



Update on the Janssen[®] (JNJ) Ad26.COVS.2.S vaccine

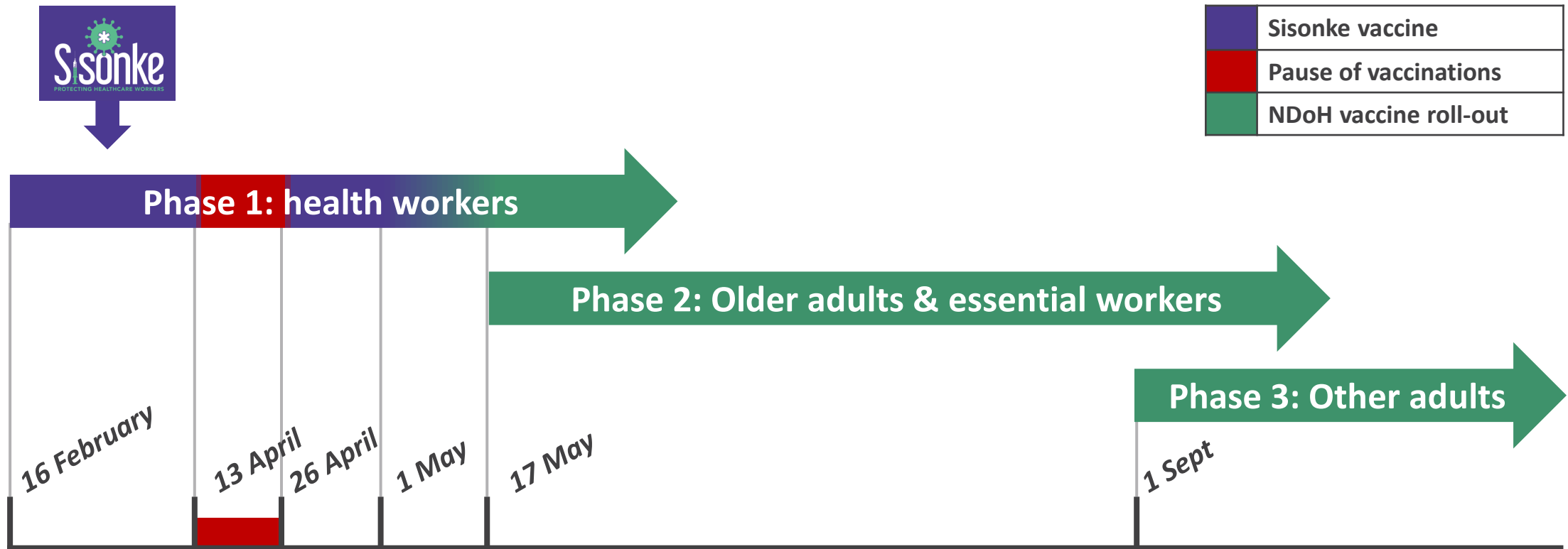
Professors Glenda Gray & Linda-Gail Bekker



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Sisonke provided the Janssen® (JNJ) Ad26.COV2.S vaccine to health workers ahead of the third wave



Sisonke phase 3B open label implementation study

- Urgent intervention when national roll-out faltered because of Beta VOC
- Able to offer HCW vaccine as part of this study as of the 17th February 2021
- National Rollout 17th May 2021, so HCW got access months before general roll-out in time for 3rd wave
- Provide effectiveness data on both Beta and Delta
- Provide additional safety on the Ad26 SARS-CoV-2 data

Sisonke Completed 17th May 2021



122

sites touched in total
including rural extensions
and mobiles

477 234

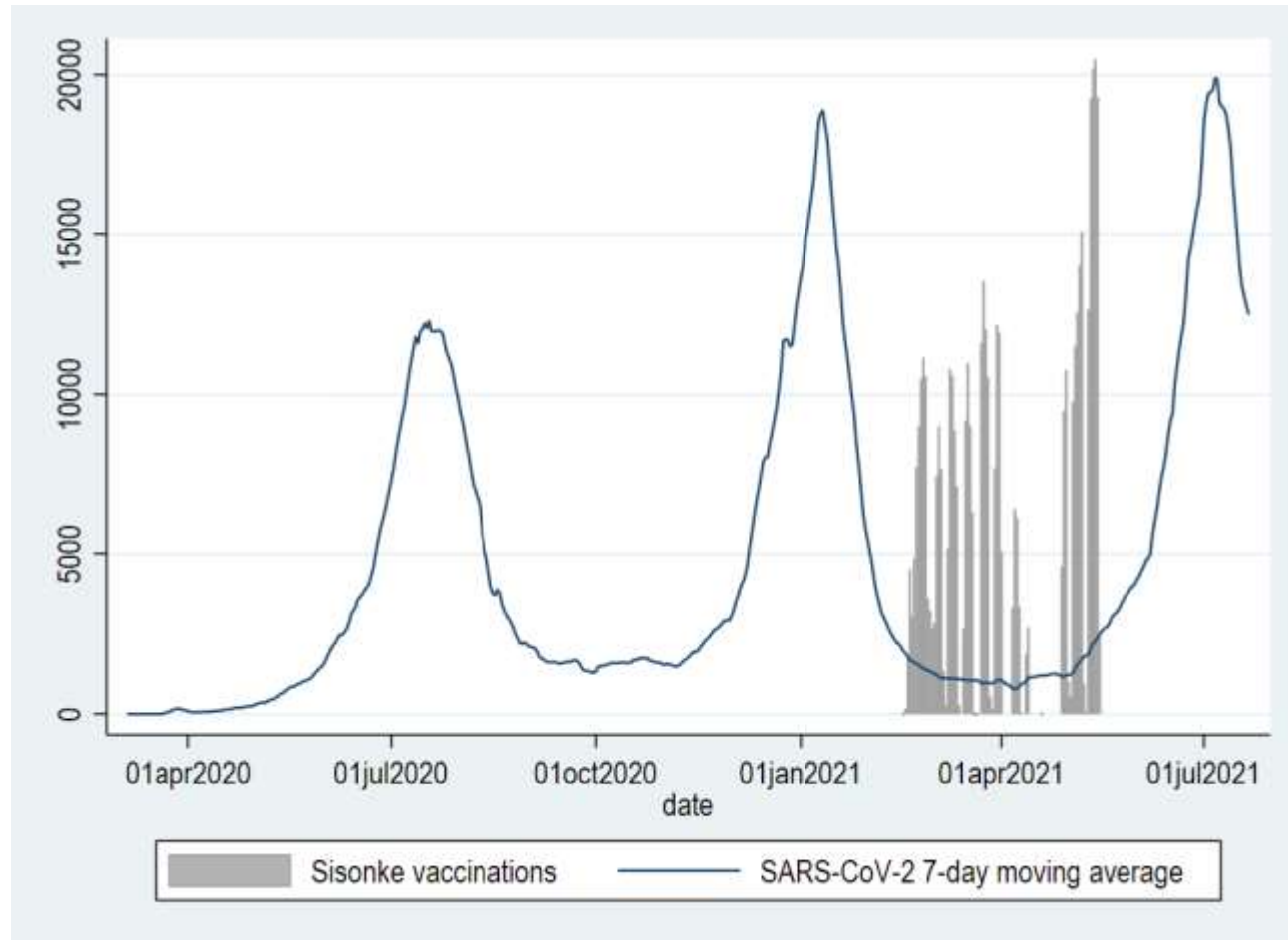
vaccinated health workers



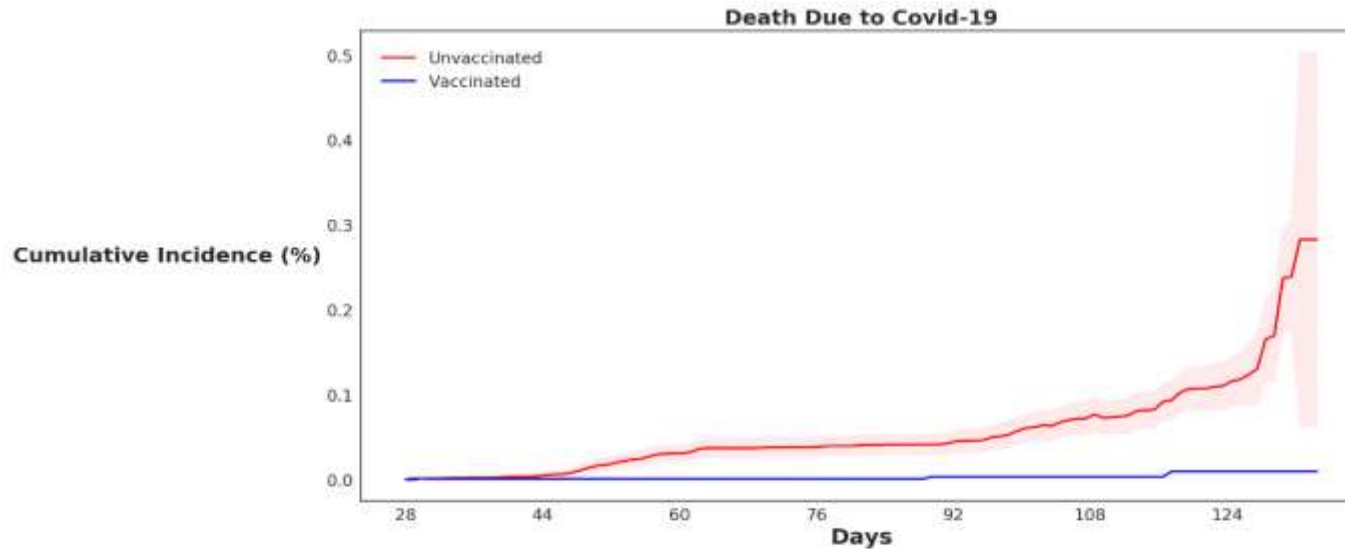
Criteria Considered for Analysis

- Adjudication of infections: Mild/Mod/Severe
- Used 3 data sets: 2 from medical insurers and one provincial persal data
- Used 2-3 different analytical methods
- For today we report on 2 data sets

Period of Analysis



Vaccine Effectiveness: Death



91-96.2%
protection
against death

No. at Risk

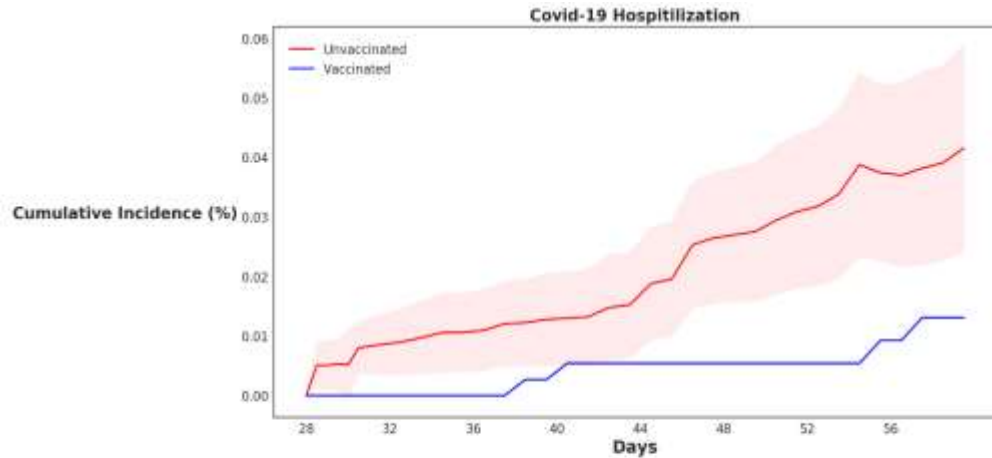
Unvaccinated	64,585	64,328	41,845	38,177	34,240	21,345	10,141
Vaccinated	64,636	64,407	41,917	38,234	34,306	21,618	10,209

Cumulative No. of Events

Unvaccinated	3	5	19	22	24	33	38
Vaccinated	2	3	3	3	4	4	5



Beta versus Delta VE



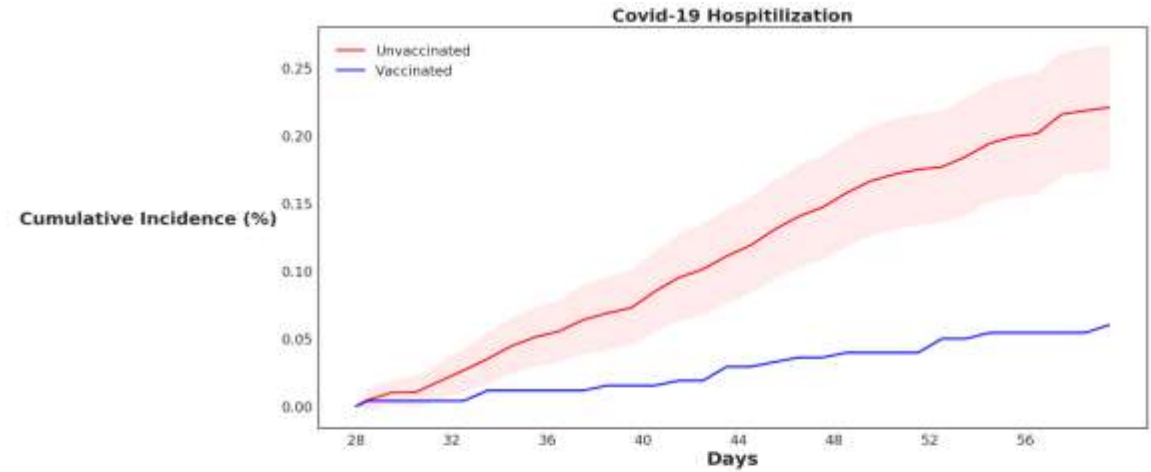
No. at Risk

Unvaccinated	38,655	38,602	38,302	36,401	36,383	32,122	29,551	26,031
Vaccinated	38,700	38,652	38,364	36,485	36,465	32,194	29,630	26,083

Cumulative No. of Events

Unvaccinated	14	15	16	17	19	22	23	25
Vaccinated	10	10	10	12	12	12	12	13

Beta VOC



No. at Risk

Unvaccinated	25,900	25,860	26,062	27,893	27,883	28,304	19,328	19,133
Vaccinated	25,919	25,885	26,095	27,554	27,915	28,340	19,338	19,165

Cumulative No. of Events

Unvaccinated	19	25	32	40	50	61	66	71
Vaccinated	12	12	14	15	19	22	24	25

Delta VOC

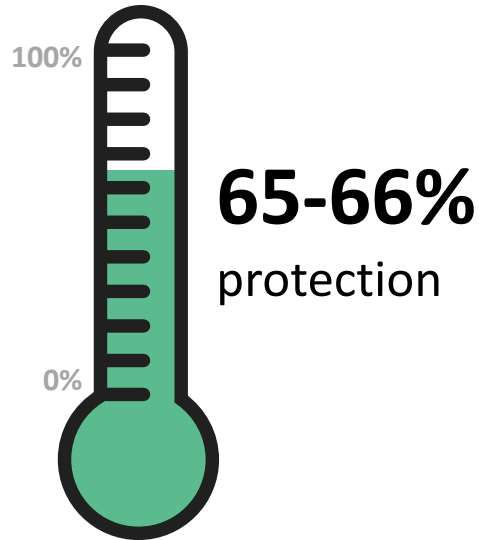


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1

The JNJ vaccine prevents hospitalisations and death (results from two data sets)



Hospitalisation

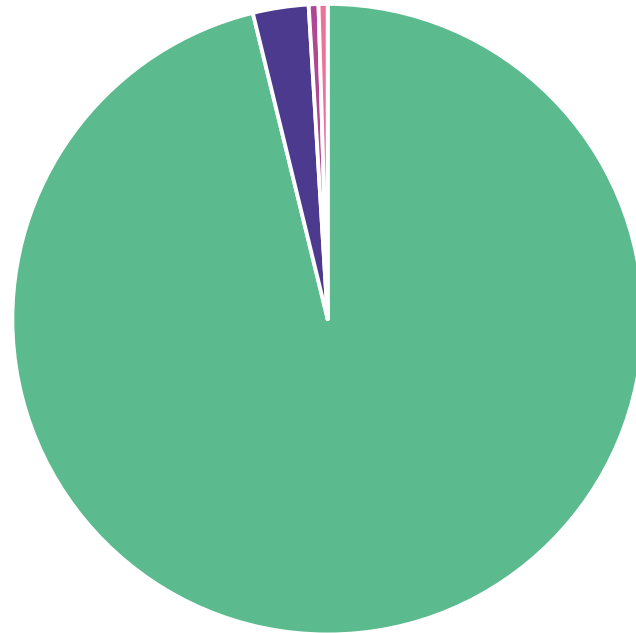


Death



2

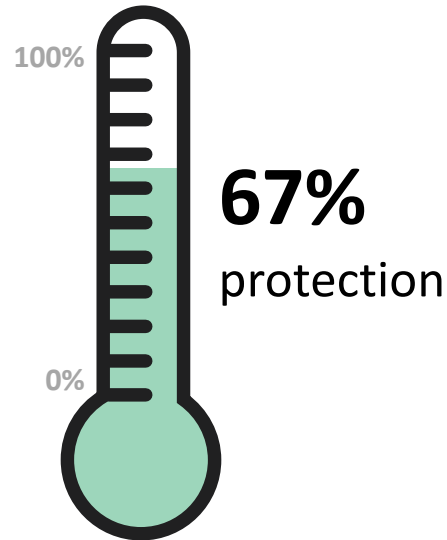
When breakthrough infections happen they are mild!



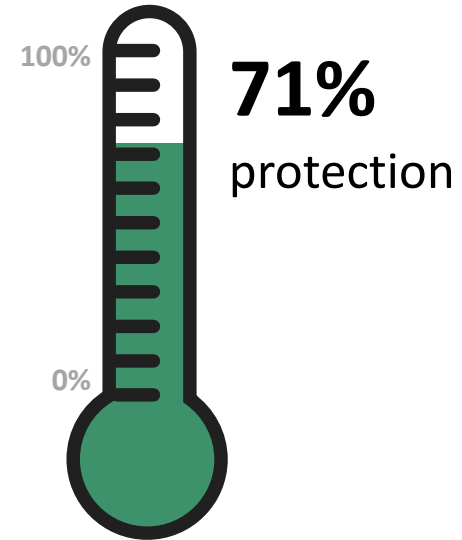
- Mild: 96%
- Moderate: 3%
- Severe: Less than 0.05%
- Death: Less than 0.05%

3

Protection is good against both beta and delta variants



Hospitalisation
(Beta dominant)



Hospitalisation
(Delta dominant)

N = 134 256 people

Protection is as good, if not better, against delta variant.

4

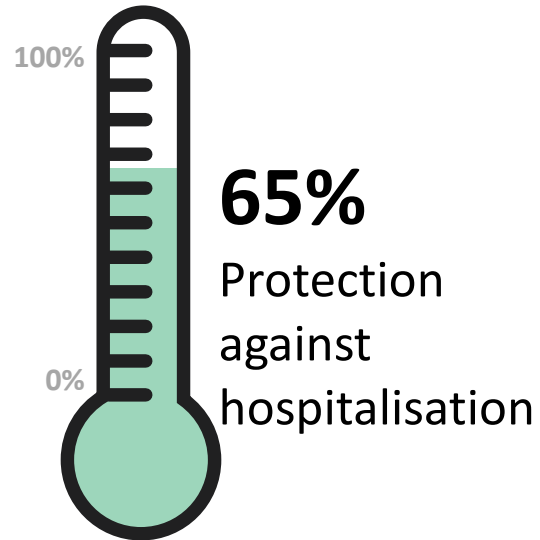
The JNJ vaccine is safe



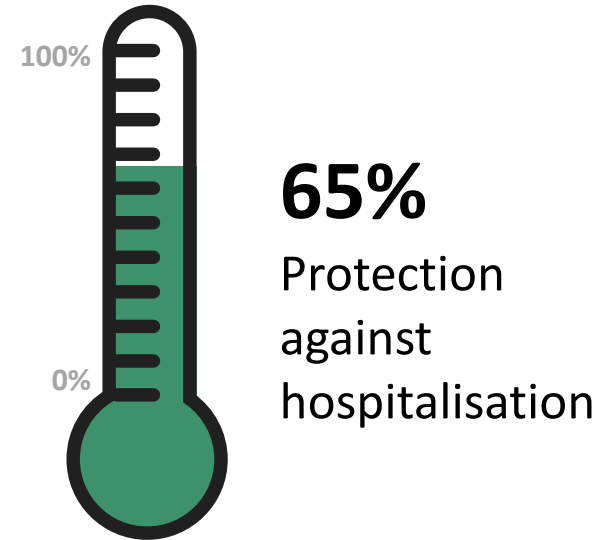
- No safety signal detected
- In line with what we are seeing globally
- Two cases of the rare clotting disorder (TTS – Thrombocytopenic Thrombosis Syndrome): Both have made a complete recovery.

5

Protection shows good durability



28-90 days post vaccination



90-120 days post vaccination

N = 134 256 people

There is no need for a booster yet.

Conclusion

- We provide the world's first evidence that the Ad26 COVID-19 (JNJ) is effective against the Delta VOC
- Ad26 JNJ vaccine works well in South Africa and protects against severe disease and death
- All the immune response data indicate good immediate and sustained immune response against Delta
- Surprising durability in the immune response seen for single dose JNJ up to 8 months
- Global real world effectiveness studies show similar VE as the phase 3 RCT

Acknowledgements

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- **Biovac**

Dr Morena Makhoana and team

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Peter Gilbert, Holly Janes

Sisonke Study Team

Protocol Leadership

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- Trevor Bell
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- Jinal Bhiman

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<http://sisonkestudy.samrc.ac.za>



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