Implanon and medical indemnity: a case study of risk management using the Australian Standard

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ABSTRACT

- The contraceptive implant Implanon (Organon) was introduced in Australia in May 2001, and in the next 18 months was associated with an unprecedented number of adverse incident reports to medical indemnity insurers, including almost 100 unintended pregnancies.
- The medical indemnity insurer, MDA National, responded to this by applying the Australian and New Zealand Standard for Risk Management (AS/NZS 4360: 1999) in two stages.
- The first stage was to contain potential costs by moving the treatment into the general practice procedural category, resulting in a one-year moratorium on its use for most general practitioner members (prudential risk management).
- The second stage was to manage the clinical risk by developing strategies to reduce identified risks associated with the procedure.
- The Royal Australian College of General Practitioners (RACGP) was enlisted to develop guidelines for use of Implanon, with a consent form and checklists for doctors and patients, enabling MDA National to reinstate the treatment to the general practice non-procedural category.
- This case demonstrates the need for early risk assessment and development of risk-management tools for new treatments and devices, a role that is appropriate for the RACGP.

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The medical profession is increasingly accepting the need to incorporate risk-management strategies into medical practice. A variety of models have been used, including accreditation, systems review, and compliance with clinical pathways and guidelines. In this article, we describe the experience of applying a simple framework, the Australia and New Zealand Standard for Risk Management (AS/NZS 4360: 1999),[1] to assess and "treat" risks in a staged manner. This standard was applied by the medical indemnity insurer MDA National to address and treat its potential exposure to litigation associated with the contraceptive implant Implanon (Organon). Other medical indemnity insurers have responded to this issue in a range of ways, which have varied over time.

MDA National's initial response was cost-containment (prudential risk management). Its second response of applying the Risk Management Standard to manage clinical risk allowed it to reinstate Implanon treatment to the general practice non-procedural category for indemnity insurance purposes.

Background

Implanon is a progestogen-only implant that acts as a long-term (3-year) contraceptive. In clinical trials it demonstrated a lower failure rate than existing forms of contraception, such as the oral contraceptive pill and barrier methods.[2-4] It was released in Australia in May 2001. Factors such as convenience, low cost to patients and the apparent low failure rate made it attractive to many Australian women, and uptake was rapid.

The manufacturer, Organon, in conjunction with Family Planning Australia and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, developed a training program for medical practitioners. This information was also available on CD-ROM and video for remote and rural practitioners. The training sessions appear to have focused on teaching practitioners how to insert the implant, with practice on a manikin, and did not fully explore the problems that could arise when the implant was used in clinical practice.

The sessions had a high attendance rate by general practitioners (GPs), who were keen to learn the technique of insertion, but many still reported problems with clinical use. The implant is supplied with an applicator that appears similar to a syringe, with a cannula and obturator ("plunger"). However, the technique of insertion is the opposite to that used with a syringe, as the obturator remains fixed while the cannula is withdrawn. Many practitioners who attended training sessions reported that this counterintuitive action was not easily mastered. In addition, the implant and obturator used in the training sessions contrasted in colour (blue and white, respectively), while those supplied in the commercial product were both white. This was extremely confusing for some practitioners when they first used the implant clinically. Further, there was little emphasis in the training sessions on the disclosure of risk and the need to adequately document the process and procedure.

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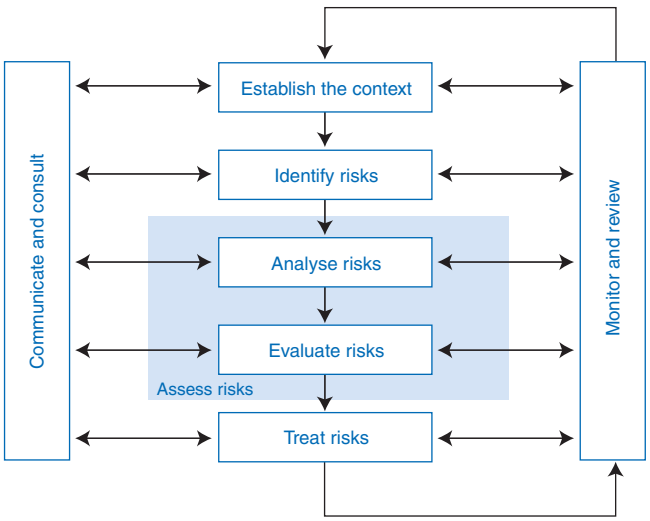
Incident notifications

Medical practitioners are required by their medical indemnity insurers to report any incident or adverse outcome that may give rise to a claim. These data are regularly reviewed by insurers to detect any trends. In June 2002, 13 months after the release of Implanon, a disturbing pattern became obvious to MDA National. Discussions with the manufacturer confirmed that the trend had been recorded by other indemnity insurers. Not since the introduction of laparoscopic surgery had indemnity insurers experienced so many incident notifications with a new technique.

Patients had selected a particular form of contraception that offered a low failure rate, but this had not been achieved, resulting in unintended pregnancies — almost 100 in the first 18 months

1 Risk management overview from the Australian and New Zealand Standard[1]



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after release (Organon [Australia] Pty Ltd. Implanon non insertion: extent of the issues and risk management strategies. Discussion paper submitted to MDA National, November 2002 [unpublished data]). The reasons for this were not always clear, but possibilities included failure to insert the implant, incorrect timing of the insertion, and implant failure, possibly, in some instances, because of interactions with other medications.

A proportion of the unintended pregnancies resulted from failure to recognise that the implant had not been inserted. The implant could be difficult to palpate if inserted deeper than the subdermal layer or if the area was swollen. Consequently, some patients remained fertile when they assumed they had adequate contraception. In some cases, pregnancies were reported over a year after patients had attended for insertion.

Some incident reports claimed that the implant was present but had "migrated" in the arm. Confirming presence of the implant is difficult. As it is not radio-opaque, it cannot be detected by x-ray. It can sometimes be identified by ultrasound examination, but this service is not readily available to remote and isolated patients and has cost implications. If the implant cannot be found by ultrasound examination, a blood test can confirm its presence. However, this test can only be performed by the manufacturer in Europe.

Other notifications related to difficult removal of the implant, resulting in scarring. Some patients required general anaesthesia for its removal.

MDA National's response

MDA National's risk management committee reviewed the notifications and recognised that the potential costs of litigation required some intervention. The level of reported incidents paralleled the rapid uptake of the implant. The manufacturer modified the training program and released further information on the need for both doctor and patient to palpate the implant and document its presence after insertion (the manufacturer provided a sticker for doctor and patient to sign and put in the medical record). The problem of spiralling adverse incidents was reported in the medical press,[5] but raising awareness alone was not sufficient to reduce the problem.

At the time of our initial review of the Implanon incidents, the High Court decision in the *Cattanach v Melchior* case for wrongful birth[6,7] had not been handed down. The success of a claim for the cost of raising a healthy child meant that the potential cost of any unintended pregnancy claim could be high. While some states have changed legislation to prevent this type of claim, this is not yet national policy. Any claims lodged before these legislative changes will be heard in the light of the High Court decision.

MDA National's response was in two stages: the initial response to contain the potential costs to the company, and the second to manage the clinical risk associated with the device.

First response — prudential risk management

MDA National mailed all GP members advising them of the situation and the likelihood that the procedure would be moved to the higher category of "procedural general practice". The higher subscription rate would prohibit many doctors from inserting the implants. The mail-out drew over 160 written responses. About 80% did not want the procedure moved to the procedural category. Their prime concern was the "deskilling" of general practice. Providing contraception has been traditionally regarded as a basic skill, and the inability to provide this type of contraception would be frustrating for many. However, some respondents opposed the cost of the adverse outcomes being carried by those not undertaking the procedure.

As it was strongly believed that many adverse outcomes were due to medical practitioners not attending the manufacturer's training sessions, MDA National conducted a telephone survey of practitioners who had notified incidents. This revealed that 90% had attended a training session, and that the remainder had watched the training video.

Regarding the problem of recognising whether the implant had been successfully inserted, the manufacturer advised that it would not change the colour of either the implant or the obturator because of the potential for complications with the dye. The manufacturer's research and development unit examined (and continues to examine) the possibility of making the implant radio-opaque but advised that this could take several years. Therefore, the challenge was to "risk-manage" the process around identified problems with the device.

MDA National convened an expert panel to examine the situation. Members' replies, claims and incident data, and a submission from the manufacturer, provided background material. The panel developed a raft of strategies to manage the clinical risk, but elected not to make any recommendation on the level of indemnity cover required. This decision was referred to the board of MDA National.

The initial intervention selected to manage liability was to limit the exposure to a smaller population by providing indemnity cover only to procedural general practitioners. This group was required to comply with the clinical risk strategies developed by the expert panel. The decision was for a year, with a planned review during that period. This first stage addressed the cost of potential claims

2 Implanon checklist and consent form

The guideline developed by the Royal Australian College of General Practitioners covers three phases.

Initial consultation

The practitioner is required to:

- Check for contraindications and allergies;
- Plan the date of insertion; and
- Disclose the risks.

Insertion

The practitioner is required to:

- Verify the consent form, confirming the patient's understanding of the risk of, and aspects particular to, the implant;
- Check the device before insertion;
- Palpate the implant after insertion;
- Advise the patient of the recommended follow-up, including ensuring removal of the implant in 3 years; and
- Complete all documentation.

The patient is required to:

- Palpate the implant after insertion; and
- Complete the consent form, acknowleging understanding of the treatment and that the implant is palpable.

This form becomes part of the patient's medical record.

Removal

The practitioner is required to:

- Document removal on the checklist and enter this in the medical record.

by protecting the mutual company. It reduced the likelihood of further incidents simply by reducing the number of treatments. However, this strategy did not reduce the risks associated with the device and was not a satisfactory solution for the GPs who wanted to be able to offer this treatment.

Second response — clinical risk management

MDA National undertook a further risk assessment using the Australian and New Zealand Standard for Risk Management (AS/NZS 4360: 1999).[1] The goal was to develop a system to ensure that the procedure could be undertaken with minimal risk for the patient and reduced exposure to liability for the practitioner.

The Risk Management Standard defines the core principles of risk management (Box 1). It is a continuous process that establishes the context, identifies, analyses, evaluates, and treats the risk. The process is undertaken within a framework of ongoing communication, consultation, monitoring and review. The risk can be either accepted or treated in one of four ways: by reducing the likelihood, minimising the consequences, transferring in part or full, or avoiding.

At this point, MDA National approached the Royal Australian College of General Practitioners (RACGP) to assist with developing a consent form. The College identified that a consent process alone would not be sufficient, and developed a guideline that included a checklist for doctors and another for patients (Box 2).

The MDA National board accepted that adequate risk strategies could be developed to reduce the clinical risk of this treatment. It agreed to return the insertion of Implanon to the non-procedural general practice category, subject to compliance with established guidelines, from July 2004. In line with the risk-management process, this decision will remain under review.

Lessons learned

The Standard for Risk Management (AS/NZS 4360: 1999) proved a useful tool to risk-assess and treat the problems that arose with the release of Implanon. It provides for ongoing review and monitoring of the proposed risk-management strategies. The Implanon story exemplifies an opportunity lost for risk assessment of a device in the clinical setting. A major intervention was required to halt the incidents. In future, a full risk assessment of the clinical implementation of a new product should be undertaken before its release. This would identify the risk barriers needed to minimise adverse incidents. If this had been undertaken, the one-year moratorium imposed on non-procedural general practitioners by MDA National might have been avoided.

The Royal Australasian College of Surgeons has established the Australian Safety and Efficacy Register of New Interventional Surgical Procedures (ASERNIP-S) to review new procedures and high-risk techniques.[8] General practice has relied on licensing bodies, in this case the Therapeutic Goods Administration, to determine the safety and efficacy of drugs and devices. While this body approves products, it does not evaluate the potential risks in delivering the treatment. Ideally, manufacturers and medical indemnity insurers would refer new products, techniques and treatments identified as high-risk to the Royal Australian College of General Practitioners, which has the experience and skills to set standards and provide guidelines for general practitioners.[9]

Competing interests

Neither author has any connection with Organon, the manufacturer of Implanon. BCAW is the Chair, Queenland Advisory Committee, MDA National.

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