

Medical Technologies Evaluation Programme

MT 257 - HumiGard Surgical Humidification System for the prevention of inadvertent perioperative hypothermia

Expert Adviser Questionnaire Responses

Name of Expert Advisers	Job Title	Professional Organisation/ Specialist Society	Nominated by	Ratified
Dr Jonathan M Cousins	Consultant Anaesthetist Intensivist	Royal College of Anaesthetists	Sponsor	Yes
Ms Jane Hendricks	Laparoscopic nurse practitioner	Royal College of Nursing	Sponsor	Yes
Mr Tan Arulampalam	General surgeon	Association of Surgeons of Great Britain and Ireland	Sponsor	Yes
Dr John Andrzejowski	Consultant Anaesthetist	Association of Anaesthetists of Great Britain and Ireland	NICE nominated	Yes
Dr Mark Harper	Consultant Anaesthetist	Association of Anaesthetists of Great Britain and Ireland	NICE nominated	Yes

YOUR PERSONAL EXPERIENCE (IF ANY) WITH THIS TECHNOLOGY

Question 2: Please indicate your experience with this technology?

Expert Advisers	I have had direct involvement with this	I have referred patients for its use	I manage patients on whom it is used in another part of their care pathway	I would like to use this technology but it is not currently available to me
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	Yes	Yes	Yes	No
Ms Jane Hendricks Laparoscopic Nurse Practitioner	Yes	Yes	Yes	No
Mr Tan Arulampalam General surgeon	Yes	No	No	No
Dr John Andrzejowski Consultant Anaesthetist	No	No	No	No
Dr Mark Harper Consultant Anaesthetist	Yes	No	Yes	No
<i>Any Comments?</i>				
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	Blank			
Ms Jane Hendricks Laparoscopic Nurse Practitioner	Blank			
Mr Tan Arulampalam General surgeon	i have over 15 months of practical experience of his technology			
Dr John Andrzejowski Consultant Anaesthetist	I would use this if the evidence for its benefit were strong enough. Many of these products have been trialled yet no Hospital I have worked at has ever bothered to use them I presume therefore that the evidence for benefit is equicocal.			

Expert Advisers	I have had direct involvement with this	I have referred patients for its use	I manage patients on whom it is used in another part of their care pathway	I would like to use this technology but it is not currently available to me
Dr Mark Harper Consultant Anaesthetist	This is a device used by surgeons on cases I anaesthetise			

Question 3: Have you been involved in any kind of research on this technology? If Yes, please describe?

Expert Advisers	Yes/No	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	Yes	assessing the role within an enhanced recovery pathway in my NHS practice
Ms Jane Hendricks Laparoscopic Nurse Practitioner	No	Blank
Mr Tan Arulampalam General surgeon	Yes	I have looked at the efficacy and outcomes in patients who have undergone laparoscopic colorectal surgery using Humiguard. I have looked at data pre and post Humiguard introduction and measured Surgical Site Infection (SSI), length of stay and stay in recovery after surgery.
Dr John Andrzejowski Consultant Anaesthetist	No	Blank
Dr Mark Harper Consultant Anaesthetist	No	Blank

THIS PRODUCT (TECHNOLOGY) AND ITS USE

Question 4: *How would you best describe this technology?*

Expert Advisers	It is a minor variation on existing technologies with little potential for different outcomes and impact	It is a significant modification of an existing technology with real potential for different outcomes and impact	It is thoroughly novel - different in concept and/ or design to any existing
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	No	Yes	No
Ms Jane Hendricks Laparoscopic Nurse Practitioner	No	Yes	Yes
Mr Tan Arulampalam General surgeon	No	Yes	No
Dr John Andrzejowski Consultant Anaesthetist	Yes	No	No
Dr Mark Harper Consultant Anaesthetist	No	Yes	No
<i>Any Comments?</i>			
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	Blank		
Ms Jane Hendricks Laparoscopic Nurse Practitioner	Blank		
Mr Tan Arulampalam General surgeon	Blank		
Dr John Andrzejowski Consultant Anaesthetist	There are many systems already on the market that heat and humidify insufflation gases.		
Dr Mark Harper Consultant Anaesthetist	Blank		

Question 5: What is the most appropriate use (e.g. clinical indication) for the technology?

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	during laparoscopy it can heat and humidify the carbon dioxide gas used to insufflate the abdomen. It reduces pain and a few surgical scope misting issues
Ms Jane Hendricks Laparoscopic Nurse Practitioner	MAJOR LAPAROSCOPIC OPERATIONS
Mr Tan Arulampalam General surgeon	The most impact that i have experienced is with the use of Humiguard in laparoscopic colorectal resections after July 2013. There has been an observed reduction in SSI and length of stay in the recovery room. This is a sustained effect and measured over a long period with significant patient numbers.
Dr John Andrzejowski Consultant Anaesthetist	Any laparoscopic abdominal surgery such as cholecystectomy
Dr Mark Harper Consultant Anaesthetist	Laparoscopic surgery-it had potential to reduce pain and prevent IPH

COMPARATORS (including both products in current routine use and also “competing products”)

Question 6: *Given what you stated is the appropriate indication (clinical scenario) for its use, what are the most appropriate "comparators" for this technology which are in routine current use in the NHS?*

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	there is a Storz device which just heats the gas. It did not seem to reduce the pain or the misting problems
Ms Jane Hendricks Laparoscopic Nurse Practitioner	NONE THAT I KNOW OF
Mr Tan Arulampalam General surgeon	The only comparator is not using Humiguard
Dr John Andrzejowski Consultant Anaesthetist	Gas straight out of a CO2 cylinder
Dr Mark Harper Consultant Anaesthetist	1. Unwarmed, non-humidified CO2 for insufflation; 2. Warmed, non-humidified CO2

Question 7: "Competing products": Are you aware of any other products which have been introduced with the same purpose as this one?

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	As above in 6
Ms Jane Hendricks Laparoscopic Nurse Practitioner	No
Mr Tan Arulampalam General surgeon	No
Dr John Andrzejowski Consultant Anaesthetist	Snowden Pencer, Storz Endoflator, Storz Laparoflator, Richard Wolf, and BEI Medical, Stryker insufflator
Dr Mark Harper Consultant Anaesthetist	No although the standard, non-humidified CO2 warming might be considered as a competing product.

POSSIBLE BENEFITS FOR PATIENTS

Question 8: *What are the likely additional benefits for patients of using this technology, compared with current practice/comparators?*

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	to improve patient outcomes especially in day cas surgery.
Ms Jane Hendricks Laparoscopic Nurse Practitioner	MAINTAINING THE PATIENTS TEMPERATURE INTRA OPERATIVELY HAS MANY BENEFITS TO THEIR POST OPERATIVE COURSE.
Mr Tan Arulampalam General surgeon	Less pain, reduced SSI
Dr John Andrzejowski Consultant Anaesthetist	Decreased post op pain. Less hypothermia. Surgeons view may be impaired or improved with this technique.
Dr Mark Harper Consultant Anaesthetist	Less pain, reduced incidence of IPH, less tissue damage leading to quicker discharge

Question 8.1: Is each additional benefit likely to be realised in practice? What are the likely obstacles?

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	yes, obstacles are the cost of a disposable that is additional when no device is used
Ms Jane Hendricks Laparoscopic Nurse Practitioner	Blank
Mr Tan Arulampalam General surgeon	Yes. I think there needs to be further research but there is evidence that this technology appears to have a substantial effect as a bundle of care to address SSI and help relieve post operative pain
Dr John Andrzejowski Consultant Anaesthetist	Pain results have been equivocal in the studies I have looked at. It seems that just using a different gas such as helium might be more beneficial. Temperature drop isnt a great problem in real clinical scenarios, since a certain volume of gas is pushed in and then is not flushed out. It has time to equilibrate with the intraabdominal contents
Dr Mark Harper Consultant Anaesthetist	Yes-but needs to be quantified

Question 8.2: *How might these benefits be measured? What specific outcome measures would enable assessment of whether additional benefits for patients are being realised?*

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	pots op pain. comfort, discharge speeds, surgical view assessments
Ms Jane Hendricks Laparoscopic Nurse Practitioner	PATIENT OUTCOMES, MONITORING TEMPERATURE , SSI, LENGTH OF STAY
Mr Tan Arulampalam General surgeon	Measure SSI pre and post introduction. Measuring pain is very difficult but high volume units with standardised techniques may be able to provide good test grounds to compare pain scores.
Dr John Andrzejowski Consultant Anaesthetist	Post op pain scores in PACU and at 6 hours. Post op and intraop temperatures.
Dr Mark Harper Consultant Anaesthetist	Post op pain scores and analgesic requirements, mean temperatures and incidence of IPH; times to discharge from recovery and hospital.

Question 8.3: How good is this evidence for each of these additional benefits?

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	clinically sound but of course fairly soft end points that would need a lot of case numbers and good RCCT to be proved beyond doubt.
Ms Jane Hendricks Laparoscopic Nurse Practitioner	RELATIVELY NEW TECHNOLOGY WE HAVE GOOD EVIDENCE AT OUR HOSPITAL THAT IT WORKS
Mr Tan Arulampalam General surgeon	SSI evidence (unpublished) is strong.
Dr John Andrzejowski Consultant Anaesthetist	Not good. The literature for the manufacturer shows all the positive results but on the internet I found a number of negative or equivocal papers.
Dr Mark Harper Consultant Anaesthetist	I'm not aware of any high-quality evidence of improved outcomes

Question 8.4: Please add any further comment on the claimed benefits of the technology to patients, as you see applicable

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	My NHS practice is convinced that the patients are better and we can more reliably offer day surgery for laparoscopy, hernias and cholecystectomy and bariatric procedures.
Ms Jane Hendricks Laparoscopic Nurse Practitioner	REDUCTION IN ADHESION PRODUCTION AND POST OPERATIVE PAIN ARE MULTI FACTORIAL AND HARD TO QUANTIFY
Mr Tan Arulampalam General surgeon	We are analysiing data and still looking at root cause analyses for SSIs. More work is needed to look at this and assess reproducibile effect across the NHS which may lead to huge benefits.
Dr John Andrzejowski Consultant Anaesthetist	Blank
Dr Mark Harper Consultant Anaesthetist	Blank

POSSIBLE BENEFITS FOR THE HEALTHCARE SYSTEM

Question 9: *What are the likely additional benefits for the healthcare system of using this technology, compared with current practice/ comparators?*

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	as there is almost no competition all th above benefits are available
Ms Jane Hendricks Laparoscopic Nurse Practitioner	Blank
Mr Tan Arulampalam General surgeon	Reduced SSI and therefore reduced cost
Dr John Andrzejowski Consultant Anaesthetist	Shorter length of stay in recovery maybe
Dr Mark Harper Consultant Anaesthetist	Reduced care costs through reduced analgesic requirements, complications and time spent in hospital.

Question 9.1: Is each additional benefit likely to be realised in practice? What are the likely obstacles?

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	yes faster and more reliable discharge and possibly shorter operation times due to surgical speed in creases
Ms Jane Hendricks Laparoscopic Nurse Practitioner	COST OF IMPEMETING THE TECHNOLOGY IN THE FACE OF THE CURRENT CONSTRAINTS ON THE NHS BUDGET
Mr Tan Arulampalam General surgeon	See above. It is likely that the effect on SSIs will be part of a bundle of care that will have an impact which will benefit the healthcare system by reducing cost.
Dr John Andrzejowski Consultant Anaesthetist	many other factors affect patients length of stay other than pain and temperature
Dr Mark Harper Consultant Anaesthetist	Potentially though not enough evidence to my knowledge to make a definitive statement

Question 9.2: How might these benefits be measured? What specific outcome measures would enable assessment of whether additional benefits for the healthcare system are being realised?

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	patient outcome and satisfaction forms, time measurements
Ms Jane Hendricks Laparoscopic Nurse Practitioner	COLLECTING DATA ON PATIENTS OUTCOMES AND COMPARING THEM TO THE OUTCOMES PRIOR TO IMPLEMENTATION OF THE TECHNOLOGY
Mr Tan Arulampalam General surgeon	Measure SSI reduction
Dr John Andrzejowski Consultant Anaesthetist	LOStay
Dr Mark Harper Consultant Anaesthetist	see 8.2

Question 9.3: How good is this evidence for each of these additional benefits?

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	Certainly not level 1!
Ms Jane Hendricks Laparoscopic Nurse Practitioner	OF GOOD STANDARD HOWEVER MORE IS REQUIRED AS THE TECHNOLOGY IS USED TO BUILD A GOOD CASE FOR ITS IMPLEMENTATION
Mr Tan Arulampalam General surgeon	Strong based on standard modelling that I have seen
Dr John Andrzejowski Consultant Anaesthetist	Uncertain
Dr Mark Harper Consultant Anaesthetist	There is a good scientific basis but a lack of RCTs

Question 9.4: Please add any further comment on the claimed benefits of the technology to the healthcare system, as you see applicable

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	Blank
Ms Jane Hendricks Laparoscopic Nurse Practitioner	Blank
Mr Tan Arulampalam General surgeon	Blank
Dr John Andrzejowski Consultant Anaesthetist	Blank
Dr Mark Harper Consultant Anaesthetist	Blank

FACILITIES, TRAINING AND FUNCTIONING

Question 10: *Are there any particular facilities or infrastructure which needs to be in place for the safe and effective use of this technology?*

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	Introductory training
Ms Jane Hendricks Laparoscopic Nurse Practitioner	BELIEVE THE COMPANY PROVIDES GOOD INSERVICE EDUCATION AND HAVE A ROBUST SYSTEM OF SUPPORT FOR PRACTITIONERS
Mr Tan Arulampalam General surgeon	Pilot studies in Colchester have ironed out implemetantion issues and technolgy is simple to use.
Dr John Andrzejowski Consultant Anaesthetist	Servuicing and prevention of overheating
Dr Mark Harper Consultant Anaesthetist	No

Question 11: Is special training required to use this technology safely and effectively?

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	only demonstration and checking that education has transferred
Ms Jane Hendricks Laparoscopic Nurse Practitioner	IT IS RELATIVELY STRAIGHT FORWARD TO USE
Mr Tan Arulampalam General surgeon	Basic training of theatre staff
Dr John Andrzejowski Consultant Anaesthetist	probably
Dr Mark Harper Consultant Anaesthetist	Very little

Question 12: Please comment on any issues relating to the functioning, reliability and maintenance of this technology which may be important to consider if it is introduced

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	very robust - no issues. Very safe, no user elements/decisions.
Ms Jane Hendricks Laparoscopic Nurse Practitioner	WE HAVE NEVER HAD A PROBLEM WITH THE TECHNOLOGY
Mr Tan Arulampalam General surgeon	Simple technology, with disposable tubing and straightforward for theatre staff to learn.
Dr John Andrzejowski Consultant Anaesthetist	unknown to me
Dr Mark Harper Consultant Anaesthetist	In my practice it has appeared to be reliable and simple to operate.

COSTS

Question 13: *Please provide any comments on the likely cost consequences of introducing this technology. In particular, please comment on the implications of this technology replacing the comparator/s you have described above*

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	depends upon turnover and purchasing agreements
Ms Jane Hendricks Laparoscopic Nurse Practitioner	TO THE BEST OF MY KNOWLEDGE THERE ARE NO OTHER COMPETATORS ON THE MARKET
Mr Tan Arulampalam General surgeon	Minor cost to implement on a per patient basis with significant cost benefit if SSI reduction is seen.
Dr John Andrzejowski Consultant Anaesthetist	likely to cost more. will any benefits offset these costs?
Dr Mark Harper Consultant Anaesthetist	I'm not sure about the exact costs but my impression is that it introduces an additional cost of less than £100/patient

GENERAL ADVICE BASED ON YOUR SPECIALIST KNOWLEDGE

Question 14: Is there controversy about any aspect of this technology or about the care pathway?

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	Not really it makes sense to warm and humidify the carbon dioxide gas but the devices prior to this one did not do this reliably to gain a clinical benefit.
Ms Jane Hendricks Laparoscopic Nurse Practitioner	NOT TO THE BEST OF MY KNOWLEDGE
Mr Tan Arulampalam General surgeon	This technology must be introduced as part of a bundle of care to reduce post laparoscopic colorectal surgery SSI. There may be other applications in laparoscopic surgery to reduce SSI and possibly pain also.
Dr John Andrzejowski Consultant Anaesthetist	Yes. I couldn't find a large scale study with this technology of sufficient power to state that it was definitely of benefit.
Dr Mark Harper Consultant Anaesthetist	No

Question 15: If NICE were to develop guidance on this technology, how useful would this be to you and your colleagues?

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	It would allow justification for purchase and to allow non - surgical groups – like anaesthetists and managers of hospital departments to believe the positive impacts of such a device.
Ms Jane Hendricks Laparoscopic Nurse Practitioner	VERY AS IT ASSISTS WITH THE IMLEMENTATION OF THE TECHNOLOGY AND ENSURES A STANDARD OF BEST PRACTICE AND GOOD PATIENT CARE.
Mr Tan Arulampalam General surgeon	Very useful
Dr John Andrzejowski Consultant Anaesthetist	Useful
Dr Mark Harper Consultant Anaesthetist	Very useful-could integrate it into update of CG65

Question 16: *Do any subgroups of patients need special consideration in relation to the technology (for example, because they have higher levels of ill health, poorer outcomes, problems accessing or using treatments or procedures)? Please explain why*

Expert Advisers	Comment
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	no it is useful for all laparoscopic surgery except if performing heat delivering operations (like liver ablations and emergencies where sepsis has caused a severe pyrexia) I have experience of paediatric use.
Ms Jane Hendricks Laparoscopic Nurse Practitioner	NO , HOWEVER ITS USE SHOULD BE CONSIDERED IN ALL MAJOR LAPAROSCOPIC PROCEDURES ; IT IS NOT NESSACARILY FOR DAYCASE LAP SURGERY IE SHORT PROCEDURES.
Mr Tan Arulampalam General surgeon	All patients undergoing laparoscopic colorectal surgery but particularly diabetics and immunocompromised.
Dr John Andrzejowski Consultant Anaesthetist	Any patient at high riskof hypothermia eg short procedures or very thin patients may be more affected. (See CG65)
Dr Mark Harper Consultant Anaesthetist	No

CONFLICTS OF INTEREST

Question 18.1: Do you or a member of your family have a personal pecuniary interest? The main examples are as follows:

Expert Advisers	Consultancies or directorships	Fee-paid work	Shareholdings	Expenses and hospitality	Investments	Personal non-pecuniary interest
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	No	No	No	Blank	No	Yes
Ms Jane Hendricks Laparoscopic Nurse Practitioner	No	No	No	No	No	Yes
Mr Tan Arulampalam General surgeon	No	No	No	No	No	No
Dr John Andrzejowski Consultant Anaesthetist	Yes	Yes	No	No	No	No
Dr Mark Harper Consultant Anaesthetist	No	Yes	No	No	No	Yes

If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.

Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	we have published the results of our enhanced NHS recovery programme that states this device was an effective part of that pathway.
Ms Jane Hendricks Laparoscopic Nurse Practitioner	I AM THE CHAIR PERSON OF THE ALTS. AS THE CHAIR PERSON OF THE ASSOCIATION OF LAPAROSCOPIC THEATRE STAFF (I HOLD A PLACE ON COUNCIL OF THE ASSOCIATION OF LAPAROSCOPIC SURGEONS OF GREAT BRITIAN AND IRELAND) I AM NOT SURE WHETHER THIS IS A PERSONAL NON-PECUNIARY INTEREST. I HAVE SPOKEN BRIEFLY ABOUT OUR EXPERIECE OF USING THE PRODUCT IN A MEETING HOSTED BY FISHER AND PAYKEL
Mr Tan Arulampalam General surgeon	Blank

Expert Advisers	Consultancies or directorships	Fee-paid work	Shareholdings	Expenses and hospitality	Investments	Personal non-pecuniary interest
<p>Dr John Andrzejowski Consultant Anaesthetist</p>	<p>I take part in private practice and have been paid by Molnlycke and the 37degree company for advice regarding their warming products. I am unaware of any competing products for laparoscopy made by either of these two companies.</p>					
<p>Dr Mark Harper Consultant Anaesthetist</p>	<p>Advisor to RCOA and NICE. I have received expenses and an honorarium for sitting on an advisory board for Molnlycke. I have received provision of equipment for research and evaluation from Molnlycke, 3M, Augustine biomedical, Inditherm and Geratherm.</p>					

Question 18.2: Do you have a non-personal interest? The main examples are as follows:

Expert Advisers	Fellowships endowed by the healthcare industry	Support by the healthcare industry or NICE that benefits his/her position or department, e.g. grants, sponsorship of posts
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	No	No
Ms Jane Hendricks Laparoscopic Nurse Practitioner	No	No
Mr Tan Arulampalam General surgeon	No	Yes
Dr John Andrzejowski Consultant Anaesthetist	No	No
Dr Mark Harper Consultant Anaesthetist	No	No
<i>If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.</i>		
Dr Jonathan M Cousins Consultant Anaesthetist Intensivist	Blank	
Ms Jane Hendricks Laparoscopic Nurse Practitioner	Blank	
Mr Tan Arulampalam General surgeon	An hourly payment was made to a data clerk to access and assemble data in Colchester.	
Dr John Andrzejowski Consultant Anaesthetist	Blank	

Expert Advisers	Fellowships endowed by the healthcare industry	Support by the healthcare industry or NICE that benefits his/her position or department, e.g. grants, sponsorship of posts
Dr Mark Harper Consultant Anaesthetist	Blank	