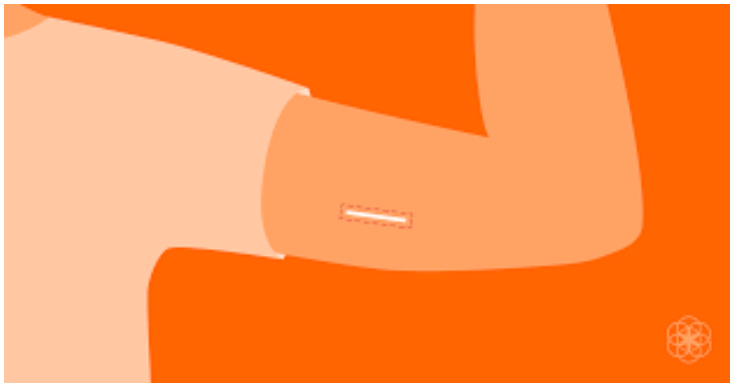
Placement of Implanon NXT at alternative sites for vulnerable persons



Clinical A/Prof Deborah Bateson
Medical Director Family Planning NSW

Family Planning NSW is a not-for-profit organisation funded by the NSW Ministry of Health

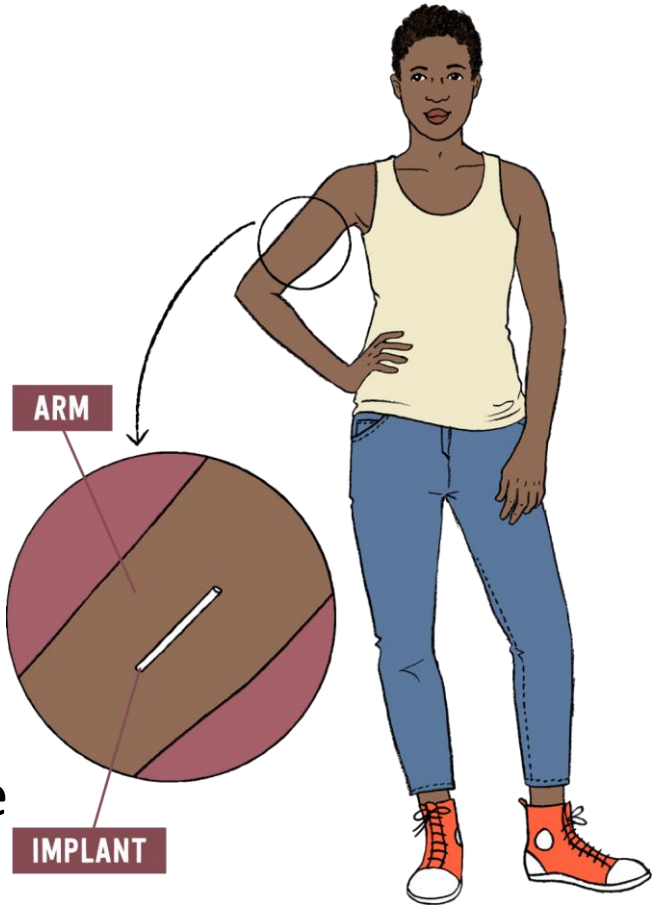
family planning nsw
Reproductive & Sexual Health

Placement of Implanon NXT at alternative sites for vulnerable persons

Upper inner non-dominant arm site carefully considered to:

- allow for easy access during insertion and removal
- easy recognition of the device around the globe
- minimise the risk of neurovascular injury

Clinical trials of safety, efficacy, side-effects and acceptability only performed for the licensed site



Placement of Implanon NXT at alternative sites for vulnerable persons

FPOs occasionally asked about alternative placement sites for vulnerable women resulted in 2015 position statement:

- **Lack of evidence for alternative sites**
- **Lack of experience amongst experts around the globe**

Risks include potential for deep placement and difficult removal, migration, breakage and injury to surrounding neurovascular structures

Placement of Implanon NXT at alternative sites for vulnerable persons: 2015 FPAA statement

- FPAA lends cautious support where benefits outweigh any potential risks
- Understanding of local anatomy imperative
- Differences in efficacy (and side-effects) unlikely but cannot be guaranteed
- Client must be aware it is ***off label***

FAMILY PLANNING ALLIANCE AUSTRALIA

'FPOs would be grateful for practitioners to share their experiences…..'

Practitioner experience and expert opinion

- Two Australian clinicians reported experience with subdermal insertion in upper thigh near buttock
- WA clinician:

➢ **report of teenager from remote community seen with subdermal implant in lower lateral abdomen ('just below bikini line')**

➢ **insertion of device in similar site for 15-year old (separated parents; girl and mother afraid to tell father; later (easy) removal due to bleeding)**

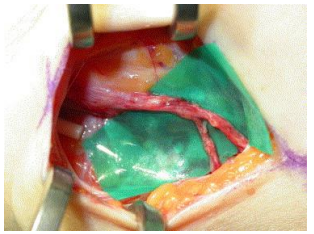
➢ **similar placement discussed with 21-year old with complex medical history**

- Plastic surgeons published concerns with chosen site for placement in the arm

Suggested:

➢ Median supraumbilical region

➢ Medial side of the thigh

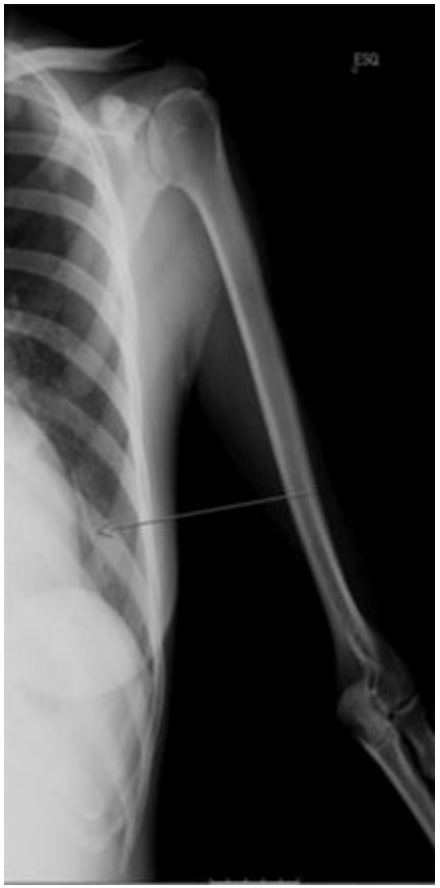


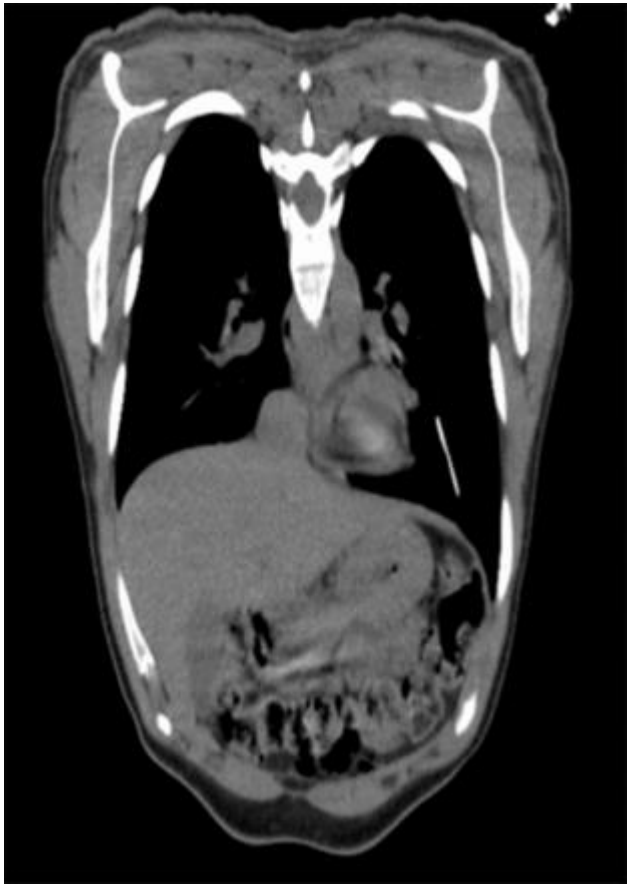
Wechselberger G et al. Nerve injury caused by removal of implantable contraceptive. Am J Obstet Gynecol (2006)

GOV.UK

June 2016

- rare reports of implants reaching the lung via the pulmonary artery
- approx 1.3 per million implants sold worldwide
- potential risk factors include:
  - **deep insertion**
  - **insertion in an inappropriate site**
  - **insertion in thin arms**

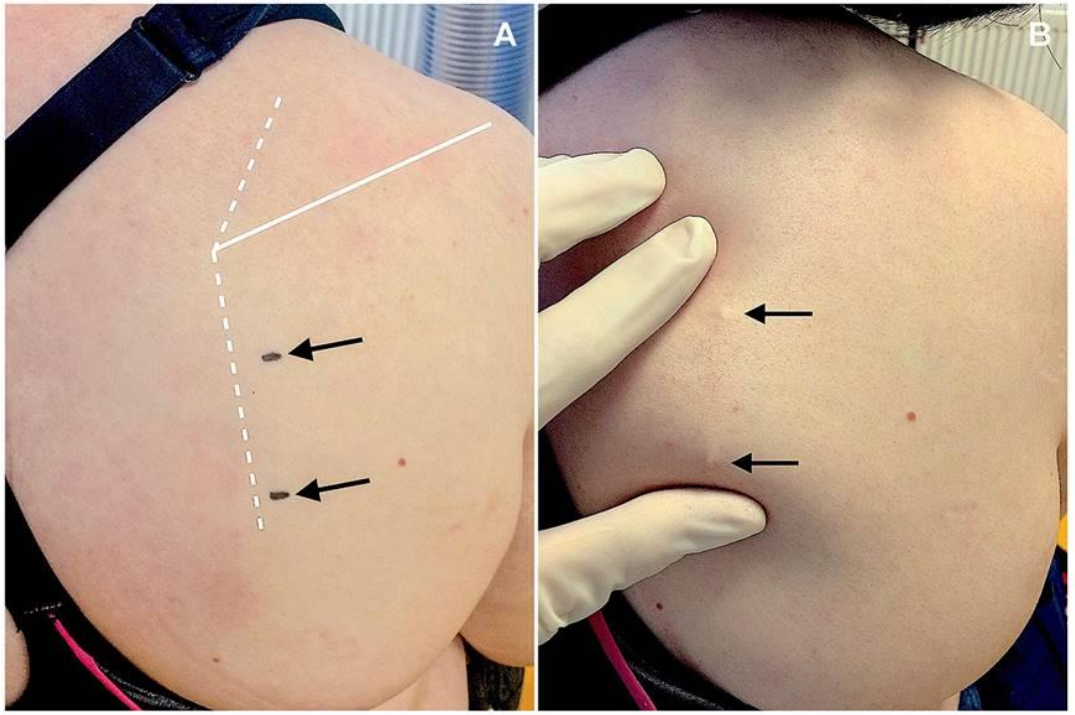




BMJ case report 2019 Carlos-Alves et al.

Placement of Implanon NXT at alternative sites: published 2018 case study in scapular region

- Site chosen to reduce risk of self-removal in a woman with a chronic psychotic illness
- 23 years, BMI 35
- Good clinical results and appropriate serum ENG levels at 4m (194 pg/ml)
- **"an interesting alternative for those not eligible for the arm"**



(**A**)Delineation of the scapular insertion site before etonogestrel contraceptive implant insertion (dark marks on the skin with black arrows): below the scapular spine (white line) and close to the medial border of the scapula (white dashed line), two anatomical landmarks easy to locate by palpation. The implant was inserted vertically (bottom to top). (**B**) Etonogestrel contraceptive implant 6 months after insertion in the scapular site (black arrows).

Taken from Pragout et al,. (2018)

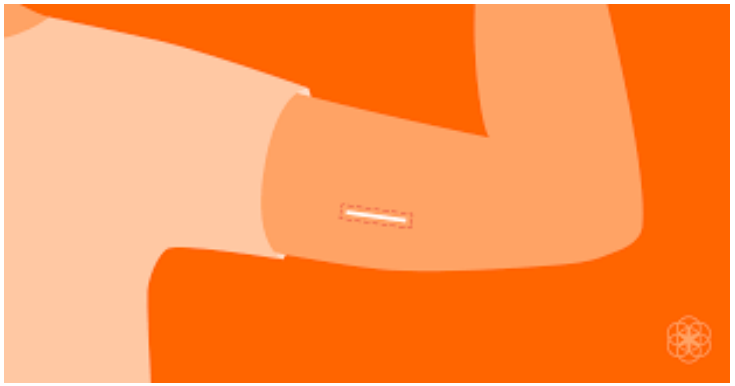
Brief Communications/European Journal of Obstetrics & Gynecology and Reproductive Biology 224 (2018)

Alternative implanon NXT sites for vulnerable persons: summing up

- Shared decision-making imperative
- Consider discrete alternatives including DMPA
- Clear documentation essential
- Please share your experiences….

CHILDREN BY CHOICE
ASSOCIATION INCORPORATED

Premenarchal implant discussions



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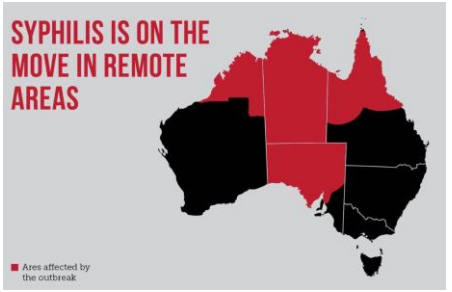
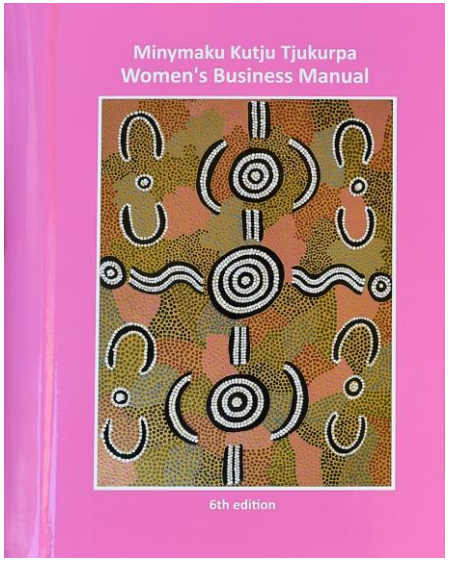
Premenarchal implant discussions

- Advice sought (2016) re insertion for vulnerable pre-menarchal girls at risk of pregnancy prior to a next visit to a health care practitioner

"general atmosphere seemed to be one of being overwhelmed"

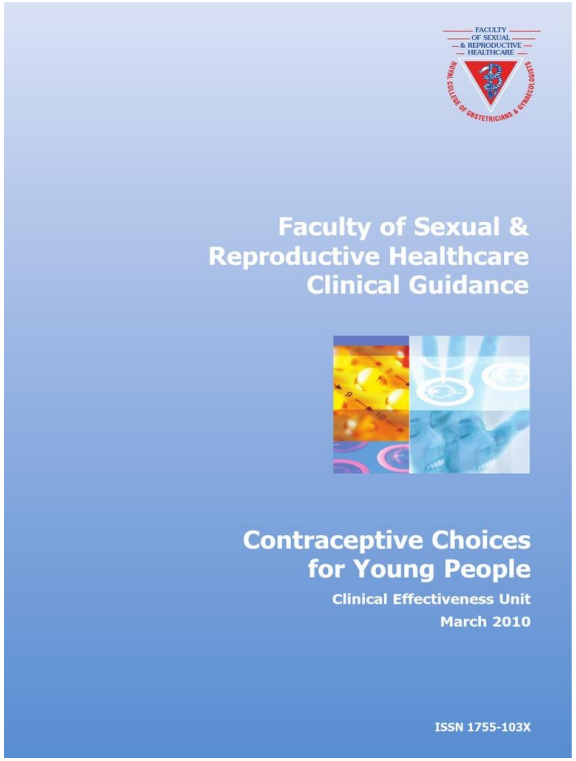




Premenarchal implant discussions

The CEU does not support the use of regular hormonal contraception prior to menarche and recommends advising use of condoms to young people requiring contraception before this time. PO emergency contraception can, however, be given to premenarchal women if required.

- Consultations with broad range of national and international experts
- Weighing up potential harms vs 'not doing anything'
- Clinical, social and ethical considerations



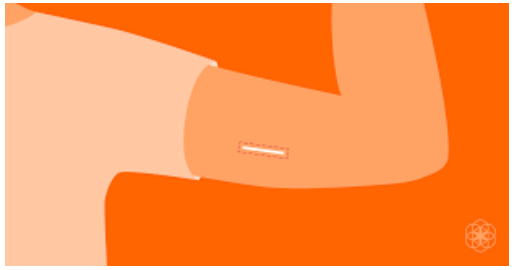
Premenarchal implant discussions: clinical considerations

Clinical data lacking……

- Possible effect on peak bone mass, bone development and final height?
- Is Tanner staging useful to predict first ovulation?
- Is there a risk of masking delayed puberty (hormone test on removal?)
- Long term effect on future menses and fertility ?
- **Can the clinical effects be separated from the social/ethical considerations?**

Premenarchal implant discussions: social and ethical considerations

- Anecdotally girls almost always brought by family members
- Gillick competency: individual control paramount, competence and consent **must be addressed**
- Poor human rights history of forced DMPA **cannot be ignored**
- Confidentiality in close-knit communities **can be limited**
- Potential for increased harm through shaming/sexual assault must be considered
- Mandatory reporting obligations **must be met**



Premenarchal implant discussions: national and international expert discussions

- Prof Bill Ledger:

  consider on a case by case approach (advice should not be 'institutionalised')

- Dr Sarah Traxler IPPF:

  generally no hesitation around 12+ years regardless of 1st menses (assuming consent and considering the circumstances in which sexual activity was occurring)

IPPF International Planned Parenthood Federation

Premenarchal implant discussions: national and international expert discussions

- Mina Barling IPPF:

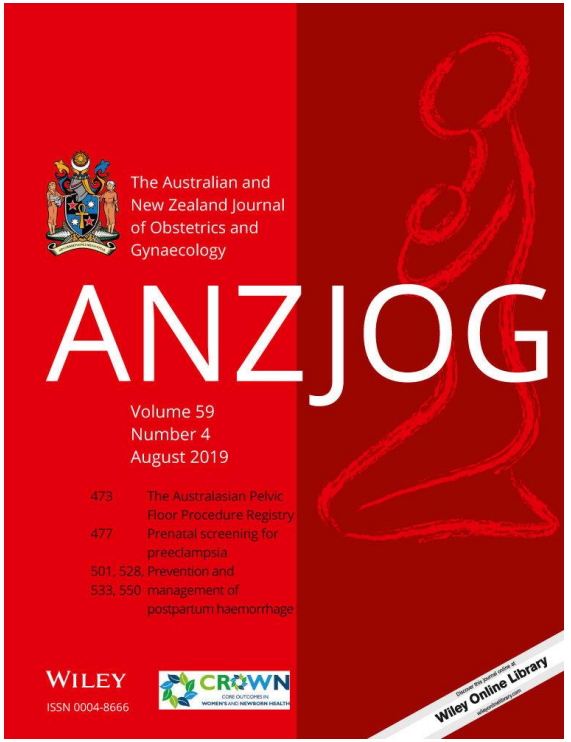
➢ *potential for individual decisions with case by case discussions between the provider and the adolescent (plus guardian (if safe)) within context of an ethical community-led framework*

➢ *encourage dialogue to move away from a single method, to avoid becoming method focused and could mean conversations re male/female condoms, emergency contraception are overlooked…*

IPPF International Planned Parenthood Federation

Premenarchal implant discussions: where to from here

- Continue community consultations
- Use this opportunity to address gaps in comprehensive sexuality education and SRHR within the context of a harm minimisation framework
- Continue advocacy around condom use and emergency contraception
- Letter to the Editor of ANZJOG under consideration



Premenarchal implant discussions

- Dr Jacqui Murdoch, FPNT
- Dr Paul Rivalland, FPNT
- Dr Sarah Traxler, Medical Director IPPF Minnesota, North and South Dakota
- Mina Barling, Director, External relations IPPF
- Prof William Ledger, UNSW