THE ROYAL AUSTRALIAN COLLEGE OF GENERAL PRACTITIONERS
COUNCIL PAPER

IMPLANON: Standards Setting And Risk Management

Background

The contraceptive device, Implanon, became available in Australia in May 2001. It is an efficient and comparatively reliable form of contraception. The decision of one medical defence organisation (MDO) to recognise implanon as a procedural activity has significant access and financial implications for patients and general practitioners.

The RACGP recognises that the insertion of implanon and the introduction of new technologies into general practice needs to be considered from a systematic quality care, a patient access and a risk management perspective.

The RACGP makes the following recommendations in relation to ongoing education and training in relation to the introduction of new technologies and specific recommendations in relation to implanon:

Specific Issues: Implanon Training

1 **Quality of Training:** General Practitioners should undertake regular upskilling and education to support the introduction of new technologies. Training needs to take account of the context within which it will be delivered. Training the GP in the specific skill is insufficient: training must consider the practice setting, and provide sufficient supports for safe service provision.
2 **Balkanising General Practice:** With increasing new technologies available to general practice, the requirement for training will increase. The QA&CPD program may need to consider how these new training requirements impact on the generalist and relatively undifferentiated program currently offered. While acknowledging the complexity of competence and upskilling assessment, it may be appropriate to consider, for example, core competency training and ancillary areas.
3 **Medico-Legal Impact**: General Practitioners may be less willing to provide new technology services if MDOs categorise them as procedural services, hence attracting a higher premium.
4 **Access:** Placing significant restrictions on new technologies, could lead to fewer GPs offering the service and patient access reduced. Some services may only be available from specialists, further reducing access.

The Briefing Paper attached outlines these issues in greater detail.

Recommendations: General

1. General Practitioners have a professional obligation to provide safe and effective services within their level of competence.
2. General Practitioners have a professional obligation to continually upgrade their competency skills.
3. Education and training for general practitioners and general practice staff should take a ‘whole of system’ approach, not just a practitioner training model. Education and training must, at a minimum, provide specific practitioner and practice setting instructions for all new services or techniques introduced.

Recommendations: Implanon

1. GPs must undertake approved training prior to using implanon.
2. The RACGP believes that implanon should be a procedure that is available to all CPD trained general practitioners, not just procedural general practitioners. Implanon insertion should not attract a procedural levy from MDOs.
3. Implanon training should take a ‘whole of system’ approach and ensure that participants receive sufficient resources and support to over come ‘human factor’ concerns of forgetfulness etc. This could include (but is not limited to) appropriate reminders, checklists and/or electronic prompts of practice technique.
4. Medical Defence Organisations, the RACGP and the Medical Industry Software Association should jointly consider options to support the safety introduction of new technology into general practice.

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Background Briefing

"Implanon is a subdermal implant containing etonogestrel, which is a metabolite of desogestrel, a third generation progestagen . . . .Etongestrel has poor affinity for androgen receptors and therefore gives fewer androgenic side effects compared to the older second generation progestagens, such as levonorgestrel. Implanon is an effective form of contraception, with a Pearl Index of 0.00-0.07, ie pregnancy risk is lower than that seen after tubal occlusion or vasectomy. . . .

Implanon comes in a ready loaded disposable sterile applicator. The needle on the applicator is designed to penetrate the skin readily but is able to tunnel under the skin without puncturing the skin from below. This enables placement of the rod in the superficial subdermal plane, so that the rod is easily palpable.

The device is Pharmaceutical Benefits Scheme listed for the cost of one prescription price to the user (although the cost to the taxpayer is $220)."[1]

The decision to use Implanon as a preferred contraceptive approach is a decision for the patient in consultation with her general practitioner. A quality consultation approach will canvas the patient's lifestyle, current situation and collaboratively determine an appropriate strategy.

Training

The RACGP has considered and recognised implanon training for continuing professional development for general practitioners. Continuing Professional Development applications have been approved as recently as mid 2003.

In late 2002, Susan Cherry[2] commented on implanon training in Australian Family Physician.

> **The importance of training**
> Training enables the doctor to counsel women on the benefits and side effects associated with Implanon use, to select appropriate users and to correctly time insertion of the implant.
>
> The technique of insertion, although simple, is different from that used with other hormone implants and needs to be learned by all doctors before they attempt their first insertion. Correct superficial placement of the rod ensures easy removal in future.
>
> It has been recommended by the Therapeutics Goods Administration and the Royal Australian and New Zealand College of Obstetrics and Gynaecology that doctors undergo a recognised training course in the use of the etonogestrel implant. Information about training sessions can be obtained from the manufacturer

Susan Cherry is a consultant to Organon Australia, the sole provider of medical education in the use of implanon.

Concerns

- **The Technique**: There have been a number of reported unplanned pregnancies and it is understood the principal concerns revolve around:
  - whether the initial pellet was inserted: that is, was the applicator loaded at the time of insertion. It appears to be important to hold the devise with the tip of the needle upright to ensure correct insertion
  - timing of insertion: patients should not be pregnant when the pellet is inserted

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[1] Cherry, S (2002) *Implanon: the new alternative* in Australian Family Physician, Vol. 31, No 10 October
[2] Cherry, Australian Family Physician (Vol 31, No 10 October 2002)

- implantation issues: the pellet may be inserted too deeply making removal difficult. The insertion and removal process may leaves scarring.

- **The Packaging of the Product:** The implant can drop out of the needle if the device is not held upright once removed from the packaging. The implant and the introducer are the same colour, making it more difficult to be sure of insertion.

- **Patient Access:** In 2002 a WA member alerted the College that an MDO "is no longer covering implanon procedures unless an extra $5000 insurance premium is paid." If Implanon is only available from procedural General Practitioners or obstetricians then access is limited in many parts of Australia. MDOs across Australia have had a variable response; many have not identified implanon insertion as a procedural issue.

- **Media concerns:** The RACGP President, Prof Michael Kidd has received media queries about General Practitioner training in the use of Implanon. The specifics of the query was whether Medical Defence Organisations (MDOs) requiring General Practitioners to undertake training prior to administering implanon was usurping the College role as the standards setter.

While Implanon is the immediate trigger for this paper, there are other instances where GPs may be requested to undertake specific training to demonstrate competence in the future. For example, for participation in Point of Care Testing, and use of a new IUD (Mirena by Schering).

This issue is more wide ranging than an individual procedure, as it intersects education and training, quality care and standards setting in general practice. This paper considers the issue of Implanon within the context of risk management in general practice.

The RACGP as the Standards Setter for Australian General Practice

Practitioner Standards

The RACGP is the "national leader for setting standards for training and quality of care.[3]" Initially the focus of much College work was on the competence of the general practitioner in recognition of the importance of technical excellence of the person delivering care. Doctors are required to demonstrate adequate clinical knowledge (basic facts), be able to apply that knowledge (know how) and be able to demonstrate effective use of that knowledge (show how) through registrar training and assessment through FRACGP.

Ongoing capacity is demonstrated through participation in the College's Quality Assurance and Continuing Professional Development (QACPD) program.

Practice Setting Standards

More recently the College and the profession have recognised the complementary role of ensuring that site and system standards as equally important. The RACGP sets the minimum acceptable standards for the general practice system, through the *Standards for General Practices*[4]. These standards address the contextual delivery of health care in terms of activities and facilities and canvas issues such as practice services, the rights and needs of patients, quality assurance and education, practice administration and physical factors.

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[3] RACGP Six Point Plan

[4] RACGP (2000) *Standards for general practices.* 2nd ed. RACGP, South Melbourne

The College has also developed specific site standards such as the *Handbook for the Management of Health Information in Private Medical Practice*[5] and the *Sterilisation/Disinfection Guidelines for General Practice.*[6]

These standards are not necessarily comprehensive, and General Practitioners are advised that State and Commonwealth legislation and regulation also provide a framework for good management.

What the RACGP Standards Indicate
The *Standards for General Practices (2nd edition)* do not specify clinical competence. However the Standards do describe the qualities required for particular practice activities:

> **1.1 Access and Availability**
> Comprehensive, whole patient care is only possible when a range of general practice services are both available and accessible.
>
> **1.2 Diagnosis and management of specific health problems**
> Practices have a responsibility to ensure that they are employing up to date methods for diagnosis and management that are broadly consistent with those of other Australian general practitioners, recognising that General Practice is increasingly moving towards clinical practice based on the best available evidence.
>
> **3.1 Quality Assurance and Continuing Education**
> Quality assurance consists of education and practice based activities that assist general practitioners to maintain a high professional standard. It involves a commitment to acquiring new knowledge and skills by a process of continuing education and training. Appropriate vocational qualifications are a prerequisite for the delivery of quality care.
>
> **5.1 Practice Facilities**
> Quality patient care is facilitated by appropriate physical structures. The practice premises, including its facilities and equipment should be adequate for the needs of the practice and should be maintained in a safe condition.

AMA Code of Ethics
The recently revised AMA Code of Ethics indicates that the general practitioner needs to " build a professional reputation based on integrity and ability . . . keep yourself up to date on relevant medical knowledge, codes of practice and legal responsibilities." (AMA 2.1(a) and (g))

Risk Management
Risk is "the chance of exposure to the adverse consequences of future events[7]" and can be related to technology, contract requirements, physical, financial, personnel and environmental issues. Risk is vested in the system, not necessarily in the individual practitioner. Consequently any consideration of risk takes account of the person in context: risk management is about systems, not establishing blame.

The key question is usually around which risk require intervention and what form such interventions such take.

It is common to consider risk management as part of good management practice.

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[5] RACGP (2002) *Handbook for the Management of Health Information in Private Medical Practice.* RACGP, South Melbourne

[6] Demediuk, Nicholas, ed (2000) *Sterilisation/Disinfection Guidelines for General Practice.* 3rd edition. RACGP, South Melbourne.

[7] Rational Management (2001) *Prince 2: Management of Risk.* RM, p.57

Standards Setting and Risk Management

While standards generally define a process or outcome of care, risk management identifies potential hazards or situations where harm may occur, estimates the probability or likelihood and offers suggestions for improvement.

Thus the College defines that General Practitioners are required to participate on ongoing professional development to “maintain a high professional standard” and maintain systems “adequate for the needs of the practice”. MDOs and other agencies of significance to general practice may, from time to time, suggest ways of meeting those professional standards.

The College’s role, as arbiter of standards within the profession, may, however, be quite important to the position that MDOs may take on whether General Practitioners have managed the risk effectively, given the particular context of general practice. For example, it is current practice for some state Medical Practitioner Boards to seek information from the RACGP on current best practice and/or endorsed approaches to care.

Implanon Training: Specific Issues

Quality of Training

The growth of knowledge of what works and what does not work in health care is phenomenal. Chassin found that the number of articles written in 1966 supported by randomised control trials was 100 articles/year. In 1995, this had increased to 10,000 articles/year. And the growth is exponential, with 49% of all articles being published between 1990-1995.[8]. It is impossible for the “average GP” to keep up to date with the latest techniques on the vast area of general practice.

Implanon requires a specific technique for insertion and is probably performed infrequently by the majority of general practitioners in undifferentiated practices. Training is essential. General practitioners require support to ensure that the ‘human factors’ in quality service provision are supported from time of training to the actual practice of insertion. It is essential that training provided in insertion technique is backed by sufficient ‘take home’ resources or in-consultation support to ensure that the general practitioner is competent in the procedure over time. This may require a checklist or, for example, a template in common prescribing software.

Furthermore, quality improvement and risk management requires education and skill development within the context of a ‘whole of system’ model: a model that recognises our imperfect systems and supports methods that strengthen knowledge gathering and implementation. Currently implanon training appears to be focused on the practitioner, rather than the practitioner in context. GPs have commented negatively on the time between training and using the technique.

‘Balkanising’ General Practice: CPD and Quality

General practitioners are currently permitted, within the College’s CPD program, to secure their ongoing professional development is areas of their interest that may or may not cover the breadth of general practice. To ensure skills in specific areas, various Joint Consultative Committees have been established to support and accredit specific training. For example, General Practitioners can undertake specific anaesthetics or women’s health training and receive recognition for that work.

Where does this level of ‘specialised CPD’ end? It is of concern that General Practitioners, in the future, may need specific training in a whole range of areas to demonstrate proficiency.

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[8] Chassin, M (1998) *Is health care ready for six sigma quality?* In Milbank Quarterly, vol 76 No 4

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Medico-Legal Insurance Impact

MDOs provide medico-legal coverage for the profession. Will MDOs require GPs to undertake specific training to provide coverage for those procedures, such as implanon insertion? Will GPs who undertake this procedure, require procedural insurance coverage?

Over time, general practitioners will find it more difficult to justify training and insurance to ensure they are practicing defensively. In increasing numbers, GPs may choose not to offer these services to their patients, thereby limiting the benefits of new technologies through limited access.

There is a role for the RACGP to provide appropriate risk management tools, either alone, or through liaison with software vendors for example, to assist GPs demonstrate to MDOs that the risks of procedures such as implanon can be managed well in the general practice setting. Such a strategy could reduce the costs, but would not alleviate the potential need to train in an increasing range of clinically specific areas.

Access

In this specific instance, implanon is a comparatively safe and effective contraceptive for many women. If too many restrictions are placed on its use, women will have reduced access to the service. It may eventuate that this service becomes cost and location prohibitive if relegated to the obstetricians and gynaecologists.

Recommendations

General

1 General Practitioners have a professional obligation to provide safe and effective services within their level of competence.
2 General Practitioners have a professional obligation to continually upgrade their competency skills.
3 Education and training for general practitioners and general practice staff should take a ‘whole of system’ approach, not just a practitioner training model. Education and training must, at a minimum, provide specific practitioner and practice setting instructions for all new services or techniques introduced.

Implanon

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