GAUTENG DEPARTMENT OF HEALTH

COVID-19 vaccine for Workers: Occupational Health Perspective

25 March 2021



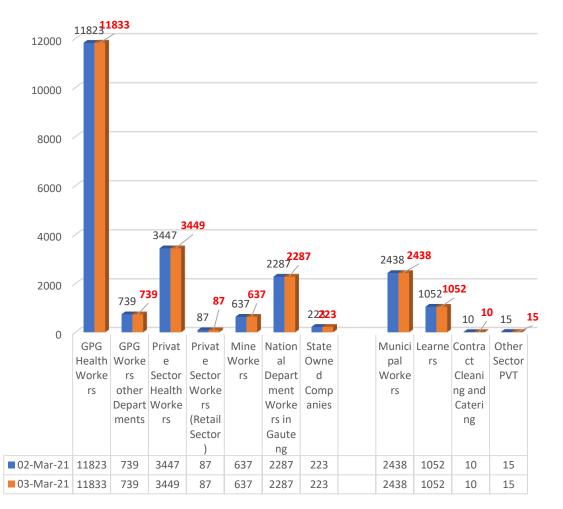






SARS Cov-2 Infected workers in Gauteng. Health Workers Infected the most

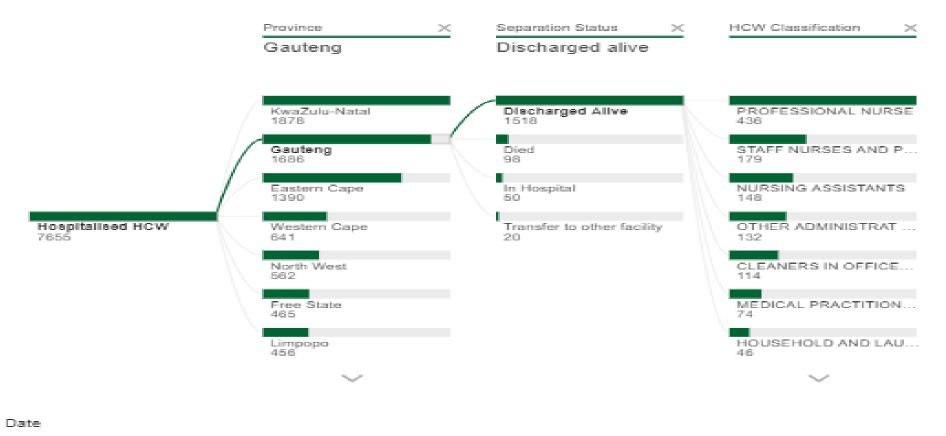
- 11833 COVID-19 Infected GDOH Health Workers. 5 New cases in the last 24 hours; 0% increase in new infections.
- 2 Demised in the last 24 hours.
- Infections in other sectors and among learners have not increased in the last 24 hours.
- Total Number who demised 98 Health Workers in the Public Sector as the3rd March 2021.
- 2 New Infection reported in Private Sector HW on the 3rd March 2021.
- **0** New Infections in State Owned Companies







Decomposition tree of Gauteng Hospitalised Health Workers, Discharged, Who Died, and Transferred to there hospitals

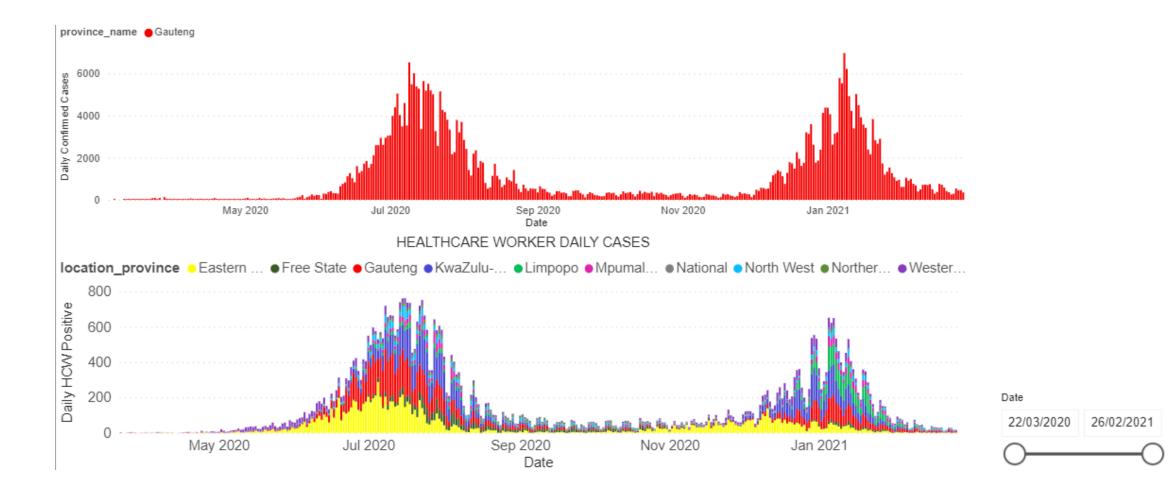


28/03/2020 01/03/2021





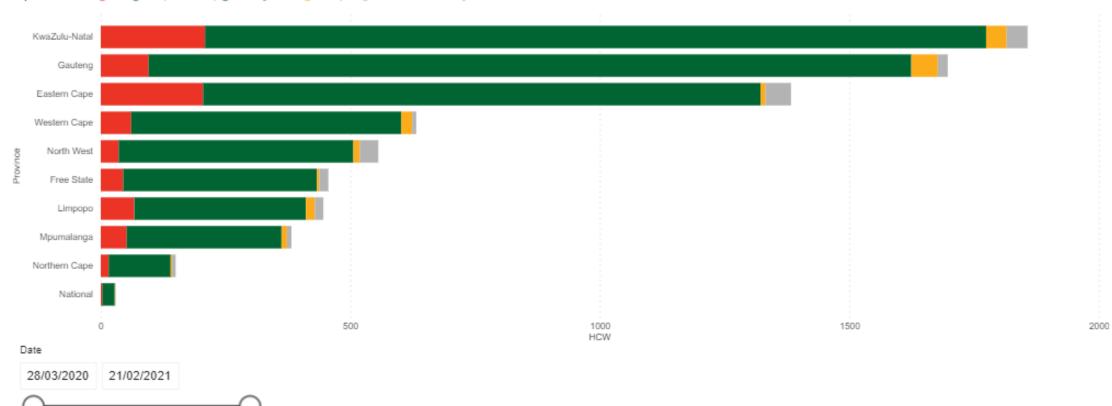
Decline in COVID-19 infections has not come down to COVID-19 infections before the fist surge







More Health workers hospitalised in Gauteng than any other province: Implications for post COVID-19 complications and surveillance



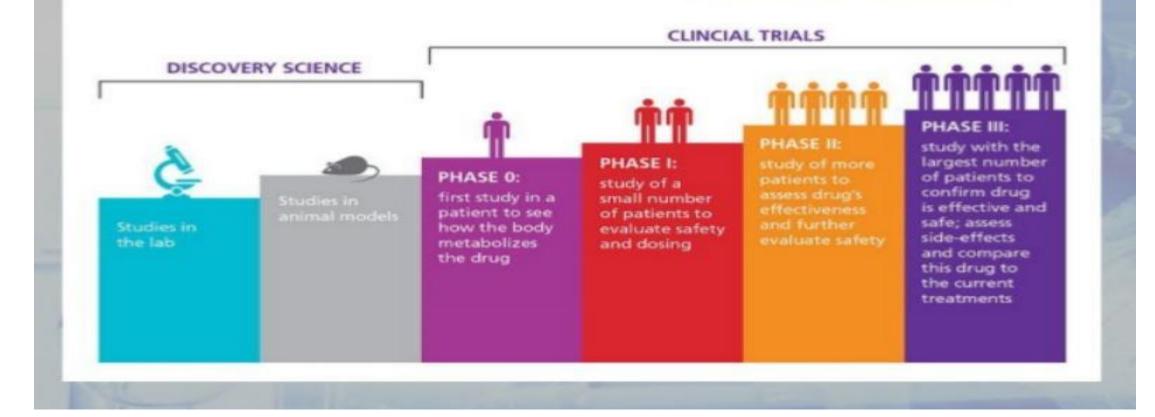
Separation Status Died Died (non-COVID) Discharged alive In Hospital Transfer to other facility





Phases of Vaccination Trials

PHASES OF CLINICAL TRIALS







Difference between Phases 3a and 3b of Clinical Trials

Phase 3 a

- Carried out in a large number of or in special category (e.g. Ensemble Trail in SA on J&J vaccine)
- Regulatory requitement (SAHPRA)
- Generates Data on safety and efficiency

Phase 3b

- Extended trial of 3a after applying for approval but before launch
- Also known as "label expansion"
- To show the drug works for additional types of patients/diseases beyond the original use for which the drug was approved for marketing
- These may supplement or complete the earlier trails or may be directed to Phase IV



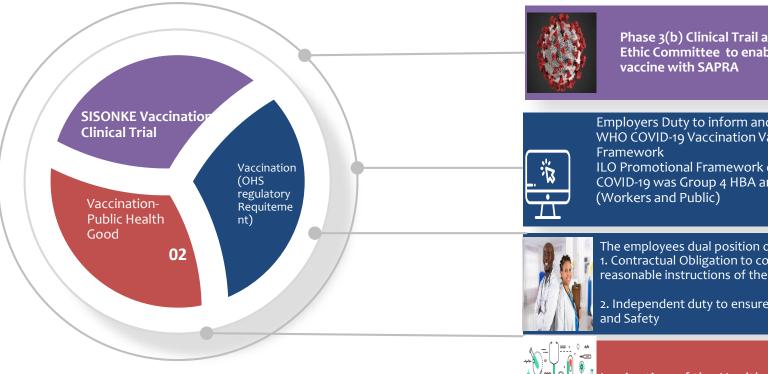


PHASED APPROACH FOR VACCINE INTRODUCTION

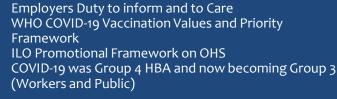
Phase I	Phase II	Phase III
Health care workers (HCW) All health sector workers	Essential workers Target population: 2,500,000	Other persons >18 years Target population: 22,500,000
Target population: 1,250,000(public and private sector) 63 000 as 21% of 300 000 doses 105 000 as 21% of 500 000 doses	Persons in congregate settings Target population: 1,100,000 Persons >60 years Target population: 5,000,000 Persons >18 years with co-morbidities	
	Target population: 8,000,000 Total: 16 600 000	
Open label programme	Expansion through usual vaccination ce	entres
cense for use n Open Label Programme	Full Licence	

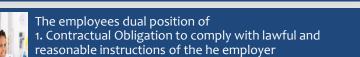


ALLIGNMENT OF SISONKE Phase 3b Clinical Trail and OHS HBA categories and SA Launch of Vaccination **Programme**



Phase 3(b) Clinical Trail approved by UKZN Ethic Committee to enable registration of J7J





2. Independent duty to ensure own and others Health



Vaccination of the Health workers to safeguard the health system



Duties of State, Employers, Employees regarding Vaccination and Trails



The Management of Adverse events and Serious Adverse events will be for the purposes of

- 1. Management of Clinical Trial (Phase 3b)
- 2. Management of Occupational injury and or Disease (Clinical Trial in an Occupational setting)
- 3. Management of quality of Vaccination Programme (Post Phase 3b trial)



Conclusion

- The Vaccination of employees in a Phase 3b trial is at the same time a an Occupational Health Intervention to monitor exposure to a Hazardous Biological Agent at the work place.
 - Using suitable procedure that is standardised, sufficiently sensitive and of proven effectiveness (as determined in Phase 3a trails)
 - COVID-19 has become Group 3 Occupational Infectious Disease as classified by the Regulations of HBA
- Ethical Principles of Informed Consent to participate in Vaccination Trail, The legal obligation to participate in a employer facilitated vaccination programme, the WHO values of reciprocity in prioritisation of health workers in COVID-19 vaccines need to be balanced.
- Management of Adverse Effects and Serous Adverse Events have to be managed as COID, Clinical Trial and Quality Management issues.
- Governance of OHS programmes and Clinical trails presents opportunity to balance ethics, law, OHS Policy, programme management and imposes a culture of collaboration and transdisciplinary interaction.