DEMOGRAPHICS

- Zimbabwe now has about 13 million people of which about 6.7 million are females.

- 3,246,000 women of reproductive age 15 – 49yrs.

ZDHS 2010 -2011
Current Use of Family Planning

Percent of currently married women age 15-49

- Currently married women
- Sexually active unmarried women

<table>
<thead>
<tr>
<th>Method</th>
<th>Currently married women</th>
<th>Sexually active unmarried women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any modern method</td>
<td>57</td>
<td>62</td>
</tr>
<tr>
<td>Injectables</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Implants</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Pill</td>
<td>41</td>
<td>18</td>
</tr>
<tr>
<td>Male condom</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>Any traditional method</td>
<td>1</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>
Historical Background

1991 – 1993: Norplant introduced to Zimbabwe – Pre-introduction acceptability study in 200 participants. All insertions performed by 2 clinicians trained by Population Council.

1993 – 2003: Regular training courses for Doctors and Clinical officers at least once every year

October 2002: Norplant phased out and replaced by Jadelle which is now the only contraceptive implant in use.
HISTORICAL BACKGROUND

- Since 2003
- **Project A15229**
  Multi-centre randomized clinical trial of two implantable contraceptives for women: Jadelle and Implanon
- Objectives:
  - Compare the annual and 3-year cumulative rates of method continuation of Jadelle and Implanon
  - Compare the contraceptive effectiveness of Jadelle and Implanon
  - Compare the incidence of adverse effects between women using implant contraceptives and women using a non-hormonal contraceptive method (Copper IUD)
Jadelle

- Conception inhibiting levels reached within 24 hours
- Serum Levonorgestrel release rate in mcg/day
  - Month one 100
  - within one yr 40
  - about 25-30 in 5th yr


Sivin, Wan, Ranta et al 2001. Contraception 64(1) 43-49
**Jadelle:**

**Mechanism of action**

- Inhibits ovulation in 50% the cycles.
- Thickens cervical mucus - inhibits sperm penetration
- Endometrial growth distortion - prevents successful implantation.
- Reduction of progesterone levels by half - prevents successful implantation.

- Brache et al 1985
- Croxatto et al 1987
- Dunson, Blumenthal 1998
PREGNANCY AFTER INSERTION

- **N** = 200
- Only two pregnancies after 12 months follow up.
- Circumstances indicate not really Norplant failure
Jadelle: Recommended time for insertion

Current Method
• Natural Family Planning
  - Within the first **7 days** of menstruation

• Combined pill
  - after the last active 21 pills - during the **next 2 days**.

• Norplant
  - at removal of the capsules

• Progestogen only pill
  - on the last day the last pill is taken
Jadelle: Recommended time for insertion (cont.)

- IUCD
  - anytime but the IUCD should be left in place for 7 days after Jadelle insertion
JADELLE/ PREGNANCY SUMMARY

- Jadelle is a highly effective reversible contraceptive.
- The cumulative pregnancy rate in clinical trials was 0.3 for three years and 1.1 percent for five years.
- Has a lower failure rate than the pill and most IUDs.
- Efficacy is comparable to that of surgical sterilization.

  - Population Council data submitted to the FDA, 2001,
Pregnancy

- Rate of ectopic pregnancy for implants: 0.4 per 1000*
  - Baseline rate 2.7 per 1000 (Franks, 1990)
- If a patient becomes pregnant, MORE likely to be an ectopic pregnancy
  - Early ultrasound to assess location of pregnancy
- With time, the risk of pregnancy increases
- No association of Norplant with congenital abnormalities identified

*among 600 Jadelle users
Menstrual Bleeding Disturbances

Norplant and Jadelle
- Prolonged and irregular bleeding
- Spotting between periods
- No bleeding at all
- Decrease in severity of disturbances over time

Implanon
- Infrequent bleeding and amenorrhea
Progestin Implant: Side Effects

- **Bleeding:** “Irregularly irregular” (40%)
  - Amenorrhea: 22%
  - 7% frequent: > 5 B-S episodes in 90-day period
  - 18% prolonged: at least 1 B-S episode > 14 days
  - 20% have B-S for >50 days in first 90-day period
  - Generally NOT heavy

Implant: Bleeding Treatment

- Estrogen reduces number of bleeding days with 6-rod implant (and DMPA)
  - 50 mcg **Ethinyl Estradiol** x 14-21 d
- Mifepristone reduces number of days
  - Plus 20 mcg EE
- NSAIDS – mixed results
  - **Ibuprofen 800mg po TID x 5 d**
  - Mefenemic acid 500 mg po BID x 5 d
  - Aspirin 80 mg po qd x 10 d
14 Years of contraceptive implants in Zimbabwe – Lessons Learnt

Prof. J. Kasule, Uganda Conference  2007
Continuation Rate

- After 1 year = 94%
- After 2 years = 90%
- After 3 years = 88%
- After 4 years = 88%
## Reasons for discontinuation before 2 years

<table>
<thead>
<tr>
<th>Reason</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prolonged bleeding</td>
<td>28</td>
</tr>
<tr>
<td>Planning pregnancy</td>
<td>26</td>
</tr>
<tr>
<td>Headaches &amp; dizziness</td>
<td>8</td>
</tr>
<tr>
<td>Weight gain</td>
<td>7</td>
</tr>
<tr>
<td>Amenorrhoea</td>
<td>5</td>
</tr>
<tr>
<td>Breakthrough bleeding</td>
<td>4</td>
</tr>
</tbody>
</table>
WEIGHT GAIN

- No weight gain in Norplant users at year one review

- Average 9 pounds (4 kgs) over 5 yrs.
  - Population Council Data

- Weight: minor changes (2.3%)
  - Mean weight gain = 1.7 kgs at year 2
  - No weight gain compared with controls
    - Blumenthal Eur J Contracept Reprod Health Care, 2008
    - Mansour Eur J Contracept Reprod Health Care 2008
REPORTED MEDICAL CONCERNS

- Risks of developing gallbladder disease (1.5x) and hypertension or borderline hypertension (1.8x) in women using levonorgestrel implants than in women not using hormonal contraception.

- Population Council, Center for Biomedical Research, New York, New York 10021, USA. sivin@popcbr.rockefeller.edu
OTHER REPORTED MEDICAL CONCERNS

- Levonogestrel implant users compared to women not using hormonal contraception had more
  - headache,
  - upper limb neuropathies,
  - dizziness, nervousness,
  - malaise,
  - minor visual disturbances,
  - respiratory conditions,
  - arthropathies,
  - Anxiety

Population Council Clinical Trials Data, Center for Biomedical Research, New York, New York 10021, USA.
ANATOMY OF UPPER ARM
INSERTION TECHNIQUE

- Local anaesthetic
- Insert trocar and plunger
- Withdraw plunger
- Insert Implants
- Pressure bandage
COMPLICATIONS SITE OF INSERTION

- Local infection
- Local swelling oedema and discomfort
- Infection at the insertion site occurred in 0.4 percent of women over five years. Attention to aseptic technique and proper insertion and removal of Jadelle rods reduce the possibility of infection.
- Population Council Clinical Trials data, Centre for Biomedical Research, New York, New York 10021, USA.
COMPLICATIONS AT SITE OF INSERTION-1

- Bruising, Cellulitis and Scarring
- Discolouration, usually reverses after removal
- There have also been reports of arm pain, numbness, and tingling following placement.
- Implant expulsion
  - Population Council, Center for Biomedical Research, New York, New York 10021, USA.
REMOVAL TECHNIQUE

- Local anaesthetic
- Small stab wound with a scalpel
- Use mosquito forceps
- Pressure bandage
DIFFICULT REMOVALS

- Removal complications or difficulties were reported in 1.5 percent of users overall.
- Included broken implants, displaced implants with prolonged removal times, multiple or long incisions.
- Nerve injury with Norplant, most commonly associated with deep placement and removal.
Conclusions

Advantages
- Long-acting, convenient, and reversible
- Highly effective and safe
- Efficacy is independent from compliance

Disadvantages
- Menstrual bleeding disturbances
- Surgical procedure for insertion & removal
- Provider-dependency of the method which can be mitigated through appropriate training of personnel.
MY VERY LAST WORDS.....

THOSE WHO WERE SLEEPING CAN OPEN THEIR EYES NOW !!