Jadelle® Levonorgestral Rod Implants: Profile and Lessons

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Client Needs and Program Challenges

- Demand for contraception will increase by 22% (618 to 754 million users) by 2020
- In developing countries, 137 million women want to avoid pregnancy but are not using a modern method
- In sub-Saharan Africa, only 17 percent of 35 million women who want to stop or delay childbearing are using LA/PM

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Ross et al, 2005; Pile, 2007

Client Issues with Implants

- Safe and effective contraception
- Both spacing and limiting
- Reversible, reliable and convenient
- Cost-effective service
- Offers no protection against STI/HIV
- Counseling and skilled provider required for insertion and removal
- Upfront costs may be high

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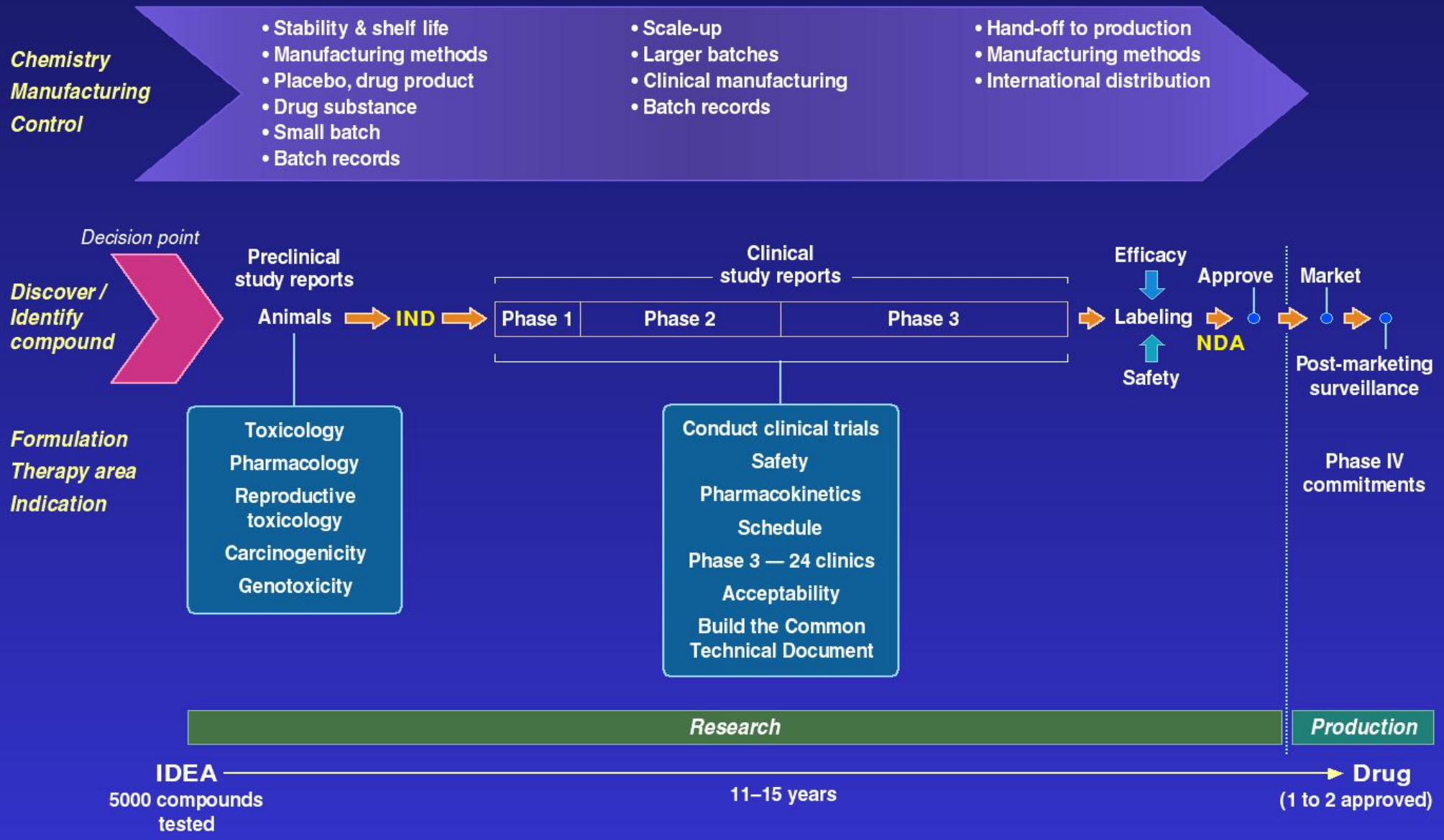
The Drug Development Process



30 Years for Development of Norplant® and Jadelle® Implants

- In 1966 an idea for continuous release of progestin (LNG) from silicone capsules
- In 1974 first clinical trials with 6 silicone capsules
- In 1983 Norplant production licensed to Leiras Oy, approved in Finland and clinical trial with two rods
- FDA approved Norplant in 1990, Jadelle in 1996
- Support from Population Council, ICCR, Wyeth-Ayerst Labs, Leiras Oy, Mellon Foundation, NIH, UNFPA, WHO and USAID

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Jadelle® Characteristics

- Long-acting 5 year reversible contraception (75 mg LNG/rod)
- 30-40 µg/day released daily
- Pregnancy rate: 0.1% at 1 year,1.1% at 5 years
- Continuation: 88, 61 and 44% at 1, 3 and 5 yrs, average use 3.35 years
- Action: Inhibition of ovulation and thickening of mucous

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Clinical Practice

- Physicians, nurses can be trained as providers
- Counseling critical for choosing method and removal
- Using trocar and aseptic procedures, provider inserts rods under the skin of inner upper arm
- Protection from pregnancy within 24 hours and return to fertility is rapid when implants removed
- Common side effects are menstrual irregularities, often less blood loss per cycle

Lessons from 30 Country Pre-introductory Experiences

- Program assessment should precede Jadelle® and any other new method introduction
- Jadelle® provision should expand method choice and focus on ethically meeting woman's needs
- Participation of stakeholders key to acceptance
- Counseling critical as is accurate information for clients, providers and community

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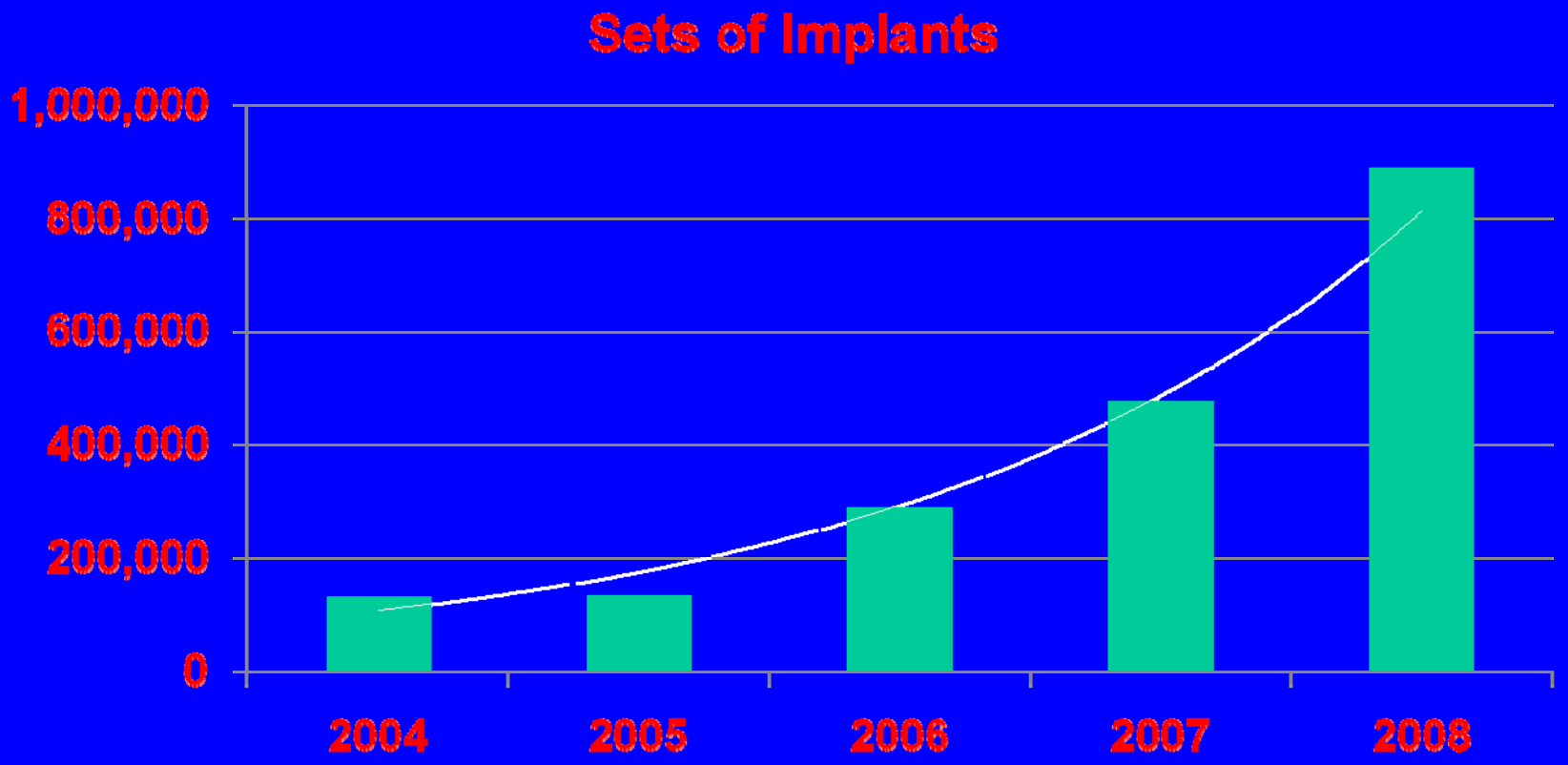
Lessons Learned (cont)

- Providers must be trained in insertion and removal of implants and management of side effects
- Supervision and evaluation needed for quality of care
- Women must have access to removal on demand or when approved duration of use is reached
- Transition to new implants is manageable

Growth in Procurement of Implants 2004-2008



RH Interchange, 2009

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Current Status of Implants

- Approved in more than 60 countries, including US, and more than 10.5 million women have used implants
- Jadelle® manufactured and marketed by Bayer Schering Pharma, AG
- WHO prequalification for Jadelle® pending
- Price to clients depends on procurement costs (about US$20) and client charges/subsidies
- In 2008 over 886,200 sets of implants procured at cost of about $20.6 million by 10 sources

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Resources

- Sivin, I, H Nash and S Waldman, Jadelle® Levonorgestrel Rod Implants: A Summary of Scientific Data and Lessons Learned from Programmatic Experience, Population Council: New York, 2002
- http://www.popcouncil.org/pdfs/jadelle_monograph.pdf

- Reproductive Health Supplies Coalition, RH Interchange
- http://www.rhsupplies.org/resources/rhinterchange.html

- Global Health Technical Briefs, USAID
- http://www.maqweb.org/techbriefs/tb43implants.shtml

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