

Making Medicines in Africa

A Risk Management Approach

Advancing Vaccine Development and Manufacture in Africa
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Geoff Banda



The Open University



THE UNIVERSITY
of EDINBURGH

What is Risk?

- Does anyone know the future?
- What is risk?
 - Italian word '*riscare*', - 'to dare' (Bernstein, 1996:8)
 - A phenomenon which is subject to scrutiny over and above the social
 - Risk = Probability x Magnitude ~ 'Black Swan' phenomenon
 - Actuarial Sciences; Engineering, Epidemiology, Gambling, Economics, Investment (risk v return)
 - Risk as a set of scenarios that may happen – think of things more systematically
 - Human beings can control their outcomes – there is free will, how do you exercise it?
 - Socially mediated and subjectively biased – leading to social amplification
 - Risk perception
 - Risk Communication

"Investigation of risk is both a scientific activity and expression of culture" (Kasperson et al, 1988)



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Risk, Uncertainty and Predicting Future Scenarios

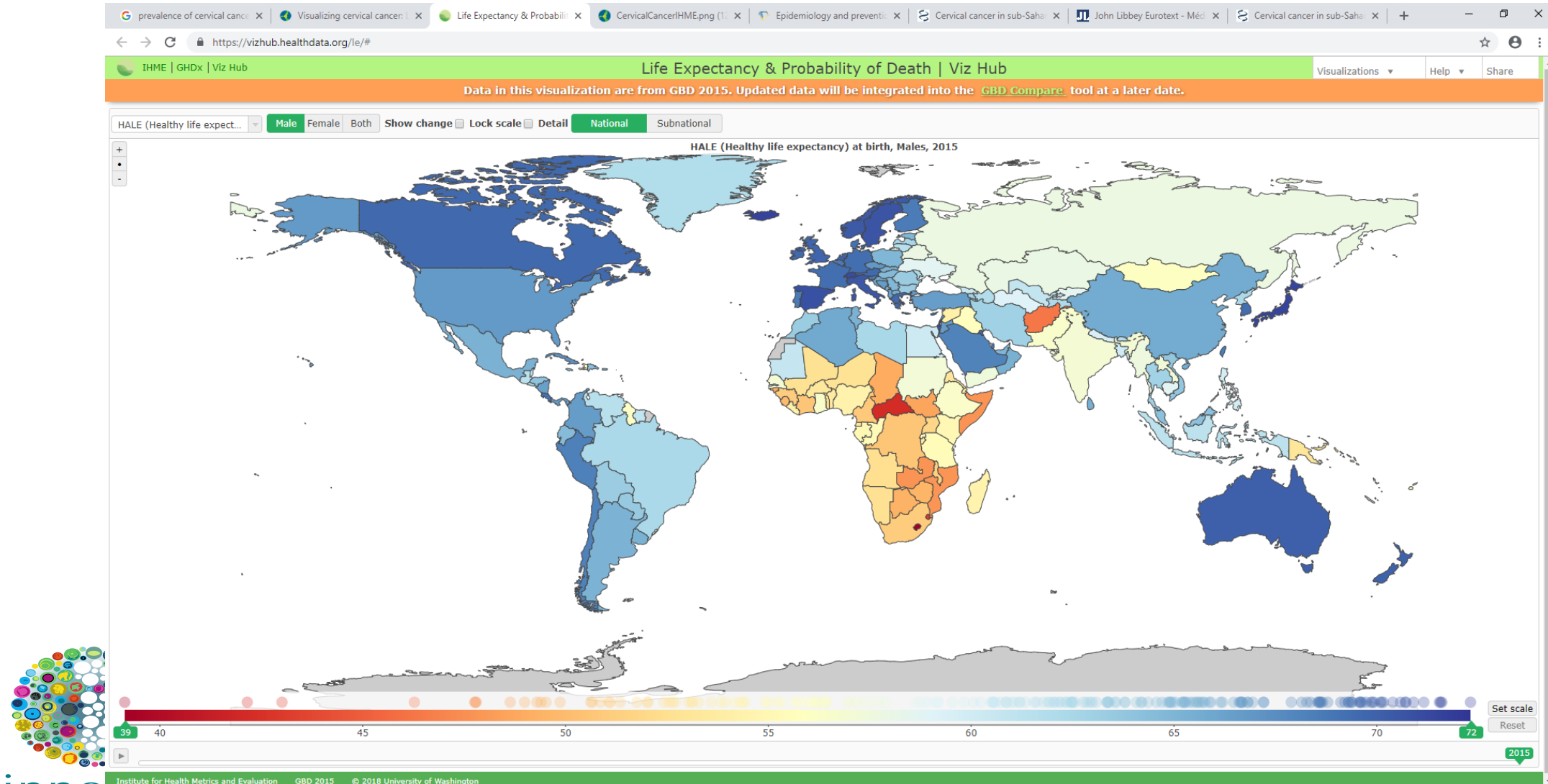
- In antiquity the future belonged to the gods
- Oracles and seers could peer into the future
- When disaster struck
 - Sacrifice and appease the gods
 - If no change then its fate

- Birth of mathematics (probability) allowed observation of patterns
- We can use risk analysis methods/models to predict certain scenarios
- Plan, execute and monitor
- Refine the model or method



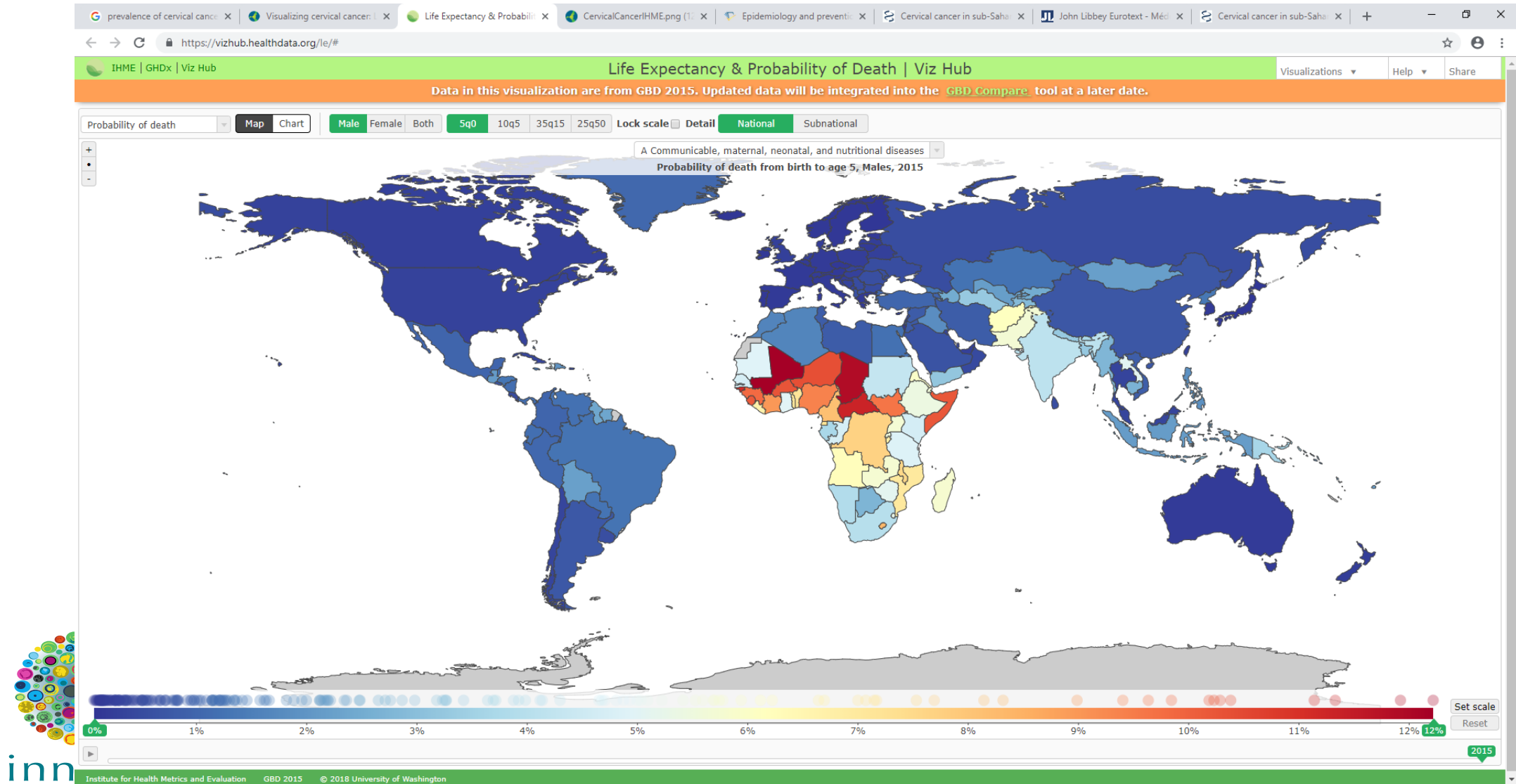
External Risks – Natural Disasters
Manufactured Risks – Man-made as a result of modernity

Healthy Life Expectancy by Region



Source: <https://vizhub.healthdata.org/le/#>

Probability of Death by Region



<https://vizhub.healthdata.org/le/#>

Cervical Cancer in Sub-Saharan Africa

According to WHO -

- Cervical cancer will kill **> 443,000 women** p.a. by 2030
- **~ 90 %** from sub-Saharan Africa
- Leading country is Malawi

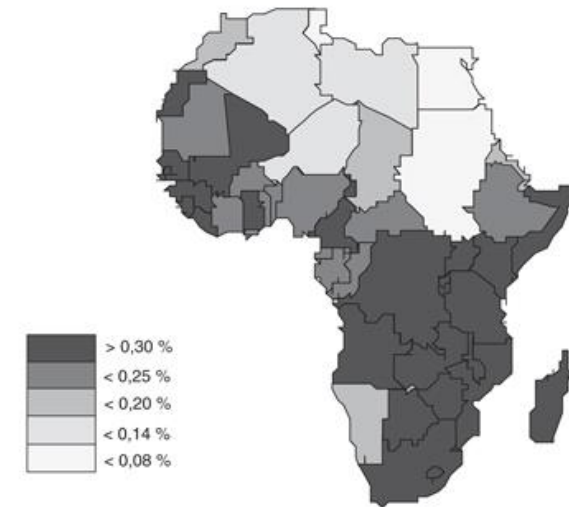
BUT

- This is a preventable non-communicable disease
- Primary intervention
 - -vaccination
- Secondary intervention
 - -early diagnosis of at risk situations
- Tertiary intervention
 - early diagnosis of proven cases of cervical neoplasia prevention.

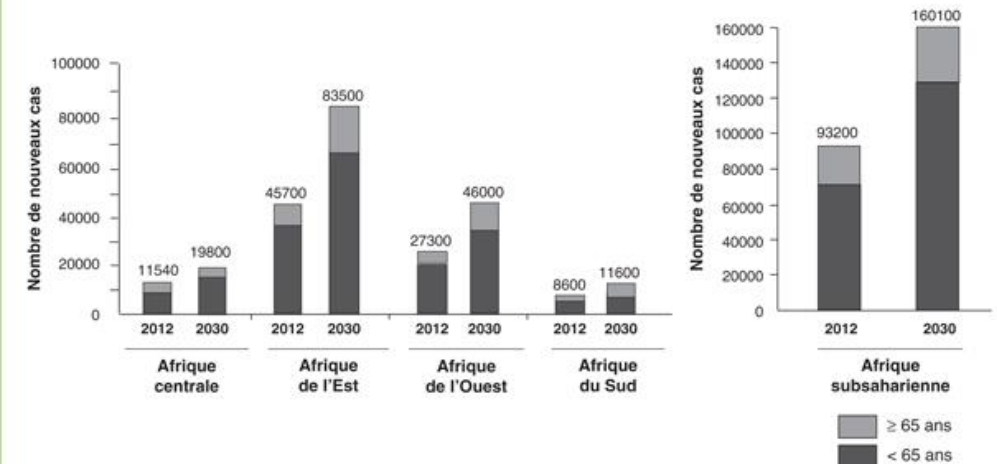


R.S. Mboumba Bouassa, T. Prazuck, T. Lethu, J.F. Meye, L. Bélec. Cervical cancer in sub-Saharan Africa: an emerging and preventable disease associated with oncogenic human papillomavirus. Médecine et Santé Tropicales. 2017;27(1):16-22. doi:10.1684/mst.2017.0648

A. Incidence du cancer du col en Afrique (2012)



B. Estimation du nombre de nouveaux cas de cancer du col en 2012 et 2030



Vaccine Preventable Diseases

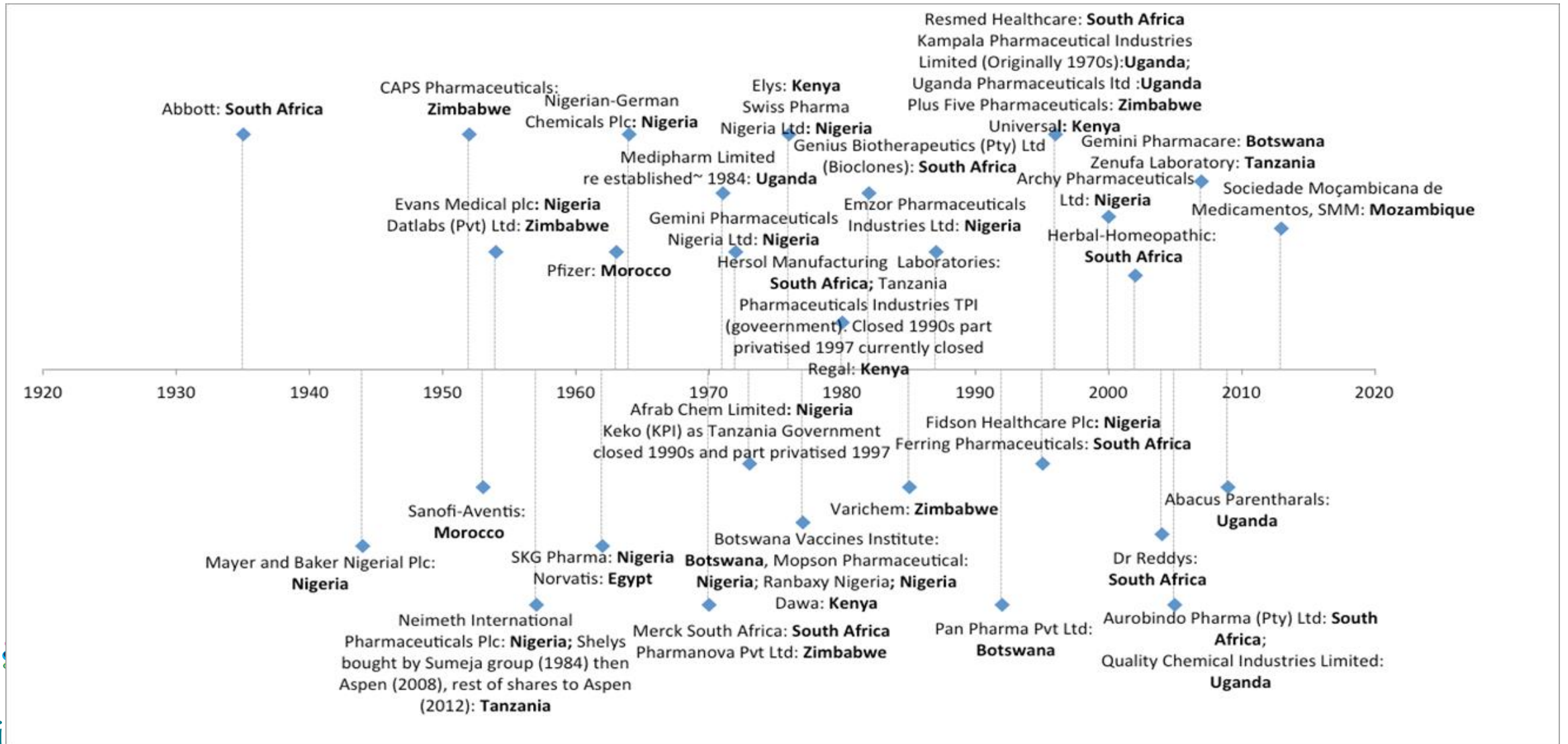
- Mumps
- Pertussis (Whooping Cough)
- Pneumococcal Infections
- Polio
- Rotavirus
- Rubella (German Measles)
- Tetanus
- Varicella (Chicken Pox)

- Diphtheria
- Haemophilus influenza type b (Hib)
- Hepatitis A
- Hepatitis B
- Human Papillomavirus (HPV)
- Influenza (Flu)
- Measles
- Meningococcal Infections

Four Pillars of Medicine

- Small Molecules - Drugs ✓
- Biologics
 - Vaccines ✓
 - Biological products ✗
- Medical Devices ✗
- Regenerative Medicine
 - Cell Therapies ✗
 - Gene Therapies ✗
 - Immunotherapies ✗

Evolution of African Pharmaceutical Manufacturing



Why do Vaccine Enterprises Fail?

- History of South African Vaccine Manufacturing

- State Vaccine Institute: Est 1965

- BCG, Rabies, Smallpox

- SAIMR: Est 1935

- DPT, Polio, Cholera/Typhoid

- National Institute of Virology: Est 1950s

- OPV, Yellow Fever

Collapsed between 1995-2001



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Need for Sustainable Innovation Ecosystems

- Support the value chain gaps
- Innovation Anchors
- Innovation Brokers
- Proportionate and Adaptive Governance of Innovative Technologies
- De-Risking of emerging technologies and early investment stages
- The innovation principle