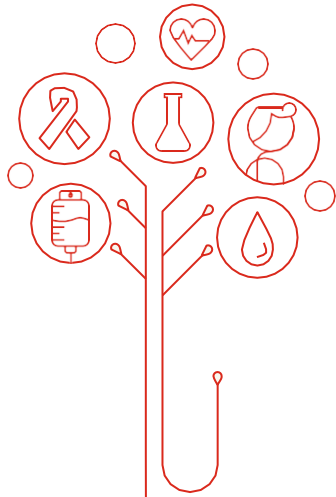
Risk Score	Priority	Recommended Action	Action By
< 1	Insignificant	Observe and monitor at site, implement actions if needed	Supervisor
1 – 2	Minor	Corrective action and monitor for effectiveness	Supervisor
>2 – 13	Moderate	Root cause and Corrective action to be done	Supervisor and QBP
14 – 30	Major	Root cause and Corrective action to be done	Supervisor, QBP, Line Manager and Zone Manger (if needed)
> 30	Critical	Root cause and Corrective action to be done	Supervisor, QBP, Line Manager, Zone Manger, Senior Manager and external parties e.g. SAPS, DoL, DoH (as needed)



This study -

Compares the number of disciplinary actions (e.g. counselling, warning, etc.) towards SANBS staff resulting from the notifications raised before and after the implementation of a risk-based approach, as well as the perception of staff that notifications are punitive.

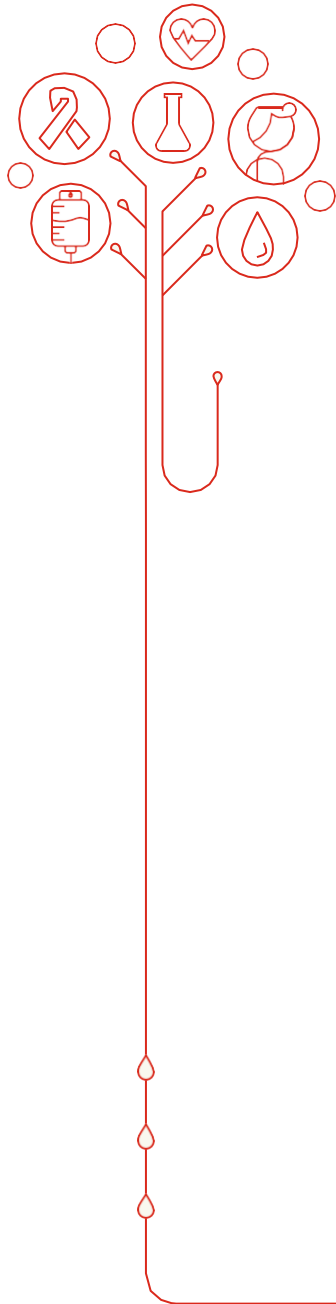




Method

- Survey was conducted to ascertain how staff perceived notifications before and after the implementation of a risk-based approach.
- Risk-based approach was piloted in the Vaal zone in August 2018 and rolled out to the remaining six zones in a phased approach.
- The roll out was completed in May 2019.

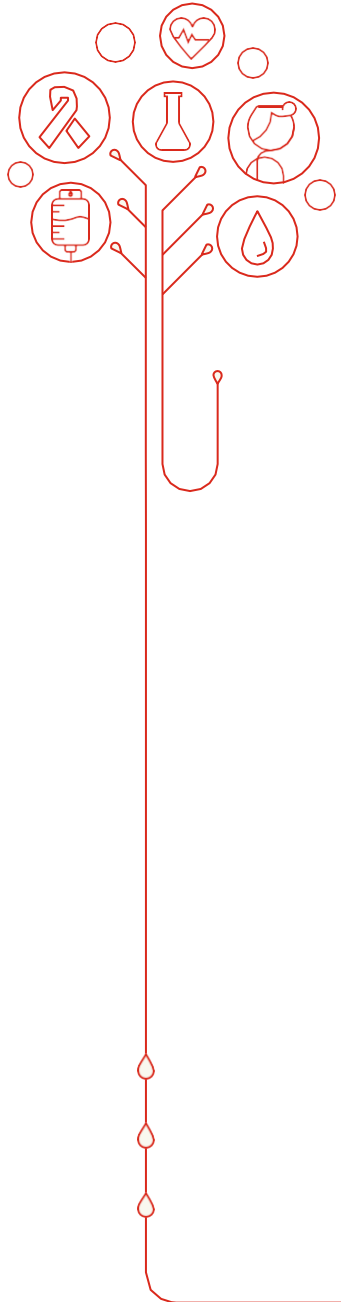




Method

- All notifications were captured on SAP from where data was extracted.
- Excel pivot tables were used to analyze the data.
- Number of disciplinary actions were investigated relating to the notifications raised.
- Excluded notifications raised -
 - By external auditors as they are not risk rated on the new system.
 - In the month of implementation, and those raised before implementation and closed after implementation.



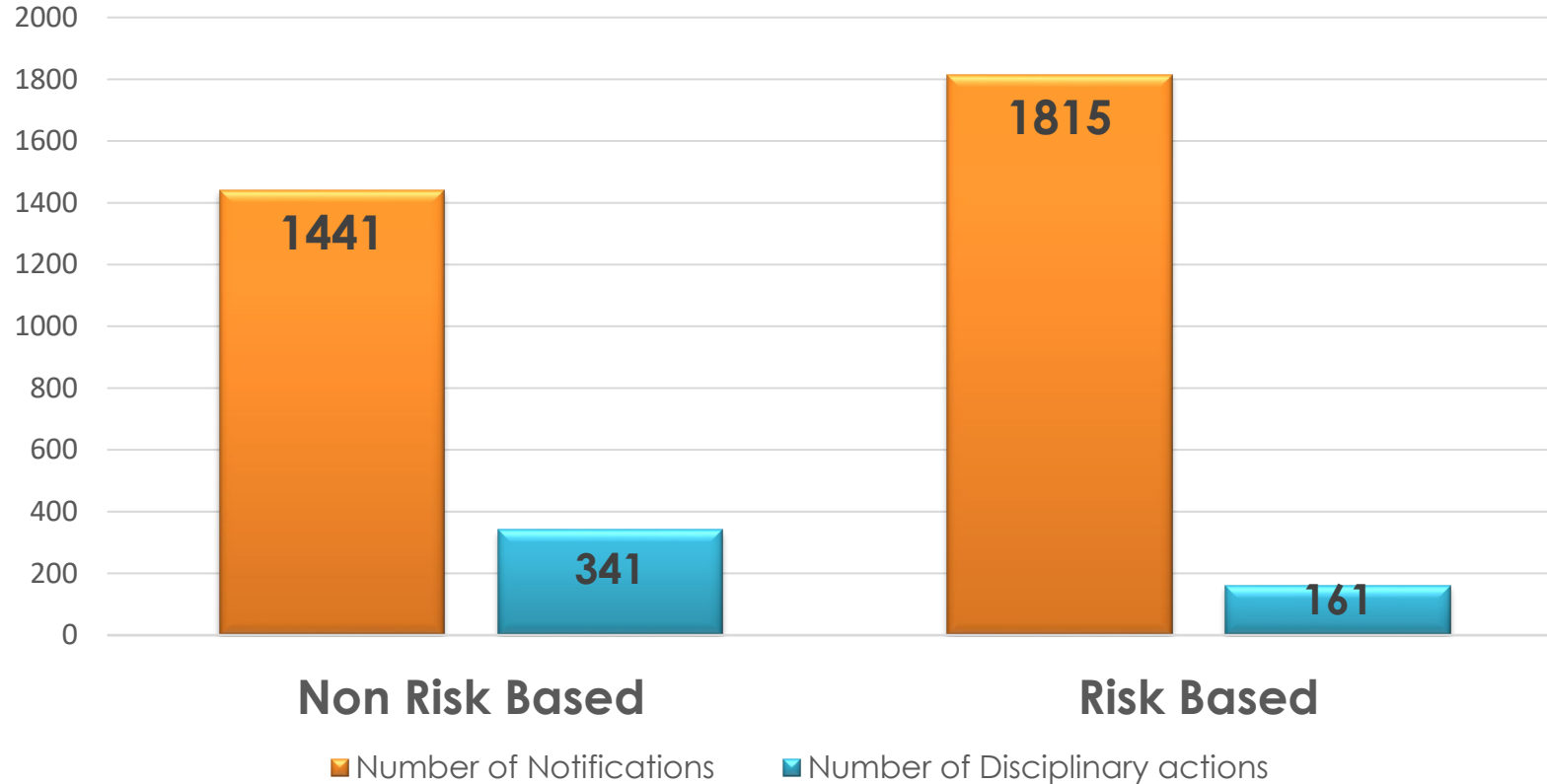


Results

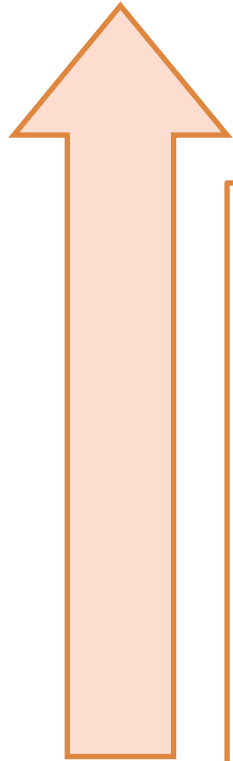
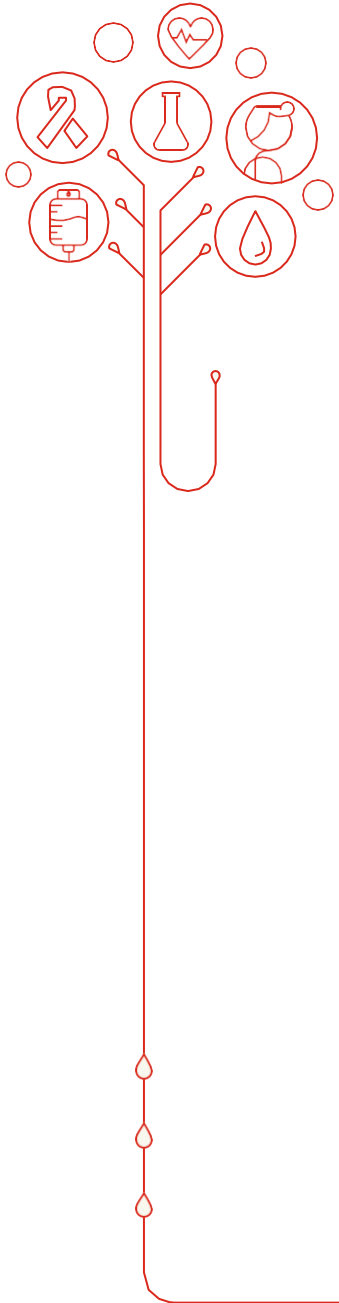
- Notification data for all zones were extracted from SAP for the period August 2017 to May 2020.



Number of Notifications vs Disciplinary action



Survey results – staff perceived system as punitive

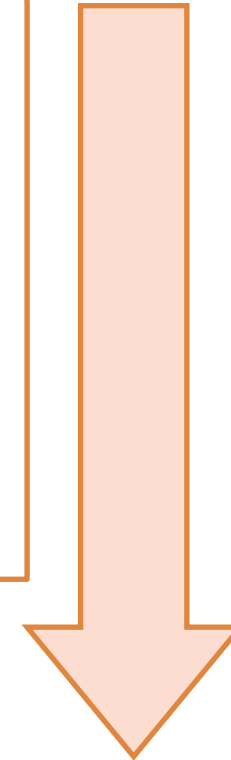


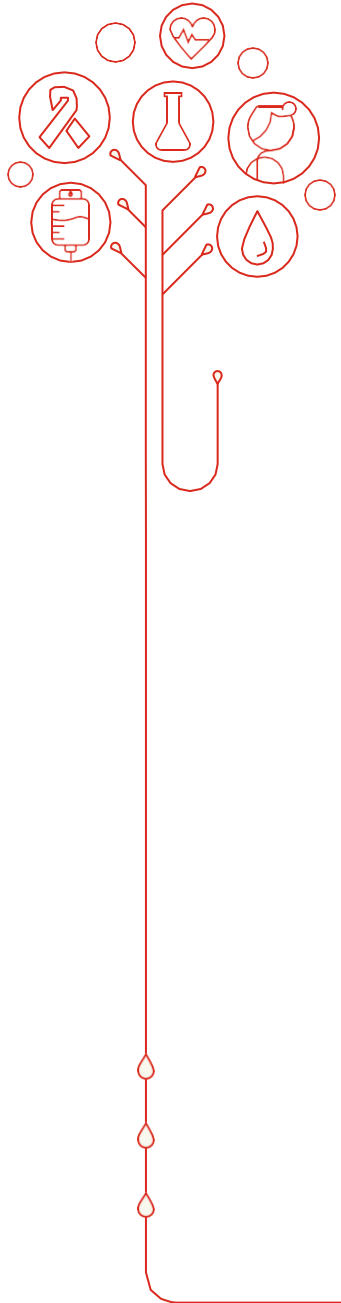
February
2018

53%

February
2020

15.5%

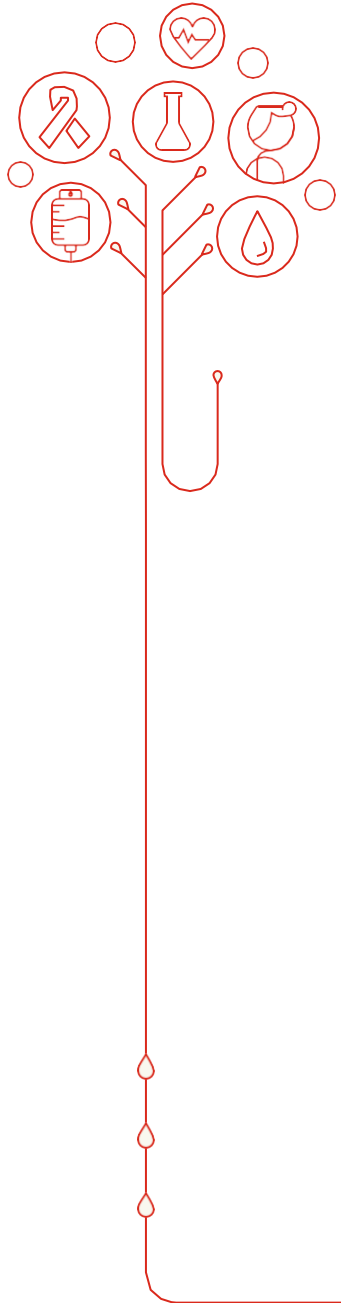




Discussion

- Percentage of notifications resulting in disciplinary actions were almost 3 fold lower following the implementation of the risk-based approach.
- Decrease in the perception that notifications are punitive following the risk-based approach,
 - positively impacting staff morale and attitude towards notifications received.





Conclusion

- Decline in the number of disciplinary actions taken could be attributed to the focus on system factors, where the non-risk-based approach focussed on personnel factors.



Thank you