NICE National Institute for Health and Care Excellence

NICE guidance

Mega Soft Patient Return Electrode for use during monopolar electrosurgery

Medical technologies guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

NICE medical technologies guidance addresses specific technologies notified to NICE by sponsors. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice.

1.1 The use of the Mega Soft Patient Return Electrode during monopolar electrosurgery may offer advantages for selected patients: for example, those who would need shaving before the application of adhesive electrode pads and those with fragile or damaged skin.

1.2 It is plausible that the Mega Soft Patient Return Electrode reduces the risk of burns related to the diathermy patient return electrode where surgery is carried out in the context of good operating theatre practice. The published clinical evidence comparing the Mega Soft Patient Return Electrode against disposable single-use patient return electrodes for use during monopolar electrosurgery is limited, but there have been no reports of burns as a result of its use in the UK.

1.3 There may be system benefits for operating theatre staff using the Mega Soft Patient Return Electrode in terms of increased convenience and reduced setting up time. These benefits are more likely to be realised for inpatient operating lists than for day case surgery, and do not appear to lead to a significant reduction in resource utilisation. The economic evidence and cost modelling demonstrate near equivalent resource use to current practice.

1.4 Clinicians and managers considering the adoption of the Mega Soft Patient Return Electrode should therefore, in judging the likely benefits, take into account current practice in their operating theatres with regard to prevention of alternative site burns and the proportion of inpatient operations for which it would be used.

2 The technology

Description of the technology

2.1 The Mega Soft Patient Return Electrode (Megadyne, Johnson & Johnson Medical Ltd) is a reusable dispersive capacitive electrode designed for use during monopolar electrosurgery. The electrode, which is incorporated into a pad, is intended to reduce the risk of burns and to provide pressure relief.

2.2 Electrosurgery uses high frequency current to achieve surgical effects such as cutting and coagulation. It is commonly referred to as diathermy. Monopolar electrosurgery (monopolar diathermy) specifically relies on the patient forming part of the electrical circuit. In addition to the patient's tissue, the electrical circuit also includes the electrosurgical unit, which generates the electrical current, an active electrode and a patient return electrode. High frequency electrical current is conducted from the target tissue to an electrosurgical unit, or generator. When the surgeon touches a selected area of the patient's tissue with the electrosurgery tool (the active electrode), current passes from the tool, is distributed widely throughout the patient's body and then returns to the electrosurgical unit via a patient return (dispersive) electrode. In current NHS clinical practice, the electrical circuit is completed by using an adhesive disposable single-use pad with an integral return electrode, which is attached directly to the patient's skin (patient return electrode). These electrodes consist of a conductive foil covered by a polymer. The Mega Soft Patient Return Electrode is incorporated into a large pressure-relieving pad (approximately 117 cm x 51 cm x 1.25 cm) that is placed on the operating table on which the patient lies. When the patient lies on the pad containing the Mega Soft Patient Return Electrode the electrical circuit is completed.

2.3 A standard disposable single-use patient return electrode measures approximately 12 cm x 13 cm. The area covered by the pad needs to be large enough to maximise conduction of electrical energy away from the patient (disperse the electrical current) and so minimise the rise in skin

temperature. A standard patient return electrode is therefore also known as a dispersive electrode. It may also be called a neutral electrode, and this is the name used in the relevant technical standard specification, for example the IEC 60601-2-2-2009. In clinical practice, the standard patient return electrode is commonly referred to as a diathermy pad.

2.4 A standard disposable single-use patient return electrode forms a resistive circuit and the direct electrical connection relies on good contact with the patient. The Mega Soft Patient Return Electrode does not rely on direct contact with the patient and forms a capacitive circuit. The Mega Soft Patient Return Electrode is much larger than a standard disposable single-use patient return electrode and the sponsor states that this leads to a reduction in current density when compared with the disposable single-use patient return electrode. It should be noted that this will depend on the position of the patient and is likely to be true when the patient is lying supine and is in contact with a large area of the mat.

2.5 Most adverse events related to electrosurgery are patient burns. During electrosurgery, patients are at risk of 2 types of burn: return electrode site burns and alternative site burns. Return electrode site burns can occur when the contact area is reduced (for example, when a disposable pad partially peels off during surgery) and the current density increases. Some split disposable single-use patient return electrodes are designed to set off an alarm and cause the electrosurgical unit to cease to function when they start to peel off. Alternative site burns occur when some of the current does not follow the main circuit route, but finds an alternative path to earth rather than returning to the generator. If the alternative path is unintentionally directed towards the patient then a burn can occur. Most electrosurgical generators are isolated, which means the high frequency circuit is not referenced to earth directly. However, whenever high frequency currents are used, there is some leakage to earth, even in an isolated circuit. If the main circuit becomes harder to complete (for example, because of reduced patient contact with the return electrode), there is, in theory, an increased possibility of alternative current pathways that can result in alternative site burns.

2.6 During 2009/10 approximately 9.7 million inpatient surgical procedures

were performed in the UK. It has been estimated that 2.81 million of these (29% of the total) involved general anaesthesia and lasted for more than 30 minutes. It is thought likely that monopolar electrosurgery is used in at least half of all surgical procedures; therefore patient return electrodes are used in around 1.4 million procedures per year.

2.7 The cost of the Mega Soft Patient Return Electrode given in the sponsor's submission is £1900 without VAT. The Mega Soft Patient Return Electrode can be used with all electrosurgical generators, with the exception of the ERBE generator when that is used on the High Cut and Endo Cut mode (as stated in the Mega Soft Patient Return Electrode instructions for use). It is recommended that each Mega Soft Patient Return Electrode is used for a maximum of 24 months.

2.8 The claimed benefits of the Mega Soft Patient Return Electrode presented by the sponsor are:

- reduction in the incidence of burns in patients having monopolar electrosurgery, with a consequent drop in treatment and litigation costs
- avoidance of skin shaving
- reduction in skin irritation because the Mega Soft Patient Return Electrode is not attached directly to the patient's skin; this may be particularly applicable to patients with burns or other skin conditions as well as to paediatric patients and older patients with fragile skin
- reduction in the risk of pressure-related injury resulting from immobility during surgery
- reduction in staff time because the Mega Soft Patient Return Electrode is reusable, is not attached directly to the patient and therefore staff do not need to consider avoiding bony prominences, scar tissue and tattoos as they would when placing a disposable patient return electrode
- cost saving and improved sustainability compared with current practice because the electrode is reusable and a separate pressure-relieving device may not be needed.

Current management

2.9 Current practice is to apply a disposable single-use patient return electrode to the skin before monopolar electrosurgery. If electrical conduction is impaired at the skin-to-pad surface interface, the current density increases and this can lead to an increase in skin temperature, which exposes the patient to a risk of return electrode site burns. Electrical conduction can be impaired when the contact area of the standard disposable single-use patient return electrode is reduced by body hair, adipose tissue, bony prominences, fluid invasion, peeling or failure of the electrode to adhere to the patient, or scar tissue. To optimise electrode contact, care must be taken to place the electrode on hair-free areas without bony prominences. This may mean that the skin needs to be shaved before the electrode is applied.

2.10 Patient return electrodes used in current practice are single-use and disposable: they vary in 2 main respects. First, they may have split (dual) and non-split (single) electrodes. Second, they may have integral lead wires to attach them to the generator or they may be supplied without lead wires. If a patient return electrode has integral lead wires then these are discarded with the disposable electrode after use. Patient return electrodes without attached lead wires are connected to the generator by reusable lead wires. All types of patient return electrode are available in a range of sizes for adults and children. NHS procurement data indicate that the most commonly used type of patient return electrode in the NHS in England is the split adult disposable single-use patient return electrode without a lead wire.

3 Clinical evidence

Summary of clinical evidence

3.1 Full details of all clinical outcomes considered by the Committee are available in the assessment report overview.

3.2 The key clinical outcomes for the Mega Soft Patient Return Electrode presented in the decision problem were:

- incidence of patient return electrode site burns
- incidence of alternative site burns
- incidence of post-operative pressure ulcers
- use of the device in certain patient subgroups.

3.3 The clinical evidence for the Mega Soft Patient Return Electrode was based on 2 published studies and 4 unpublished documents. The published studies were 1 technical evaluation (ECRI 2000) and 1 observational study (Sheridan 2003). Both studies evaluated the earlier version of the Mega Soft Patient Return Electrode, the Mega 2000. The unpublished evidence was 1 technical evaluation from the sponsor, testimonials from 2 USA hospitals about the Mega 2000 and the Mega Soft Patient Return Electrode, and 1 questionnaire from 3 London hospitals on the Mega Soft Patient Return Electrode.

3.4 ECRI (2000) was a laboratory study that examined the safety, efficacy and cost consequences of the Mega 2000 compared with standard disposable single-use patient return electrodes, in relation to relevant American and international technical standards. The tests were performed on 1 adult volunteer and on a piece of meat (tests that assessed the occurrence of burns). No statistical tests were reported. Mega 2000 was rated 'acceptable (with conditions)'. All the test results were rated as good except the results for the test of alternative current pathways, which were rated as fair. The Mega 2000 is the immediate

predecessor product to the Mega Soft Patient Return Electrode and differs in not having a gel layer. Although the results cannot therefore be extrapolated between products, the External Assessment Centre considered that any observed differences between Mega 2000 and standard electrodes would be relevant to the Mega Soft Patient Return Electrode.

3.5 Sheridan (2003) reported an observational study of 17 children with extensive burns in a tertiary hospital in the USA. The children had only a few areas of the body suitable for placing the electrode and grounding the current. No statistical tests were reported. The results showed that Mega 2000 did not cause any burns, was convenient to use, and enabled effective patient grounding despite the presence of extensive burns.

3.6 A laboratory-based comparative technical study comparing the Mega Soft Patient Return Electrode with a disposable single-use split patient return electrode was submitted by the sponsor. The study has not been peer-reviewed. The tests were carried out on anaesthetised pigs. The main outcome was whether or not electrode site burns were observed (recorded as, yes or no). No statistical tests were reported. There was a rise in temperature of 9.7°C with the disposable split electrode compared with 1.2°C with the Mega Soft Patient Return Electrode. The IEC 60601-2-2-2006 standards for electrosurgery allow a maximum temperature increase of 6°C to minimise the risk of electrode site burns.

3.7 The sponsor provided 2 testimonial reports from Christus St Joseph's Hospital, USA in 2011. These were not clinical studies and no statistical tests were reported. There were no pre-defined outcomes. These hospitals initially used Mega 2000 and then switched to using Mega 2000 Soft (the US equivalent of the Mega Soft Patient Return Electrode) when it came onto the market. In both reports, Mega 2000/Mega 2000 Soft was compared indirectly with standard disposable single-use patient return electrodes for patient comfort and cost savings. Both hospitals issued statements saying that the Mega Soft Patient Return Electrode improved patient comfort and provided cost savings.

3.8 An evaluation report was based on the use of the Mega Soft Patient Return Electrode at 3 London hospitals. Over a period of 2 weeks,

theatre nurses completed a questionnaire after surgery to rate the use of the Mega Soft Patient Return Electrode. No information was provided about the selection criteria of patients, the total sample size or the number of non-responders. Data were obtained after procedures were completed on 18 paediatric patients at 1 hospital and on 12 and 24 adult patients respectively at the other 2. Mean scores were provided, together with raw data submitted for each question. Scores were from 0 to 5, with a higher score indicating a better outcome, and were averaged. Overall, a rating of 4.7 was recorded for the Mega Soft Patient Return Electrode. The highest scores were for skin irritation and power settings (4.9) and the lowest score was for positioning (4.2).

Committee considerations

3.9 The Committee noted that patient return electrode site burns are rare. It was advised that, on average, 117 electrosurgery burns are reported to the MHRA each year. Of these, approximately one-third are patient return electrode site burns and about two-thirds are alternative site burns. Expert advisers stated that, in their experience, patient return electrode site burns are very uncommon indeed, are not severe and can be treated with topical cream only. The Committee was advised that all types of burn can usually be avoided by good operating theatre practice.

3.10 The Committee noted that the published clinical evidence comparing the Mega Soft Patient Return Electrode against disposable single-use patient return electrodes for use during monopolar electrosurgery is limited and did not provide evidence of whether or not the device reduced the incidence of patient return electrode site burns in practice. The Committee accepted that there have been no reports of burns as a result of its use in the UK, and it acknowledged, therefore, that it is plausible that using the Mega Soft Patient Return Electrode reduces the risk of patient return electrode site burns, based on theoretical considerations. The Committee concluded that technical testing had shown that the Mega Soft Patient Return Electrode was safe in the normal circumstances of UK practice. It noted that no adverse incidents (and specifically no burns of any kind) had been reported from use of the Mega Soft Patient Return Electrode in the UK.

3.11 The Committee noted that the type of electrical circuit formed by the Mega Soft Patient Return Electrode can be associated, if good operating theatre practice is not adhered to, with an increased risk of alternative site burns compared with standard disposable single-use patient return electrodes. In the absence of evidence of this, and balancing the plausible reduction in patient return electrode site burns against the possible increase in alternative site burns if good operating theatre practice is not adhered to, the Committee judged that there was likely to be a similar overall risk of burns with the Mega Soft Patient Return Electrode compared with current practice. Any reduction in the overall risk of burns using the Mega Soft Patient Return Electrode would depend on good standards of operating theatre practice to minimise the incidence of alternative site burns. Therefore, clinicians and managers considering the adoption of the Mega Soft Patient Return Electrode should take into account current practice in their operating theatres with regard to prevention of alternative site burns.

3.12 The Committee accepted it was likely that the Mega Soft Patient Return Electrode may have practical advantages in selected patient groups, but despite a limited number of positive user feedback reports, there was a lack of clinical studies to support these claims. Examples are patients with fragile or damaged skin, and patients who would need shaving before application of standard disposable single-use patient return electrodes. The Committee noted estimates from clinical experts that between 20% and 30% of patients need to be shaved before the use of standard disposable single-use patient return electrodes. The Committee noted that adipose tissue, bony prominences, tattoos and scar tissue need to be considered, as well as body hair, when placing single-use patient return electrodes but not when using the Mega Soft Patient Return Electrode.

4 NHS considerations

System impact

4.1 The sponsor claimed that using the Mega Soft Patient Return Electrode can reduce staff time. A patient can be placed on the Mega Soft Patient Return Electrode (which is already on the operating table) and does not need to have a suitable site selected for attaching a standard disposable single-use patient return electrode. The site of the Mega Soft Patient Return Electrode does not need to be checked at the end of the operation. In addition, some patients may need shaving before the use of a standard disposable single-use patient return electrode and this involves staff time and the use of a disposable razor.

4.2 The sponsor claimed that the Mega Soft Patient Return Electrode would be cost saving by offering improved sustainability compared with current practice because it is reusable and a separate pressure-relieving device may not be needed. During consultation, the sponsor submitted 6 sources of information, 1 of which was not relevant to this device. One was a pressure map evaluation of Mega 2000 Soft (the US equivalent of the Mega Soft Patient Return Electrode) from 2007. This showed that the best average pressure of 24.8 mmHg was measured using Mega 2000 Soft. If no pressure-relieving pad was used, the average pressure was 40.3 mmHg. Four studies evaluated pads made of the same visco-elastic polymer that is used in the Mega Soft Patient Return Electrode (including a randomised controlled trial of 446 patients). Overall, pads made of this material were found to reduce pressure and provide support.

4.3 During consultation, the sponsor submitted a simple waste calculator (a Microsoft Excel spreadsheet) to support the claim of improved sustainability. The calculator showed that waste is likely to be reduced if the Mega Soft Patient Return Electrode is used instead of disposable single-use patient return electrodes. The estimate from this waste calculator for 1 operating room, based on 3 operations a day, 4 days a week for 50 weeks of the year, was 9 lb of waste disposed for the Mega Soft Patient Return Electrode compared with 74.06 lb for single-use

patient return electrodes. The waste calculator is based on US practice and has not been validated. It was not specified whether the waste figures were based on disposable single-use patient return electrodes with integral lead-wires or without integral lead wires.

Committee considerations

4.4 The expert advisers stated that any necessary shaving of patients and placement of standard disposable single-use patient return electrodes are normally done at the same time as other tasks and therefore using the Mega Soft Patient Return Electrode would not save as much time as claimed. The Committee accepted these views and concluded that using the Mega Soft Patient Return Electrode would not normally result in a substantial reduction in theatre time and the time taken to prepare patients in the operating suite.

4.5 The Committee noted comments that, even if operating theatre time was unlikely to be reduced, the use of the Mega Soft Patient Return Electrode might be more convenient and reduce the burden on theatre staff. This could include removing the need to: shave some patients; select appropriate sites and fix adhesive standard disposable single-use patient return electrodes; adjust or change electrodes during surgery; or check electrode sites at the end of operations.

4.6 The Committee was advised that the possible advantages of using the Mega Soft Patient Return Electrode would be significantly influenced by whether it was used for inpatient or for day-case surgery. It heard that at least half of operations performed in the NHS are carried out as day cases and for these a fixed operating table is not generally used. For inpatient operations, the Mega Soft Patient Return Electrode can be placed on the operating table at the start of a day and left in place throughout any operating list. Patients can then be placed on the Mega Soft Patient Return Electrode when they are moved from the trolley on which they are anaesthetised to the operating table. The Mega Soft Patient Return Electrode is left on the operating table and cleaned between patients. By contrast, most day-case surgery is performed with the patient on a trolley. Patients are anaesthetised while on the trolley, which is then moved into the operating theatre and then to the recovery

area: the patient remains on the same trolley throughout. This means that at least 2 Mega Soft Patient Return Electrodes would be needed for each day-case operating suite. Otherwise, placing each patient on the Mega Soft Patient Return Electrode would involve more time and inconvenience than applying and removing a standard disposable single-use patient return electrode. The Committee concluded that the patient, health system and any cost advantages of the Mega Soft Patient Return Electrode were likely to be realised only when it was used for inpatient surgery and not for day-case surgery.

4.7 The Committee considered the results from the waste calculator and whether these supported the claim for improved sustainability and the cost impact associated with the reusable nature of the Mega Soft Patient Return Electrode. It accepted that waste was likely to be reduced but was unable to reach any specific conclusions on this because of the lack of validated data.

4.8 The Committee noted that the Mega Soft Patient Return Electrode is compatible with all electrosurgical generators apart from certain settings on 1 specific generator (see section 2.7). It regarded compatibility with existing electrosurgical generators as fundamental to any consideration to adopt the Mega Soft Patient Return Electrode.

4.9 The Committee accepted the submitted evidence to support the claim that the Mega Soft Patient Return Electrode has acceptable pressure-relieving properties making it unnecessary (in most operations) for an additional pressure-relieving device to be used.

5 Cost considerations

Cost evidence

5.1 No published economic evidence on the Mega Soft Patient Return Electrode was identified by the sponsor. The External Assessment Centre found 1 study (ECRI 2000) that undertook a cost consequences analysis of the Mega 2000 in the USA. The External Assessment Centre noted that ECRI reported that the frequency of use and cost differential meant that with greater use Mega 2000 became more cost saving; however, the values used in the study were not considered relevant to the decision problem.

5.2 The External Assessment Centre stated that no clinical evidence was presented on which to base the incidence of skin burns from standard disposable single-use patient return electrodes and their associated costs in the sponsor's model. Evidence was not included on the cost of procuring, storing and disposing of standard disposable single-use patient return electrodes. No independent evidence was supplied on the time saved in theatre by using the Mega Soft Patient Return Electrodes rather than standard disposable single-use patient return electrodes.

5.3 The sponsor submitted a de novo economic model that estimated the cost per operation for the Mega Soft Patient Return Electrode compared with a split standard disposable single-use patient return electrode and a non-split standard disposable single-use patient return electrode in adult and paediatric patients undergoing monopolar electrosurgery. The analysis was from the NHS and personal social services perspective. Full details of all cost evidence and modelling considered by the Committee are available in the assessment report overview.

5.4 The model used linear formulae that described the relationships between the resource and cost variables. The model did not use any health states. The External Assessment Centre noted that this structure was appropriate to quantify the main cost differences between the technologies given the level of clinical evidence available.

5.5 The sponsor stated that several parameters were not included in the model because a lack of data meant that cost savings were not quantifiable. These included:

- disposal of standard disposable single-use patient return electrodes
- further surgery to treat skin burns from standard disposable single-use patient return electrodes
- litigation because of skin burns from standard disposable single-use patient return electrodes
- treatment of skin irritation from standard disposable single-use patient return electrodes
- ordering and storing boxes of standard disposable single-use patient return electrodes.

5.6 The sponsor's base-case analysis included several key assumptions:

- The cost of the adult or paediatric Mega Soft Patient Return Electrode (without VAT) is £1900.
- The Mega Soft Patient Return Electrode is used 3 times a day, 5 days a week, and 52 weeks a year (based on expert adviser estimates).
- Four types of standard disposable single-use patient return electrode are used in the NHS. The prices given are based on prices from the manufacturers of the different electrodes. (The sponsor did not supply any prices for electrodes without lead wires.)
  - Split adult standard disposable single-use patient return electrodes with lead wire: £2.44 per electrode
  - Non-split adult standard disposable single-use patient return electrodes with lead wire: £2.60 per electrode
  - Split paediatric standard disposable single-use patient return electrodes with lead wire: £1.92 per electrode
  - Non-split paediatric standard disposable single-use patient return electrodes with lead wire: £1.74 per electrode

- The price of an operating table pressure-relieving mattress was taken from 1 manufacturer and is £334.
- The pressure-relieving mattress is used 3 times a day, 5 days a week for 52 weeks a year based on assumptions and estimates.
- Costs of razors to shave patients were from razor manufacturers and are £1.13 for a disposable razor and £2.09 for a clipper head.
- All patients need shaving before using a standard disposable single-use patient return electrode.
- The discount rate of the Mega Soft Patient Return Electrode is 3.5% applied in year 0.
- The lifespan of the Mega Soft Patient Return Electrode is 24 months.
- The resource costs from the Personal Social Services Research Unit (PSSRU) are based on 'per operation hour' and are £347 per hour each for a surgeon and an anaesthetist and £41 per nurse.
- The estimated time needed for site preparation when using a standard disposable single-use patient return electrode is 5 minutes.

5.7 The sponsor tested several of the base-case assumptions in deterministic 2-way sensitivity analyses. In these analyses, the following parameters were increased and decreased by 50% (with no probabilities attached for the likelihood of these events occurring):

- number of operations per week
- cost of standard disposable single-use patient return electrodes
- cost of an operating table pressure-relieving mattress
- life of an operating table pressure-relieving mattress
- cost of razors for shaving
- staff time and hourly staff costs.

5.8 The sponsor's base-case analysis estimated the cost per operation using the Mega Soft Patient Return Electrode compared with a standard

disposable single-use patient return electrode with a lead wire. The findings showed savings of £70.83 per operation for adults and £70.31 for children when using the adult or the paediatric Mega Soft Patient Return Electrode respectively when the Mega Soft Patient Return Electrode was compared with split pad standard disposable single-use patient return electrodes. These were greater savings than when the Mega Soft Patient Return Electrode was compared with non-split pad standard disposable single-use patient return electrodes because of the higher cost of the split pads. More than 95% of the savings were from improving efficiency by saving 5 minutes per operation. More than 80% of the savings were from surgeon and anaesthetist time saved. The largest contribution to the cost saving was from surgeon and anaesthetist time saved (£57.84 per operating hour). Nurse time saved resulted in a further saving of £10.25 per operating hour.

5.9 The External Assessment Centre noted that the sponsor had not justified why its assumptions were the most plausible range of values. Furthermore, the sensitivity analysis did not capture the lower prices for standard disposable single-use patient return electrodes in 1 NHS trust. The sensitivity analyses demonstrated that the results of the sponsor's model were sensitive to assumptions about staff time and the cost per hour for surgeons, anaesthetists and nurses.

5.10 The External Assessment Centre expressed particular concerns about a number of parameters in the sponsor's model and carried out additional analyses to examine the impact of changing the following parameters:

- Inclusion of VAT in the price of the Mega Soft Patient Return Electrode (£2280).
- The most common type of disposable single-use patient return electrode used in the NHS is the split adult disposable single-use patient return electrode with no lead wire (£0.87). This is based on NHS Supply Chain figures.
- The Mega Soft Patient Return Electrode is used 3 times a day, 4 days a week for 50 weeks a year (based on clinician estimates). This equates to 600 operations per year.
- A razor costs £2.09 (disposable razors are no longer used).

- Shaving of 40% of patients (based on clinician estimates that were obtained by the External Assessment Centre as part of its assessment).
- There is no overall delay for site preparation when using a standard disposable single-use patient return electrode based on clinician advice.

5.11 The overall cost per operation when using the parameters described in section 5.10 is £2.16 for the comparator and £1.97 for an adult Mega Soft Patient Return Electrode. Therefore, this analysis demonstrated a cost saving of £0.19 per operation when using an adult Mega Soft Patient Return Electrode compared with a standard disposable single-use patient return electrode.

5.12 The overall cost per operation when using the parameters described in section 5.10 for the paediatric comparator (split paediatric standard disposable single-use patient return electrode with no lead wire) is £2.30 and for the paediatric Mega Soft Patient Return Electrode it is £1.97. This demonstrated a cost saving of £0.33 per operation using a paediatric Mega Soft Patient Return Electrode compared with a standard disposable single-use patient return electrode.

Committee considerations

5.13 The Committee discussed the different assumptions presented to decide which were the most appropriate to use. It judged that:

- VAT should be included for the price of the Mega Soft Patient Return Electrode.
- NHS Supply Chain figures provided the most appropriate comparator (a split disposable single-use patient return electrode with no lead wire).
- The External Assessment Centre's assumption of use of operating table pressure-relieving mattresses 3 times a day, 4 days a week, 50 weeks a year was reasonable.
- There was unlikely to be any substantial saving of operating theatre time as a result of using the Mega Soft Patient Return Electrode.

5.14 The Committee considered that there was unlikely to be any substantial saving of operating theatre time as a result of using the Mega Soft

Patient Return Electrode. Therefore, it did not accept the sponsor's base-case cost saving of £70.83 and judged that no significant saving would be made.

5.15 The Committee noted that the sponsor's base-case analysis assumed that 100% of patients are shaved before monopolar electrosurgery with a disposable single-use patient return electrode, but that the External Assessment Centre advised that the percentage is nearer to 40%, based on advice from clinicians. However, the Committee was advised by experts and heard from some of its members that in clinical practice the percentage of patients who need shaving is more likely to be between 20% and 30%. The Committee concluded that 30% was a reasonable figure to use for the cost model. If 30% of patients are shaved and all the other parameters in section 5.10 remain the same then the External Assessment Centre advised that the overall cost per operation when using the comparator would be reduced from £2.16 to £1.94. The overall cost per operation when using the Mega Soft Patient Return Electrode remains at £1.97 because patients do not need shaving for this electrode.

5.16 For paediatric patients, the sponsor's base-case analysis was also based on 100% of patients having monopolar electrosurgery needing to be shaved. The Committee was advised that it is unlikely that any child would need shaving and this figure should be 0%. If no patients are shaved and all the other parameters in section 5.10 remain the same then the Committee noted that the overall cost per operation when using the paediatric comparator is reduced from £2.30 to £1.46. This means that it would cost 51p more per operation to use the Mega Soft Patient Return Electrode because the overall cost per operation when using Mega Soft Patient Return Electrode would remain at £1.97.

5.17 The Committee concluded that the economic evidence and cost modelling demonstrate near equivalent resource use for the Mega Soft Patient Return Electrode to current practice. Expert advice suggested that claims for the Mega Soft Patient Return Electrode's benefit are greatly influenced by the circumstances in which it is used.

6 Conclusions

6.1 The Mega Soft Patient Return Electrode may have particular advantages for patients with fragile or damaged skin; these include patients with burns, patients with skin conditions, paediatric patients and older patients. It also has the advantage that no patient needs shaving whereas about 30% of patients may need to be shaved when disposable single-use patient return electrodes are used.

6.2 The Committee accepted that it is plausible that the Mega Soft Patient Return Electrode reduces the risk of patient return electrode site burns, based on theoretical considerations and on the lack of any reported burns in the UK. It made this judgement despite a very limited amount of published clinical evidence comparing the Mega Soft Patient Return Electrode with disposable patient return electrodes in monopolar electrosurgery.

6.3 Use of the Mega Soft Patient Return Electrode might theoretically increase the risk of alternative site burns. Good operating theatre practice minimises this risk and use of the Mega Soft Patient Return Electrode in this context could reduce the overall risk of burns from electrosurgery.

6.4 The Mega Soft Patient Return Electrode may be more convenient for theatre staff to use than standard disposable single-use patient return electrodes, but it is not likely to provide substantial savings in operating theatre time. The economic evidence and cost modelling demonstrated near equivalent resource use to current practice. Any health system or cost advantages are likely to be influenced significantly by whether the Mega Soft Patient Return Electrode is being considered for use for inpatient operating lists or day-case surgery.

7 Implementation

7.1 There are no implementation tools to accompany this guidance.

8 Related NICE guidance

Published

- Suction diathermy adenoidectomy. NICE interventional procedure guidance 328 (2009).
- Electrosurgery (diathermy and coblation) for tonsillectomy. NICE interventional procedure guidance 150 (2005).

Under development

There is no related guidance under development.

Andrew Dillon
Chief Executive
August 2012

Appendix A. Committee members and NICE lead team

A Medical Technologies Advisory Committee members

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

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ProfessorPeterGaines
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B NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a technical expert, a patient expert, a non-expert member of the Medical Technologies Advisory Committee and a representative of the External Assessment Centre.

JoBurnett
Technical Analyst

SallyDoss
Technical Adviser

DrIanArmstrongandDrLiamHorgan
Lead Expert Advisers

DrPaulKnox/DrPeterGroves
Non-Expert MTAC Member

MeganDale/JustinMcCarthy–Cedar
JoyceCraig–NUTHandYHEC
External Assessment Centre Representatives

Appendix B: Sources of evidence considered by the Committee

The External Assessment Centre reports for this assessment were prepared by Cedar (Clinical evaluation device assessment reporting) and NUTH (Newcastle upon Tyne Hospitals) and YHEC (York Health Economic Consortium):

Technical testing assessment report – Cedar

- Dale M, McCarthy JP. EP141 Technical testing of Mega Soft Patient Return Electrode, January 2012.

Clinical and economic assessment report – NUTH and YHEC

- Craig J, Reay C, Willits I et al. External assessment report for Mega Soft Patient Return Electrode for use during monopolar electrosurgery, January 2012.

Submissions from the following sponsor:

- Advance Surgical (sponsor/UK distributor) until March 2012 and Megadyne (USA manufacturer)

The following individuals gave their expert personal view on the Mega Soft Patient Return Electrode by providing their expert comments on the draft scope and assessment report:

- Dr Ian Armstrong, nominated/ratified by the British Association of Day Surgery – clinical expert
- Dr Liam Horgan nominated/ratified by the British Association of Day Surgery – clinical expert

The following individuals gave their expert personal view on the Mega Soft Patient Return Electrode in writing by completing a patient questionnaire or expert adviser questionnaire provided to the Committee:

- Josef Crutchley, nominated/ratified by the Healthcare Professional Council
- Maureen Theakston, nominated/ratified by the Nursing and Midwifery Council

- Jilly Hale nominated/ratified by the Association for Perioperative Practice
- Kim Wall nominated/ratified by the College of Operating Department Practitioners

About this guidance

NICE medical technology guidance addresses specific technologies notified to NICE by sponsors. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This 'case' is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies, which may offer similar advantages.

This guidance was developed using the NICE medical technologies guidance process.

We have produced a summary of this guidance for patients and carers.

Yourresponsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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