Potential patient risk from vented caps on pressure transducer

Sir,

The TruWave pressure monitoring kit with TruWave disposable pressure transducer (Edwards Lifesciences LLC, Irvine, USA) is regularly used for invasive monitoring via arterial catheters in the operating theatres, critical care and high dependence units.

Both the transducer port and the four-way stopcock are packaged with protection caps, which are non-occlusive, 'ventilated', in order to ensure thorough penetration of ethylene oxide gas during sterilization (*Figure 1*). Packaged separately are two occlusive caps, intended to replace vented caps once the set is readied for use.

One of the authors previously highlighted risk of ventilated caps with intravenous infusion lines, including risk of air entrainment and embolism as a result of the Bernoulli effect (Kapur et al, 2007). Additionally, air bubbles in an arterial line can result in transducer signal 'damping' and, therefore, inaccurate blood pressure readings. The risk of leakage of blood is also potentially detrimental to patient safety.

We have concerns regarding product information provided by the manufacturer informing users of the need to change the caps. First, information provided ('Replace all vented caps on sideports of the stopcocks with non-vented') is easily missed, printed in tiny font lost within a large multi-lingual information leaflet (*Figure 2*). Furthermore, there is only one such leaflet per box of 20 pressure monitoring sets.

Figure 1. Non-occluded 'vented' cap on TruWave pressure monitoring kit.

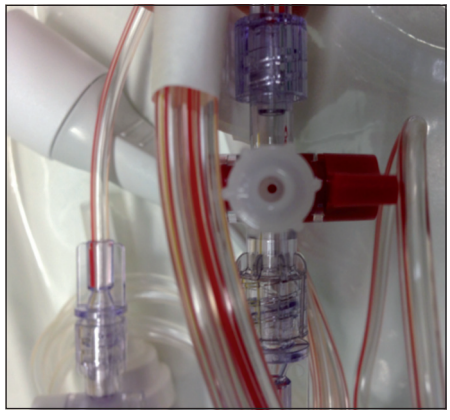
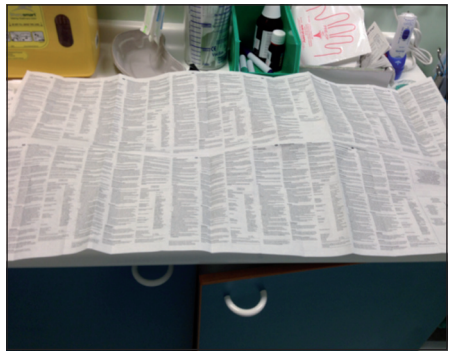


Figure 2. Manufacturer's product information leaflet.



The authors believe that the manufacturer could easily address these issues by either removing both ventilated caps completely, providing more information leaflets per box, or by clearly stating on each individual pack the need to change caps appropriately. While this is not the current case, we urge vigilance by the user.

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Kapur S, Ahuja N, Moors AH (2007) Air embolism risk from malfunctioning anti-reflux Y-connectors. *Br J Hosp Med* **68**(6): 335

Sir,

We appreciate the comments from Dr McCormick and colleagues regarding protection caps for the TruWave disposable pressure transducer. Edwards is committed to patient safety and providing the highest quality products to our customers. The TruWave disposable pressure transducers are among an extensive line of Edwards' haemodynamic monitoring tools considered the gold standard in critical care medicine, and have been used safely for over 20 years worldwide.

We strive to make our products and documentation as easy to use as possible and our instructions for use for the TruWave products clearly state: 'Replace all vented caps on side ports of the stopcocks with non-vented caps'.

As a technology innovator, Edwards is dedicated to improving product effectiveness for the patient and ease-of-use for the clinician, and will continue to explore ways to improve product education.

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Single drug regimen for treatment of acute venous thromboembolism in oncology patients

Sir,

Venous thromboembolism is the second leading cause of mortality in oncology patients (Noble and Jenkins, 2009; den Exter et al, 2013). The conventional treatment regimen is parenteral anticoagulation with low-molecular weight heparin and concomitant warfarin for non-oncology patients, and low-molecular weight heparin alone for oncology patients (Noble and Jenkins, 2009). While low-molecular weight heparin has better safety and efficacy than warfarin, this regimen is costly, presents challenges with requirement of subcutaneous injections, lacks patient preference, and has a 9% recurrence rate of venous thromboembolism (den Exter et al, 2013).

Agnelli et al (2013a) compared the efficacy of apixaban, a new oral anticoagulant, with the standard regimen in treatment of acute venous thromboembolism (AMPLIFY trial). New oral anticoagulants are given in fixed doses, administered orally and demonstrate predictable effects without need for laboratory monitoring of coagulation unlike the standard regimen (Gonsalves et al, 2013). Indeed, Agnelli and colleagues (2013a) showed that the apixaban regimen was non-inferior for efficacy and superior for safety compared to standard treatment in non-oncology patients.

However, cancer patients with planned long-term treatment with low-molecular weight heparin were excluded, because of the risk of anticoagulant-induced bleeding complications. Evidence of efficacy and

safety of new oral anticoagulants in cancer patients with venous thromboembolism is limited. Few cancer patients have been included in phase III trials, most of which were inadequately powered (Noble and Jenkins, 2009). Moreover, in the AMPLIFY-EXTENSION trial, comparing two different dosages of apixaban, only 1.7% of the patients with active cancer were included and without subgroup analysis (Agnelli et al, 2013b).

Future trials must evaluate the efficacy of new oral anticoagulants in oncology patients, as well as comparing the efficacy of new oral anticoagulants with low-molecular weight heparin for superiority or non-inferiority. Outstanding issues surrounding new oral anticoagulants, including monitoring and management of bleeding, require further consideration.

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Agnelli G, Buller HR, Cohen A et al (2013a) Oral apixaban for the treatment of acute venous thromboembolism. *N Engl J Med* **369**(9): 799–808

Agnelli G, Buller HR, Cohen A et al (2013b) Apixaban for extended treatment of venous thromboembolism. *N Engl J Med* **368**(8): 699–708

den Exter PL, Kooiman J, van der Hulle T, Huisman MV (2013) New anticoagulants in the treatment of patients with cancer-associated venous thromboembolism. *Best Pract Res Clin Haematol* **26**(2): 163–9

Gonsalves WI, Pruthi RK, Patnaik MM (2013) The new oral anticoagulants in clinical practice. *Mayo Clin Proc* **88**(5): 495–511

Noble S, Jenkins DA (2009) Management of venous thromboembolism in patients with cancer. *Br J Hosp Med (Lond)* **70**(7): 380–5

Caveats in the diagnosis of iron deficiency

Sir,

The point is well made that iron deficiency sometimes manifests itself as a fall in mean corpuscular haemoglobin without a concurrent fall in mean cell volume or a fall in haemoglobin (vol 74(12), 2013, C184). The same observation was made in four patients with serum ferritin <10 µg/litre, in whom mean corpuscular haemoglobin <27 pg was associated with mean cell volume >80 fl in the presence of a haemoglobin level of 12 g/dl or more (Jolobe and Rakicka, 1993).

It is also important to recognize that the microcytic haematological profile can sometimes totally replace the macrocytic picture in some patients who have coexisting iron deficiency anaemia and vitamin B_{12} deficiency (Jolobe, 2009).

This phenomenon is probably attributable to the fact that some risk factors, such as autoimmune gastritis and helicobacter gastritis, are common to both haematinic deficiencies (Jolobe, 2009).

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Jolobe OMP (2009) Microcytic anaemia can "mask" co-existing cobalamin deficiency. *Q J Med* **102**: 362–3

Jolobe OMP, Rakicka H (1993) Significance of low serum ferritin in elderly inpatients. *Postgrad Med J* **69**: 892

Registration would not provide sufficient oversight

Sir,

There have been considerable and welcome improvements in the quality of patient care and safety since the publication of the Francis Report. It is important that we continue to identify further areas for improvement to ensure patients are as safe and well cared for as possible.

This should include revisiting the need for robust oversight and regulation for sections of the NHS workforce that are not currently regulated but perform invasive procedures on patients. This includes clinical physiologists, who diagnose patients and increasingly administer treatment, but are subject to voluntary registration rather than regulation.

The Chief Executive of the Health and Care Professions Agency has publicly endorsed the need for clinical physiologists to be statutorily regulated. In continuing to improve the NHS, the government should consider this expert recommendation, which would better enforce codes of practice, help identify mistakes and best protect patients.

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