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MEDICAL TECHNOLOGIES ADVISORY COMMITTEE

Mega Soft Patient Return Electrode for use During Monopolar Electrosurgery

Produced by NUTH and YHEC External Assessment Centre

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Section 1: Background and Process

1.1 BACKGROUND

In August 2012, medical technologies guidance (MTG11) [NICE, 2012] on the use of the Mega Soft Patient Return Electrode during monopolar electrosurgery was published. The device 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.

The guidance concluded the device offered advantages for selected patients: for example, those who would require shaving before the application of adhesive electrode pads and those with fragile or damaged skin. It also noted that:

> '*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.*
>
> *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.*
>
> *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.'*

The comparator was current NHS clinical practice whereby an electrical circuit is completed using an adhesive disposable single-use pad with an integral return electrode, which is attached directly to the patient's skin (patient return electrode).

No relevant published economic evidence on the Mega Soft Patient Return Electrode was identified by the Newcastle and York External Assessment Centre (NY EAC). It critiqued a de novo economic model submitted by the sponsor. This 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 solid 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.

The EAC concluded that the model structure was valid for the decision-making context but excluded several relevant parameters. When these were included and some existing assumptions modified to better reflect NHS practice, the results showed that using an adult or paediatric Mega Soft Patient Return Electrode, compared with a standard disposable single-use patient return electrode, and had similar resource and costs.

The pathway did not include the incidence and cost of diathermy burns. Statistics obtained from the NHS Litigation Agency and Medicines and Healthcare products Regulatory Agency (MHRA) were provided by the EAC to report the incidence of such burns reported to MHRA and the annual cost of settling claims related to such burns.

1.2 PROCESS TO UPDATE COSTINGS

In December 2017, NICE commissioned the NY EAC to update the costs used in the model. The EAC updated costs using three sources:

- Mr Aaron Mulligan, Director, Interglobal Surgical, distributor of the Mega Soft Patient Return Electrode, provided advice by telephone on the cost of the Mega Soft Patient Return Electrode and its comparators;
- NHS Supply Chain product catalogue for cost information on diathermy pads, razors and mattresses;
- A national database, published by the Personal Social Services Research Unit (PSSRU) [Curtis and Burns, 2017] for cost of theatre staff.

The assumptions used to inform the recommendations by the Medical Technologies Advisory Committee (MTAC) in 2012 and the changes arising from this costing update are reported in Section 2, with Section 3 reporting the updated cost comparisons.

This update of costs exercise did not extend to updating the incidence and cost of burns. However, the EAC has sourced this information and provided it to Neil Hewitt, National Institute for Clinical Excellence (NICE).

Section 2: Updated Assumptions on Cost Comparisons

2.1 ASSUMPTIONS USED BY MTAC IN 2012 AND 2018 VALUES

Table 2.1 sets out the assumptions that informed the original MTAC decision, together with the updated cost and usage assumptions for the Mega Soft Patient Return Electrode and the diathermy pad comparator.

Table 2.1: Existing and updated assumptions on Mega Soft Patient Return Electrode and diathermy pads pathways

Parameter	Value		Source
	2012	2018	
Cost of adult Mega Soft Patient Return Electrode	£2,280	£2,400	Distributor
Cost of paediatric Mega Soft Patient Return Electrode	£2,280	£3,000	Distributor
Usage (procedures per annum)	600	600	NICE experts
Comparator: Current practice diathermy plates plus mattress			
Adult diathermy plate split without leadwire	£0.76	£2.02	NHS Supply Chain catalogue 2012 & 2017
Adult diathermy plate split with leadwire	£1.92	£1.76	NHS Supply Chain catalogue 2012 & 2017
Infant diathermy plate split without leadwire	£0.68	Not reported	NHS Supply Chain catalogue 2012 & 2017
Infant diathermy plate split with leadwire	£5.91	£4.84	NHS Supply Chain catalogue 2012 & 2017
Reusable lead wire from ESU	£21.86	£31.58	NHS Supply Chain catalogue 2012 & 2017
Band 3 30 seconds to affix and remove wire	£0.11	£0.12	NICE experts
Usage of lead wire	100 times		Assumption from sponsor and verified by NICE clinical experts
Mattress purchase price	£334		2012 price still applicable as checked NHS Supply Chain catalogue on 15/12/2017
Usage of mattress	5 times a day, 200 days a year		2012 assumption by NICE clinical experts
Razor clip head	£2.09		2012 price still applicable as checked NHS Supply Chain catalogue on 15/12/2017
% patients shaved	Adults 30%; infants 0%		2012 assumption by NICE clinical experts
Theatre staff cost per minute			
Surgeon and consultant anaesthetist	£2.27	£1.78	Theatre staffing from NICE clinical experts; cost per minute from PSSRU 2012 and 2016
Band 6 nurse	£0.57	£0.75	
Band 4 technician	£0.38	£0.52	
Band 3 healthcare assistant	£0.22	£0.23	Salary midpoints in 2012 and 2017 plus 25% overheads, expressed per minute

The most important changes are now discussed.

Mega soft patient return electrode unit cost and usage

Mr Aaron Mulligan, Director, Interglobal Surgical, the UK distributor of Mega Soft, advised the price for adult (£2,000) and paediatric (£2,500) Mega Soft Patient Return Electrode products. These prices were exclusive of VAT; this was added at 20%, to give prices of £2,400 and £3,000 for the adult and paediatric products respectively.

These represent an increase of £100 (excluding VAT) for an adult product and £600 (excluding VAT) for the paediatric product from the prices adopted in 2012.

The assumed annual usage rate in 2012 of three procedures a day for 200 days a year for the Mega Soft Patient Return Electrode, as advised by NICE experts, was retained.

Diathermy pads and lead cable unit cost and usage

In 2012, the MTAC advised the relevant source of cost information for diathermy pads was the NHS Supply Chain catalogue. The 2017 NHS Supply Chain catalogue had fewer diathermy products than in 2012; for example, no solid pads are now quoted. These are now seldom used in the NHS, being less safe than split pads (Personal communication; Mr A Mulligan, Director, Interglobal Surgical telephone call 21/12/2017). This update hence excludes cost for solid pads.

The cost of split diathermy pads varies between those with lead wires and those without lead wires; the latter are connected to an electrosurgical unit through a reusable cable. In this costing update, there was no need to average prices from NHS Supply Chain catalogue for each type as there was only one pad with lead wires (cost £2.02) and one without lead wires (cost £1.76) reported. These prices are counterintuitive; the cost of a diathermy pad with no lead wire should be more expensive than one without. With the latter, staff must use a cable to connect the pad to the unit, ensure it is sterilised, and retain it safely for reuse.

The cost of the split pad with no lead wire is now materially higher than reported in 2012 (£2.02 versus £0.76). The catalogue noted that a second pad costing £0.99 was no longer available. A sensitivity analysis will be conducted using this lower unit price. The cost of a split pad with lead wire is now slightly cheaper (£1.76 versus £1.92).

In 2017, the NHS Supply Chain catalogue reported the price of a diathermy pad with lead wire for an infant as £4.84. In 2012 this item was priced at £5.91 on the product catalogue. No products for an infant without lead wires are now available on the NHS Supply Chain product catalogue; in 2012, a price of £0.68 was quoted for this item.

The cost of a lead cable quoted in the NHS Supply Chain catalogue has risen from £21.86 in 2012 to £31.58. The 2012 modelling assumed each cable would be used 100 times. This was an assumption made by the sponsor and validated by NICE experts.

For this update, Mr A Mulligan, Director, Interglobal Surgical, advised such cables may have a longer life, with each theatre using 3 or 4 a year (Personal communication; Mr A Mulligan, Director, Interglobal Surgical telephone call 21/12/2017). A sensitivity analysis will be conducted assuming each theatre has five procedures a day, operates 200 days a year and uses a mean of 3.5 cables a year (about 285 procedures per cable).

The 2012 assumption that a healthcare assistant will spend 30 seconds affixing, removing and storing the reusable cable has been retained.

Theatre mattresses unit cost and usage

Current prices from the NHS Supply Chain catalogue remain about £334 for a pressure mattress. The assumptions made in 2012 of a one year life and usage rate of five times a day for 200 days a year have been retained.

Razors unit cost and usage

The assumption made by NICE experts in 2012 that electric razors with disposable heads are used for shaving is retained. The unit cost of £2.09 used in 2012 is consistent with indicative prices from the current NHS Supply Chain catalogue. The assumptions on shaving rates are also retained, being 30% of adults and 0% of infants.

Theatre time saved and value thereof

In 2012, the MTAC took the view that there was unlikely to be any substantial saving of operating theatre time as a result of using the Mega Soft Patient Return Electrode. In this update, a sensitivity analysis will assume savings of one minute per procedure; however, the EAC notes the MTAC advised this can be avoided by applying the diathermy pads in the preparation room. The staffing level advised by NICE experts was an average of five per procedure (a surgeon, an anaesthetist, a nurse, an operating department technician and a health care assistant).

The same source has been used to value staff time namely 'Unit Costs of Health and Social Care', published by PSSRU, with the update using the 2017 edition. This source does not provide cost data for a band 3. Hence the cost of 30 seconds of a healthcare assistant's time was calculated using the mid-point salary for an agenda for change band 3, £18,333 (http://www.nhsemployers.org/your-workforce/pay-and-reward/agenda-for-change/pay-and-conditions-circulars). With 25% on-costs for national insurance and superannuation added and assuming a 37.5 hour week and 44 weeks a year, the cost per minute is £0.23.

Comparing the 2012 and 2017 values shows the cost per minute of consultants has declined from £2.27 to £1.78. This change arises because the calculations now assume a longer working week for consultants than that used in 2012.

Time horizon

A two-year time horizon, consistent with the warranty on the Mega Soft Patient Return Electrode has been retained, with costs discounted in year 2 at a rate of 3.5%.

Clinical outcomes

No clinical outcome measures were applied in 2012 nor in this update. The EAC made a Freedom of Information request to the NHS Litigation Authority (NHSLA) to identify the cost to the NHS of diathermy pad burns. The response has been provided to NICE.

Section 3: Results

3.1 BASE CASE COST COMPARISON

The base case costs and savings per procedure for Mega Soft Patient Return Electrode compared with diathermy pads, as calculated in this update and in 2012 are presented in Table 3.1.

Table 3.1: Cost of Mega Soft Patient Return Electrode and diathermy pads per procedure 2012 and 2017

Cost Element	2012				2017			
	Adult		Infant		Adult		Infant	
	No lead wire	With lead wire	No lead wire	With lead wire	No lead wire	With lead wire	No lead wire	With lead wire
Mega Soft Patient Return Electrode								
Cost	**£1.93**		**£1.93**		**£2.03**		**£2.54**	
Diathermy pathway								
Pads	£0.76	£1.92	£0.68	£5.91	£2.02	£1.76	NA	£4.84
Reusable cable	£0.22		£0.22		£0.32		£0.32	
Band 3 to affix cable	£0.11		£0.11		£0.12		£0.12	
Mattress	£0.33	£0.33	£0.33	£0.33	£0.33	£0.33	£0.33	£0.33
Shave	£0.63	£0.63	£0.00	£0.00	£0.63	£0.63	£0.00	£0.00
Total cost	**£2.05**	**£2.88**	**£1.34**	**£6.24**	**£3.42**	**£2.72**	**NA**	**£5.17**
Savings with Mega Soft*	**£0.12**	**£0.95**	**-£0.59**	**£4.31**	**£1.39**	**£0.69**	**NA**	**£2.63**

NA = Not available. *A positive value indicates a saving with Mega Soft; a negative value indicates a higher cost with Mega Soft. Numbers may not add precisely due to rounding.

3.2 SENSITIVITY ANALYSES

Adopting a cost in 2018 of £0.99 per adult diathermy pad with no lead wire reduced the cost of this combination to £2.38, £0.35 more expensive than the Mega Soft Patient Return Electrode. As noted in Section 2, the NHS Supply Chain product catalogue referred to such a price but added this line was no longer available.

If one assumes each cable is re-used 285 times, not 100 times, then the 2018 cost of all the non-wired diathermy pad combinations is reduced by 20.5 pence. Hence with a cost per adult diathermy pad, with no wire, and if the cable is used 285 times, the cost of this option falls to £2.18, or £0.15 more expensive than the Mega Soft Patient Return Electrode.

Retaining all assumptions about cost and use of razors, mattresses and reusable cables the NHS hospitals will find it cost saving to adopt the Mega Soft Patient Return Electrode adult product if they pay more than £0.64 for a pad with no wires and £1.07 for a pad with wires. The EAC has not asked NHS Trusts whether such prices are realistic.

The Mega Soft Patient Return Electrode for use with infants is estimated to cost £2.54 per procedure. Assuming only split pads with lead wires are placed on infants, consistent with the advice from Mr A Mulligan (Personal communication; Mr A Mulligan, Director, Interglobal Surgical telephone call 21/12/2017) if NHS hospitals pay more than £2.21 for such pads then the Mega Soft Patient Return Electrode is cost saving. This assumes all other assumptions are held constant.

The MTAC judged that savings in theatre time are unlikely if a staff members applies the diathermy pad in the preparation room. If some settings do not adopt this practice and the fitting of these does delay the theatre team then the diathermy pad pathway has an additional cost of just over £5 per minute 'lost'.

3.3 CONCLUSIONS

In 2012, the MTAC concluded that the Mega Soft Patient Return Electrode device had the potential to be cost saving, particularly if patients required to be shaved or had sensitive skin. In this update, the potential groups where savings with the Mega Soft Patient Return Electrode are likely can be extended to all infants. Indeed, adopting the cost from the NHS Supply Chain product catalogue per diathermy pad, then the Mega Soft Patient Return Electrode is always cost saving for patients who do not require shaving and for an average cohort of adults, assuming 30% require to be shaved.

NHS Trusts may be able to purchase diathermy pads at a lower price than those quoted in the NHS Supply Chain product catalogue. Applying the central 2018 assumptions indicate that savings with Mega Soft Patient Return Electrode may be achieved if the pads for adults cost more than £0.64 and £1.07 each respectively. For infants, savings accrue if diathermy pads cost more than £2.21 each.

References

Curtis, L. & Burns, A. Unit Costs of Health and Social Care 2017, Personal Social Services Research Unit, University of Kent, Canterbury.

NICE. Mega Soft Patient Return Electrode for use during monopolar electrosurgery. Medical technologies guidance [MTG11] August 2012.