The first Universal Anaesthesia Machine: An evaluation

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JAP 2011, 4, 128-134.

Introduction

The Universal Anaesthesia Machine (UAM) was developed to provide an anaesthetic machine for use in developing countries where compressed gases and electricity cannot be relied upon.[1-3] The design of the UAM is a collaboration between Paul Fenton, anaesthetist, and OES Medical, a UK-based anaesthesia equipment manufacturing company. The components of the UAM have been safely used since 1999 during 24,000 cases and 10 years of anaesthetic provision in Malawi.[4,5] This high specification machine, comprehensively manufactured to meet CE requirements, ISO and British Standards, heralds new possibilities for the provision of safe anaesthesia in a variety of settings and needed evaluation.[6-8]

Meeting all the above standards was imperative in gaining the necessary support at all levels in our hospital Trust, including the need to go through the standard procurement process and Electro-Biomedical Engineering checks.[9] Subject to all these essentials being fulfilled, our hospital advisory consultants and Research and Development Lead advised that Research Ethics approval was not required.

Figure 1. The Universal Anaesthesia Machine

Machine Design

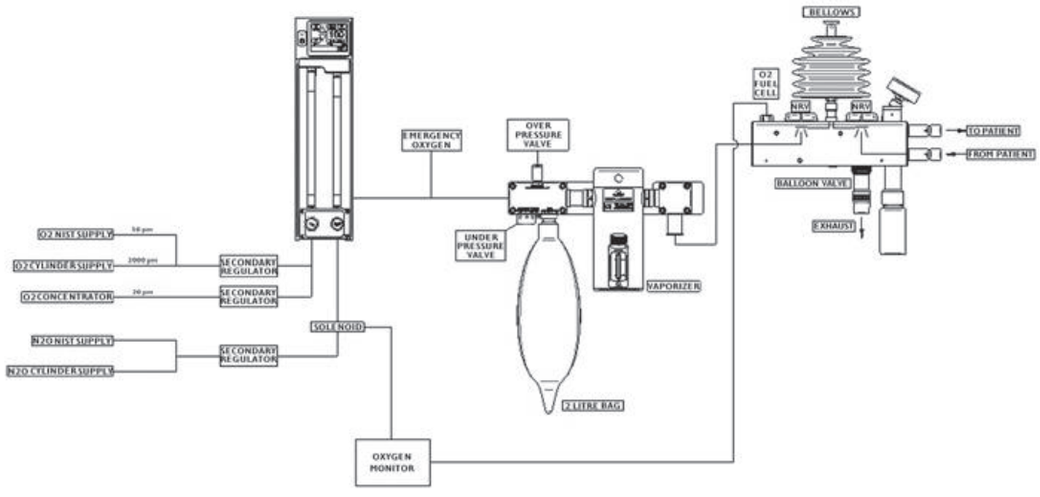
The UAM is designed on time-honoured anaesthetic principles housed in modern technology. It is a simple anaesthetic workstation that looks familiar with a clear layout. Key differences from a standard Boyle's machine are the oxygen concentrator, drawover vaporiser, bellows and balloon valve. The system provides continuous flow anaesthesia, reverting to drawover mode if air is entrained or if electricity fails, with the vaporiser and bellows continuing to function as normal. In both modes, oxygen can alternatively be provided via cylinder, pipeline or the side emergency inlet. All parts are designed to have minimal to no service requirements.

Oxygen Concentrator and Gas Supply

The oxygen concentrator is electrically powered and produces 10 $l.min^{-1}$ of 95% oxygen by passing room air through filters, a compressor and zeolite. Nitrogen is adsorbed yielding oxygen and some residual argon. An 'On/Off' switch controls power to the concentrator, and recharges the oxygen sensor battery. The UAM has a conventional oxygen flowmeter (with a maximum flow of 10 $l.min^{-1}$) with a second flowmeter for either nitrous oxide (cylinder or pipeline, up to 12 $l.min^{-1}$) or air (from the concentrator). Ours, the first manufactured UAM, had nitrous oxide. A solenoid anti-hypoxic guard cuts the flow of nitrous oxide if the oxygen falls below the minimum set on the oxygen monitor. Nitrous oxide cannot be delivered in the absence of the oxygen monitor.

The touch-screen oxygen monitor is sited above the flowmeters, displaying the

Figure 2. Machine Circuit Illustration



oxygen concentration monitored by a fuel cell just proximal to the inflating bellows. It is electrically powered, has an independent on-off touch button, touch screen calibration and a rechargeable back up battery which lasts over two hours. The fuel cell lasts 20 months and replacement is then recommended. While desirable, the oxygen sensor is not integral or essential to the functioning of the UAM.

The back of the UAM has both cylinder yokes and hose connections for oxygen and nitrous oxide cylinders and pipelines.

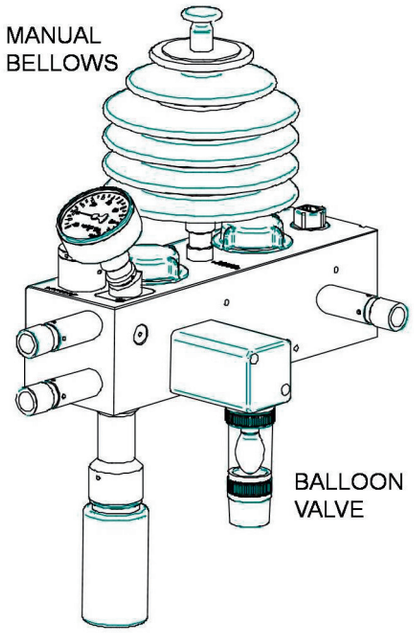


Figure 3. Bellows Assembley

The Backbar

Distal to the flowmeters on the backbar is a two litre reservoir bag which acts as a store of surplus fresh gas flow (FGF). Increasing reservoir volume in drawover techniques helps to maintain a high FiO_2 when higher minute volumes are required, such as during preoxygenation or attempts to flush the breathing system in an emergency.[10] A negative pressure valve allows entrainment of air below the back bar, and a positive pressure relief valve prevents overpressure of the bag. This ensures the pressure within the back bar remains within 3 cmH_2O of ambient pressure. The OES Medical vaporiser is a low resistance, CE-marked drawover type,[11] fitted securely on the backbar via a unique specific connection bracket. The isoflurane vaporiser (used for our evaluation) is calibrated to deliver up to 4%. A similar halothane vaporiser is interchangeable.

The Bellows Assembly

FGF is transferred to the bellows, which is placed between two one-way valves to ensure unidirectional gas flow. The silicone bellows, with a maximum volume of 1600ml, and a light interior spring, allows manual ventilation through a standard dual limb circuit. The expiratory valve is a long-life silicone balloon housed in a clear plastic tube on the side of the machine.[12] There is an additional non-return spring loaded exit valve to prevent rebreathing during spontaneous ventilation. This configuration avoids the need for a cumbersome expiratory valve at the patient's head, and filter humidifiers and scavenging can be used conventionally.

Workstation Function

During spontaneous ventilation (SV) the reservoir bag fills with FGF which is then delivered to the patient, with clearly discernable up and down movement of the bellows.

If the FGF is less than the patient's minute ventilation (SV or manual ventilation) air will be entrained via the negative pressure valve upstream of the vaporiser, and the oxygen sensor monitors the air and FGF mix delivered to the patient. When the FGF approximates minute ventilation the reservoir bag remains neutral. Tidal volume is assessed by observation of the bellows and chest expansion. Minute volume is estimated from the FGF, or if air is being entrained, by dividing the oxygen flow by the FiO_2 (expressed as a decimal). A gauge downstream of the bellows shows inspiratory and expiratory pressures, and a circuit pressure relief valve triggered at 40 cmH_2O prevents overpressure of the inflating system.

Evaluation

Consent for anaesthesia was sought as usual. Specific written consent to use the UAM was not deemed necessary as it is not standard practice to seek such consent when using CE marked equipment which has been formally approved for use via our procurement process. Likewise, Research Ethics Approval was not deemed necessary by our advisory consultants and Research and Development Lead as the UAM meets all the required CE, ISO and British Standards.

The UAM was regarded as supernumerary with standard checked anaesthetic machines in both theatre and anaesthetic rooms. The UAM was checked prior to use following a simple check list. The oxygen concentrator was used with a backup oxygen cylinder available. All monitoring to minimum monitoring standards[13] was applied using our standard equipment, including agent monitoring, to confirm the accuracy of the vaporiser. A protocol was in place that mandated instantly switching to the standard anaesthetic machine if there was any concern, whether or not this related to the UAM.

Training sessions were given by the developer and manufacturer, with a commitment to deal immediately with any concerns. Five consultants at Poole Hospital NHS Foundation Trust were involved in the evaluation which took place for a three month period during appropriate lists and for ASA Grade 1 and 2 patients only. Basic information about each case was logged, including age, sex, specialty, and whether the machine was used for induction and/or maintenance, and spontaneous or manual ventilation. Paul Fenton and the director of OES Medical remained present during the first three days of the evaluation and their evaluation form was completed at the end of the three month period by each of the five consultants.

Modifications to the UAM

The UAM was used in a total of 136 cases over the three month period. Several minor modifications were made during the first two days of the evaluation. During initial demonstration of the UAM prior to clinical use in SV mode, one evaluator self assessed the circuit, and felt that the resistance was high. On this basis a valve on the inspiratory limb was removed as it was considered redundant. The minute ventilation alarm (designed to measure over- or under-pressure of the reservoir bag) was deemed to be oversensitive, unnecessary and the noise distracting, therefore it was disabled.

An apnoea alarm that triggers and displays 'apnoea' after a latent period of 30 seconds was designed as replacement. Further refinement included a design modification to the vaporiser filler block thread to avoid cross threading of the filler cap, which occurred once. During one preoperative check it was noted that the bellows had developed a small leak. A modification with a deeper bellows rim and secure seal prevented recurrence. At one point, rebreathing was noted with lower flows during SV, due to negative pressures of the scavenging causing the exit flap valve to lift. A new spring loaded exit valve was designed to prevent this occurring.

Evaluation Results

The feedback questionnaire consisted of Section A "user rating" and Section B, "comparative evaluation". Table 1 displays the results of Section A, and Figure 4 displays the spread of scores pictorially.

User Rating

91% of scores awarded were 4 or 5; there were no scores of 1. All questions, bar the one about noise, scored an average (median) of at least 4. Several positive comments about the design of the machine included its robust appearance and - with specific reference to the bellows - the com-

Table 1: Results of the "User Rating" evaluation

Section A		Assessor Scores					
Part (i)	**Rate the user perspective of layout and setting up**	**A**	**B**	**C**	**D**	**E**	**Median Score**
1.1	User can see all necessary features eg. security of attachments	5	4	4	4	4	**4**
1.2	User can see all necessary information eg. labels/gauges	5	4	4	4	5	**4**
1.3	User manual is easy to understand; set up and pre-use check easy to perform	4,5	3	4	5	-	**4**
1.4	User can set all gas flows easily	5	5	5	5	5	**5**
1.5	User can set all vapour concentrations easily	5	5	5	3	5	**5**
1.6	User can set oxygen monitor easily	5	4	5	4	5	**5**
1.7	The manual ventilator is in a comfortable position	5	5	4	5	5	**5**
1.8	The manual ventilator is comfortable to operate for duration of procedure	4,5	5	4	3	5	**4.5**
1.9	Set parameters are protected adequately from accidental readjustment	5	5	4	5	5	**5**
1.10	The noise level is acceptable	3	2	2	4	4	**3**
1.11	The Fenton valve (balloon valve) function is easy to view and monitor	5	5	4	-	5	**5**
		Assessor Scores					
Part (ii)	**Administering anaesthesia: UAM response to patient variables**	**A**	**B**	**C**	**D**	**E**	**Median Score**
2.1	Adequate gas flows and vapour concentrations can be set	5	5	4	4	5	**5**
2.2	Set values are maintained for the duration of the procedure	4	5	4	4	4	**4**
2.3	After induction, values of EtAA correspond as expected to set values on vaporiser	5	3	4	4	4	**4**
2.4	Lung volumes and compliance can be adequately "felt" during manual ventilation	4	4	4	3	4	**4**
2.5	Inflation pressure and volume during inspiratory phase of IPPV is sufficient	5	5	4	4	5	**5**
2.6	The patient breathes out unimpeded during the expiratory phase of IPPV	5	3	4	4	5	**4**
2.7	The patient breathes unimpeded during spontaneous breathing	4	2	4	4	5	**4**
2.8	The patient is being adequately ventilated	5	5	4	4	5	**5**
2.9	The patient is being adequately anaesthetised	5	5	4	4	5	**5**
2.10	Anaesthesia is adequately maintained throughout the procedure	5	5	4	4	5	**5**
2.11	Allowing for confounding factors, the patient recovered as expected	5	5	4	4	5	**5**

Scores are on a five point scale where 1 = poor and 5 = excellent; if a score was not given this is denoted by a dash.

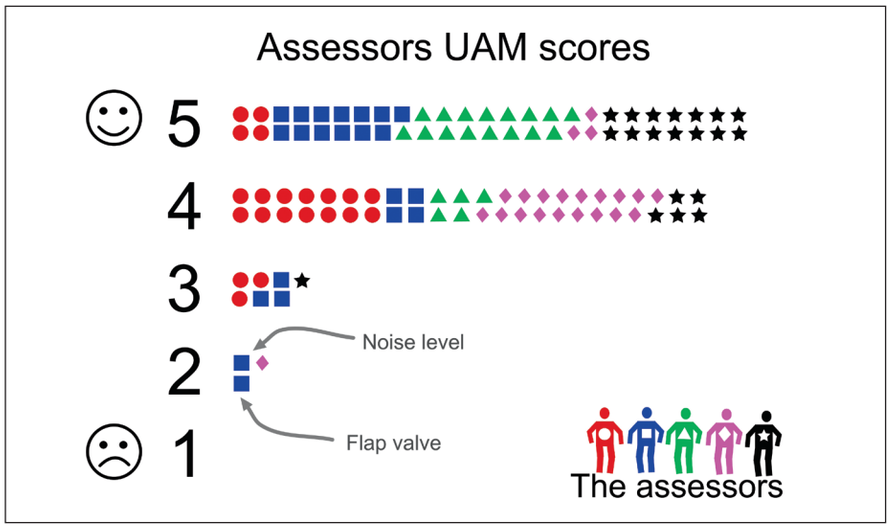


Figure 4. Results Section A: User rating. An illustration of the range of scores given, from 1 (poor) to 5 (excellent).

fort, perfect height and ease with which the bellows could be used on either side of the patient. It was deemed easier to assist ventilation by using the bellows due to the absence of an adjustable pressure limiting (APL) valve.

Noise acceptability had a lower average score of 3; however, most of the comments clearly related to the minute volume alarm prior to its deactivation early in the evaluation. The noise of the oxygen concentrator did not concern most users, although one commented that "a quieter machine would be advantageous". The observation was made that the vaporiser was generous by approximately 1% during the first five minutes of anaesthesia. Thereafter it was accurate, with no reported incidences of under-delivery. Comments about this early variation in delivered volatile concentration did not

concern users enough to score low points.

The use of the bellows appeared to require some practice to become familiar with volumes and compliance. One user felt it was adequate and safe but not quite "as hands on" as a normal reservoir bag. There were several comments about good transition from manual ventilation with the bellows to spontaneous ventilation and the ease of maintaining reasonable end tidal carbon dioxide levels with the bellows.

One commented that it was easy to inflate the lungs with the bellows despite the patient being obese, and another that poor compliance was gauged through the bellows in the case of a wheezy patient with asthma. There was one case of an obese smoker being ventilated via a microlaryngeal endotracheal tube with minimal relaxant where the user had difficulty feeling changes in compliance; however, realistically this scenario could have been as much of a problem with their usual machine.

It was not possible to fully evaluate SV on an oxygen/air mix (i.e. entraining air where oxygen flows are set to levels below minute ventilation) as the exit valve was not adjusted to cope with the negative pressures of scavenging until the end of the evaluation period. This led to comments about rebreathing on lower flows during SV (although very low flows should not be used in drawover mode). Questions regarding adequacy of ventilation and anaesthesia pointed out that our own end-tidal carbon dioxide and isoflurane monitoring gave reliable and reassuring feedback, confirming adequacy and accuracy. There were no reports of high negative inspiratory pressures during SV.

There was space for free text next to all questions, and an "Undesirable Features" free text box at the end of Section A. One evaluator commented that there was no disconnection alarm within the UAM. Our more traditional anaesthetic machines also rely solely on separate end-tidal monitoring and vigilance to detect disconnection during SV. Another comment suggested the apnoea alarm was occasionally inaccurate. This may have related to the need to use higher flows due to the scavenging issue described above and so further evaluation may elucidate this.

Comparative Evaluation

Figure 5 displays the results of the first part of Section B. Four out of the five consultants felt the machine was as safe as their existing system; however, one did note that there could be a potential safety issue in the case of a difficult airway in which there is difficulty gaining a seal between the mask and patient's face. The UAM lacks an oxygen flush and although high minute volumes are obtainable, FiO_2 decreases as air is entrained.

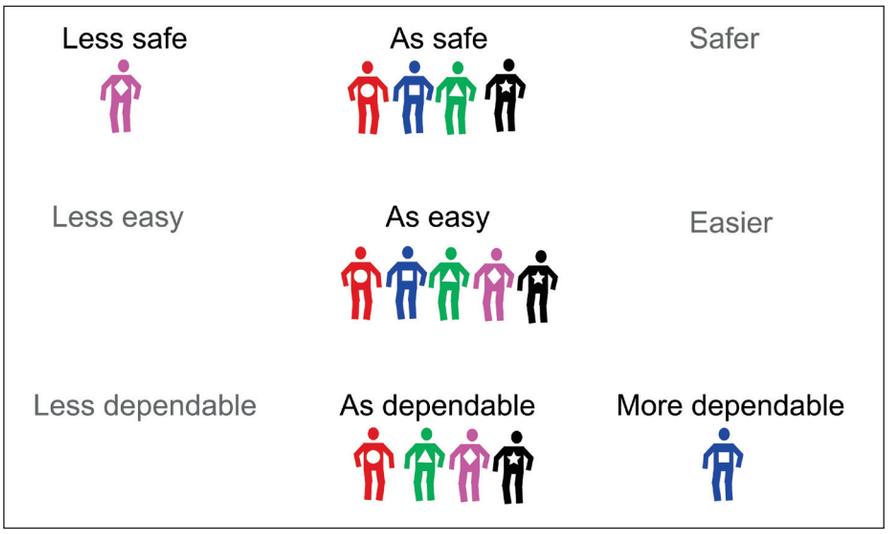


Figure 5. Results Section B: Comparative Evaluation. An illustration of the scores given to the UAM for safety, ease and dependability, in comparison to the evaluator's usual machine.

Positive comments about the safety of the UAM included it having all the relevant features, clear alarms and displays of inspired oxygen, being more manoeuvrable than a normal machine, the valves being clearly visible, and finally it "reassuringly consistently performed well". The fifth consultant felt the UAM was less safe because of the lack of a disconnection alarm and suggested an inbuilt expired volume monitor would be useful for this (rather than relying on separate end-tidal monitoring to act as a disconnection alarm, which may not be available in developing countries).

One evaluator felt the UAM was more dependable than their usual machine, because it is "simpler and logical and there is less to go wrong". Another commented there were no failures. Table 2 displays the results of the "Special Features" comparison.

The majority of scores suggested these special features were useful. "Bellows with paediatric top section" was only scored by one (as a 2) and another wrote that they thought it was a "neat idea" but had not used it enough to score. Scores for the oxygen analyser were skewed to an average of 2 because the question combined it with the minute ventilation alarm (disabled as described earlier); the comments made very clear the users found the oxygen analyser accurate and helpful.

Discussion

The UAM proved surprisingly easy to use and provoked a lot of interest and enthusiasm amongst a broad range of anaesthetists to beyond those evaluating it. During the three month placement period, time was taken to demonstrate the UAM to different grades of staff, including visiting anaesthetists. Ease of training and understanding was considered essential. Whilst it is accepted that the evaluation was observational and descriptive, overall the results were very positive.

The UAM was thought to be well designed and manufactured, its simplicity and basic nature making it easy to use safely and fit for purpose. When demonstrated to other anaesthetists, they found it easy to understand and commented favourably, for example "Ideal high-spec low-tech anaesthetic machine". Views echoed those of the five evaluators: "safe, reliable, dependable; simple and straightforward; virtually instinctive to use; good mobility and ease of use in a small space". Trainees who were planning to spend time abroad felt it required little training to gain familiarity and welcomed exposure to different delivery concepts.

It was evident that there was a lot of support for the UAM, indeed interest to the extent of proposing such machines for areas in our hospital where smaller size, simplicity and special features yield advantages. The competitive price was considered attractive during current spending cuts. The UAM was broadly compared to standard equipment in Section B of the evaluation, where one of the evaluators deemed it more dependable.

Conventional sophisticated anaesthetic equipment is not without its own complexity and hazards. During the evaluation period, three safety notices were served on our standard anaesthetic machines in current use.[14-16] These issues are a consequence of complexity, and would not arise with the simple clear design and function of the UAM.

The UAM design enabled the use of scavenging, but negative pressures un-

Table 2: Results of the "Special Features" Evaluation

Section B	Assessor Scores					
"Special Features"	A	B	C	D	E	Median Score
IPPV with mounted bellows	3	3	2	3	3	**3**
Bellows paediatric top section	-	-	2	-	-	**2**
Oxygen Concentrator operation, flow control, preoxygenation	3	3	3	3	3	**3**
Vaporiser control, speed of induction	3	3	3	3	3	**3**
Oxygen analyser; Minute Ventilation alarms	3,1	2,1	2	3	2	**2**
FGF to Drawover system with reservoir bag, SV	3	3	3	3	3	**3**
Balloon valve operation (Fenton valve)	3	3	3	-	2	**3**

Scores are on a three point scale where 1 = inferior to my usual machine, 2 = no opinion, 3 = an advance on my usual machine.

seated the exit valve leading to rebreathing at low flows. This limited the evaluation of oxygen and air mix anaesthesia during lower flow SV during the first phase of evaluation. However, since the exit valve has been changed to a spring loaded valve, no further rebreathing has occurred in around 100 cases. The UAM has not been evaluated in pure drawover mode (no oxygen and entraining only air) for ethical reasons, as it is not normal UK practice to deliver a general anaesthetic without supplemental oxygen.

The UAM has three potential drawbacks:1) in the case of electrical failure a backup generator would be required to power the oxygen concentrator; alternatively a different oxygen source or air entrainment can be used to deliver the volatile agent; 2) consumption of volatile anaesthetic agents will be higher than a modern low flow circle system; 3) manual ventilation may become tiring in long cases and therefore work is underway to design a simple ventilator to complement the UAM, although clearly this has cost and complexity implications.

The evaluation of the first manufactured UAM proved worthwhile for many reasons. Subsequent UAM production has taken all issues raised and advisory suggestions into account, producing a more refined version: the improved vaporiser filler block with deeper screw-thread; a tighter bellows rim seal to ensure a secure seal; a spring-loaded exit valve to avoid rebreathing at lower flows; amending and simplifying the preoperative check list. The next phase of production has already produced a quieter machine by adding insulation around the oxygen concentrator.

In summary, the UAM was well received for its simplicity and good design, safety, reliability and functionality. It was easy to learn to use and demonstrate to others, anaesthetists and other health professionals alike. Its service requirement should be minimal. These features along with its low cost are likely to propagate its popularity. As the only CE-marked anaesthetic machine designed for use in low resource settings, potentially the UAM has an important universal role to play. Ideally full monitoring should be used alongside the UAM, but this may be hard to achieve in resource-scarce countries.

Complemented by a comprehensive but straightforward teaching program, the UAM has a lot to offer for the safe provision of anaesthesia in developing countries, as judged by its first evaluation. Since the majority of cases in the developing world are women and children, evaluation in paediatrics centres in the UK is being undertaken. Training and evaluation are underway at four sites in Nepal, with further evaluations both at Poole Hospital NHS Trust and Groote Schuur Academic Unit, Cape Town, as the hub for Africa.

British hospitals have a fine tradition of being home to innovation and expertise that is then exported to benefit the less well resourced. This is often underpinned by the contribution of industry and the generosity of philanthropic organisations. It is hoped that the UAM coupled with a simple teaching program will enable safe anaesthesia on a broadened global scale.

Acknowledgements

We would like to thank the following people for their support during the UAM placement: Professor Paul Fenton, formerly Head of Anaesthetic Services, Malawi; Richard Fiedorowicz, Director of OES Medical, the UK based manufacturer of the UAM; Staff at Poole Hospital NHS Foundation Trust, where the first UAM evaluation took place; Anaesthetic colleagues and co-evaluators Drs William Ashton, Simon Jackson, Tammy Dodd and Michael Girgis; Dr Matthew Cordingly for the creation of figures 4 and 5.

The UAM has been developed with the financial aid of the Nick Simons Foundation, a private foundation based in the United States dedicated to providing medical care in rural Nepal.

Declarations

None of the authors or evaluators has any financial interest in this project. Dr Gillian van Hasselt was one of the five evaluators.

Dr Katharine Barr was not an evaluator and analysed the evaluation results.

Dr Gillian van Hasselt is a member of the clinical advisory committee (in formation) for UAM Global www.uamglobal.org; there is no financial reward for this role.

References

1 Ezi-Ashi TI, Papworth DP, Nunn JF. Inhalational anaesthesia in developing countries. Part I The problem and the proposed solution. Anaesthesia 1983; 38: 729-735

2 Ezi-Ashi TI, Papworth DP, Nunn JF. Inhalational anaesthesia in developing countries. Part II Review of existing apparatus. Anaesthesia 1983; 38: 736-747

3 Hodges SC, Mijumbi C, Okello M, McCormick BA, Walker IA, Wilson IH. Anaesthesia services in developing countries: defining the problems. Anaesthesia 2007; 62: 4-11

4 Fenton PM. Maternal deaths and anaesthesia technology in the 21st century. Anaesthesia News 2010; 273: 5-8

5 Fenton PM. Maternal deaths and anaesthesia technology in the 21st century. World Anaesthesia News 2010; 11(3): 12-16.

6 OES Medical (2010) Universal Anaesthetic Machine User Manual CE 0120 Doc 1973-510

7 AAGBI (2009) Section 4: Standards. In: Safe Management of Anaesthetic Related Equipment. AAGBI, London: 8-9 http://www.aagbi.org/publications/guidelines/docs/safe_management_2009.pdf

8 Davey A, Diba, A. Ward's Anaesthetic Equipment. 6th Edition (In Press)

9 MHRA (Medicines and Healthcare products Regulatory Agency, 2011) Section 4: Using medical devices safely. In: Devices in Practice – a guide for professionals in health and social care. MHRA, website version http://www.mhra.gov.uk/Publications/Safetyguidance/Otherdevicesafetyguidance/CON007423 http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON087755

10 Eales M, Rowe P, Tully R. Improving the efficiency of the drawover anaesthetic breathing system. Anaesthesia 2007; 62: 1171-1174

11 OES Medical (2010) Draw Over Vaporiser User Manual CE 0120 Doc 1983-510 issued April 2010

12 UAM Global Website (balloon valve) http://www.uamglobal.org/how_it_works/

13 AAGBI (The Association of Anaesthetists of Great Britain and Ireland, 2007) Recommendations for standards of monitoring during anaesthesia and recovery. 4th Edition. AAGBI, London http://www.aagbi.org/publications/guidelines/docs/standardsofmonitoring07.pdf

14 MHRA (2010) All anaesthetic breathing systems, anaesthetic machines and anaesthetic ventilators MDA/2010/036 Issued 6 May 2010 http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON081785

15 MHRA (2010) Anaesthetic Vaporizers – all manufacturers MDA/2010/052 Issued 28 June 2010 http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON085024

16 MHRA (2010) Various models of Anaesthetic Carestations manufactured by GE Healthcare MDA/2010/058 Issued 6 July 2010