

# HBV INFECTION RATES IN SANBS BLOOD DONORS BORN BEFORE AND AFTER THE IMPLEMENTATION OF UNIVERSAL HBV VACCINATION



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# Background



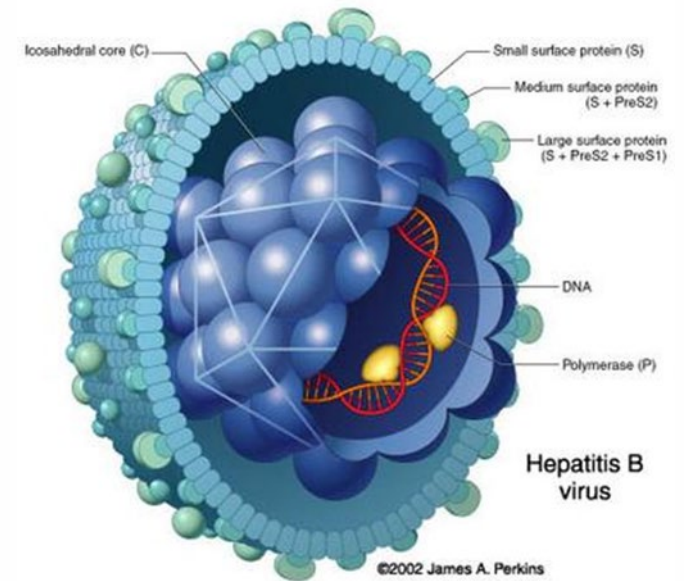
- Hepatitis B is a potentially life threatening infection of the liver caused by the Hepatitis B Virus (HBV)
- There are:
  - over 2 billion people living with hepatitis B worldwide
  - 250 – 400 million chronic carriers
- Hepatitis B is endemic in South Africa (SA) with more than 70% of the population exposed and 2.5 million chronic infections



# Background



- Even though it is a vaccine preventable disease, it remains one of the main causes of liver related diseases
- An estimated 25% of chronic carriers are expected to die from cirrhosis or hepatocellular carcinoma



# HBV Vaccination in SA



- In April 1995, SA incorporated universal hepatitis B vaccination into the Expanded Programme on Immunisation (EPI)
- Newborns received vaccinations at 6, 10, and 14 weeks of age
- Currently no birth dose vaccine



# Vaccines



- Vaccines used:
  - 1995 – 1999: Plasma derived vaccine\* - Hepaccine B vaccine
  - Later switched to genetically engineered recombinant HB vaccines shown to be more immunogenic in the South African setting\* - Engerix-B, Heberbiovac HB
  - Currently using combination vaccines
    - diphtheria, tetanus, acellular pertussis, poliomyelitis, *Haemophilus influenzae* b and Hepatitis B\*\* - Infanrix Hexa® and Hexaxim®

# Vaccine Coverage



- Vaccine coverage in SA and Africa  
(estimates by WHO)\*

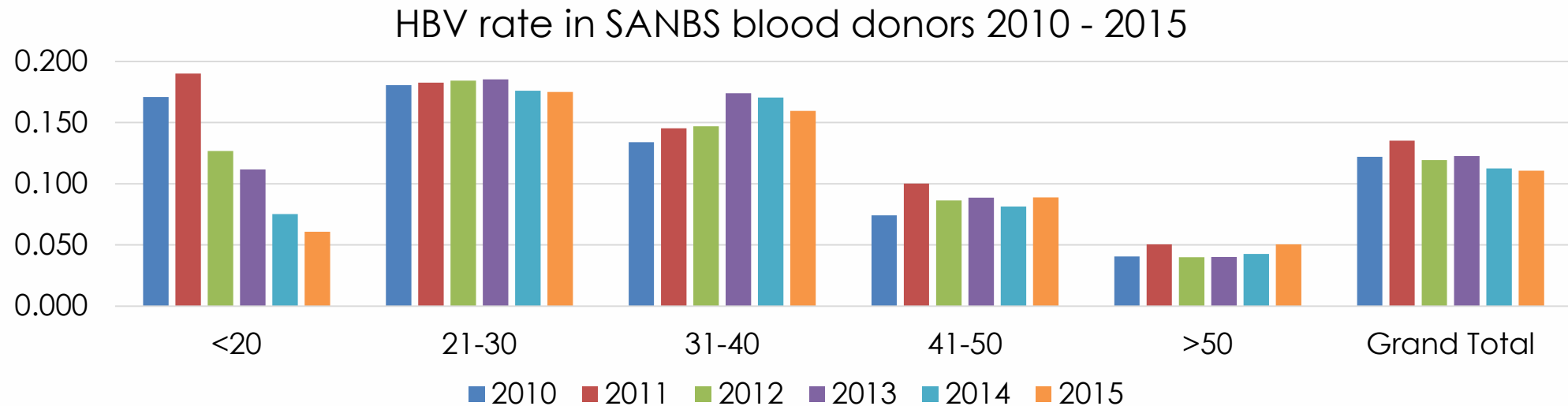
Country	Year of introduction	2011 (%)	2015 (%)	Administered
South Africa	1995	<b>76</b>	<b>71</b>	6,10,14 weeks
Botswana	1995	95	95	0,2,3,4 months
Gambia	1990	96	97	0,2,3,4 months
Burkina Faso	2006	91	91	8,12,16 weeks

\*Breakwell et al. Pan African Medical Journal (2017)

# Background: Donors



- SANBS collects in excess of 800 000 units of blood annually from 8 of the 9 provinces in SA
- Infants vaccinated in 1995 became eligible to donate blood in 2011 at the age of 16
- A decrease in the HBV rate in blood donors aged 16 – 19 years was noted between 2011 and 2015



# Aims



In **First Time** blood donors **< 20 years of age** in **2010** (probable non-vaccinated donors) and **2015** (probable vaccinated donors)

- compare HBV infection rate
- compare rate of HBV Serology Yields (SY)
- compare rate of HBV Nat Yields (NY)
  - Broken down into
    - Vaccine breakthrough
    - Window Period





# Methods

- All donations were screened for
  - Hepatitis B Surface Antigen (HBsAg)
    - Abbott Prism (Wiesbaden, Germany)
  - HBV DNA
    - Procleix TIGRIS (Grifols, Barcelona, Spain)
      - Ultrio assay - 2010
      - Ultrio Plus assay (with improved HBV sensitivity) - 2015
  - No routine screening for anti-HBc or anti-HBs
- HBV positive rates were analysed by gender and population group in first time donations from
  - 2010 (probable non-vaccinated donors) and
  - 2015 (probable vaccinated donors)
- Significance was determined using Chi square statistics



Abbott Prism



Procleix Tigris



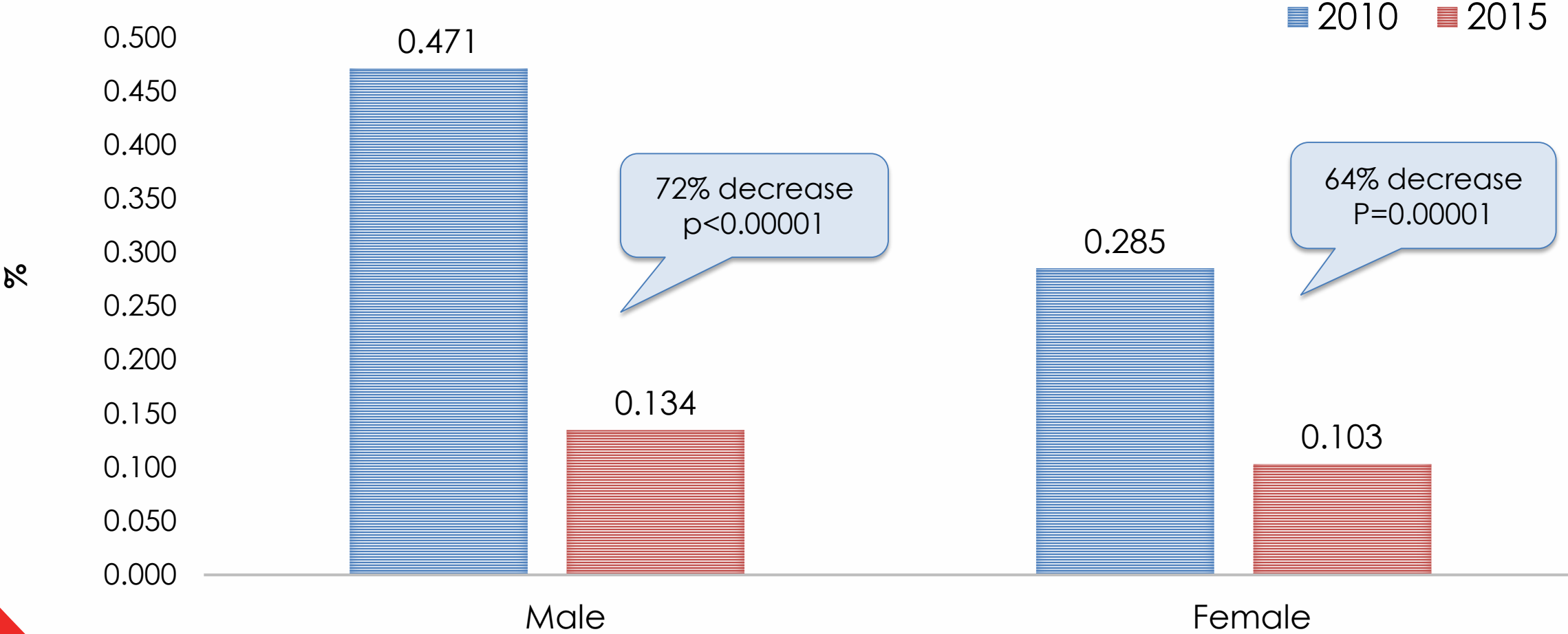
# Results - First Time Donors < 20 Years of Age in 2010 and 2015



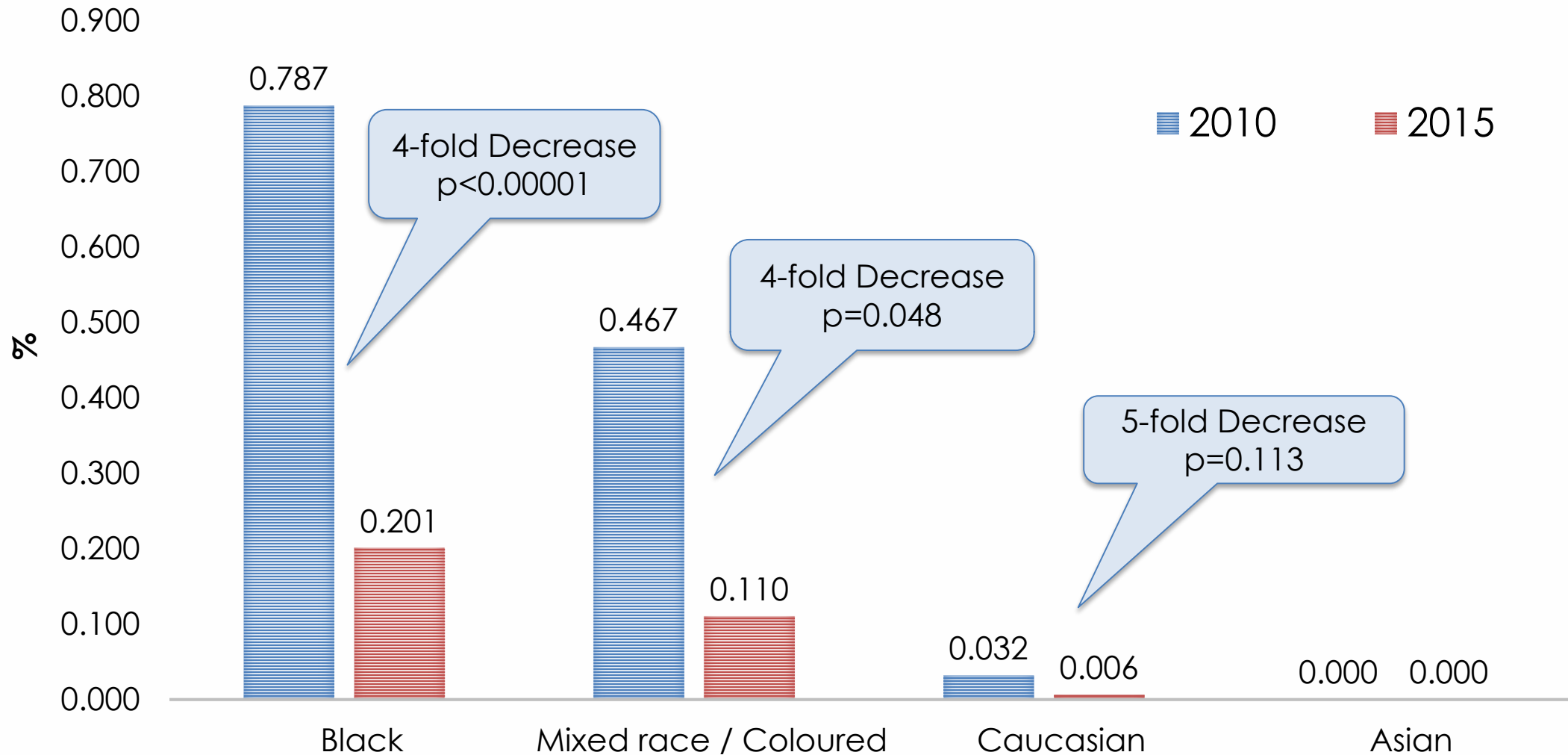
	TOTAL		2010		2015		% Difference	p value
	Number	%	Number	%	Number	%		
<b>Collections</b>	<b>91,540</b>		44,514		47,026			
<b>HBV Positives</b>	223	0.24	168	<b>0.38</b>	55	<b>0.12</b>	<b>-69</b>	p<0.00001
<b>Confirmed Positive HBV DNA + / HBsAg +</b>	201	0.22	157	<b>0.35</b>	44	<b>0.09</b>	<b>-74</b>	p<0.00001
<b>NAT Yield (NY) HBV DNA + / HBsAg -</b>	18	0.020	7	<b>0.016</b>	11	<b>0.023</b>	<b>49</b>	p=0.55
<b>Serology Yield (SY) HBV DNA - / HBsAg +</b>	4	0.004	4	<b>0.01</b>	0	<b>0.00</b>	<b>-100</b>	p=0.12



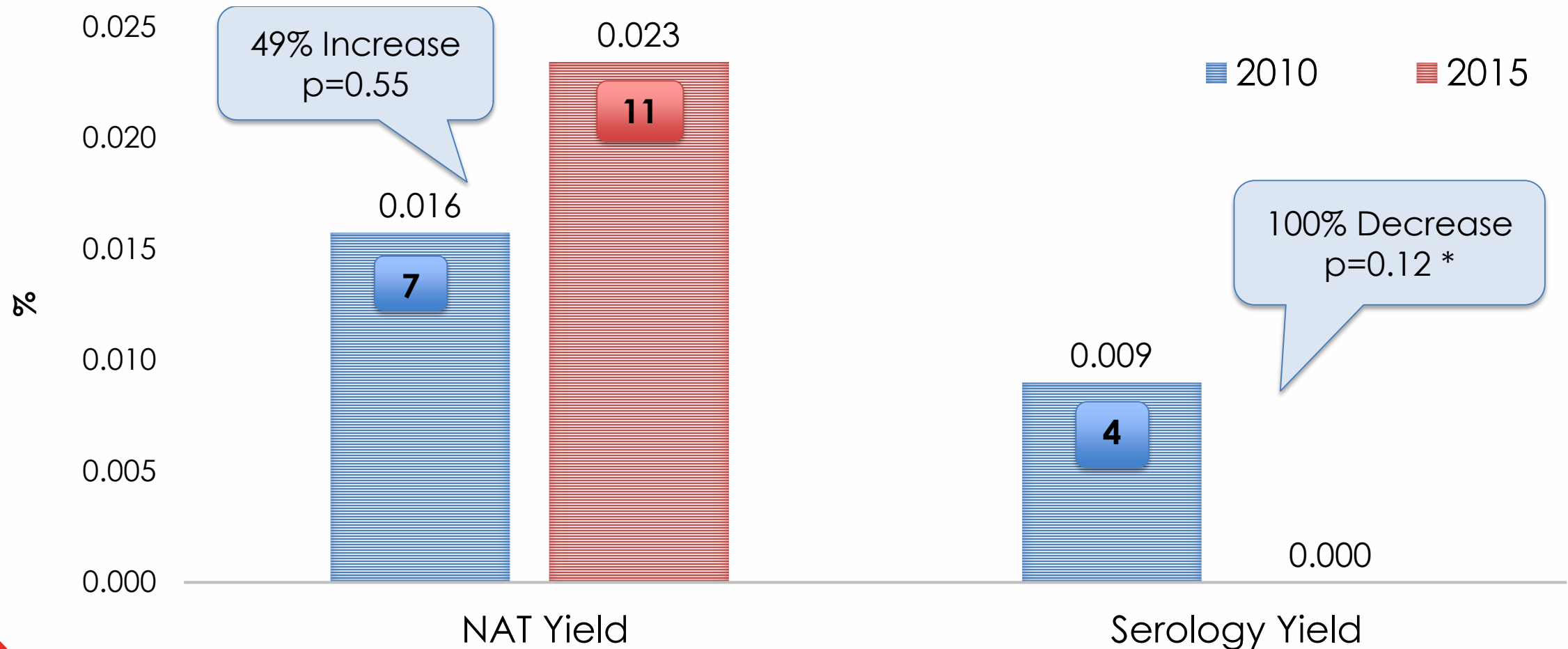
# HBV Rate in First Time Donors < 20 years of age in 2010 and 2015 by Gender



# HBV Rate in First Time Donors < 20 years of age in 2010 and 2015 by Population Group



# HBV NAT & Serology Yields in First Time Donors < 20 years of age in 2010 and 2015



\*Increase in NY due to increased sensitivity of NAT Assay in 2015



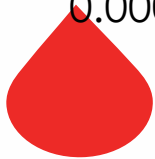
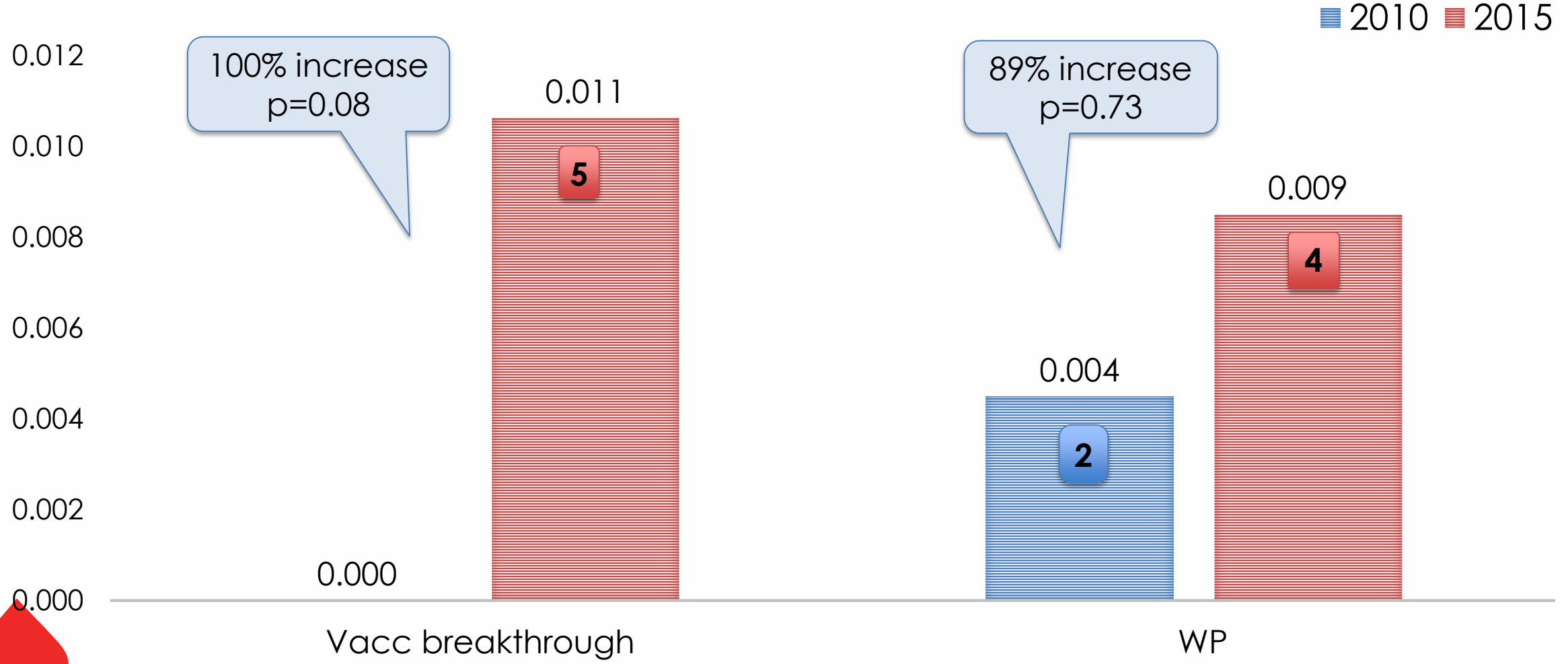
# Categories of HBV NAT Yields



- HBV NAT Yield: HBV DNA + / HBsAg –
  - Additional testing performed including anti-HBc, anti-HBs titre and viral load,
  - The donor is contacted to request a follow-up sample
- Broken down into 2 categories
  - **Window period (WP)**
    - Seroconversion (HBsAg or anti-HBc) confirmed on a follow-up sample or
    - Repeat NAT reactivity in index donation plasma bag
  - **Potential Vaccine breakthrough**
    - Anti-HBs booster effect (anti-HBs titre increase from index donation to follow-up) with anti-HBc seroconversion on follow up and repeat NAT reactivity in index donation plasma bag



# Breakdown of HBV NAT Yields in First Time Donors < 20 years of age in 2010 and 2015



# Discussion



- HBV rates in first time blood donors < 20 years of age decreased by **69%** from
  - 2010 (probable non-vaccinated) to
  - 2015 (probable vaccinated)
- There was a significant decrease in HBV rate in both male and female donors between 2010 and 2015
- The decrease was slightly greater in male donors possibly due to greater impact of the vaccination program on male donors who started with a higher prevalence in 2010





# Discussion



- The decrease in HBV rate was slightly greater in White donors as compared to Black and Coloured donors
  - Insignificant due to small sample size and
  - Impact was much bigger in the Black and Coloured donors due to the higher baseline HBV prevalence
- The **89%** increase in **Window Period** donations from 2010 to 2015 is most likely due to the improved sensitivity of the NAT assay with the change from the Ultrio to the Ultrio plus assay in 2011



# Discussion



- The emergence of **vaccine breakthroughs** in the probable vaccinated donors in 2015 could be due to factors such as \*
  - Lack of immune response following vaccination or delayed vaccination
  - High maternal viral load or intrauterine infection
  - Vaccine escape mutants
  - Genotype
    - Vaccine parent strain genotype A2\*\*,
    - South African population - 90% genotype A1, 10% genotype D
  - Waning of immunity over time in young donors vaccinated at birth resulting in antibody levels being reduced below protective levels



# Conclusion



- More work in the area is required including performing **anti-HBs titre** and **anti-HBc testing** on HBsAg and HBV DNA negative donors in order to conclude that the decline in HBV rates in young blood donors is related to the implementation of universal HBV vaccination in SA (*study in progress*)
- The **69% decrease in HBV rate** in younger blood donors demonstrates the public health benefit of improved access to health care in terms of the introduction of HBV vaccination in South Africa



Thank you

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