Appendix 1. Comments received from the EFLM National societies during public consultation of the Joint EFLM-COLABIOCLI Recommendation for venous blood sampling (v 1.1, October 2017)

Public consultation was done through October 2017 – January 2018. Comments from 11 National societies were received. Below are our replied to individual comments. If the part of the document to which a comment has been addressed has not been provided by the National society, NA (not available) is stated in the first column.

1. Croatia (Croatian Society of Medical Biochemistry and Laboratory Medicine)

#	Part of the document	Comment	Response to comment
1.	Page 7	All steps in the Pre-Sampling section are not numbered, while all steps in the Post-Sampling section are numbered. It would be better to unify step labeling.	Pre-sampling paragraph contains some general considerations related to communication with the patient (before and after the blood sampling) and patient position. Sampling starts with patient ID. This is why numbering starts with this step.
2.	Page 7 (and throughout the manuscript)	Greiner should be replaced with Greiner Bio-One	Done.
3.	Page 8, After you have identified the patient correctly (see Step 1),…	It seems that this sentence refers to the point above (for identification of phlebotomist) and not to the text after this section. It would be better to state: (see Step 1 below), or something like that. Use subtitle before Steps for phlebotomy.	Done.
4.	Page 9, Steps 1.1. to 1.4.	Steps 1.1. to 1.4. are graded 1C. The author state: ...*there is unfortunately a paucity of evidence for exposing a patient to harm in the case of non-compliance*. This should be explained in more details.	Postponing the procedure until the identification issue has been resolved, actually means that further steps should not be performed unless ID problem

		It is unclear to me how for example, postponing the procedure until the identification issue has been resolved, could in any case be beneficial for the patient, when patient identification errors have already been identified as the most critical step in the phlebotomy procedure by the EFLM WG-PRE. Strongly believe that these steps should be highly graded.	has been resolved. Recommendations 1.1-1.4 are grade 1C recommendations. 1C is a strong recommendation. The evidence base supporting the recommendation is, however, of low quality.
5.	Page 10, step 2.2	Additional requirement should be added: c) tests for which lipemia (turbidity) of the sample doesn't cause significant preanalytical error	This is already contained in: „…or for which there is evidence that fasting is not required."
6.	Page 11, step 3.3	There should be hand washing facilities with soap, running water and paper towels in the room. Should it have hand sanitizer also?	Yes, sentence was corrected into: „There should be hand sanitizing or washing areas with soap and/or appropriate sanitizers and paper towels."
7.	Page 15, step 6	In the first paragraph authors state that blood collection is done preferably without tourniquets. This should be presented as a separate recommendation (6.1) (revise other numbers accordingly)	Done.
8.	Page 27, step 18	After all tubes are mixed according to previously described steps, tubes should be left in upright position prior to further processing. This should be added to step 18 (18.3)	Done.
9.	Page 30, Implementation of the guidelines	Please present recommendations on implementation of the guidelines in the form of bulleted list at the end of the paragraph. All concrete recommendations kindly provided by authors are *hidden* within the text. For example:	All recommendations are now presented in the Table.

		• Education about blood sampling procedure should also be available to all newly employed medical staff involved in blood sampling • Newly employed staff should undergo a practical training of the blood collection procedure in the laboratory outpatient unit. • Practical training should last 1 week during which a new staff member should perform at least 100 blood collections. • An observational audit should be done during the first five and last five collections. • Institution should establish its own system of certification… etc	
10.	Page 39, Table 2.	Table should be placed on one page in order to be easier to follow recommended steps	We agree. This will be done by the Journal typesetting staff.
11.	NA	Since link to www.eflm.eu/index.php/wg-preanalytical-phase.html is not working properly, three last tools (knowledge test, checklist, posters with a cartoon) should be included in this recommendation	Instead of the link, full path is provided for the location at which all EFLM tools are going to be freely available.

2. Denmark (Danish Society for Clinical Biochemistry)

Thank you for the opportunity to comment on the first official EFLM Recommendations for venous blood sampling prepared by the WG-PRE. We have sent the document to all members of the Danish Society for Clinical Biochemistry.

	Page	**Comment**	**Response to comment**
1.	NA	We find the recommendation very thorough and think it will be helpful in the work and education in the preanalytical field. We support the idea of a european standardisation.	Thank you for your positive comments.

		However, we do see several issues that make the current recommendation challenging.	
2.	NA	We think the level in the recommendation should be more uniform in quality and language.	Document was thoroughly edited for grammar and style.
3.	NA	Several issues are not quite applicable in a daily phlebotomy ward. The issues regarding blood sampling between 7 and 9 in the morning and changes in patient position is not quite possible to implement.	This is correct. This was already emphasized under Scope of the guidance (first paragraph): The outpatient blood collection differs mostly in the patient preparation, patient position and physical activity prior to blood sampling. These issues are covered in the respective parts of the manuscript. The rest of the document applies equally for in- and outpatients.
4.	NA	And although we find the idea of registration of every deviation from the recommendation regarding fasting, position and time of blood sampling tempting – how should the clinicians react to these information's?	This information will help them to interpret the test results.
5.	NA	We miss a table of contents	We have added the table of contents.
6.	NA	The part concerning the implementation of the guideline should be moved to an appendix.	We disagree. Our intention was to have this as an integral part of the document.
7.	Page 8, General considerations on appropriate mode of communication with the patient	Under General considerations on appropriate mode of communication with the patient, 3) The informed consent can be different in different countries due to different legislation or culture. However, it should be stated that a blood sample is never drawn if the	Done.

		patient resists.	
8.	Page 8, General considerations on appropriate mode of communication with the patient	Under General considerations on appropriate mode of communication with the patient, Remove 5) as it is considered unnecessary and too time consuming.	We believe that it does not take too much time. Patients may often have some helpful comments.
9.	Page 8, General considerations on appropriate mode of communication with the patient	Under General considerations on appropriate mode of communication with the patient, 6) The paragraph should start: If considered relevant, ask the patient if he/she.	We believe that this every patient should be asked that question.
10.	Page 10, Step 2.1	We suggest fasting to be 8-12 hours due to minimal patient inconvenience. Chewing gum should also not be used. Water should be restricted to 1-2 glasses of water. Morning medicine should be avoided unless it is vital for the patient.	EFLM has published a fasting definition (Simundic AM, et al. Standardization of collection requirements for fasting samples: for the Working Group on Preanalytical Phase (WG-PA) of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM). Clin Chim Acta. 2014;432:33-7.) and this fasting definition is also used in this document. We believe that EFLM fasting definition should be consistently used to ensure standardization. We are therefore not in favor of changing it. Nevertheless, we have added these two requirements to the document: - Chewing gum should also not be used. - Morning medicine should be avoided

			unless it is vital for the patient.
11.	Page 10, paragraph 2.4)	The paragraph should be rephrased: Physical activity that exceed normal daily activity level.	Done.
12.	Page 10, paragraph 2.2.	Ideally we acknowledge this, but it is not possible, especially for out-patients.	We recognize that fasting requirement might pose certain logistical difficulties.
13.	Page 10, paragraph 2.6.	Correct, but should be removed from the guideline.	We disagree. Laboratory should document all relevant facts and issues which ensure a correct interpretation of test result.
14.	Page 11, paragraph 3.1.	The blood collection area may contain pictures…should be removed – not relevant in the guideline.	It is not a requirement, but a recommendation. We prefer to keep it.
15.	Page 11, paragraph 3.3.	Ethanol should be available for proper hand cleaning.	We have rephrased it into: “There should be hand sanitizing or washing areas with soap and/or appropriate sanitizers and paper towels.”
16.	Page 14, paragraph 5.1.	paragraph 5.1. We recommend that the guideline acknowledges national differences on the use of gloves. Otherwise one would fear that the guideline is not endorsed in several (Nordic) countries.	As stated under the Scope of the guidance (third paragraph), all national rules and recommendations take precedence over this document if they are different in any way.
17.	Page 16, paragraph 6.2.	We recommend that the following paragraph is removed: “Unfortunately, disposable tourniquets are not widely used, especially in some developing or non-developed countries in Europe (50). Hospital management should be made aware of the risk associated with the use of reusable tourniquets and potential benefit of the use of	We disagree and prefer to keep it as is.

		disposable tourniquets for the safety of the patients and healthcare staff." We find it a bit patronizing.	
18.	Post sampling	Post sampling. We think that the paragraphs 20, 20.1 and 20.2 should be removed as they are considered unnecessary. However, a paragraph regarding patients that experience dizziness or other symptoms could be added.	We disagree and prefer to keep it as is.
19.	Page 28, Post sampling.	paragraph 20. The patients should be encouraged to tell the phlebotomist at the next venipuncture that they previously have experienced such symptoms (dizziness) and would like to have the venipuncture performed lying down.	This is already covered under Pre-Sampling/General considerations on appropriate mode of communication with the patient (point 6).
20.	Step 6.	It should be mentioned that palpation of the vein could be included in the assessment of the site of venipuncture.	Step 6 does not relate to the selection if the venipuncture site. Nevertheless, we have added a sentence: "Palpation of the vein could help in the assessment of the appropriate venepuncture site." to the Step 7.1 (Select venepuncture site)
21.	Paragraph 7.3.	Artero-venous shunt should be added as unacceptable for a venipuncture.	Done.
22.	Paragraph 9.3.	We believe the paragraph "so that at least one-fourth of the needle is inserted into the vessel" should be changed to "so that at least 0.5 cm of the needle is inserted into the vessel". Needles come in very different lengths.	Done.

3. Finland (Finnish Society of Clinical Chemistry, Association of Biomedical Laboratory scientists)

	Part of the document	Comment	Response to comment
1.	NA	Good that the client view is stressed.	Thank you for your positive comments.
2.	General	For a topic this limited should not have to erquire any follow-up groups. The whole preanalytical phase should be handled. In this recommendation nothing is said about the further handling of the tubes or of the biological variations of the patient.	The intention was to cover only blood sampling. Sample handling and transport is out of the scope of this document.
3.	General	Some parts are written with too little and pars with too much details. Association of Biomedical Laboratory scientists in Finland sees this as being suitable for other profession than biomedical scientists.	This document is intended to be used for specialists in laboratory medicine, who are responsible for the implementation and quality management of the blood sampling procedure.
4.	General, Soap and other washing facilities, antiseptics	Perhaps it should be stressed that antiseptics to the puncture site and the hand desinfection liquids are two different products. In Finland we use usually glycerol based hand desinfectants and for the punture site we use A12T, Neoamisept, chlorhexidine.	We feel it is too detailed. The choice of antiseptics will depend on institutional policy.
5.	Step 3, Obtain supplies required	There are often needles and tubes from several manufacturers available.	This is unfortunately true. But, we strongly recommend that individual components from different manufacturers are never used together, since their combinations are not validated for the intended use and may compromise patient and healthcare worker

			safety.
6.	Step 1.4, Labelling	Label the samples after phlebotomy. Ask date of birth again to rule out mistakes in the barcode	According to the EFLM recommendation (van Dongen-Lases EC, Cornes MP, Grankvist K, Ibarz M, Kristensen GB, Lippi G, Nybo M, Simundic AM. Patient identification and tube labelling - a call for harmonisation. Clin Chem Lab Med. 2016;54(7):1141-5), whether the tubes should be labeled before or after blood collection should be based on a prospective risk analysis of the phlebotomy process in each institution. Nevertheless, if tubes are labeled after the blood sampling, it should be done in presence of the patient. If prelabeled tubes are used, the patient identity should always be checked in the presence of the patient, before the blood sampling.
7.	step 3, Tube colouring	Tube manufacturers have several different colours for their tubes. Purple is not necessarily always an EDTA-tube.	This is true. For more see: Simundic AM, Cornes MP, Grankvist K, Lippi G, Nybo M, Ceriotti F, Theodorsson E, Panteghini M. Colour coding for blood collection tube closures - a call for harmonisation. Clin Chem Lab Med. 2015;53(3):371-6.

8.	step 4	In Finland also others than physician make orders	Requesting physician is changed into: A requestor (authorised person to order blood test under national law).
9.	Pre-sampling 1	In Finland the phlebotomist does not introduce her/himself other than if asked. Everybody has a name tag. We do not ask for concent since it is presumed that when the patient comes to phlebotomy they have given their consent. Same is presumed for ward patients.	We recommend that a person who will perform blood collection should introduce him-/herself. This is an appropriate mode of communication with a patient.
10.	NA	We do not ask if patient is afraid but if this is stated in the reservation, then we automatically lay down the patient. If fear comes up during phlebotomy, then patient is also instructed to lay down.	We recommend that a patient is asked if he/she is afraid of blood collection. It may prevent some serious injuries. A sentence is added to the last paragraph of the General considerations on appropriate mode of communication with the patient: “If a patient declares to be afraid of the blood collection or if fear appears during the procedure, a patient is instructed to lay down.”
11.	Pre-sampling 1	Official ID like driver's licence or passport needed	The choice of the identifier depends on the institutional policy and national legislation.
12.	Patient position step 4, Labelling	Good that they stress labeling the tubes in the company of the patient. Client address or phlebotomist name is not needed on the label.	This information does not need to be on the tube, but essential information about the sample and the patient must be registered within the laboratory and easily

			retrievable.
13.	Sampling step 5, Gloves	Not mandatory to use gloves	See above (Denmark, comment #16).
14.	Sampling step 6, Apply tourniquet	Disposable tourniquets are used only for patients in isolation	We recommend that only disposable tourniquets are used to minimize the risk of infection and cross-contamination of patient and healthcare staff. The evidence (references available in the document) shows that reusable tourniquets can be colonised with multiresistant microorganisms and may thus serve as a reservoir and source of transmission of various pathogens to hospitalised patients.
15.	Sampling step 8, Clean sampling site	Alcohol disinfection not to be use if alcohol measurements are to be made from the sample	The use of ethanol before venous blood collection does not interfere with blood alcohol measurement. For more see: Lippi G, Simundic AM, Musile G, Danese E, Salvagno G, Tagliaro F. The alcohol used for cleansing the venipuncture site does not jeopardize blood and plasma alcohol measurement with head-space gas chromatography and an enzymatic assay. Biochem Med (Zagreb). 2017;27(2):398-403.
16.	Sampling step 9,	In Finland there are several	The aim of this

	Puncture the vein: bevel up	ways how to bevel the needle	recommendation is to ensure standardization.
17.	Step 2.1.	From 7-9 restriction is not suitable for Finland, perhaps on wards it could work. And the wish that all aptients have fasted is not possible. Also length of fasting not suitable. Decided in a big international endocrinology congress that fasting is not needed and samples can be taken during the whole day. Some e.g. hormone tests to be taken in a fasting status and during a certain time. However, not restricted to 7-9.	See above (Denmark, comment #10). Also, to address this comment, step 2.7 was added: "2.7 Additional collections during the day may be advisable for tests with circadian variations. Specific recommendations from the ordering physician for the exact time of blood sampling for these tests should be followed."
18.	2.6. Intake of drugs	There are a lot of drugs which influence laboratory tests and all cannot be taken into account. E.g. prolactine is influenced by a lot of drugs.	Laboratory should document all relevant facts and issues which ensure a correct interpretation of test result. Moreover, the below sentence has been added to the document: Morning medicine should be avoided unless it is vital for the patient.
19.	Page 23, Inverting the tubes	This varies between the manufacturer. Always follow the manufacturers guide how many times to invert.	We disagree and prefer to keep it as is. Mixing tubes during blood collection (If more than one tube needs to be collected) is not practical and prolongs the blood collection time.
20.	Table 2 point 20, Waiting time	Cannot wait 5 minutes with each patient	Patient can wait in the waiting room, as long as it is supervised. As stated in the document,

			there are patients who are afraid of needles or feel discomfort when seeing blood. Such patients, may experience syncope during or immediately after the blood collection. To make sure that patient is well and that no acute complications have occurred, we suggest that a patient is monitored in the blood collection area or waiting room for at least 5 minutes, or longer until the bleeding has stopped.
21.	Page 33	Add information on ergometry to be taken into account when taking samples	We did not consider this issue.
22.	Page 23-27	Good that the importance of tube invertion is stressed.	Thank you for your positive comments.

4. Germany (German society for Clinical Chemistry and Laboratory Medicine)

	Part of the document	**Comment**	**Response to comment**
1.	Time of drawing blood.	If we have an elective drawing of blood this fixed time setting (7-9:00) is sometimes possible. But of course there are other situations in a hospital, when blood is needed outside this time setting. This recommendation should apply to these situation also, or? Therefore a differentiation make sense? (e.g. Hepatitisserology or Crea prior to X-Ray?). What do you think?	We have added a step 2.7 to deal with this issue: "Additional collections during the day may be advisable for tests with circadian variations. Specific recommendations from the ordering physician for the exact time of blood sampling for these tests should be followed."
2.	NA	Washing hands next to the patient is sometimes not	As stated under the Scope of the

		allowed, just disinfection is mandatory due to some official hygiene guidelines.	guidance (third paragraph), all national rules and recommendations take precedence over this document if they are different in any way.
3.	NA	Use of single-use tournique. How big is the effect? If we do not have a problem in our institution with nosocomial infections, would you really recommend it. We just said in the German recommendation, if you want to reduce nosocomial infection considering single-use tourniques is recommended. This point is also an economic issue.	See above (Finland, comment #14).
4.	NA	Patient address should only be used where it is allowed. There several situations where due to confidentiality we are not allowed to get these information.	As stated under the Scope of the guidance (third paragraph), all national rules and recommendations take precedence over this document if they are different in any way.
5.	NA	Name of phlebotomist, additionally it could be necessary, because it is a medical prescription, to know the name of the prescribing doctor.	See step 4.3. We recommend that essential information about the sample and the patient must be registered within the laboratory in such a manner that the tube is traceable and unambiguously linked to the patient, collected sample, test request, requestor and phlebotomist. These data also include the identity of a requesting individual and the phlebotomist.

6.	NA	Again the order of draw is questioned. E.g. as a discard tube a normal serum-tube could be possible. We also weakend the strong order in our German recommendation focusing more on few really “do not do”s. We decided, this is probably more helpful.	EFLM has published a recommendation regarding the order of draw (Cornes M, van Dongen-Lases E, Grankvist K, Ibarz M, Kristensen G, Lippi G, Nybo M, Simundic AM. Order of blood draw: Opinion Paper by the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for the Preanalytical Phase (WG-PRE). Clin Chem Lab Med. 2017;55(1):27-31.) and that recommendation is incorporated into this document. We believe that the order of draw should be consistently followed to minimize the risk of sample contamination. We are therefore not in favor of changing it.
7.	NA	Use of ethanol for disinfection. There are other disinfectants which also could considered (like one member mentioned).	This is correct. We have rephrased it into: “Venepuncture site should be cleaned with 70% ethyl alcohol or any other appropriate disinfectant.”

5. Hungary (Hungarian Society of Laboratory Medicine, HSLM)

Comments from HSLM the below comments represent the view of 30% of the Hungarian medical laboratories. The comments were summarized and all recommendations of the EFLM recommendation for venous blood sampling were cross-reviewed with the recommendations of the “Hungarian national guideline for

preanalytical phase (in force since 20th April 2017 for 5 years) by the Extra-analytical WG of HSLM.

	Part of the document	Comment	Response to comment
1.	Scope of the guidance	84% of the responding Hungarian laboratories indicated that the EFLM guideline should contain specific recommendations for catheter blood collection, like the Hungarian national guideline on preanalytical phase uses recommendations from CLSI H21-A5: Collection of the blood through lines previously flushed with heparin should be avoided, if possible. If the blood must be drawn through a vascular access device (VAD), possible heparin contamination and specimen dilution should be considered. In this case the line should be flushed with 5 mL of saline and the first 5 mL of blood or six dead space volumes of the VAD discarded. If blood is obtained from a normal saline lock (a cappedoff intravenous port), two dead space volumes of the catheter and extension set should be discarded.”	As stated under the Scope of the guidance, catheter collection is out of the scope of this document. EFLM WG-PRE is currently working on another document specifically aimed to provide guidance for catheter collections.
2.	Patient position	86% of the responding Hungarian laboratories indicated that these recommendations of EFLM guideline are not feasible and in their phlebotomy sites are non-implementable. In addition, 8% of respondents found it realistic exclusively in inpatient service. The Extra-analytical WG of HSLM suggests that these recommendations should be	Change of the patient position may have a substantial effect on test results. However, we understand that this requirement may be difficult to meet. For this reason, we have modified the sentence into: “Therefore, the patient should ideally not change his/her position within 15 min

		deleted from EFLM guideline if EFLM wants to implement the guideline in all EFLM member countries.	prior to blood sampling.”
3.	Step 2.2	90% of the responding Hungarian laboratories suggested that the EFLM guideline should be supplemented with a list of references describing the existing evidence on the fact that fasting sample is not required.	We also agree that such list would be useful, but the production of such list was out of the scope of this project.
4.	step 6.3	100% of the responding Hungarian laboratories indicated that this recommendation is too general and unfeasible. The recommendation represents significant extra economical burden on healthcare institutions. Therefore this recommendation should be more specific in that sense which patient populations represent significant risk. In addition, EFLM guideline should provide evidence on the degree of the increased risk of infection and cross contamination when not disposable tourniquets are used in these specific populations. Otherwise this recommendation should be deleted from the EFLM guideline, because will make the recommendation difficult if at all to implement.	See above (Finland, comment #14)
5.	Step 14, Remove the needle from the vein and ensure the safety mechanism is activated	We fully agree with this recommendation. Though the recommendation will cause extra financial burden in many healthcare institutions, but the safety-benefit is clear and it will make decision-making for FEOs easier, who can refer to	Thank you for your positive comments.

		this recommendation and gain more safety for their employee and “blame” the extra cost on the international guideline.	
6.	Post-sampling, step 20	What do we mean under “blood collection facility”?. Keeping patients in the blood collection room for 5 minutes after blood drawing is not realistic. Patients might be asked to wait in the waiting room until the bleeding has stopped, but in a big outpatient service it is also hardly feasible.	We agree and have rephrased the sentence into: “…we suggest that a patient is monitored in the blood collection area or waiting room for at least 5 minutes, or longer until the bleeding has stopped.”

6. Iceland (Icelandic Society of Laboratory Medicine)

	Part of the document	**Comment**	**Response to comment**
1.	Page 9:	We do label the blood collection tubes in the presence of the patient but prefer to label the tubes after the blood has been drawn rather than before. This is because in case a sampling goes wrong for example if a tube does not fill properly we need not pluck the labels off the tubes again.	See above (Finland, comment #6).
2.	Page 10:	Impractical to limit blood collections to only morning samplings (7-9 am). Our outpatient phlebotomy service is open from 08:00-16:00. Fasting requirements are extensive. Would be helpful to have a list of analytes that require fasting or a list of analytes where there is evidence that fasting is not required. We only ask about fasting when samples are	See above (Hungary, comment #3).

		being collected for analytes known to be affected by fasting status.	
3.	Page 11: Step 3.1:	" may contain pictures with relaxing landscapes". Isn´t this to detailed recommendation ?	We believe that it may help relax patients. We prefer to keep it.
4.	Page 14:	We recommend using gloves but it is not mandatory.	As stated under the Scope of the guidance (third paragraph), all national rules and recommendations take precedence over this document if they are different in any way.
5.	Page 15:	We believe that giving up tourniquet use may prove to be difficult in practice.	See above (Finland, comment #14)
6.	Page 18:	7.3: Shouldn´t "indurated" be "indured".	The entire step has been rewritten into: 7.3 Do not collect blood from previously placed peripheral venous catheters, hardened veins, artero-venous shunt, from the sites of haematoma, inflammation or swelling and from an arm with a vascular graft should be avoided paretic arms or arms with lymphatic drain disorders.
7.	Page 19: 9.3:	We would recommend that instead of saying that at least one-fourth of the needle should be inserted into the vein it should be stated that so and so many cm or mm should be inserted, because not all needles are of the same length.	Done. The entire step 9.3 has been rewritten into: Insert the needle longitudinally into the vessel with determination and prudence at an approximatelly 5-30 degree angle depending on the

			vein's depth so that at least 0.5 cm of the needle is inserted into the vessel.

7. Norway (Norwegian Society of Medical Biochemistry)

We have received comment from three laboratories, and the comments are attached below. In summary, all approve the EFLM Recommendation for venous blood sampling. There are some diverging opinions on some of the suggested issues, like the recommendation for blood sampling between 07 to 09 in the morning after 12 hours of fasting, the recommendation for disinfection of the puncture site and the recommendation for patient positioning. Please see the various comments below.

	Part of the document	**Comment**	**Response to comment**
1.	NA	Preanalytic Resource Center at Haukeland University Hospital in Bergen believes that the overall impression of the document is positive. It's a solid and well-written document. It may be shortened at certain points.	Thank you for your positive comments. Our aim was to provide an informative recommendation, as detailed as possible.
2.	NA	Many good practices are suggested, but not everything is practically feasible. The document may fit better with outpatient sampling because it focuses less on the challenges of blood sampling of inpatient patients at hospitals.	We agree, challenges of blood sampling in inpatients are bigger than in outpatients. However, as stated under the Scope of the document, this document covers all steps of the venous blood collection procedure for in- and outpatients. The outpatient blood collection differs mostly in the patient preparation, patient position and physical activity prior to blood sampling. These issues are covered in the respective parts of the manuscript. The rest of the document applies equally for in- and

			outpatients.
3.	Table 1, page 36-38	The graduation (page 36-38) may be difficult to understand, and to some extent it also may be discussed. It is possible that the rating confuses more than it benefits. One possibility is that the authors draw the grading out of the actual text, and that table 2 page 39 may contain a more detailed explanation of the different grades.	Grading recommendations used in the evaluation of available evidence are presented in Table 1. Also, for all interested in learning more about this procedure, we have in the document provided a link to the on-line reading resource.
4.	Page 8:	About a change in patient position. We do not have the opportunity to comment in the lab data system for any change in patient position. This may also fill up our patient data system, and clinicians do not want this information.	The information about the change of the patient position is as important as the information about e.g. hemolysis and any other preanalytical source of variation. Providing information about possible effects of some preanalytical sources of variation is essential for the proper interpretation of the results.
5.	Page 9, Section 1.3:	We are required to identify the patient with both the name, date of birth and the national identification number for Norwegian citizens.	As stated under the Scope of the guidance (third paragraph), all national rules and recommendations take precedence over this document if they are different in any way.
6.	Page 9, Section 1.3:	Maybe section 1.1 - 1.4 should have 1A graduation?	Recommendations 1.1-1.4 are grade 1C recommendations. 1C is a strong recommendation. The evidence base supporting the recommendation is, however, of low quality.
7.	Page 10, Section	In a hospital the blood samples	This is correct. To

	2.2:	are taken 24 hours a day.	acknowledge this, we have added additional sentence: "2.7 Additional collections during the day may be advisable for tests with circadian variations. Specific recommendations from the ordering physician for the exact time of blood sampling for these tests should be followed."
8.	Page 10, section 2.3:	Normally we are not checking whether the patient is fasting or not.	We recommend that this is done always.
9.	Page 10, Section 2.6:	Consequences of food intake, physical activity etc. is taken into account in research projects, but not in daily sampling routine. The clinicians do not want this information. This sort of information would also fill up our patient data system.	See above (Norway, comment #4).
10.	Page 11, Step 3:	This section focuses mostly on blood sampling in an outpatient clinic and not in a hospitalized ward with bedridden patients. It may be pointed out in the heading (step 3).	Done.
11.	Page 14, Section 4.4:	We require the patient's full name, date of birth and the national identification number for Norwegian citizens. Only the name and date of birth is not good enough.	See above (Norway, comment #5).
12.	Page 14, sections 5.1 and 5.2:	We do not recommend using gloves during blood sampling. We believe that is unnecessary. We follow the same procedure as other healthcare practitioners are performing towards the patients, cleaning the hands with water and soap or alcohol/disinfection fluid,	As stated under the Scope of the guidance (third paragraph), all national rules and recommendations take precedence over this document if they are different in any way.

		before touching the patient. We recommend gloves if the patient is infectious or if the biomedical laboratory scientist has wounds or eczema on his/her hand. It becomes very inconvenient in a ward to wash hands in front of the patient. We do not use sterile gloves during sampling for blood culture, but the finger used to palpate the blood vessels is disinfected. It is desirable to reduce the consumption of plastic, and also for that reason we should not introduce to use more gloves when it is not strictly necessary. However, the biomedical laboratory scientist is not allowed to use watch or wedding ring during the sampling.	
13.	Page 15:	We believe that tourniquet should be used. If we should introduce a routine that tourniquet is to be avoided, then the sampling will take much more time and it will probably become a lot more problems in filling the tubes. This is unpleasant for the patient, and will also give bad quality for the tests, and in addition also be very time-consuming. Our experience in using "Vein Illumination Device" is not very good, and our experience is that it cannot replace a good biomedical laboratory scientist in blood sampling. If this instrument is recommended instead of using a tourniquet, we disagree. In patients with difficult sampling and where frequently blood tests are needed a central venous	A skilled phlebotomist can in most patients find a vein and successfully collect blood without a tourniquet. Nevertheless, we do not discourage the use of tourniquet. We just state that they are used only when necessary. It is OK to use them, but it is even better not to use them (to minimize the venous stasis).

		catheter is often used.	
14.	Page 16, section 6.2	The routine at our laboratory is that each tourniquet probably is washed after about 10 sampling times or between every 10 patients. Sometimes they are probably also washed more often, and sometimes less often. Disposable tourniquets are not practical in use.	See above (Finland, comment #14)
15.	Page 17	The lower figure should be deleted, as it provides minimal information.	This image of the cross-section at the elbow helps the understanding the anatomy of the cubital fossa. We therefore prefer to keep it.
16.	Page 18, Section 7.3	References to the recommendation "Do not collect blood from previously placed peripheral ...." may be missing.	See above (Iceland, comment #6). References are provided in the document.
17.	Page 18, Section 8.2	Blood cultures are very often ordered at a hospital. It may be a separate detailed section for the sampling of blood cultures.	We chose to provide instructions related to blood cultures as an integral part of this document.
18.	Page 19, 2nd paragraph:	Are there any references for accepting a venipuncture before the alcohol has dried on the skin, and that is does not affect the blood test?	Yes, as stated under step 8.3, it has been shown that the presence of alcohol (in case the venepuncture site was not let to dry) on the collection site is not a source of spurious hemolysis. Moreover, under ideal blood collection conditions, the use of ethanol before venous blood collection does not interfere with blood alcohol measurement. References are provided in the

			document.
19.	Page 19, 2nd paragraph:	What about cleaning the sampling site on infants, and patients with skin disease?	As stated under 7.3 blood should not be collected from the sites of inflammation or swelling. Regarding the step 7.3 same rules apply for infants and adults.
20.	Page 20 Section 9.4:	Is reference 71 correct?	Yes, it is correct.
21.	Page 21, 10.1:	Gel tubes should be mentioned in the "recommended order" list, both ordinary gel tubes for serum, and heparin and EDTA with and without gel. For trace elements see CLSI.	We have intentionally avoided the mention of gel. Same order applies, regardless of whether the tubes are with or without gel.
22.	Page 23, Step 12:	From the text it may be easy to misinterpret and think you only need to mix the blood samples once. It may be written that the samples should be mixed totally for 5-10 times, and that the sample is mixed rapidly 1-2 times as soon as the tube is removed from the holder and before inserting the next tube into the holder. It is also advisable to mix the tubes during the sampling, especially if 8- 10 tubes should be filled up. The detailed text about how to mix the blood samples may preferably be shortened.	We disagree and prefer to keep it as is. Mixing tubes during blood collection (If more than one tube needs to be collected) is not practical and prolongs the blood collection time.
23.	Page 27, Section 16.1:	We put a cotton wad over the sampling site with one (two when the bleeding danger is increased) 3M Micropore surgical paper tape over. We do not check that bleeding has stopped before leaving the patient.	In order to minimize the risk of hematoma or prolonged bleeding, we recommend that this is done as stated under steps 16 and 17.
24.	Page 29:	Most people do not feel sick after blood sampling. It is only in special situations we recommend the patient to wait 5 minutes before leaving.	See above (Finland, comment #20)
25.	Page 35:	A local e-learning course about venous blood sampling is being developed at our	EFLM WG-PRE considers e-learning is an excellent mode

		laboratory.	of education.
26.	Page 35:	"The EFLM WG-PRE as the leading professional entity involved in preanalytical phase feels responsible ..." Based on the lack of more hospital blood sampling procedures in this document we hope that the settled working groups have participants that are close to blood sampling and challenges in the daily hospital laboratory.	See above (Norway, comment #2).
27.	Step 8	I haven't looked through the whole recommendation but since there was a 1A recommendation for disinfection the puncture site I wanted to look at the new evidence (since 10-15 years ago). There are a couple of references here about bacteria contamination (actually transfusion medicine), but no reference to any study comparing no disinfection to use of disinfection. As pointed out disinfection is important during collection for blood culture, but that doesn't make it a general thing. You can't grade this 1 A evidence unless you can refer to a study showing harm to the patient, interference with analyze etc. This part is not convincing.	No Ethical committee would grant the approval for a controlled experimental study to compare the use of disinfection to the lack of the use of disinfection, in order to demonstrate the harm for the patient. This is why we felt that the existing studies were convincing enough to demonstrate the necessity to disinfect the venipuncture site. To acknowledge the missing high quality evidence, we have downgraded the recfommendation to 1B.
28.	Step 7.3.	By coincidence I saw the recommendation above 7.3. «Do not collect blood from previously placed peripheral venous catheters, indurated veins, paretic arms or arms with lymphatic drain disorders." Further it is written that this might lead to serious injuries. That might be so, but your references are 1 case study and an article from transfusion looking at 11 patients with	To acknowledge the missing high quality evidence, we have downgraded the recfommendation to 1B.

		possible nerve damage. The references doesn't represent the patient population for the actual recommendation and even if the had I'm surprised to see that also this is graded 1A.	
29.	NA	I would recommend to look through all the references for the whole document and make sure that your grades correspond to the grading-recommendations.	Done.

8. Slovenia (Slovenian Association for Clinical Chemistry and Laboratory Medicine)

	Part of the document	**Comment**	**Response to comment**
1.	Patient position	Hand position for optimum blood collection isn't mentioned (streched arm in a downward position).	The sentence was added to the step 7.1: "7.1 To select the venepuncture site, patient's arm should be stretched in a downward position."
2.	Step 4, Labeling and/or identifying tubes	We support labelling of tubes in front of the patient but after the collection of blood (to avoid unsuccessfully filled tubes attached with pre-prepared labels).	See above (Finland, comment #6).
3.	Step 5. Put on gloves	In order to reduce errors of prolonged blood stasis and to fulfill the safety measures we suggest below described procedure. Phlebotomist disinfects hands in front of a patient, applies tourniquet to select the puncture site and disinfect the site (with released tourniquet). In meantime, when disinficient is drying and disinfecting the puncture site, the phlebotomist puts on the gloves, applies tourniquet again and draws the blood according to procedure. Tourniquet (reusable,	Gloves need to be put before any contact with the patient. We therefore disagree with the described order of steps and prefer to keep our recommendation as is.

		disinfected) is first applied and constricted just to select the vene puncture site, then released and constricted again just before the puncture (after disinfection of the site).	
4.	Step 6. Apply tourniquet	We think the use of reusable tourniquet could be allowed for use with outdoor patients. To minimize the risk of infection and cross-contamination the tourniquet should be disinfected between patients. For disinfection of tourniquet, wet pads with a fast-acting alcoholic agent could be used.	See above (Finland, comment #14).
5.	Step 7. Select venepuncture site (Recomendation 7.3)	Also the collection of blood from the sites of haematoma, inflammation or sweeling and from arm with a vascular graft should be avoided.	This is correct. The sentence had been rephrased. See above (Iceland, comment #6).
6.	Step 8. Clean sampling site	What' the alternative for using ethanol as a disinfectant? Which nonalcoholic antiseptic cleaners should be used to avoid risk of contamination with ethanol?	For disinfecting the venipuncture site 70% ethyl alcohol or any other appropriate disinfectant may be used. The choice will depend on the available resources locally and/or nationally.
7.	Step 11. Release the tourniquet	Please specify alternative sites for blood collection.	The cubital vein is the most preferable choice. Only if these veins are unavailable should dorsal hand veins be used as an alternative. Blood collection from the veins in the wrist is discouraged.
8.	Step 18. Invert all tubes at least 4 times	After the mixing procedure all the tubes should be set in vertical position.	See above (Croatia, comment #8).

9. Spain (Spanish Society of Laboratory Medicine)

	Part of the document	Comment	Response to comment
1.	Abstract	In the abstract EFLM WG-PRE speaks about "from over 16 EFLM countries", but in the methodology "from over 15 EFLM countries".	Corrected. This document has been produced through a collaboration of 16 EFLM member countries.

10. Turkey (Turkish Biochemical Society)

Thank you for sharing with us the draft of EFLM Recommendations for Venous Blood Sampling. This is a well prepared and much useful guideline for all EFLM members. We have compiled the views of our colleagues about the draft Recommendations as follows.

	Part of the document	Comment	Response to comment
1.	page 7	Turkish Biochemical Society (TBS) has also prepared a National Phlebotomy Guideline. It has been circulated in Turkey and posted on EFLM website. Would you also cite this guideline in the Recommendations or specify with other national guidelines one by one?	This document was not available at the time when our recommendation was produced.
2.	page 5	The Recommendations will be beneficial for worker safety as well as patient safety. Therefore, we recommend the addition of workers' safety to the last sentence in page 5.	Done.
3.	page 7	We suppose the consensus opinion was prepared according to the opinions of stakeholders from 16 EFLM member countries not 15.	Correct.
4.	item 3.3 (page 11).	We suggest the addition of “eye wash devices” to item 3.3 (page 11).	Step 3.3 was rephrased into: “There should be hand sanitizing or washing areas with soap and/or appropriate sanitizers and paper towels.”
5.	item 5.1, page 14,	We suggest adding the word	Done. Step 5.1 was

	item 19.1, page 27.	"new" in order to prevent cross contamination risk (item 5.1, page 14). (Indeed, it is also defined at item page 19.1, page 27).	rephrased into: "5.1 New pair of gloves should always be worn to protect the patient and the staff performing the venous blood sampling."
6.	page 5 and 6, and item 7.3 on page 18.	Blood collection from the catheter is out of the scope of the Recommendations as mentioned on page 5 and 6. But there is a sharp restriction in item 7.3 again (page 18).	We strongly discourage the use of intravenous catheters for venous blood collection.
7.	step 9.5	We suggest to add "Needle movement should be just back and forward instead of left and right" to item 9.5 (page 20).	Done. Step 9.5 was rephrased into: "9.5 If a vein cannot be located, a slight repositioning of the needle (by moving the needle backward and forward) may help to find the vein."
8.	step 12.5	8. A reference may be given for the item 12.5 (page 25).	We were not able to identify a reference to support this recommendation.
9.	step 15.2	We suggest to add "The sharps container should be in a length of arm's distance" to the item 15.2 (page 26).	step 15.2 was rephrased into: "15.2 Sharps containers should be within arms length. Walking to sharps container is not an acceptable practice."

10. United Kingdom (Association for Clinical Biochemistry and Laboratory Medicine)

	Part of the document	**Comment**	**Response to comment**
1.	General	The ACB welcomes this document providing advice and guidance to underpin standardisation and quality improvement in venous blood sampling.	Thank you for your positive comments.

2.	General	The ACB would encourage the group to prepare a similar document covering collection of blood samples from children and babies	EFLM WG-PRE will consider this suggestion for its future projects.
3.	General	The ACB would be keen to see a modern review of the use of plasma versus serum for core routine testing	EFLM WG-PRE will consider this suggestion for its future projects.
4.	General	The document would benefit from full disclosure of the names and affiliations of contributors and stakeholders consulted e.g. as an appendix	All who have participated have been listed as authors.
5.	Page 7, List of contributor types, especially blood tube manufacturers	The ACB recognises that the group went to great lengths to avoid bias, seeking input from a broad range of stakeholders and is to be commended for engaging with the 3 main blood tube suppliers	Thank you for your positive comments.
6.	Page 10, Fasting	The ACB recognises that the fasted state is essential for some tests e.g. diagnostic glucose; and is desirable for others e.g. creatinine, urea, cortisol. However fasting is difficult to achieve and has little or no influence on the majority of tests. The ACB therefore believes that the default position for sampling should be that fasting is generally not required, with specific advice if fasting is required for correct interpretation. Fasting for all venous samples is not standard practice in the UK. It is our view that the fasted state should not be seen as the gold standard for practice in phlebotomy as this would be unnecessarily restrictive.	See above (Denmark, comment #10).
7.	Page 10, Fasting	In respect of lipid tests, the stipulation around fasting is at odds with the UK NICE Guideline CG 181 and others which state that non-fasting specimens and use of non-HDL cholesterol is preferred.	Step 2.2 states that it is acceptable to collect blood in the non-fasting state for tests for which fasting is not required. Thus, in this specific

		The recommendation from the present guideline is therefore unlikely to be complied with in the UK.	example (non-HDL cholesterol), recommendation under the step 2.2 applies.
8.	Page 10, Circadian variations	The overwhelming majority of tests have little or no meaningful circadian variation. Those which do are well known (e.g. cortisol) and most UK laboratory guidance identifies such tests	We have added step 2.7 to acknowledge that.
9.	Page 10, section 2.6, Gathering relevant information	It is part of normal professional competence in the UK that all state-registered staff (BMS, Clinical Scientist) are aware of factors that can influence test interpretation. It is unlikely that the phlebotomist would be able to collect and report all data suggested, and there would be a significant time resource required even to attempt it. We suggest that the requester should be responsible for making all relevant information available for the laboratory and to 'check whether the patient has followed necessary instructions before blood sampling'.	We agree that a requestor should be responsible to provide all necessary information to the patient. Unfortunately, the evidence shows that this is not happening consistently. Exactly because of this, we recommend that this is checked when a patient comes for blood collection.
10.	Page 10, section 2.6, Gathering relevant information	It is agreed that it is good practice to document any and all relevant facts that may affect interpretation and issue these as comments with the reported result. Standardised comment codes are the preferred option to ensure consistency and this is standard practice in many UK labs.	This is indeed a good reporting practice.
11.	Page 13, section 4.1. Labelling	Mislabelling of specimens presents a significant risk to patients. Wrong results could lead to treatment being inappropriately started; or clinicians could be falsely reassured so that necessary treatment is wrongly withheld.	Thank you for your positive comments.

		A focus on adequate and accurate labelling is welcome, and the direction to label at the patient's side is also welcome.	
12.	Page 22, section 10.3, Order of draw	This is a welcome re-iteration of what should be standard best practice. EDTA and drip-arm contaminations are on the rise, and Therapeutic Drug Monitoring is also vulnerable.	Thank you for your positive comments.
13.	General,	Taking account of the comments above, the ACB welcomes and strongly supports the statement of the EFLM WG-PRE.	Thank you for your positive comments.

11. The Netherlands (Netherlands Society for Clinical Chemistry and Laboratory Medicine)

	General comments	**Response to comment**
1.	In general, the recommendations provide a clear and systematical approach for venous blood sampling. However some recommendations are very difficult to comply to in the everyday setting of a phlebotomy department.	Thank you for your positive comments.
2.	Very adequate and comprehensive guideline. We endorse the initiative for standardization but emphasize that local country guidelines should also be weighed in.	Thank you for your positive comments.
3.	The document deals with all aspects of venous blood collection in a well-organized manner. However, the maximum conceivable is recommended, as a result of which the venous blood collection becomes almost impracticable. See use of gloves, blood sampling in a fasted state, body position should not change 15 minutes prior to blood collection (otherwise register), use sample mixer.	Our document is a recommendation on the best practice. We do understand that some recommendations may pose certain logistical and organizational difficulties to a particular institution. We believe that everyone should aim to fulfill as many recommendations from this document as possible.
4.	○ very descriptive with many recommendations with limited evidence; ○ contains many specific requirements (for example	See above (The Netherlands, comment #3).

	minimum mandatory rest time, information duty, washing hands in the presence of the patient, etc.) that do not apply to the majority of the patient population and/or increase the level of quality. In addition, the mandatory aspect of certain requirements will have consequences for the operation of a "high throughput" outpatient blood collection department; o based on personal taste (landscape pictures) on some points.	
5.	Too prescriptive without evidence.	The evidence was provided, wherever available.
6.	Clear document with well described recommendations and background information why these recommendations are chosen. However, sometimes the evidence to support these recommendations is limited or even absent. My comment would be to give guidelines and suggestions instead of hard recommendations that have to be followed and are not always compatible with daily practice.	See above (The Netherlands, comment #3).
7.	Furthermore, there is no reference to capillary blood sampling.	Indeed, capillary blood sampling was out of the scope of this document.
8.	We appreciate the European initiative to formulate recommendations on the preanalytical aspects of venipuncture.	Thank you for your positive comments.

	Page	**Line**	**Comments**	**Text suggestion**	**Response to comment**
9.	General comments		ISO/TS 20658:2017 Medical laboratories -- Requirements for collection, transport, receipt, and handling of samples misses in the references. Is the EFLM aware of the impact of this ISO standard with normative reference to ISO15189? Compliance to ISO20658 is obligatory for ISO15189 accreditation	Add to general introduction and scope: “ISO/TS 20658:2017 Medical laboratories -- Requirements for collection, transport, receipt, and handling of samples” describes requirements that are essential for sample procurement in ISO15189 setting.	Suggested text is added. We have checked for consistency in shall/should throughout the document and potential conflicts.

		due to this normative reference. In ISO20658 the use of 'shall' and 'should' is precisely chosen. The EFLM guideline cannot conflict with the ISO 20568 standard. Did the authors check for potential conflicts? At least the EFLM guideline is more prescriptive than the ISO standard, in cases where the ISO working group deliberately was not prescriptive. The beauty of the approach of ISO15189 and ISO20658 is that it is prescriptive in what has to in place, but not about the 'how'. For the 'how' the ISO standards rely on risk analysis based local procedures. Assessment of such procedures can also be based on proper risk management. The standard for instance describes the need for proper hand hygiene and demands the availability of protective gloves, but does not demand in which situation gloves have to be worn. In my opinion this is better than	This guideline discusses best practices to fulfil those requirements, but these are never obligatory or superior over local risk management according to recommendations in ISO15189 and ISO20658. Add ISO20658 to references.	

			prescription without knowledge of local circumstances.		
10.	6	8	The reference for ISO20658:2017 is missing.	Add reference.	Done.
11.	7	4	The phlebotomist should introduce him-/herself to the patient prior to phlebotomy. The level of (in)formality regarding the introduction is the responsibility of the institution and/or phlebotomist.	Delete: "*maybe also with your first name for a more personal note*,"	We prefer to leave it. This is just a recommendation.
12.	7	12	Phlebotomists are not required to inform patients with respect to TAT. This should be communicated to patients and physicians via other media. The TAT(s) are dependent on many factors, i.e. measuring method(s), batch or 24/7 analysis, authorisation procedures, reporting procedures etc.	Remove: "if asked, give a reasonable time expectation for the venous blood collection itself and for the laboratory results to be returned. Be precise in your explanations."	We prefer to leave it. This is just a recommendation.
13.	7	12	Phlebotomists are not qualified to inform patients on how long it takes for the test results to be completed. Many factors of influence: type of method, track system or batch, or whether the doctor is requesting a second opinion by their colleagues or other	Delete: "*4) if asked, give a reasonable time expectation for the venous blood collection itself* ***and for the laboratory results to be returned****. Be precise in your explanations*."	We have added a following text under Pre-sampling (point 4): It is increasingly common practice that only electronic order

			experts. It is increasingly common practice that only electronic order management barcodes are visible for the phlebotomist. It is therefore impossible to give a reasonable time of expectation for laboratory results if individual tests ordered are not visible for the phlebotomist.		management barcodes are visible for the phlebotomist. It is therefore impossible to give a reasonable time of expectation for laboratory results if individual tests ordered are not visible for the phlebotomist. In such cases, a phlebotomist should advise a patient where to look for that information.
14.	7	19	Inquiring the patient for fear of the phlebotomy-procedure may result in unnecessary anxiety. Maybe it's better to comfort the patient and estimate risk of syncope via other ways.	Remove: "ask the patient is he/she is afraid for blood collection". Replace by: "Ask the patient if he/she has had negative experiences with phlebotomy procedures in the past, to estimate the risk of syncope."	We prefer to keep this recommendation. The evidence (provided in the document) shows that a simple fear question predicts vasovagal reactions without causing them.
15.	7	19	Proactive questioning all patients concerning fear of blood collection is unnecessary and in many instances out of place. For	Delete the whole of recommendation 6. "*Ask the patient if he/she is afraid of blood collection. The evidence shows that*	See above (The Netherlands, comment #14). Although the

			example, in outpatient phlebotomy units of large health care centres the majority of the patients are adults whom routinely undergo phlebotomy. These patients will not appreciate the “fear of needle/blood collection” question every time they visit the phlebotomy unit. The reference used (12) is specific for a high school population. This population is not predominant in most health care centres. Leave it to the professionalism of the phlebotomist to identify and take preventative measures when helping patients with fear of blood collection.	*this simple question may help identify individuals who are at increased risk of experiencing vasovagal reaction (syncope) (12). If a patient is afraid, he/she should be closely monitored during and after the blood collection, in order to prevent injuries from fall during fainting. If you feel that the patient is nervous about the forthcoming blood collection, you can give her/him a simple task to perform, such as counting upwards or taking a deep breath before the puncture*”	study was done in children, we felt that same may help in adult population. This is just a recommendation.
16.	7	29	The current text suggests that any change of body position should be avoided within 15 minutes prior to blood collection, including from sitting to standing and vice versa. However it is practically impossible to have a patient to sit for this period in the phlebotomy chair. A patient nearly always moves (walking) from the waiting area (sitting) to the	It has been shown that change of a body position from supine to upright and vice versa can dramatically affect the concentration of many laboratory parameters (13-16). Therefore, the patient should not change his/her position within 15 min prior to blood sampling. If the	We have added a sentence below to the document: If a patient has properly rested for 15 minutes in the waiting area, a short walk from the waiting area to the collection

			collection area within minutes before blood collection. Most regular blood collections should then be accompanied by documentation that body position was altered prior to blood collection.	patient was lying, blood sampling should be done in the lying state (this is mostly the case for hospitalized patients). Outpatients should ideally sit for 15 min prior to blood sampling. If a change in posture is unavoidable within this time period, it should be documented to allow correct interpretation of test results (17). **It is not necessary to document a short walk from waiting area to the collection area.**	area is considered to be acceptable and does not need to be documented.
17.	7	31	Therefore, the patient should not change his/her position within 15 min prior to blood sampling.	Therefore, the patient should not change his/her position within 15 min prior to blood sampling **when a specific test is ordered that is known to be affected by body position.**	We believe that this recommendation should be consistently used to ensure standardization to its maximum. We are therefore not in favor of changing it.
18.	7	31	It is practically impossible for patients to sit in the same chair for 15 minutes prior to phlebotomy. This procedure is patient unfriendly and unfeasible for reasons of waiting-time and/or rigorous	Remove: “the patient should not change his/her position within 15 min prior to blood sampling”.	The sentence was changed into: Therefore, the patient should ideally not change his/her

			reorganisation of the phlebotomy offices. For the same reason(s) it is not relevant to add a comment to the reported result when the suggested procedure is not followed (it applies to all ambulatory patients!). The suggested procedure is not supported by firm clinical evidence.	Or change into: "the patient should preferably not significantly/rigorously change his/her position within 15 min prior to blood sampling. A short (10-30 seconds) walk (e.g. from the waiting room/reception space to the phlebotomy space) is considered to be acceptable. Perhaps the above can be supported by evidence from scientific literature?	position within 15 min prior to blood sampling.
19.	7	31	Regarding the 15 min. sitting time prior to phlebotomy. By default, almost all outpatient patients will walk from the waiting room to the place where blood is taken. Just letting them sit idle for 15 minutes seriously affects throughput of patients. Documenting this for the bulk of the patients is very inefficient. If necessary, documenting that some outpatient patients did not move has our preference.	Whilst it is recommended that patients upon entering the blood collection area have to sit for 15 minutes prior to blood sampling, this seriously affects the throughput and prolongs the waiting time for patients. Not meeting this requirement should be taken for granted in daily clinical practice. At best, documenting that outpatient patients met this 15 minutes waiting requirement is worth considering.	See above (The Netherlands, comment #16).

20.	7	31	Large high throughput outpatient phlebotomy units aim for a short patient waiting time to ensure fast laboratory results to reduce total patient hospital time. 15 Minutes of sitting time and documentation in case of non-compliance has an enormous impact on the patient waiting time and human resources. Moreover and even more important, any evidence for clinical relevance is missing!	Delete: "*Outpatients should ideally sit for 15 min prior to blood sampling. If a change in posture is unavoidable within this time period, it should be documented to allow correct interpretation of test results (17).*"	See above (The Netherlands, comments #14 and #18).
21.	8	10	For adequate identification, at least two (patient name and date of birth) and preferably one additional identifier should be used. Additional identifiers which may be used for patient identification include: …	For adequate identification, at least two (patient name and date of birth) identifiers should be used. Additional identifiers are needed if the patient has a twin brother or sister.	We agree. This is why we recommend a minimum of two and preferably three identifiers.
22.	9	4	It has not been proven that patients should be fasting for all laboratory tests. For reasons of clarity 2.1 and 2.2 should be switched and merged. This is especially relevant to glucose, but for lipids this is not necessary anymore: see Nordestgaard et al. Eur Heart J 2016 "Fasting is	Remove 2.1. and 2.2 and replace by: 2.1 Blood should preferably be drawn in the morning (between 7-9 am) in a fasting state, 8-12 hours after the last meal for several reasons [reference]. The fasting preference might pose certain logistical difficulties and it is therefore	We prefer to keep it as is. This is just a recommendation. Also, see above (Denmark, comment #10).

			not routinely required for determination of a lipid profile: clinical and laboratory implications including flagging at desirable concentration cut-points - a joint consensus statement from the European Atherosclerosis Society and European Federation of Clinical Chemistry and Laboratory Medicine." Overall, the suggested procedure is unfeasible and patient unfriendly.	acceptable to collect blood during the day for non-fasting patients for: a) tests which do not have circadian variations and for which there is evidence that fasting is not required; and for b) emergencies. *Recommendations with respect to the fasting requirement*: Water consumption is allowed during the fasting period, but patients should refrain from alcohol for 24 h prior to blood sampling. In the morning, prior to blood sampling, patients should not drink caffeine-containing beverages (coffee, energy drinks and tea). Cigarette smoking should be discouraged in the morning before the blood sampling (19).	
23.	9	4	Verifying patient's fasting status is only necessary when analytes are ordered of which there is evidence that a fasting status is required (i.e. glucose). This information can be indicated on the order form or on the tube labels from the laboratory information system when	Delete: "2.3 Patient fasting status should be verified before blood is drawn. Whenever possible, blood should not be drawn if the patient is not properly prepared (emergencies are exceptions to this rule). If blood	See above (Denmark, comment #10).

			these tests are ordered. This alternative process configuration does not require fasting status verification of each individual blood collection. Note also that there is recent evidence that fasting state is not required anymore for lipid profiling! See Nordestgaard et al. Eur Heart J 2016. Fasting is not routinely required for determination of a lipid profile: clinical and laboratory implications including flagging at desirable concentration cutpoints – a joint consensus statement from the European Atherosclerosis Society and European Federation of Clinical Chemistry and Laboratory Medicine.	collection is done in the non-fasting state, or a patient has not been properly prepared, this fact should be documented to allow correct interpretation of test results." Add: When tests are ordered whereby a fasting state is required the phlebotomist should have access to this information. Prior to blood collection the fasting status should be verified and non-compliance be documented to allow correct interpretation of test results.	
24.	9	5	Drawing blood strictly in the morning is unrealistic as it is a continuous 24/7 activity in most health care centres. Blood collection outside the 7-9 am time frame is not restricted to emergency situations.	Delete: "*In accordance with our previously published recommendation, blood for all blood tests should be drawn in the morning (between 7-9 am)"* Change into: "**Laboratory staff ensures that analytes with circadian rhythm are drawn within a prerequisite time**	See above (Denmark, comment #10).

				frame of the day. Non-compliance is documented in order to allow correct interpretation of test results"	
25.	9	5	There is no evidence that fasting samples should be collected between 7 and 9 a.m.	Remove: "between 7-9 hours"	See above (Denmark, comment #10).
26.	9	6	Fasting state is achieved after 8 to 12h of fasting. See Dutch guideline "NVKC veldnorm venapunctie".	Replace by: "8 to 12 hours after the last meal"	See above (Denmark, comment #10).
27.	9	6	Fasting status is achieved after 8 to 12 hours. Reference: Sacks et al. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Diabetes Care 2011;34.	Replace by: **8 to 12 hours after the last meal**	See above (Denmark, comment #10).
28.	9	8-10	How strong is the evidence that even 1 cup of coffee or tea is of influence on lab test results?	Change "Patients should not drink caffeine-containing beverages." into: Patients should not drink too many caffeine-containing beverages. Also, milk and sugar are not allowed.	See above (Denmark, comment #10).
29.	9	11	We recognise that fasting requirement might pose	We recognise that fasting requirement	See above (Denmark,

			certain logistical difficulties and find it acceptable to collect blood during the day for non-fasting patients only for: a) emergencies and b) tests which do not have circadian variations and for which there is evidence that fasting is not required.	pose certain logistical difficulties and find it acceptable to collect blood in fasting patients only for the tests which do have circadian variations and for which there is evidence that fasting is required.	comment #10).
30.	9	16-18	The phlebotomist should not consider not executing the phlebotomy. They should not consider postponing medical care.	Remove sentence.	In the document, we state that blood sampling procedure must be postponed until issues have been resolved. Who will take the responsibility, will depend on the national and institutional circumstances.
31.	9	16-18	Phlebotomists will never postpone any blood drawing! They should not be responsible for delaying medical care since they are not educated for doing this and they also cannot foresee the consequences.	Delete: Whenever possible, blood should not be drawn if the patient is not properly prepared (emergencies are exceptions to this rule).	See above (The Netherlands, comment #30).
32.	9	16-20	Blood collection in a non fasting state is more common than in a fasting state. For most parameters fasting is not required and does not	If blood collection is done in the ~~**non**~~ fasting state, or a patient has not been properly prepared, this fact should be	See above (Denmark, comment #10).

			influence the results.	documented to allow correct interpretation of test results.	
33.	9	20	Most blood is collected from patients in a non-fasting state. Please change this sentence.	If blood collection is done in the fasting state, this fact should be documented to allow correct interpretation of test results.	See above (Denmark, comment #10).
34.	9	31-33	For the phlebotomist it is virtually impossible to assess/evaluate and register all factors possibly affecting the reported result. Moreover, the effect of different factors on the reported result, differs for each test and factor considered. The phlebotomist should not consider not executing the phlebotomy. It is the responsibility of the requesting physician to inform the patient with respect to pre-examination procedures/requirements. Not fulfilling pre-examination requirements should be registered and reported.	Remove section. Comments not fulfilling requirements should be reported to requesting physician. Change into: "Where appropriate the laboratory (phlebotomist) shall register pre-analytical conditions relevant for test value interpretation".	We do not understand which section exactly is discussed in this comment. We have changed the sentence into: If some of the above issues have been identified and blood sampling can not be postponed, the laboratory should where appropriate, document all relevant pre-analytical conditions to allow a correct interpretation of test results

35.	10	15	"Intense physical activity should be avoided 24 hours before the blood sampling." How is intense physical activity quantified? If intense physical activity is to be avoided prior to blood collection the guideline should recommend criteria which have to be verified prior to blood collection.	Add criteria (or add a reference) defining intense physical activity which can be verified prior to blood collection by the phlebotomist.	Sentence was changed into: Intense physical activity (that exceed normal daily activity level) should be avoided 24 hours before the blood sampling.
36.	10	15	"Intense physical activity should be avoided 24 hours before the blood sampling." How is intense physical activity quantified? If intense physical activity is to be avoided prior to blood collection the guideline should recommend criteria which have to be verified prior to blood collection. E.g. marathon running.	Add criteria (or add a reference) defining intense physical activity.	See above (The Netherlands, comment #35).
37.	10	15	What is the definition of intensive physical activity? Many patients cycle to the phlebotomy location.	Remove of define 'intense physical activity' with clear examples.	See above (The Netherlands, comment #35).
38.	10	21-22	Advice regarding interior design style has no place in a guideline.	Delete: "*The blood collection area may contain pictures with relaxing landscapes on the walls, to make the space more comfortable*"	See above (Denmark, comment #14).
39.	10	28-29	Large outpatient phlebotomy units are different in design. Some have separate rooms	Change "3.3 *There should be hand washing facilities with soap, running water*	The sentence was changed into: Hand sanitizing

			others consist of an open area separated in phlebotomy cubicles.	*and paper towels in the room*." into: There should be **ample accessibility** to hand washing facilities with soap, running water, **hand disinfectants** and paper towels **at the outpatient phlebotomy unit to ensure proper hand hygiene**.	or washing areas with soap and/or appropriate sanitizers and paper towels should be available and accessible to ensure proper hand hygiene.
40.	10 11	30 4	All blood drawing facilities must have a separate waiting and reception area for privacy reasons. There is a new tendency to combine these facilities to reduce waiting time and improve efficiency. If this recommendation is accepted, the consequence will be that this development will no longer be possible.	Remove this recommendation from the guideline.	We have rephrased a sentence into: Patient sample collection facilities should be separated from reception/waiting areas to ensure patient privacy.
41.	11	27-33	It is common practice to use vacuum tubes from different manufacturers with a single type of blood collection needle. Recommendation 3.9 would imply separate serial venepunctures when using blood tubes from different manufactures. This is very patient unfriendly and unacceptable practice.	Change "*3.9 Needle, holder and the blood tube make together an integral blood collection system. Only individual components of the same manufacturer should be used as a part of the blood collection system. Whereas manufacturers ensure the full compatibility between the components of their*	We have added a following sentence: If for whatever reasons, this requirement can not be fully respected and individual components from different manufacturers need to be used together (e.g. special

			Example: Paxgene, quantiferon tubes, hemoculture, and trace elements tubes are often of a different manufacturer than the standard safety needle and/or push button in use. Furthermore, the reference (33) is less stringent than the EFLM guideline. “Therefore, the possibility of using separate parts of the blood collection system obtained or purchased from different manufacturers is <u>strongly discouraged</u> by the EFLM WG-PRE except when the integration has been previously validated by the manufacturer(s) or by national or supranational regulation bodies”.	*system, individual components from different manufacturers <u>should never be used together</u>, since their combinations are not validated for the intended use and may compromise patient and healthcare worker safety (33).”* into: “3.9 Needle, holder and the blood tube make together an integral blood collection system. Only individual components of the same manufacturer should be used as a part of the blood collection system. Whereas manufacturers ensure the full compatibility between the components of their system, individual components from different manufacturers **should be discouraged where possible** since their combinations are not validated for the intended use and may compromise patient and healthcare worker safety (33). **Serial venepunctures to safeguard single manufacturer**	blood drawing tubes are not available by the main company whose tubes are in use in the particular institution), serial venepunctures to safeguard single manufacturer compatibility of blood component collection systems is not justified.

				compatibility of blood component collection systems are however not justified.	
42.	11	27-33	All blood drawing systems must be from the same company. This might be preferable in most situations; however this recommendation limits the possibility and flexibility to choose for example alternative or special blood drawing tubes that are not available by the leading company or to choose small pediatric tubes in combination with the capillary puncture device from two different manufacturers.	Remove this recommendation from the guideline.	See above (The Netherlands, comment #41).
43.	12	29	Recommendation 4.3. A physician is not the only requestor for blood tests in different European countries.	Change *"identification of a requesting physician"* into: "identification of the **requestor (authorised person to order blood test under national law)"**	See above (Finland, comment #8).
44.	13	3	For most routine lab tests the time of blood drawing is not relevant. See also ISO15189 5.4.3.f, 5.4.4.2.d and 5.4.4.3.f.	Delete: *and time of*	We disagree and prefer to keep it.
45.	13	14-17	As the guideline indicates, there is no high end evidence that wearing gloves protect the patient and the staff performing	Change "*5.1 Gloves should always be worn to protect the patient and the staff performing the venous*	See above (Denmark, comment #16).

			the venous blood sampling. The Working Group for Preanalytical Phase (WG-PRE) however advices the use of gloves during phlebotomy (strong recommendation). This expert opinion however does not take into consideration the drawbacks of glove usage during phlebotomy. 1) Less tactile sense which makes vein localisation more challenging. 2) Observational/inter view: Many phlebotomists experience reduced dexterity while using gloves (possibly) making them more prone to needle stick injury. We therefore advise the guideline to describe criteria when protective glove usage is mandatory. We consider wearing gloves during phlebotomy optional but not mandatory when using a closed blood collection system with a straight needle device.	*blood sampling."* into: **Protective gloves should be worn during venous blood collection when using any open blood collection system.**	

46.	13	14-20	Wearing gloves using closed phlebotomy systems is, in daily practice, not practical. In fact it is stated that there is no high quality evidence to support wearing gloves. We therefore will adhere to our local infection-prevention protocols stating that as long as the patient is able to hold down the gauze to prevent spilling of blood drops we will not use gloves.	No suggestion. For this part we will adhere to our local UNIP (unit infection prevention) guidelines.	See above (Denmark, comment #16).
47.	13	16	Gloves should always be worn to protect the patient and the staff performing the venous blood sampling.	Gloves could be worn to protect the patient and the staff performing the venous blood sampling.	See above (Denmark, comment #16).
48.	13	16-17	It has not been proven that using gloves is preferred. Using gloves diminishes tactile sense in fingers for tapping venes, complicates application of tourniquet and therefore interferes in the phlebotomy procedure thereby increasing the risk of accidents/contamination.	From the Dutch phlebotomy guideline: When a closed blood collection system is used and the patient applies pressure to the blood collection site, gloves are not required.	See above (Denmark, comment #16).
49.	13	16-17	As the guideline indicates, there is no high end evidence that wearing gloves protect the patient and the staff performing	Change "*5.1 Gloves should always be worn to protect the patient and the staff performing the venous*	See above (Denmark, comment #16).

			the venous blood sampling. The Working Group for Preanalytical Phase (WG-PRE) however advices the use of gloves during phlebotomy (strong recommendation). This expert opinion however does not take into consideration the drawbacks of glove usage during phlebotomy. 1) Less tactile sense which makes vein localisation more challenging. 2) Observational/inter view: Many phlebotomists experience reduced dexterity while using gloves (possibly) making them more prone to needle stick injury. We therefore advise the guideline to describe criteria when protective glove usage is mandatory. We consider wearing gloves during phlebotomy optional but not mandatory when using a closed blood collection system with a straight needle device. It has been described that	*blood sampling."* into: **Protective gloves should be worn during venous blood collection when:** - **using any open blood collection system;** - **using a butterfly needle (push button); whereby the manufacturer cannot guarantee zero blood spatter;** - **the phlebotomist has any type of hand wounds;** - **local infection prevention protocols state so;** - **the patient requests usage.**	

			butterfly needles with safety needle devices cause visible blood spatter [reference]. It should therefore be recommended that gloves are used in combination with butterfly needles with safety devices. Reference: Haiduven DJ, McGuire-Wolfe C, Applegarth SP. (2012). Contribution of a winged phlebotomy device design to blood splatter. Infect Control Hosp Epidemiol 33(11); 1069-1076.		
50.	13	16-17	Gloves should always be worn during venapuncture. This will reduce the risk of contamination for both patient and professional. Wearing gloves will reduce the risk of blood contamination in the case of an puncture accident. The evidence to support this recommendation is minimal and no comparison is made between wearing gloves and disinfecting hands for contamination risk. By wearing gloves the process of venepuncture will be less efficient (slower) and more prone to mistakes (not puncturing the vene).	Remove this recommendation from the guideline.	See above (Denmark, comment #16).

51.	13	16-17	The declaration is made that gloves should be worn when performing venipuncture, even when a closed system is used. The authors state that gloves should be worn even in the absence of scientific evidence.	Gloves should be worn when an open system is used. When closed systems are used gloves are not compulsory.	See above (Denmark, comment #16).
52.	13	18-20	Hand hygiene should be performed prior to each new phlebotomy. In large phlebotomy units an electronic customer flow management system is used to call the patient to the phlebotomy room/cubicle. While the phlebotomist waits for the patient arrival he/she uses this time efficiently to prepare the next phlebotomy. This includes hand hygiene. Making hand hygiene obligatory in front of the patient jeopardizes patient throughput and thus elongating patient waiting time.	Change *"5.2 Hands should be cleaned <u>in front</u> of the patient, before putting on gloves. Cleaning of hands (washing or sanitizing) in front of patients is important not only to minimize the risk of transmitting the infection during glove removal, but also to reassure the patient*." into: **Hand hygiene should be performed prior to each new phlebotomy to reduce the risk of transmitting pathogens.**	We disagree and prefer to keep it as is.
53.	13	18-20	Hands must be washed in presence of the patient and before gloves are worn. This seems more of the same. By washing hands and alcohol the hands are already disinfected. Wearing gloves does not add anything and will slow down the process of	Remove this recommendation from the guideline.	We disagree and prefer to keep it as is.

			drawing blood.		
54.	14	24-27	Phlebotomy using a tourniquet for up to 1 minute is preferred. See Dutch guideline on page 22. Not using a tourniquet may result in multiple attempts to perform a correct phlebotomy.	Change into: "… we recommend that blood collection is done with tourniquet **up to 1 minute**."	We disagree and prefer not to change the original recommendation. However, we have added the below sentence: In case when tourniquet is used, we prefer that total tourniquet time is up to 1 minute.
55.	14	24-27	Patients for which blood drawing is challenging. It is for the patient comfort and safety to use tourniquets. Otherwise the number of patients that will be exposed to an additional attempt of blood drawing will increase.	Change *We recommend that blood collection is done preferably without tourniquets.* into: **We recommend that blood collection is done with tourniquet for up to 1 minute.**	See above (The Netherlands, comment #54).
56.	15	1-2	Disposable tourniquets have some disadvantages and are therefore not always preferred: they are less comfortable for the patient, less easy to apply and adjust. With a proper cleaning/disinfection procedure, multiple-use tourniquets are also	Change into: "Either reusable or disposable tourniquets can be used. In case of reusable tourniquets are used, a SOP for periodic cleaning and disinfecting of tourniquets should be available and	We disagree and prefer not to change the original recommendation.

			acceptable.	implemented."	
57.	15	1-2	Disposable tourniquets have several disadvantages and not preferable: less comfortable for the patient, less practical in positioning, less practical to adjust so that it fits to the patient. In case a good cleaning procedure is present than there is no objection to use reusable tourniquets.	Change "*We recommend that disposable tourniquets are used to minimize the risk of infection and cross-contamination of patient and healthcare staff.*" into: "**Either reusable or disposable tourniquets can be used. In case of reusable tourniquets a procedure is required to clean and disinfect them."**	We disagree and prefer not to change the original recommendation.
58.	15	24	According to this EFLM guideline blood drawing should preferably take place without tourniquet and without fist. Again this will result in more patients that are exposed to an additional attempt of blood drawing.	Change *Warn the patient not to clench or pump the fist.* into: **Take care the patient will make a fist no longer than minimally needed, until the blood starts to flow into the tube.**	We disagree and prefer not to change the original recommendation.
59.	17	12-13	'Do not collect blood from previously placed peripheral venous catheters, indurated veins, paretic arms or arms with lymphatic drain disorders'. In the Netherlands it is stated that blood may be drawn from arms with lymphatic drain disorders, e.g. after breast cancer surgery. This change has	Change "*7.3 Do not collect blood from previously placed peripheral venous catheters, indurated veins, paretic arms or arms with lymphatic drain disorders."* into: **7.3 Do not collect blood from previously placed**	We disagree and prefer not to change the original recommendation.

			been made in collaboration with the physicians Internal Medicine while scientific evidence is lacking. Reference: Onnodig om de arm te ontzien na okselklierdissectie. Het verbod op handelingen als een venapunctie is obsoleet. Ragna L.A. van der Linden, Ignas P.T. van Bebber, Koop Bosscha en Maud Bessems. Ned Tijdschr Geneeskd. 2015;159:A9302 en A9510	**peripheral venous catheters, indurated veins or paretic arms."**	
60.	17	14	Adding text to register/document alternate vene puncture sites other than the ones mentioned is advisable.	7.4 Make sure to document when alternate vene puncture sites other than the before mentioned sites are used (i.e. veins in hand, foot).	Sentence was rephrased into: Make sure to document when alternate venepuncture sites (e.g. veins in hand and foot, or any other than the above mentioned sites) are used.
61.	18	4-7	The venapuncture site must always be disinfected by alcohol. This is contrary to the national guideline we have.	Remove this recommendation from the guideline.	See above (Denmark, comment #16).
62.	18	4-7	Recommending the use of water for cleaning the	8.1 Selected site should be cleaned	We disagree and prefer not

			sampling site should not be excluded. The use of alcohol before collection for a blood culture is still covered in paragraph 8.2.	with **water or** 70% ethyl alcohol prior to blood sampling to prevent contamination **~~with skin pathogens~~**. Cleaning should be performed with one wipe and the selected site should be left to dry. Do not wipe the sampling site with the same gauze twice.	to change the original recommendation.
63.	18	10-11	What is the evidence that disinfecting twice is needed instead of once?	Delete: *"Cleaning the sampling site by disinfecting twice using separate gauze pads seems advisable*."	We do not have the evidence. This recommendation is a consensus opinion based on experience and expertise of the group.
64.	21	2	Commonly used trace elements tubes <u>do</u> contain additives such as EDTA or clot activators	Change "7. *Other tubes (e.g. tube with no additives for trace elements*)" into: **7. Other tubes (e.g. tube with no additives)**	Changes into: tubes with no additives.
65.	21	5-11	The authors state that a butterfly needle can be used for analysis of coagulation disorders. In literature there is no clear evidence of the potential influence of use of a butterfly needle on coagulation results.	Delete: "*and a winged blood collection set (butterfly devices) is used, a discard tube must be collected to prevent underfilling of the tube with subsequent bias in test results (6).*" Add: **Discourage winged blood collection set**	We disagree and prefer not to change the original recommendation. This recommendation is a consensus

			Reference: Spronk et al. Thromb Haemost 2009; 101: 1156; Loeffen et al. J Tromb Haemost 2012; 10: 2544; Lippi et al. J Tromb Haemost 2005; 3: 389.	**(butterfly devices) usage when drawing tubes for coagulation testing since extension tubing can activate coagulation.**	opinion based on experience and expertise of the group.
66.	21	5-11	The authors state that a butterfly needle can be used for analysis of coagulation disorders. In literature there is no clear evidence of the potential influence of use of a butterfly needle on coagulation results. Reference: Spronk et al. Thromb Haemost 2009; 101: 1156; Loeffen et al. J Tromb Haemost 2012; 10: 2544; Lippi et al. J Tromb Haemost 2005; 3: 389.	While not only aPTT and PT are performed but also analysis of individual coagulation factors that are more susceptible to activation of coagulation upon venepuncture we suggest that the use of a butterfly needle should be discouraged.	See above (The Netherlands, comment #65).
67.	26	17	A pressure should be applied until the bleeding has stopped, which is usually a period of up to 2 minutes for routine draws and up to 10 minutes for patients on anticoagulation.	A **soft** pressure should be applied until the bleeding has stopped, which is usually a period of up to 2 minutes for routine draws and up to 10 minutes for patients on anticoagulation.	Rephrased into: a gentle pressure.
68.	27	3	Standardise number of inverts. Guideline states all tubes should be inverted at least 4 times unless only 1 tube is drawn → invert 5 times.	Delete: "18.2 *If only one tube is collected invert it 5 times directly after collection*."	This part was rephrased into: Step 18. Invert all tubes at least 4 more

					times (1B) 18.1 After removing the needle from vein and activating the safety mechanism in place, invert all tubes at least 4 more times, so that a total number of inversions is 5 (once immediately after the tube has been filled and remaining 4 times, once all tubes have been collected (after removing the needle from vein). Ideally, the number of full rotations should correspond to manufacturers' instruction. For information about the proper mixing procedure please refer to Step 12.
69.	27	21-23	For ambulatory patients it is not possible to wait for 5 minutes after phlebotomy. Showing empathy and identifying/monitoring	Remove: “advise the patient to rest for 5 min”	We disagree and prefer not to change the original recommendatio

			patients at risk of syncope is required		n.
70.	27 28	21 5	The post sampling criteria are too rigid concerning the minimal 5 minute observational/rest period. The majority of patients <u>do not</u> suffer from fear of needles/blood or are not dizzy/faint post phlebotomy. Furthermore an obligatory observational/rest period jeopardizes patient throughput thus elongating patient waiting time. Leave it to the professionalism of the phlebotomist and/or input from the patient when an observational/rest period is implied post phlebotomy. A observational/rest period should be mandatory when: - The patient shows any signs of faintness/dizziness. - The patient says not to be feeling well. The duration of the observational/rest period cannot be specified since	Suggestions for new text: - **Eliminate an obligatory observational/rest period after every phlebotomy.** **- An observational/rest period should take place if the patient and/or phlebotomist see the patient becoming faint or dizzy.** **- Specify that the duration of observational/rest period depends on the individual condition of the patient.**	We disagree and prefer not to change the original recommendation. However, to elaborate our position we have added the below sentence: Although we recognise that the majority of patients do not suffer from anxiety or dizziness post phlebotomy, we also believe that a benefit of complying to this step has an obvious benefit which outweighs a possible difficulties in meeting this recommendation.

			this depends on the individual patient.		
71.	27 28	21-23 15	The post sampling criteria are too rigid concerning the minimal 5 minute observational/rest period. The majority of patients <u>do not</u> suffer from fear of needles/blood or are not dizzy/faint post phlebotomy. Furthermore an obligatory observational/rest period jeopardizes patient throughput thus elongating patient waiting time. Leave it to the professionalism of the phlebotomist and/or input from the patient when an observational/rest period is implied post phlebotomy. A observational/rest period should be mandatory when: - The patient shows any signs of faintness/dizziness. - The patient says not to be feeling well. The duration of the observational/rest period cannot be specified since	Suggestion for new text: **An observational/rest period should take place if the patient and/or phlebotomist see the patient becoming faint or dizzy.**	See above (The Netherlands, comment #70).

			this depends on the individual patient.		
72.	28	4-5	Phlebotomists are not required to inform the patient with respect to the TATs Wrong information might be supplied, because most phlebotomists are not equipped with this knowledge. Expectations of patients may therefore be incorrect. See page 7, line 12.	Remove: "Thank the patient and leave her/him with the assurance that she/he will obtain laboratory results **as soon as possible**".	We disagree and prefer not to change the original recommendation. Giving assurance is not giving the exact information.
73.	28	4-5	Again, phlebotomists are not qualified to inform patients on how long it takes for the test results to be completed and might give even wrong information.	*Delete: Thank the patient and leave her/him with the assurance that she/he will obtain laboratory results **as soon as possible.***	This step was rephrased to be in line with Pre-sampling, point 4.
74.	28	15	Who should monitor the patient 5 minutes after the phlebotomy? This is unfeasible.	Remove.	We have added the below sentence: Preferably, the patient should be monitored by authorised personnel, or left to rest unsupervised and advised to inform the staff or ask for help if in need for

					any assistance.
75.	30	24-32	We completely agree with the educational and assessment of ongoing competency text. However the specifications on the number of blood collections during practical training and observational audits and which location this training is performed should be removed. The set number of blood collections is highly variable and depends on the institution and (medical) experience level of the trainee. It is the responsibility of the laboratory specialist that a minimal demonstrable standard of phlebotomy experience/knowledge is achieved.	"*Practical training should ~~preferably~~**(remove)** be offered ~~in the laboratory outpatient unit~~, ~~during the period of 1 week during which a new staff member~~ **should** ~~perform at least 100 blood collections~~ (**remove**), under the supervision of the responsible staff. An observational audit should be done ~~during the first five and last five collections~~ (**remove**),, to assess the level of compliance with the recommended procedure and identify potential deviations*."	We have added the below paragraph: The below stated numbers of blood collections and duration of the practical training are a recommendation for minimum criteria. These criteria are a consensus opinion based on experience and expertise of the authors of this document. We do recognise that the minimum number of blood collections may depend on the institution, the level of skill and experience of the trainee, complexity of intended patient category etc. It is therefore the responsibility of the educators and trainers that a minimal

					demonstrable standard of phlebotomy experience/knowledge is achieved.
76.			Moreover the criteria for certification and assessment of ongoing competency are already covered in the ISO 15189 guideline and this reference is lacking in the guideline.	Add: Reference to the ISO 15189 guideline in connection to training, certification and ongoing competency assessment.	ISO 15189 is referenced in this document.
77.	30	29	Where does the number of 100 blood collections originate from? The training and competence assessment is dependent on the type of organisation, situation and person/employee. No number should be required. Maybe it's sufficient to advise/recommend this number.	Consider to change into: Practical training should preferably be offered in the laboratory outpatient unit, during a longer period (e.g. multiple days) during which a new staff member performs multiple blood collections (minimum number dependent on complexity of intended patient category etc.), under the (indirect) supervision of the responsible staff. An observational audit should be done during e.g. the first five and last five collections to support and evaluate the competence of the trainee.	See above (The Netherlands, comment #75).

78.	30	29-30	What is meant with "under supervision of the responsible staff"? Does this mean continuous supervision in <u>the same space/room</u> or is this to be determined by the responsible staff member? The training program should have certain flexibility.	Change into: "in good guidance"	This means a continuous supervision in the same space/room.
79.	31	5-7	…..80% of the correct replies. This score is fully dependent on the degree of difficulty of the questions. A pass score should be predefined by the institution itself.	Change "*To obtain a certificate, a member of the staff should successfully pass the knowledge test (80% of the correct replies).*" into: To obtain a certificate, a member of the staff should successfully pass the knowledge test **above a predefined minimal standard**.	We rephrased a sentence into: We recommend 80% of the correct replies, as a success criteria, but it is completely up to the institution to define a minimal standard.
80.	31	6	The minimum performance score should be test-dependent. The requirement/criteria should be set by the responsible specialist in laboratory medicine.	Remove: "80% of the correct replies"	See above (The Netherlands, comment #79).
81.	31	11-13	Is there any evidence that every department should be evaluated 1x per year, for 20 blood collections with at least 20 phlebotomists?	Change into: "Observational audit should be done periodically."	We have rephrased this part into: During each observational audit, a sufficient number of

			This can be recommended/advised but not required. Venous blood sampling should be supported by a quality management system.		phlebotomies and phlebotomists should be observed. We recommend that at least 20 blood collections, performed by at least three different phlebotomists (at least three per each phlebotomist) should be observed during each audit. Again, as already stated above, it is completely up to the institution to define a minimal standard.
82.	31	11-14	See comments above concerning the specification of quantities.	Change "*Observational audit should be done periodically in each clinical department at least once per year. During each observational audit at least 20 blood collections, performed by at least three different phlebotomists (at*	See above (The Netherlands, comment #81).

				least three per each phlebotomist) should be observed." into: Observational audit should be done **periodically at random (representative) departments**. During each observational audit **a sufficient number of phlebotomies and phlebotomists should be observed.**	