

SPECIAL ARTICLE

The European Board of Anaesthesiology recommendations for safe medication practice

First update

David Whitaker, Guttorm Brattebø, Stefan Trenkler, Indulis Vanags, Flavia Petrini, Zuhail Aykac, Dan Longrois, Stephan Alexander Loer, Tomasz Gaszynski, Jurate Sipylaite, Elena Copaciu, Vladimir Cerny, Jonas Akeson, Jannicke Mellin-Olsen, Carmel Abela, Adela Stecher, Sibylle Kozek-Langenecker, Indrek Rätsep, The European Section and Board of Anaesthesiology of the UEMS

These European Board of Anaesthesiology (EBA) recommendations for safe medication practice replace the first edition of the EBA recommendations published in 2011. They were updated because evidence from critical incident reporting systems continues to show that medication errors remain a major safety issue in anaesthesia, intensive care, emergency medicine and pain medicine, and there is an ongoing need for relevant up-to-date clinical guidance for practising anaesthesiologists. The recommendations are

based on evidence wherever possible, with a focus on patient safety, and are primarily aimed at anaesthesiologists practising in Europe, although many will be applicable elsewhere. They emphasise the importance of correct labelling practice and the value of incident reporting so that lessons can be learned, risks reduced and a safety culture developed.

Published online 20 August 2016

How were these guidelines produced?

This is a consensus document produced by safety experts from the Patient Safety Committee of the European Board of Anaesthesiology (EBA). It is based on a revision of the first edition of the EBA recommendations published in 2011 (http://html.esahq.org/patientsafety-kit/resources/downloads/05_Checklists/Various_Checklists/Safe_Medication_Practice.pdf). This included two face-to-face meetings at which the wording of the docu-

ment was discussed line by line. Evidence was considered from the references in the bibliography and URLs in the text and there were e-mail iterations in between and after the meetings. It has been seen and approved by the European Section and Board of Anaesthesiology of the UEMS (Union Européenne des Médecins Spécialistes). The latest date for the next review of these guidelines is 2020.

From the Department of Anaesthesia, Manchester Royal Infirmary, Manchester, UK (DW), Department of Anaesthesia and Intensive Care, Haukeland University Hospital, Bergen, Norway (GB), Department of Anaesthesiology and Intensive Medicine, P.J. Safarik University, Kosice, Slovakia (ST), Krompachy Agel Hospital, Krompachy (ST), Falck Zachranna a.s., Kosice, Slovakia (ST), Department of Anaesthesiology and Reanimation, Pauls Stradins Clinical University Hospital, Riga, Latvia (IV), Department of Perioperative Medicine, Pain Therapy, RRS and ICU, Chieti University Hospital, Chieti, Italy (FP), Department of Anaesthesiology and Reanimation, Marmara University, Istanbul, Turkey (ZA), Département d'anesthésie-réanimation, Hôpital Bichat-Claude-Bernard, Paris, France (DL), Department of Anaesthesiology, VU University Medical Center, Amsterdam, The Netherlands (SAL), Department of Anaesthesiology and Intensive Therapy, Medical University of Lodz, Poland (TG), Clinic of Anaesthesiology and Intensive Care, Vilnius University, Vilnius, Lithuania (JS), Department of Intensive Care, University Hospital, Carol Davila University of Medicine, Bucharest, Romania (EC), Department of Anaesthesiology, Perioperative Medicine and Intensive Care, J.E. Purkinje University, Masaryk Hospital, Usti nad Labem (VC), Department of Research and Development, Faculty of Medicine Hradec Kralove, Hradec Kralove, Czech Republic (VC), Department of Anaesthesia, Pain Management and Perioperative Medicine, Dalhousie University, Halifax, Canada (VC), Department of Anaesthesiology and Intensive Care Medicine, Lund University, Skåne University Hospital, Malmö, Sweden (JA), Department of Anaesthesiology and Intensive Care Medicine, Baerum Hospital, Oslo, Norway (JM-O), Department of Anaesthesia, Intensive Care and Pain Medicine, Mater Dei Hospital, Msida, Malta (CA), Clinical Department of Anaesthesiology and Intensive Therapy, University Clinical Center Ljubljana, Slovenia (AS), Sigmund Freud Private University Vienna and Department of Anaesthesia and Intensive Care, Evangelical Hospital Vienna, Vienna, Austria (SK-L), Department of Anaesthesiology and Intensive Care, North Estonia Medical Centre, Tallinn, Estonia (IR)

Correspondence to David Whitaker, FRCA, FFPMRCA, FFCM, FCARCSI (Hon), Department of Anaesthesia, Manchester Royal Infirmary, Manchester, UK
E-mail: whitaker2000@gmail.com

What other guideline statements are available on this topic?

The EBA produced a first set of recommendations for safe medication practice reflecting European conditions in 2011. The US Institute for Safe Medication Practices (<http://www.ismp.org/Tools/guidelines/IVSummitPush/IVPushMedGuidelines.pdf>) and the Australian and New Zealand College of Anaesthetists (<http://www.anzca.edu.au/Documents/ps51-2009-guidelines-for-the-safe-administration-o>) have both produced guidelines for the safe administration of intravenous medications in anaesthesia. The US-based Anesthesia Patient Safety Foundation has also produced a video (<http://www.apsf.org/resources/med-safety/>) following a consensus conference on the subject.¹

Why were these guidelines developed?

The first EBA recommendations were developed because medication errors were thought to be a major safety issue in anaesthesia, intensive care, emergency medicine and pain medicine. Early reports from retrospective surveys² put the medication error rates at one in 133, but a recent observational study³ has put it as high as one in 20. Medication errors reported by anaesthesiologists to the National Reporting and Learning System critical incident database in the United Kingdom increased from 100 per month in 2011 to over 350 per month in 2015 and this is usually the second highest category of all the incident types in the Safe Anaesthesia Liaison Group reports (http://www.aagbi.org/sites/default/files/SALG%20PSU%20Apr-Jun%202015_PDF.PDF). Because this is a voluntary reporting system, it probably underestimates the real incidence,⁴ so from all this evidence there is a need for relevant up-to-date clinical guidance for practising European anaesthesiologists based on evidence wherever possible and with a focus on patient safety.

How and why does this latest addition differ from existing recommendations?

These recommendations emphasise that labels should never be put on to empty syringes and that syringes should be labelled immediately after the drug has been drawn into them and before they leave the operator's hand. This follows standard operating procedures⁵ (<http://www.nrls.npsa.nhs.uk/resources/?entryid45=59812>) and standard labelling practice in other high-risk situations, for example collecting blood samples for cross-matching. Failure to follow this procedure has been a frequent cause of error.

Additional recommendations for separately storing high-risk medicines such as local anaesthetic agents and intravenous (i.v.) potassium follow published guidelines, for example Royal College of Anaesthetists' Accreditation Standard 2.2.4.1 (https://www.rcoa.ac.uk/system/files/ACSA-STANDARDS-2015_9.pdf). Open containers for

drugs, antiseptics and saline, such as bowls, dishes or Gallipots, are no longer recommended for use on the sterile field because their use has been associated with a number of fatal errors (<https://www.virginiamasoninstitute.org/2014/03/terrible-tragedy-and-powerful-legacy-of-preventable-death/>). Standardisation of the anaesthetic work surface for drawing up, arranging and holding syringes is recommended.

Flushing cannulae to remove any residual anaesthetic drugs is recommended so that the drugs are not administered inadvertently in the recovery room or on the wards (<https://www.aagbi.org/sites/default/files/CSQ-PS-PSU-MAR2015.pdf>). This again has been a source of serious incidents.

Distractions are significant causes of medication errors,⁶ and all members of the team should be aware of this to try to minimise the risk.

Recommendations are also made about the reliability and resilience of medication supplies, a problem which has acquired increased interest since publication of the first recommendations.

All anaesthetists are recommended to report medication incidents, enable promulgation of lessons learned and focus on risk reduction and developing and promoting a safety culture (<https://www.rcoa.ac.uk/salg>).

The European Board of Anaesthesiology recommendations for safe medication practice

Drug syringe preparation and labelling

All medications prepared for routine use in anaesthesia, intensive care, emergency medicine and pain medicine should be clearly labelled.

The EBA recommends that pre-filled syringes should be used wherever possible. Hospital pharmacies and manufacturers should be encouraged to supply them particularly in the first instance for high-risk medicines and those administered as infusions because of the risks of dilution errors and infection.

The EBA recommends the International Organisation for Standardisation (ISO) anaesthetic and respiratory equipment – *User-applied labels for syringes containing drugs used during anaesthesia – Colours, design and performance*. 1st ed. Geneva: ISO, 2008. ISO 26825:2008(E).

Labels should never be put on to empty syringes. Once a drug is drawn into a syringe, the syringe should be immediately labelled before it leaves the operator's hand. The medication name on the user-applied label should be matched with the drug name on the ampoule, one medication and one syringe at a time.

All drug infusion bags and infusion lines should similarly be labelled. It is particularly important that infusion lines should be labelled at both ends close to the connectors to

facilitate checking and to reduce wrong connection errors.

In the absence of pre-printed labels for syringes, hand-written ones should be prepared, or syringes should be labelled directly using permanent marker pens.

In an urgent situation, if a medication is prepared and immediately administered to a patient with the syringe or container never leaving the hands of the person drawing it up, labelling is not required, but it is still good practice if there is sufficient time.

Any medicine or fluid that cannot be identified at any time during a procedure (e.g. in an unlabelled syringe or other container) should be considered unsafe and immediately discarded.

Drug packaging and labelling

The labelling and packaging of all drugs should facilitate their easy identification. When a drug is available from more than one manufacturer, the clarity of the labelling and the avoidance of look-alike packaging or labelling should be considered when making purchasing decisions. Labelling should conform to applicable national or international standards as these are adopted.

Drug contamination and transmission of infections

Contamination of any drug must be avoided. To minimise the risk of cross-infection between patients, the contents of any one ampoule should be administered to only one patient. The use of multi-dose ampoules is not recommended.

To prevent the transmission of nosocomial infections such as hepatitis C and malaria between patients, the use of saline bags with reusable administration ports to provide fluid for drug dilution and syringes for flushing i.v. lines for more than one patient should no longer take place. Single ampoules of saline or preferably single pre-filled syringes of saline should be used instead.

Drug cupboards, anaesthetic trays and storage systems

Drugs should be stored in ways designed to facilitate their easy identification and minimise the risk of error or misidentification. Arranging medicines in drug cupboards in their pharmacological medication class groups can reduce the risk of between-class errors, which are generally likely to be more dangerous than within-class errors. Consideration should be given to storing drug ampoules in their original packaging until just before they are drawn up. Special care should be taken with ampoules that look similar, have similar names or have labels that are difficult to read.

Local anaesthetic agents should be stored separately from anaesthetic drugs and high-risk medicines such as i.v. potassium should be stored securely. Gallipots, bowls or

other open containers for drugs, antiseptics or saline should no longer be used on the sterile field to prevent possible contamination and drug errors, some of which have been fatal.

Adequate, uncluttered surface space and appropriate trays, clean for each patient, should be provided for drawing up, arranging and holding the syringes and drugs used in each anaesthetic. Wherever possible, this should be standardised.

Cannulae should be flushed after administration of drugs to reduce the risk of inadvertent administration of anaesthetic drugs in the recovery room or on the ward.

Distractions

Distractions are a significant cause of medication errors. All members of the anaesthesia team should avoid distractions or interrupting others during the preparation and administration of patients' medications. Similarly, working under pressure of time and in unfamiliar circumstances should be avoided. Double-checking at any stage, particularly with high-risk medications, is recommended.

Reliability and resilience of medication supply

All drugs supplied should meet current national standards and regulations. When there are supply problems, like-for-like replacements should always be sought and end-users promptly made aware of any changes to packaging or concentrations. For high-risk medicines, for example heparin/protamine, hospitals should invest in sufficiently large buffer stocks to be able maintain continuity of supply to clinicians throughout periods of external shortages.

Incident reporting

All anaesthetists should report any medication incidents to their local and/or national incident reporting systems and these should be regularly reviewed in departmental meetings so that lessons can be learned and passed on. The focus should be on having a safety culture, the prevention of the recurrence of adverse events and managing such events when they occur.

Checklist

To assist departments that may wish to implement these guidelines and monitor their introduction locally, an implementation assessment/checklist has been developed (Appendix).

Acknowledgements relating to this article

Assistance with the article: all members of the European Board of Anaesthesiology.

Financial support and sponsorship: none.

Conflicts of interest: DW has lectured on medication safety but all the fees for these activities have been donated to the charity Lifebox (<http://www.lifebox.org/>).

Presentation: none.

Comment from the editor: these recommendations were checked and accepted by the editors of the *European Journal of Anaesthesiology* but did not undergo external peer review. The European Society of Anaesthesiology (ESA) was not involved in the development of these recommendations and has not been asked to endorse them.

References

- Eichhorn JH. Anesthesia Patient Safety Foundation hosts medication safety conference: consensus group defines challenges and opportunities for improved practice. *APSF Newslett* 2010; **25**:1–20.
- Webster CS, Merry AF, Larsson L, *et al.* The frequency and nature of drug administration error during anaesthesia. *Anaesth Intensive Care* 2001; **29**:494–500.
- Nanji KC, Patel A, Shaikh S, *et al.* Evaluation of perioperative medication errors and adverse drug events. *Anesthesiology* 2016; **124**: 25–34.
- McLennan SR, Engel-Glatzer S, Meyer AH, *et al.* Disclosing and reporting medical errors: Cross-sectional survey of Swiss anaesthesiologists. *Eur J Anaesthesiol* 2015; **32**:471–476.
- US Pharmacopeial Convention, Inc. General Chapter <797> Pharmaceutical Compounding-Sterile Preparations. In: The United States Pharmacopeia, 32nd Revision and The National Formulary, 27th ed. Rockville, MD: United States Pharmacopeial Convention; 2009:318-354.
- Prakash V, Koczmara C, Savage P, *et al.* Mitigating errors caused by interruptions during medication verification and administration: interventions in a simulated ambulatory chemotherapy setting. *BMJ Qual Saf* 2014; **23**:884–892.

Appendix. Safe medication practice implementation assessment/checklist

- Are all medications prepared for routine use in anaesthesia, intensive care, emergency medicine and pain medicine clearly labelled? **YES / NO**
- Are pre-filled syringes used wherever possible, e.g. atropine, epinephrine, norepinephrine, insulin, morphine? **YES / NO**
- Is a supply of user-applied colour-coded syringe labels [ISO, 2008. ISO 26825:2008(E)] available in every necessary location? **YES / NO**
- Is there a policy for labelling drug-containing syringes and infusion lines? **YES / NO**
- Is there a policy to minimise the risk of drug contamination and transmission of infections between patients, e.g. the contents of any one ampoule should be administered to only one patient? **YES / NO**
- Are drugs stored in ways designed to facilitate their easy identification and minimise the risk of error or misidentification? **YES / NO**
- Are local anaesthetic agents stored separately from general anaesthetic drugs? **YES / NO**
- Is intravenous potassium stored securely? **YES / NO**
- Are bowls, gallipots or other open containers for drugs, antiseptics or saline no longer used on the sterile field? **YES / NO**
- Is there a policy for flushing cannulae to reduce the risk of inadvertent administration of anaesthetic drugs in recovery units or on the ward? **YES / NO**
- Do all drugs supplied meet current national standards and regulations? **YES / NO**
- Do all anaesthetists report medication incidents to a local and/or national incident reporting system which is regularly reviewed in departmental meetings so that lessons can be learned and passed on? **YES / NO**
- Is there a policy for managing and learning from adverse events when they occur? **YES / NO**