Making LifeVac part of your BLS training

- *a guide for first aid providers in Australia*.

Background

The LifeVac is a novel self-powered anti-choking device used for the removal of an upper airway obstruction by suction after the failure of other first-aid measures. BLS providers in Australia may not have had any experience with his device and have limited training to first aid measures contained in the Australian Resuscitation Council (ARC) guidelines i.e. back blows and "chest thrusts" (See *Note 1).* There are sadly, incidents that occur where these current first aid measures have failed to relief an obstruction in time to prevent death or serious brain injury, especially in children. The LifeVac has been developed for just this eventuality i.e. to relieve airway obstruction after the failure of first-aid measures. Choking is a significant cause of death and hospital admission in people under 4 years old and the second most common reason for unexpected death in aged care. There are also many people who suffer with dysphagia (difficulty swallowing) who are at a higher risk of choking. These include people with MS, MD, Stroke, MND and CP. LifeVac was invented in the USA, is listed on the ARTG. LifeVac has already saved 1500 lives (including over 900 children) after first-aid attempts have failed and tests on cadaver and anatomical models has shown it can remove 97% of obstructions on the first pull and 100% of obstructions by the third pull. LifeVac can generate nearly four times the pressure able to be created with the best first aid measure with no reports of injury or any harm. LifeVac has a 100% success rate in removal of FBAO.

Certification, Approval and Guidelines

BLS guidelines used in Australia are used to assist in describing current method. A guideline by definition is "a general rule, principle, or piece of advice". In the context of BLS they only have the status of consensus opinion about practice and cannot be considered specific limiting rules, legislation, law or finite directions. Currently in Australia there are two organisations that are primarily involved in the development of guidelines for BLS practice and industry codes.

1. The Australian Resuscitation Council (ARC) – is a private (non-government), voluntary organisation that is a member of the International Liaison Committee on Resuscitation (ILCOR), and produces its own local guidelines based for the most part on ILCOR recommendations. Although a non-government, voluntary organisation most government and industry groups recognise the ARC as the default authority BLS practice. The exception in treatment concurrence is the management of choking where the ARC recommendations are divergent from ILCOR recommendations and evidence i.e. back blows, chest thrusts (not as recommended by the ARC) and abdominal thrusts for patients over 1 year of age.

2. The Industry Skills Council – is a Government controlled group that regulates codes and standards for training in industry. Among these are BLS requirements across industry, drawn substantially from the ARC guidelines and recommendations.

Neither the ARC nor the ISC have a process or methodology for the review and/or approval of any device used in first aid practice. In the future, LifeVac will be seeking the inclusion of "self-powered ant-choking devices" into the International Liaison Committee on Resuscitation (ILCOR) recommendations for the management of choking as world's best practice after other measures fail. The ILCOR (although not having regulatory powers on medical devices) has recently completed an evidence review of airway obstruction methods, including suction devices like the LifeVac.

Summary of ILCOR Systematic Review: Removal of Foreign Body Airway Obstruction

Created: January 02, 2020 · Updated: January 03, 2020

The International Liaison Committee on Resuscitation (ILCOR) recently conducted a systematic review of the evidence surrounding various techniques used for the removal of upper airway obstruction. The techniques included both first aid measures and equipment, including Magill forceps and suction-based airway devices (such as the LifeVac).
https://costr.ilcor.org/document/removal-of-foreign-body-airway-obstruction-tfsr-costr

- It is the opinion of ILCOR that foreign body airway obstruction (FBAO) is a common problem and many cases are likely to be resolved easily, without the need to involve healthcare providers. ILCOR did recognise that FBAO is however an important cause of early mortality that typically affects the young and old, or individuals with impaired neurological function / swallowing. Further that current strategies to remove FBAO are well known to many people, but all interventions can cause harm that may lead to death, as well as delays in treatment (of any kind). Therefore, there is a need to carefully balance the risks and benefits of strategies to removing foreign airway (by any means).
- Overall, the ILCOR found that all the evidence on choking management to be rated as very low quality (via the GRADE methodology they use) for all outcomes primarily due to a very serious risk of bias due to confounding. Because of this and a high degree of heterogeneity, no meta-analyses could be performed and they found all individual studies to be difficult to interpret. This was the case regardless of whether the studies concerned first aid measures or suction-based devices.
- ILCOR found evidence of harm has been reported for strategies of back blows, abdominal thrusts, chest thrusts, and blind finger sweeps but no case reports of harm were identified in relation to Magill forceps or suction-based airway clearance devices, although the number of uses is likely to be low.
- That in recent years, manual suction devices (airway clearance devices) have been developed but these devices have not previously been considered by ILCOR.
- ILCOR noted a higher level of risk with airway clearance devices which incorporate a plastic tube that is inserted in to the mouth (e.g. Dechoker), that could conceivably cause harm in a similar way to a blind finger sweep and that further evidence on safety is required.

- ILCOR found that there are reported cases of benefit for back blows, chest thrusts/ compressions, abdominal thrusts, Magill forceps, finger sweeps, and suction-based airway clearance devices. They also reported cases of harm for all interventions (except suction-based devices) i.e. back blows, chest thrusts, abdominal thrusts, and blind finger sweeps.
- The task force acknowledges that there are some data from a case series demonstrating the efficacy of suction-based airway clearance devices.
- At this time the ILCOR felt that the data were insufficient to support the implementation of a new technology with an associated financial cost. This reflects the primary function of treatment recommendations at ILCOR in regard to i.e. that measures are focused on first aid measures that can be implemented by anyone without specialised or additional equipment.
- The ILCOR noted in regard to suction-based devices, that the limited number of cases is likely insufficient to provide preliminary data on harm. On this basis, the task force felt that there was insufficient evidence to make a treatment recommendation in relation to these devices. The task force has outlined recommendations for further research in relation to these devices. The format and detail of this data reflects the detail already collected by LifeVac in post-market surveillance. i.e. accurately describe the incidence of FBAO, patient demographics (age, setting, comorbidities, food type, conscious level), full range of interventions delivered, who delivered interventions (health professional/ lay responder), success rates of interventions, harm of interventions, and outcomes. The ILCOR has noted in their report what LifeVac has been asserting for some time i.e. that it is unlikely that such a study can be conducted using only health service data.
- The ILCOR believes that there is a need for further evidence on the benefits and harms of suction-based airway clearance devices and suggested the prospective registration of all device uses and published case series. This has always been the intention of LifeVac. Importantly ILCOR made no comment regarding the limitation of use of the suction-based devices and assumed evidence would be forthcoming from health professionals and laypeople, from all demographics i.e. paediatric and adult patients.
- The treatment recommendations made by the ILCOR based on currently available evidence, directly contradict the divergent opinions of the Australian Resuscitation Council and used in the ANZCOR guidelines:
    1. We suggest that back slaps are used initially in patients with a FBAO and an ineffective cough (weak recommendation, very low certainty of evidence).
    2. We suggest that abdominal thrusts are used in adults and children with a FBAO and an ineffective cough where back slaps are ineffective (weak recommendation, very low certainty of evidence).
    3. We suggest that rescuers consider the manual extraction of visible items in the mouth (weak recommendation, very low certainty of evidence).
    4. We suggest against the use of blind finger sweeps in patients with a FBAO (weak recommendation, very low certainty of evidence).
    5. We suggest that appropriately skilled individuals consider the use of Magill forceps to remove FBAO in OHCA patients with a FBAO (weak recommendation, very low certainty of evidence).
    6. We suggest that chest thrusts are used in unconscious patients with a FBAO (weak recommendation, very low certainty of evidence).
    7. We suggest that bystanders undertake interventions to support FBAO removal as soon as possible after recognition (weak recommendation, very low certainty of evidence).

Note 1: The *"chest thrust"* method recommended by the ARC is not the same method as recommended by ILCOR ,that is evidence-based.

The Therapeutic Goods Administration (TGA) is the Government organisation that regulates pharmaceuticals and medical devices sold in Australia. Medical Devices are classified by risk and must be registered with the TGA and satisfy scaled evidentiary standards and other regulatory requirements including safety, labelling and claims made. The LifeVac device is listed as a Class 1 Medical Device with the TGA as this is the recommended status in other countries and best matches the risk associated with use of the device. The LifeVac has been tested on a cadaver, anatomical models and has already saved 1500 lives after first aid measures have failed from 3 weeks of age to 95 years of age.

Liability in BLS in Australia

A concern raised by BLS providers with any new technique or equipment is that of liability both of the first-aider and the provider. In relation to the provider, the LifeVac is designed to be used after the failure of first-aid measures to relieve an upper airway obstruction. It does not therefore replace current training requirements as set out by the ISC or ARC. The LifeVac can therefore be included in current strategies without compromising the existing regimes. Codes for industry and guidelines in BLS do not limit content and in fact the ARC acknowledges that "other techniques may be more effective".

In relation to individual liability, Australia, like many other countries around the world has "Good Samaritan" type laws that protect persons from liability in rendering emergency assistance to another person. These are essential so that those who render assistance (and particularly non-professionals) are not held personally liable for just "trying to help" others in an emergency.

"A good Samaritan does not incur any personal civil liability in respect of any act or omission done or made by the Good Samaritan in an emergency when assisting a person who is apparently injured or at risk of being injured."

A '**"Good Samaritan"** is a person who, in good faith and without expectation of payment or other reward, comes to the assistance of a person who is apparently injured or at risk of being injured'.
To be a good Samaritan the person has be

1) acting in good faith;
2) without expectation of payment or other reward;
3) to assist a person who is;
4) apparently injured or at risk of being injured.

Nothing in that list says anything about 'acting within one's qualifications' and that is for obvious reasons. The Act is intended to encourage people, including those without any qualifications, to help when help is needed. Applying that reasoning to the Good Samaritan provisions requires that the rescuer is acting 'not maliciously or to achieve an ulterior purpose' so they're acting to assist the injured person, not to steal their wallet or do them harm and it's a genuine attempt not to harm the person, i.e. to do the right thing. So, for example, a person who is confident in the use of oxygen (but has no "certification") and who genuinely believes that oxygen is warranted in the best interest and to avert harm to the patient is acting in good faith when they administer that oxygen; or if they were to use the person's Epi-pen or help them with their Ventolin; or do CPR or use an automated

defibrillator, or use the LifeVac when first aid has failed. In contrast, the person who says 'I always wanted to do a chricothyroidotomy using a Swiss army knife and a pen (as in M*A*S*H *Season 5 Episode 8, 'Mulcahy's War'*) and now I can because I can't be sued' is not, under the law, acting in good faith. Using a new skill or piece of equipment does not in itself create liability. Teaching first responders to use a new device or technique does not in itself create liability. ARC guidelines are essentially (and by their own admission) the "opinion" of the individuals who make up the ARC committee and not the organisations represented in their membership. The ISC (which bases training codes on the ARC guidelines, provides a framework for the "minimum" training requirements and not the limit of best practice in industry and business.

The LifeVac is designed to be used without specific training (online training is available) and after first aid attempts have failed. We believe that using the LifeVac therefore does not constitute a rescuer "exceeding their training" i.e. constituting negligence or reckless behaviour under law; regardless as to whether specific LifeVac training was included in their first aid training.

The use of LifeVac has already been incorporated into local emergency protocols in the US and Europe, where litigation is far more likely. In incorporating the LifeVac into BLS training it is important to recognise that any technique is not an absolute guarantee of success.

Example of Choking Procedure incorporating LifeVac

1. Encourage the casualty to cough
2. Diagnose the presence of an effective or ineffective cough and/or deteriorating perfusion
3. Apply up to five back blows between the shoulder blades in a head down posture (checking between each blow for the obstruction)
4. If fails back blows fail apply:
5. Call for help and;

- Up to five chest thrusts (using two-hands from behind the casualty or abdominal thrusts (if > than 12 months). Use chest thrusts (from behind the casualty) in pregnant or obese casualties). Checking between each thrust for the obstruction.
- CPR like chest thrusts in infants
- Use up to five pumps of the LifeVac device, checking after each pump for the obstruction.
    - Select appropriately sized mask
    - Fit the mask tightly to the device
    - Hold the mask tightly against the casualties mask
    - Push the handle forcefully toward the casualties face and immediately pull back on the handle
    - Examine the mask for the obstruction
- If fails ensure Ambulance is enroute and repeat procedure.

- Commence CPR if casualty unconscious and not-breathing

Important Training Points

Although the simple operation of the LifeVac has been designed to be used without formal training, it is expected that when the LifeVac is incorporated into current BLS training some rudimentary training be conducted. Although the use of a resuscitation mask is usually a part of BLS training i.e. the use of a pocket resuscitation mask with one-way valve and viral filter; the correct selection of a mask to match the patient's size and associated fitment is not.

The most important factor in ensuring that the LifeVac is effective and that the obstruction is removed quickly is the accurate selection and use of the face mask i.e.

1. The right size for the patient
2. It is fitted correctly to achieve a proper seal

Correctly sizing the mask

The LifeVac kits comes with various sized masks to match the most common range of patients i.e. child (x1), small adult (x2) and large adult (x1). [Picture 1]. An extra-large mask is also available. The additional small adult mask is included for practice using the device prior to emergency use. It is important that the mask is fitted to the face with the mouth in the open position when using the LifeVac. To ensure proper sizing the mask should be test fitted to the patient prior to operation of the device. Approximate the mask size visually. Start by sliding the nose (narrow) section of the mask seal around the bridge of the nose [Picture 2] and then rotate the mask against the face, ensuring the lower seal sits between the chin and lower lip [Picture 3] of the patient (with the mouth open). If the mask does not properly match these two landmarks an alternate mask should be selected.

Picture 1 – Range of masks

Picture 2 – Positioning the mask over nose

Picture 3 – fit mask over face with mouth open

Picture 4 – Holding the mask on the person's face during use

Correctly fitting the mask

Once the correctly sized mask has been selected, and it is firmly attached to the LifeVac plunger unit, the mask should be held firmly to the patient's face using one hand (the index finger and thumb around the centre port of the mask and the remaining fingers gripping the patient's lower jaw. [Picture 4]

Demonstrating the LifeVac

The one-way valve assembly of the LifeVac ensures that any foreign body is not forced further into the airway during operation. This feature is easily demonstrated during training using any hard, smooth surface; sealing the mask with one hand then using the push pull action.

Removing an Obstruction

Demonstrating the removal of an airway obstruction using the LifeVac device, during training, is straightforward when the appropriate equipment is available. As the LifeVac produces nearly four times the pressure generated by abdominal thrusts; it is not recommended to demonstrate the device on a living volunteer. The device also cannot be demonstrated effectively using conventional resuscitation manikins i.e. where the simulated airway is not constructed for this purpose. A dedicated choking training manikin is recommended.

Further information, including instructional videos can be found at www.lifevac.net.au

A sample choking protocol (incorporating the LifeVac and ILCOR evidence-based recommendations) is provided below for information purposes.

Management of Choking Emergency Protocol (Sample)

[incorporating current ILCOR recommendations and use of a suction anti-choking device]