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ZAJEDNIČKA EFLM-COLABIOCLI PREPORUKA ZA UZORKOVANJE VENSKE KRVI

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Ovo je prevod na srpski jezik dokumenta *Ana-Maria Simundic*, Karin Bölenius, Janne Cadamuro, Stephen Church, Michael P. Cornes, Edmée C. van Dongen-Lases, Pinar Eker, Tanja Erdeljanovic, Kjell Grankvist, Joao Tiago Guimaraes, Roger Hoke, Mercedes Ibarz, Helene Ivanov, Svetlana Kovalevskaya, Gunn B.B. Kristensen, Gabriel Lima-Oliveira, Giuseppe Lippi, Alexander von Meyer, Mads Nybo, Barbara De la Salle, Christa Seipelt, Zorica Sumarac and Pieter Vermeersch, on behalf of the Working Group for Preanalytical Phase (WG-PRE), of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and Latin American Working Group for Preanalytical Phase (WG-PRE-LATAM) of the Latin America Confederation of Clinical Biochemistry (COLABIOCLI) Joint EFLM-COLABIOCLI Recommendation for venous blood sampling. Clin Chem Lab Med 2018; 56(12): 2015–38.* Prevod dokumenta je izradilo Društvo medicinskih biohemičara Srbije. EFLM nije autorizovala niti, odobrila sadržaj ovog prevoda. Zvanična verzija dokumenta nalazi se na www.EFLM.eu. Korisnici treba da citiraju zvaničnu verziju kada citiraju dokument.

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Sadržaj:

Sažetak: Ovaj dokument daje zajedničku preporuku za uzimanje uzoraka venske krvi radne grupe Evropske federacije za kliničku hemiju i laboratorijsku medicinu (EFLM) za preanalitičku fazu (WG-PRE) i Latinsko-američke radne grupe za preanalitičku fazu (WG-PRE-LATAM) Konfederacije za kliničku biohemiju Latinske Amerike (COLABIOCLI). Dokument nudi smernice o tome šta je potrebno uraditi da vađenje krvi bude sigurna procedura koja u svom središtu ima pacijenta, i takođe pruža praktična uputstva o tome kako uspešno prevladati potencijalna ograničenja i izazove za njegovu široku primenu. Ciljna grupa za primenu ove preporuke je zdravstveno osoblje koje je direktno uključeno u vađenje krvi. Ova preporuka se odnosi na upotrebu zatvorenog sistema za vađenje krvi i ne daje smernice za vađenje krvi otvorenom iglom uz upotrebu špriceva i katetera. Dodatno, ovaj dokument se ne odnosi na pristanak pacijenta, zahtev (uput) za laboratorijska ispitivanja, rukovanje i transport uzoraka, niti vađenje krvi kod dece i pacijenata koji su u nesvesti. Preporučena procedura se zasniva na najboljim dostupnim dokazima. Svaki korak je procenjen korišćenjem sistema koji ocenjuje kvalitet dokaza i snagu preporuke. Proces ocenjivanja je sproveden u toku nekoliko sastanaka kojima su prisustvovali isti učesnici, a koji su ranije navedeni. Glavni delovi ove preporuke su: I) Procedure pre uzorkovanja, II) Postupak uzorkovanja, III) Procedure posle uzorkovanja i IV) Sprovođenje. Prvi nacrt preporuke je upućen članovima EFLM na javnu raspravu. WG-PRE-LATAM je takođe pozvan da dâ komentar na ovaj dokument. Revidirana verzija je poslata na glasanje svim članovima EFLM i COLABIOCLI i zvanično je odobrena od strane 33 od ukupno 40 članova EFLM i svih 21 članova COLABIOCLI. Pozivamo stručno osoblje širom Evrope i Latinske Amerike da usvoji i implementira ovu preporuku kako bi se poboljšao kvalitet prakse uzimanja krvi i povećala bezbednost pacijenata i osoblja.

Ključne reči: gladovanje, bezbednost u zdravstvenom sistemu, identifikacija pacijenta, priprema pacijenta, vađenje krvi, preanalitička faza, sigurnosna igla, uzorkovanje venske krvi.

Uvod

Cilj ovog dokumenta je da pruži jednostavnu, sažetu preporuku za uzimanje uzoraka venske krvi koja se bazira na proceni rizika i dokaza. Iako već postoji nekoliko dokumenata sa istim ili sličnim ciljem i okvirom interesovanja, smatramo da je ovaj dokument potreban kao podrška standardizacijipostupka vađenja krvi širom Evrope i Latinske Amerike. Postoji nekoliko razloga za to. Studija objavljena od strane EFLM WG-PRE 2013. godine je pokazala da je od 28 evropskih zemalja uključenih u istraživanje, samo sedam imalo svoje pisane protokole prihvaćene na nacionalnom nivou (smernice, preporuke) za uzimanje uzoraka venske krvi (1). Postojeće međunarodne smernice i preporuke ne pružaju jasna i nedvosmislena uputstva za sve korake tokom uzimanja krvi, a i neki važni detalji nisu uzeti u obzir. (taviše, pošto svi koraci nisu podjednako važni sa stanovišta bezbednosti, verujemo da smernice i preporuke treba da pruže određeni nivo kritične procene potencijalnog rizika koji potiče od neusklađenosti. Ovo je važno kako bi se pomoglo laboratorijama u određivanju prioriteta i fokusiranju njihovih korektivnih i preventivnih

aktivnosti. Konačno, dokazi koji stoje iza nekih preporuka nisu dobro definisani ili ih uopšte nema, ili pak kvalitet dokaza nije ni ocenjen ni vrednovan.

Jedan važan aspekt koji nije razmatran u postojećim dokumentima, jeste kako uspešno implementirati preporučenu proceduru. Sadašnji dokument pruža sveobuhvatan pregled najkritičnijih koraka za standardizovanu proceduru uzimanja krvi i praktična uputstva o tome kako uspešno prevazići potencijalna ograničenja i prepreke za njegovu široku primenu.

Ovaj dokument je rezultat aktivnosti radne grupe Evropske federacije za kliničku hemiju i laboratorijsku medicinu (EFLM) za preanalitičku fazu (WG-PRE) i Latinsko-američke radne grupe za preanalitičku fazu (WG-PRE-LATAM) Konfederacije za kliničku biohemiju Latinske Amerike (COLABIOCLI) i on se bavi svim prethodno navedenim pitanjima. Osim stručnjaka za laboratorijsku medicinu, autori ovog dokumenta su predstavnici nacionalnih udruženja medicinskih sestara (K.B.), medicinske sestre iz bolnica (T.E.), tehničari koji vade krv (R.H.) i predstavnici proizvođača sistema za vađenje krvi (S.C., C.S. i H.I.). Njihov doprinos je bio neprocenjiv i želimo da im se na tome zahvalimo. Pozivamo stručno osoblje širom Evrope i Latinske Amerike da usvoje i sprovedu ovu preporuku kako bi se poboljšao kvalitet prakse vađenja krvi i povećala bezbednost pacijenata i osoblja.

Područje primene

Ovaj dokument pokriva sve korake postupka vađenja venske krvi za pacijente u bolničkim i vanbolničkim uslovima. Vađenje krvi u vanbolničkim uslovima se razlikuje od iste aktivnosti u bolničkim uslovima uglavnom u pripremi pacijenta, poziciji pacijenta i fizičkoj aktivnosti pre uzimanja uzorka krvi. Ova pitanja su pokrivena odgovarajućim delovima dokumenta. Ostatak dokumenta odnosi se podjednako na vađenje krvi u obe pomenute situacije.

Ovaj dokument se odnosi samo na upotrebu zatvorenog sistema za vađenje krvi (tj. sistema za vađenje krvi gde se čep epruvete ne uklanja tokom procesa vađenja krvi) i ne daje smernice za vađenje krvi otvorenom iglom i špricem. Takođe, on je ograničen na vađenje krvi pomoću igala i stoga ne pokriva korišćenje katetera. Mi ne savetujemo uzimanje uzoraka krvi intravenskim kateterom, jer, kao što su to pokazale mnoge studije, takva procedura povećava rizik od hemolize (2–4). U slučajevima kada je jedina opcija za vađenje krvi kateter, mora se voditi računa da se rizik od hemolize i kontaminacije uzorka svede na najmanju moguću meru zbog mešanja intravenskih (i.v.) tečnosti ili rastvora za ispiranje (ovi koraci su izvan okvira ovog dokumenta). Kako bi rešila ovo važno pitanje, EFLM WG-PRE trenutno radi na preporukama za vađenje krvi kateterom.

Standard ISO/TS 20658:2017 »Medicinske laboratorije – Uslovi za prikupljanje, transport, prijem i rukovanje uzorcima« opisuje uslove koji su neophodni za uzimanje uzoraka, transport, prijem i rukovanje u okviru ISO 15189. Naša preporuka govori o najboljoj praksi da bi se ispunili ovi zahtevi, ali nije obavezujuća, niti superiornija u odnosu na lokalno upravljanje rizikom u skladu sa preporukama u ISO 15189 i ISO 20658 (5, 6).

Ovaj dokument namenjenje zdravstvenom osoblju koje je direktno uključeno u vađenje krvi (u tekstu se koristi termin flebotomičar) kao primarnoj ciljnoj grupi i ograničen je na postupak vađenja venske krvi. On nudi smernice o uslovima koje treba ispuniti da bi se obezbedilo da vađenje krvi bude bezbedna procedura sa fokusom na pacijenta. Međutim, treba napomenuti da sva nacionalna pravila i preporuke imaju prednost nad ovim dokumentom ako su različiti u bilo kom pogledu.

Ovaj dokument se ne bavi pitanjem kako se dobija pristanak pacijenta, jer to može zavisiti od politike institucije. Davanje uputa za laboratorijska ispitivanja, rukovanje i transport uzoraka, kao i vađenje krvi kod nesvesnih pacijenata i dece su nešto što je takođe van okvira ovog dokumenta.

Izjava

Različiti proizvođači nude različite proizvode za vađenje venske krvi. Ovaj dokument se jednako odnosi na sve njih. Autori ove preporuke izjavljuju da nemaju preference prema korišćenju bilo kog proizvoda ili prema bilo kom proizvođaču.

Metodologija

Ovaj dokument je izradila EFLM WG-PRE i odobrila WG-PRE-LATAM nakon identifikacije kritičnih preanalitičkih procedura u vezi sa uzorkovanjem venske krvi (7) i on je, gde god je to moguće, u skladu sa smernicama Instituta za kliničke i laboratorijske standarde (CLSI) i smernicama Svetske zdravstvene organizacije (WHO) (8, 9). Koraci u ovoj proceduri zasnovani su na najboljim dostupnim dokazima i postignut je konsenzus nakon detaljnih diskusija i uključivanja različitih zainteresovanih strana, uključujući medicinske i naučne laboratorijske stručnjake iz 16 zemalja članica EFLM, medicinske sestre (K. B. i T. E.), tehničare koji vade krv (R. H.), specijaliste za laboratorijsku medicinu i predstavnike kompanija koje izrađuju proizvode za vađenje venske krvi (S. C., C. S. i H. I.).

Nakon što su dogovoreni svi koraci u postupku vađenja venske krvi, svaki je ocenjen na osnovu sistema koji ocenjuje kvalitet dokaza i snagu preporuke (10, 11). Korišćen je sistem ocenjivanja koji omogućava uspostavljanje zlatnog standarda, ali i dalje

ostavlja prostor za prilagođavanje lokalnim zahtevima kod koraka koji su ocenjeni kao manje strogi. Raspon ocenjivanja je od 1A najjači i najbolji dokaz, do 2C – slaba preporuka i dokazi niskog kvaliteta. Sistem ocenjivanja je dat u *Tabeli I*. Koraci i odgovarajuće ocene za kvalitet dokaza i snagu preporuka dati su u *Tabeli II*. Proces ocenjivanja je sproveden, kao što je već rečeno, kroz diskusiju na sastanku istih zainteresovanih strana koje su prethodno navedene. Tamo gde dokazi nisu bili dostupni, preporuka je izrađena kao mišljenje do kojeg se došlo konsenzusom na osnovu stručnosti i iskustva članova grupe.

Prvi nacrt preporuke je upućen na javnu raspravu članovima EFLM. Članovi EFLM i WG-PRE-LATAM su pozvani da podele ovaj dokument sa svojim članovima i da vrate svoje kolektivno mišljenje i komentare na predloženu preporuku. Jedanaest od 40 članova EFLM je poslalo svoje komentare. Komentari primljeni tokom javne rasprave, odgovori ili odbacivanje svih pitanja koja su pokrenula nacionalna društva su dostupni na kraju ovog dokumenta (Dodatni materijal, Dodatak 1). Prilikom revizije ovog dokumenta uzeti su u obzir svi komentari. Revidirana verzija je poslata na glasanje na adrese svih 40 članova EFLM i 21-og člana COLABIOCLI. Prema Priručniku za procedure EFLM, preporuke i smernice EFLM moraju biti prihvaćene od strane više od polovine društava članica EFLM da bi se smatrale konačnim stavom EFLM (12).

Na osnovu rezultata glasanja, ovaj dokument je zvanično odobren od strane EFLM i COLABIOCLI i treba ga smatrati zvaničnim stavom EFLM i COLABIOCLI. Rezultat glasanja je bio sledeći: trideset troje od četrdeset članova EFLM je glasalo za ovaj dokument (Albanija, Austrija, Belgija, Bosna i Hercegovina, Hrvatska, Kipar, Češka Republika, Danska, Estonija, Finska, Francuska, Nemačka, Grčka, Mađarska, Mađarska, Irska, Izrael, Italija, Litvanija, Makedonija, Crna Gora, Poljska, Portugal, Rumunija, Rusija, Srbija, Slovačka, Slovenija, Španija, Švedska, Švajcarska, Turska, Velika Britanija i Ukrajina), dva člana EFLM-a su glasala protiv (Holandija i Norveška), a pet članova EFLM se uzdržalo od glasanja (Bugarska, Island, Kosovo, Letonija, Luksemburg). Svi COLABIOCLI članovi, 21 od 21, (Argentina, Bolivija, Brazil, Kostarika, Kolumbija, Kuba, Čile, Ekvador, El Salvador, Španija, Gvatemala, Honduras, Meksiko, Nikaragva, Panama, Paragvaj, Peru, Portoriko, Dominikanska Republika, Urugvaj i Venecuela) su glasali za.

Autori ovog dokumenta žele da se zahvale svima koji su prihvatili i podržali ovu preporuku.

Glavni delovi ove preporuke su: I) Procedure pre uzorkovanja, II) Postupak uzorkovanja, III) Procedure posle uzorkovanja i IV) Sprovođenje.

I Procedura pre uzimanja uzorka

Opšta pitanja i adekvatan način komunikacije sa pacijentom

Komunikacija sa pacijentom je ključ za uspešan rad sa pacijentom (13, 14). Empatična i sigurna komunikacija sa pacijentom je važna tokom čitavog procesa vađenja krvi i uvek treba da se sastoji od sledećih osnovnih koraka:

1. Predstavite se, možda i svojim imenom, zbog ličnije note komunikacije i objasnite svoju ulogu u okviru konkretne delatnosti zdravstvene zaštite.

2. Nakon što ste pravilno identifikovali pacijenta (vidi korak 1), objasnite šta ćete raditi, zašto želite da to uradite i šta pacijent mora da radi. Delujte pouzdano i mirno. Znajući da ste profesionalna i kompetentna osoba pacijent će se osećati prijatnije.

3. Recite pacijentu da ste došli da uzmete uzorak njegove/njene krvi i pitajte da li pacijent pristaje da mu/joj se krv izvadi. Ako se pacijent opire, nikada ne treba uzeti uzorak krvi.

4. Ako vas pitaju, dajte razumno očekivanje vremena koje je potrebno za postupak vađenja venske krvi i preuzimanje laboratorijskih rezultata. Budite precizni u svojim objašnjenjima. Uobičajeno je da tehničar vidi samo elektronske bar-kodove radnog naloga. Stoga je ponekad nemoguće dati razumno očekivano vreme za laboratorijske rezultate ako tehničar nema uvid u to koje pojedinačne testove je potrebno uraditi. U takvim slučajevima tehničar bi trebalo da posavetuje pacijenta gde da traži tu informaciju.

5. Pitajte pacijente da li smatraju da su pravilno obavešteni o postupku i da li imaju dodatnih pitanja. Budite pažljivi i slušajte šta pacijente interesuje. Često ćete dobiti neke korisne komentare o tome koje su vene bolje za vađenje krvi.

6. Pitajte pacijenta da li se boji vađenja krvi. Postoje dokazi da ovo jednostavno pitanje može pomoći da se identifikuju pojedinci koji su pod povećanim rizikom od vazovagalne reakcije (sinkopa/gubitak svesti) (15). Takođe je preporučljivo da pitate pacijenta da li je u prošlosti imao negativna iskustva sa postupcima vađenja krvi, da bi procenili rizik od sinkope ili bilo koji drugi rizik od štete ili neželjenog dejstva vađenja krvi. Ako se pacijent plaši, potrebno je da se on/ona pažljivo prati tokom i nakon vađenja krvi, kako bi se sprečile povrede od pada u slučaju nesvestice. Ako osećate da je pacijent nervozan zbog predstojećeg uzimanja krvi, možete mu/joj dati da izvrši jednostavan zadatak, kao što je brojanje ili da udahne duboko pre punkcije. Ako se pacijent izjasni da se boji vađenja krvi ili ako se pojavi strah tokom postupka, pacijenta treba savetovati da legne.

Tabela I Rangiranje preporuka za procenjivanje dostupnih dokaza.

Stepen preporuke	Uočljivost odnosa rizik/korist	Kvalitet pratećih dokaza	Implikacije
1A. Jaka preporuka, kvalitetni dokazi	Korist jasno nadmašuje rizik i probleme, ili obrnuto.	Konzistentni dokazi iz dobro sprovedenih na sumično biranih, kontrolisanih ispitivanja ili jaki dokazi u nekoj drugoj formi. Malo je verovatno da će dalja istraživanja promeniti naše uverenje što se procene koristi i rizika tiče.	Jaka preporuka koja se može primeniti na većinu pacijenata i u većini slučajeva bez rezerve. Kliničari bi trebalo da uvaže ovakvu preporuku, osim ako postoji jasan i ubedljiv razlog za alternativni pristup.
1B. Jaka preporuka, dokazi umerenog kvaliteta	Korist jasno nadmašuje rizik i probleme, ili obrnuto.	Dokazi iz nasumično biranih, kontrolisanih studija sa bitnim ograničenjima (nedosledni rezultati, metodološki nedostaci, indirektni ili neprecizni), ili veoma jaki dokazi iz nekog drugog istraživanja. Dalja istraživanja (ako se sprovedu) će verovatno uticati na naše uverenje o proceni koristi i rizika i mogu promeniti procenu.	Jaka preporuka, koja se odnosi se na većinu pacijenata. Kliničari bi trebalo da uvaže ovakvu preporuku, osim ako postoji jasan i uverljiv razlog za alternativni pristup.
1C. Jaka preporuka, dokazi niskog kvaliteta	Utisak je da korist prevazilazi rizik i probleme, ili obrnuto.	Dokazi iz opservacionih studija, nesistematskog kliničkog iskustva ili iz nasumično biranih, kontrolisanih studija sa ozbiljnim nedostacima. Svaka procena efekta je neizvesna.	Jaka preporuka, koja se odnosi se na većinu pacijenata. Osnova nekih dokaza koji govore u prilog preporuke je, ipak, niskog kvaliteta.
2A. Slaba preporuka, kvalitetni dokazi	Korist prilično uravnotežena sa rizicima i problemima.	Konzistentni dokazi iz dobro sprovedenih nasumično biranih, kontrolisanih ispitivanja ili ozbiljni dokazi u nekoj drugoj formi. Malo je verovatno da će dalja istraživanja promeniti naše uverenje u procenu koristi i rizika.	Slaba preporuka. Ono što je najbolje preduzeti se može razlikovati u zavisnosti od okolnosti ili od pacijenata ili društvenih vrednosti.
2B. Slaba preporuka, dokazi umerenog kvaliteta	Korist dobro izbalansirana sa rizicima i problemima; ima nekih neizvesnosti u proceni koristi, rizika i problema.	Dokazi iz nasumično biranih, kontrolisanih ispitivanja sa bitnim ograničenjima (nekonzistentni rezultati, metodološki nedostaci, indirektni ili neprecizni), ili veoma jaki dokazi nekog drugog istraživanja. Dalja istraživanja (ako se izvedu) će verovatno uticati na naše poverenje u procenu koristi i rizika, mogu izmeniti procenu.	Slaba preporuka. Alternativni pristupi će verovatno biti bolji za neke pacijente i u nekim okolnostima.
2C. Slaba preporuka, dokazi niskog kvaliteta	Nesigurnost u proceni koristi, rizika i problema; korist može biti prilično uravnotežena sa rizicima i problemima.	Dokazi iz opservacionih studija, nesistematskog kliničkog iskustva, ili iz randomizovanih, kontrolisanih studija sa ozbiljnim nedostacima. Svaka procena efekta je neizvesna.	Jako slaba preporuka, treba razmatrati alternativne pristupe.

(http://www.uptodate.com/home/grading-guide#GradingRecommendations).

Tabela II Uzorkovanje venske krvi – redosled koraka.

	Korak	Jačina dokaza
1.	Identifikacija pacijenta	1C
2.	Proverite da li je pacijent adekvatno pripremljen i da li je gladovao	1B
3.	Uzmite materijal/opremu neophodnu za uzimanje uzorka venske krvi	2C
4.	Obeležavanje i/ili identifikacija epruveta	1C
5.	Stavljanje rukavica	1C
6.	Stavljanje poveske	1A
7.	Odabir mesta venepunkcije	1B
8.	Čišćenje mesta uzorkovanja	1B
9.	Punkcija vene	1A
10.	Vađenje krvi u prvu epruvetu	1A
11.	Uklanjanje poveske	1A
12.	Lagano okrenite epruvetu jednom odmah nakon vađenja krvi (jedan ceo okret)	1B
13.	Napunite dodatne epruvete u skladu sa preporučenim redom punjenja	1B
14.	Uklonite iglu iz vene i proverite da li je aktiviran sigurnosni mehanizam	1A
15.	Odložite iglu	1A
16.	Previjte mesto punkcije	1C
17.	Recite pacijentu da lagano pritisne i da ne savija ruku (5 do 10 minuta)	1C
18.	Okrenite sve epruvete još 4 puta	1B
19.	Skinite rukavice	1A
20.	Savetujte pacijenta da odmori 5 minuta i bude siguran da je krvarenje prestalo pre nego što napusti mesto uzimanja uzorka 1B	

Položaj pacijenta

Pokazano je da promena položaja tela iz ležećeg u uspravni i obratno može dramatično da utiče na koncentraciju mnogih laboratorijskih parametara (16–19). Stoga ne bi trebalo da pacijent menja svoj položaj u roku od 15 minuta pre vađenja krvi. Ako je pacijent ležao, potrebno je izvršiti uzimanje uzoraka krvi u ležećem položaju (to je uglavnom slučaj kod hospitalizovanih pacijenata). U idealnom slučaju, ambulantni bolesnici treba da budu u sedećem položaju 15 minuta pre vađenja krvi. Ako je promena položaja u tom vremenskom periodu neizbežna, treba je dokumentovati kako bi se omogućilo pravilno tumačenje rezultata ispitivanja (20). Ako je pacijent pravilno odmarao 15 minuta u čekaonici, kratko kretanje od čekaonice do mesta uzimanja uzorka se smatra prihvatljivim i ne mora biti dokumentovano.

Korak 1. Identifikacija pacijenta (1C)

1.1 Preporučujemo korišćenje identifikacionih narukvica za sve hospitalizovane pacijente.

1.2 Svi pacijenti moraju biti pozitivno identifikovani na aktivan i angažovan način postavljanjem pitanja: »Kako se zovete?« i »Koji je vaš datum rođenja?« (21)

1.3 Za adekvatnu identifikaciju treba koristiti najmanje dva parametra identifikacije (ime, prezime pacijenta i datum rođenja) i poželjno je još jedan dodatni. Dodatni identifikatori koji se mogu koristiti za identifikaciju pacijenta uključuju:

- adresu,
- broj zdravstvenog osiguranja,
- identifikacioni broj pacijenta,
- detalje iz lične karte ili JMBG.

Razumljivo, što se više podataka koristi za identifikaciju pacijenta, manja je mogućnost greške u identifikaciji (13).

1.4 Identitet pacijenta mora da se uporedi sa identitetom sa zahteva za laboratorijska ispitivanja (uputa). Ako su epruvete obeležene pre uzimanja uzoraka krvi, tehničar takođe treba da se pobrine za poređenje identiteta pacijenta sa podacima na nalepnici epruvete i na taj način bude siguran da se identitet pacijenta slaže sa podacima na nalepnici epruvete. Ako se podaci dobijeni od pacijenta ne podudaraju sa podacima na obrascu zahteva ili na nalepnici epruvete, procedura uzimanja uzorka krvi mora biti odložena dok se ne reši problem identifikacije.

Preporuke 1.1–1.4 su preporuke 1C nivoa. Moraju se primeniti na sve pacijente iu svakoj prilici, bez izuzetka. Iako mi izrazito preporučujemo da se ovaj korak izvrši upravo onako kako je gore opisano, postoji nažalost mali broj dokaza o problemima koji

mogu nastati u slučaju neusklađenosti. Međutim, smatramo da je korist od ovog postupka nedvosmisleno veća od količine vremena i napora koje treba uložiti da bi se obezbedila usklađenost podataka.

Korak 2. Proverite da li je pacijent adekvatno pripremljen i da li je gladovao (1B)

2.1 U skladu sa našom ranije objavljenom preporukom za sve testove uzorak krvi treba uzeti ujutro (između 7 i 9 časova) u stanju gladovanja, 12 sati posle poslednjeg obroka. Uzimanje vode je dozvoljeno tokom perioda gladovanja, ali pacijenti treba da se uzdrže od alkohola 24 časa pre davanja krvi. Ujutro, pre davanja krvi, pacijenti ne bi trebalo da pijutečnosti koje sadrže kofein (kafa, energetska pića i čaj). Pušenje cigareta takođe nije dozvoljeno ujutru pre davanja uzoraka krvi (22). Ne treba koristiti ni žvakaću gumu. Jutarnje lekove treba izbegavati ukoliko nisu od vitalnog značaja za pacijenta.

2.2 Svesni smo da uzdržavanje od hrane može predstavljati određene logističke poteškoće i smatramo prihvatljivim vađenje krvi tokom dana za pacijente koji jedu, ali samo za hitne slučajeve ili za parametre za koje postoje dokazi da nije potrebano uzdržavati se od hrane.

2.3 Status pacijenta u odnosu na uzimanje hrane treba proveriti pre uzimanja uzorka krvi. Kad god je to moguće, ne uzimati krv ako pacijent nije pravilno pripremljen (hitni slučajevi su izuzeci od ovog pravila). Ako se vađenje krvi vrši u slučajevima kada pacijent uzimahranu, ili ako pacijent nije pravilno pripremljen, tu činjenicu treba dokumentovati kako bi se omogućilo pravilno tumačenje rezultata ispitivanja.

2.4 Treba izbegavati intenzivnu fizičku aktivnost (koja premašuje normalan dnevni nivo aktivnosti) 24 sata pre uzimanja uzoraka krvi.

2.5 Vreme uzimanja krvi za terapijsko praćenje lekova (TDM)[1] zavisiće od leka i indikacije za testiranje (optimizacija doze leka, praćenje sadejstva lekova, nuspojava, trovanje lekovima itd.). U slučaju TDM treba ispoštovati konkretne preporuke za tačno vreme uzimanja uzoraka krvi od strane lekara.

2.6 Postoje i drugi potencijalni faktori kao što su redovna i/ili nedavna fizička aktivnost, unos hrane i unos lekova, lekovi koji se kupuju bez recepta, dodaci ishrani i biljni preparati itd., za koje se zna da utiču na koncentraciju određenih analita,te treba proveriti da li je pacijent pratio neophodna uputstva pre davanja uzoraka krvi (23–25). Ako su neki od gore navedenih problema identifikovani a vađenje krvi ne može biti odloženo, laboratorijsko osoblje bi trebalo da, kad god je to moguće, dokumentuje sve relevantne preanalitičke uslove kako bi se omogućilo pravilno tumačenje rezultata ispitivanja.

2.7 Dodatno uzimanje uzorka tokom dana može biti preporučljivo za parametre koji imaju u vidu dnevne oscilacije. Treba se pridržavati konkretnih preporuka od strane lekara koji određuje tačno vreme uzimanja uzoraka krvi za ove parametre.

Postprandijalna reakcija na hranu i piće zavisi od različitih faktora koji ne mogu biti modifikovani (starost, pol, genetika, krvna grupa itd.) i promenjivih faktora. Promenljivi faktori su ishrana (26–29), unos lekova, lekovi koji se kupuju bez recepta, dodaci ishrani i biljni preparati (30), način života, fizička aktivnost, kao što su ronjenje, maraton, naporne vežbe i neke druge aktivnosti (31–33), telesna težina, pušenje, konzumiranje alkohola itd. Da bi se ograničila varijacija u postprandijalnoj reakciji kao posledice interindividualne heterogenosti, EFLM WG-PRE je 2014. objavio preporuku o tome kako standardizovati definiciju potrebe za uzdržavanjem od hrane (22). Prethodno navedeni zahtevi su u potpunosti u skladu s ovom preporukom.

Fizička aktivnost je veoma važan promenjivi faktor za koji se zna da ima i akutne i hronične efekte na metabolizam čoveka i sastav krvi. Dok se hronični efekti sporta mogu smatrati adaptacijom ljudskog organizma, akutni efekti se mogu izbeći izbegavanjem intenzivne fizičke aktivnosti 24 sata pre davanja krvi.

Korak 3. Uzmite materijal/opremu neophodnu za uzimanje uzorka venske krvi (2C)

Ovaj deo se uglavnom fokusira na uzimanje uzoraka krvi u ambulanti, a ne toliko na bolničkom odeljenju sa ležećim pacijentima.

3.1 Vađenje venske krvi treba obaviti u čistom, tihom i privatnom okruženju. Prostor za vađenje krvi može sadržati slike sa opuštajućim pejzažima na zidovima kako bi bio što prijatniji pacijentima.

3.2 Treba da postoje namenske stolice i/ili kreveti za vađenje venske krvi, kao i stolica za tehničara. Nasloni za ruke na stolici moraju biti podesivi kako bi se omogućila optimalna pozicija za vađenje krvi. Ako namenska stolica za vađenje venske krvi nije dostupna, stolica mora imati naslone za ruke kako bi se sprečilo da pacijenti padnu u slučaju nesvestice (8, 9, 34).

3.3 Treba da postoje lako pritupačna mesta za dezinfekciju ili pranje ruku sapunom i/ili odgovarajućim sredstvima za čišćenje i papirnim ubrusima kako bi se obezbedila pravilna higijena ruku.

[1] Eng. Therapeutic Drug Monitoring – terapijski monitoring lekova.

3.4 Prostorije za uzimanje uzoraka treba da budu odvojene od prostora za prijem/čekanje kako bi se obezbedila privatnost pacijenata. Privatnost pacijenta treba da postoji tokom čitavog postupka uzimanja uzoraka krvi. Shvatamo da se uslovi mogu razlikovati u ambulantama i bolnicama, kao i kod bolničkih pacijenata u različitim kliničkim stanjima. Ipak, treba voditi računa o tome da se uzimanje uzoraka krvi uvek radi imajući u vidu privatnost pacijenta.

3.5 Oprema i potrošni materijal treba da budu dostupni u dovoljnim količinama i da odgovaraju nameni procesa vađenja venske krvi. Dostupna oprema može uključivati:

- laboratorijska kolica,
- stalke/kutije za epruvete,
- rukavice,
- sistem za uzorkovanje krvi sa sigurnosnim karakteristikama (igle i držači ili igle sa integrisanim držačima),
- epruvete za uzorkovanje (širok opseg različitih epruveta sa adekvatnim rokom upotrebe),
- poveska (po mogućstvu za jednokratnu upotrebu),
- antiseptik za čišćenje mesta punkcije,
- zavoji,
- komprese od gaze,
- kanta za medicinski otpad,
- mešalica za uzorke,
- transportne vreće otporne na curenje.

3.6 Svi potrebni materijali moraju biti obezbeđeni pre uzimanja venske krvi, a u skladu sa traženim nalazima. Radno mesto treba organizovati tako da sva potrebna oprema bude dostupna tehničaru bez napuštanja radnog mesta.

3.7 Oprema treba biti čista i pravilno održavana.

3.8 Potrebno je uspostaviti sistem upravljanja zalihama kako bi se zalihe iskoristile pre isteka roka trajanja.

3.9 Igla, držač i epruveta za krv zajedno čine integralni sistem za vađenje krvi. Treba koristiti pojedinačne komponente istog proizvođača kao deo sistema za vađenje krvi. Iako proizvođači obezbeđuju potpunu kompatibilnost između komponenti njihovih sistema, pojedinačne komponente različitih proizvođača se ne bi smele koristiti zajedno, jer njihove kombinacije nisu potvrđene kao adekvatne za upotrebu i mogu ugroziti bezbednost pacijenata i zdravstvenih radnika (35). Ako iz bilo kojih razloga ovaj zahtev ne može biti u potpunosti ispoštovan i pojedinačne komponente različitih proizvođača moraju biti korišćene zajedno (npr. specijalne epruvete za vađenje krvi nisu dostupne od strane glavnog dobavljača, čije se epruvete koriste u određenoj ustanovi), nije opravdano provoditi višekratne venepunkcije kako bi se osigurala kompatibilnost komponenata sistema za uzorkovanje.

Čuvanje epruveta u uslovima koji nisu u skladu sa preporukama proizvođača može uticati na zapreminu uzorka, kao i na stabilnost gelova i aditiva. Ekološki faktori, kao što su temperatura, vlažnost, nadmorska visina i izloženost svetlu, mogu imati značajan uticaj na kvalitet opreme za uzorkovanje krvi. Epruvete koje se ne koriste zbog isteka roka trajanja imaju smanjen vakuum, što može dovesti do smanjenja volumena krvi, kao i do nepravilnog odnosa krvi i aditiva (36, 37). Štaviše, epruvete sa isteklim rokom mogu imati problem zbog hemijskog propadanja aditiva. Da bi se obezbedio kvalitet uzorka, epruvete za vađenje krvi treba baciti nakon isteka roka trajanja.

Preporuke navedene pod 3.1–3.8 su preporuke 2C nivoa (slaba preporuka, dokazi niskog kvaliteta). Osim preporuka proizvođača, jedne studije rađene na ljudima i jedne veterinarske studije (36, 37), nismo uspeli da pronađemo nikakve čvrste dokaze koji govore u korist navedene preporuke.

Korak 4. Obeležavanje i/ili identifikacija epruveta (1C)

4.1 Obeležavanje ili identifikacija epruvete (za epruvete na kojima je već prethodno stavljena nalepnica) se mora obaviti u prisustvu pacijenta. U suprotnom, postoji rizik da epruvete ostanu neobeležene i eventualno pogrešno identifikovane. Izbor o tome da li da se epruvete obeleže ili identifikuju pre ili posle vađenja krvi treba da bude zasnovan na analizi rizika procesa vađenja venske krvi u svakoj ustanovi.

4.2 Svaka institucija treba da ima standardnu pisanu proceduru koju sve osoblje treba da poštuje.

4.3 Osnovne informacije o uzorku i pacijentu moraju biti registrovane u laboratoriji na takav način da se epruveta može pratiti i nedvosmisleno vezati za pacijenta, prikupljeni uzorak, zahtev za laboratorijsko testiranje, tražioca testiranja i flebotomičara koji je izvadio krv. Ovi podaci uključuju, ali nisu ograničeni na:

- identifikaciju onoga ko traži laboratorijsko testiranje, to jest ovlašćena osobe koja zahteva laboratorijsko testiranje krvi (po nacionalnom zakonodavstvu),
- ime i prezime pacijenta,
- datum rođenja pacijenta,
- adresa pacijenta (kućna adresa,aza bolničke pacijente odeljenje),
- jedinstveni broj uzorka,
- datum i vreme uzimanja uzorka,
- identifikacija flebotomičara.

4.4 Treba koristiti najmanje dva nezavisna identifikatora (ime i prezime pacijenta i datum rođenja),a po mogućnosti i tri (dva navedena i dodatni). Na primer, za identifikaciju epruvete treba koristiti jedinstveni identifikacioni broj uzorka. Nije neophodno da svi gore navedeni podaci budu zabeleženi na epruveti. Ako se ne nalazi na epruveti, ova informacija mora biti dokumentovana u pisanoj formi ili povezana sa laboratorijskim informacionim sistemom i lako dostupna.

II Uzimanje uzorka

Korak 5. Stavljanje rukavica (1C)

5.1 Uvek treba nositi novi par rukavica da bi se zaštitio pacijent i osoblje koje vadi vensku krv.

5.2 Ruke treba oprati pre nego što se staverukavice kako bi se smanjio rizik od prenošenja infekcije tokom uklanjanja rukavica, ali i zbog poverenja pacijenta.

Nažalost, iako smatramo da je to jaka preporuka, nismo bili u mogućnosti da pronađemo kvalitetne dokaze koji bi je podržali. Nedavni sistematski pregled Cochrane baze podataka pokazao je da je uloga i nivo zaštite koju pruža lična zaštitna oprema još uvek nejasna (38). Ipak, imajući u vidu potencijalno povezane rizike, dok se ne dokaže suprotno, preporučujemo da se rukavice koriste kako zbog zaštite pacijenata tako i radi zaštite zdravstvenog radnika. U slučaju povrede iglom, rukavice deluju kao barijera ili zaštita kako bi se smanjila količina krvi koja se može preneti tokom povrede iglom (39, 40). Imajući u vidu činjenicu da je znatan deo zdravstvenog osoblja koje je direktno uključeno u vađenje krvi u nekom trenutku izloženo povredama iglom tokom radnog vremena, nošenje rukavica zvuči kao razumna mera za prevenciju zaraze (41, 42). Dokazi takođe pokazuju da upotreba sterilnih rukavica tokom vađenja krvi za kulturu krvi smanjuje rizik od kontaminacije uzorka (43, 44). Pored toga, osim izloženosti zdravstvenih radnika koju nose povrede iglom, uzorkovanje venske krvi je uvek povezano sa rizikom za kontakt sa krvlju i kontaminaciju tokom procedure. Postoje dokazi da je ovaj rizik smanjen upotrebom rukavica (45, 46). Pokazalo se da je pranje ruku ključ za smanjenje rizika od infekcije zdravstvenog osoblja i prenošenja patogena rezistentnih na antimikrobne lekove. Štaviše, pravilno pranje ruku i nošenje rukavica štite pacijenta od infekcija (47). Nažalost, dokazi pokazuju da rukavice nisu široko rasprostranjene među zdravstvenim radnicima (48).

CLSI GP41-A7 smernice preporučuju stavljanje rukavica nakon stavljanja poveske. Međutim, postoje dokazi da vreme primene poveske može da bude duže od 1 min ako se sledi ova CLSI procedura (49). Zbog toga, a da bi se smanjio dugotrajni zastoj krvi, predlažemo da se rukavice stave pre stavljanja poveske.

5.3 Sastavite iglu: a) i držač (ako već nije prethodno montiran); ili b) sa integrisanim držačem sa epruvetom za vađenje krvi (za korisnike sistema za vađenje krvi tehnikom aspiracije).

Korak 6. Stavljanje poveske (1A)

Poveska se uobičajeno definiše kao stezna ili kompresivna (elastična) naprava, koja se može koristiti za ograničavanje venske cirkulacije do ekstremiteta (obično nadlaktice) u ograničenom vremenskom periodu. U odsustvu nečega drugog što se može koristiti da bi se vene učinile vidljivim, upotreba poveske može biti od pomoći, posebno kod pacijenata sa tankim ili jedva vidljivim venama.

6.1 Međutim, preporučujemo da se vađenje krvi odvija po mogućnosti bez poveske (posebno kod pacijenata sa izraženim venama) i da se poveske koriste samo kada je to potrebno. U slučaju kada se koristi poveska, tehničar mora da učini sve da to traje manje od jednog minuta.

6.2 Poveska se stavlja približno za jednu širinu ruke (7,5 cm) iznad očekivanog mesta punkcije i treba da bude dovoljno čvrsta da zaustavi venski, ali ne i arterijski protok krvi.

6.3 Preporučujemo da se koriste poveske za jednokratnu upotrebu i time minimizuje rizik od infekcije i unakrsne kontaminacije pacijenta i zdravstvenog osoblja.

Postoje dokazi da multirezistentni mikroorganizmi mogu kolonizovati poveske za višekratnu upotrebu i stoga one mogu postati rezervoari i izvor prenosa različitih patogena na hospitalizovane pacijente (50–52). Poveske za višekratnu upotrebu mogu biti kontaminirane bakterijom Staphilococcus aureus (MRSA) otpornom na meticilin i stoga predstavljaju veliki rizik za pacijente i zdravstveno osoblje. S obzirom na rizik koji je povezan sa upotrebom višekratnih poveski i kvaliteta dostupnih dokaza, mi smo ovu preporuku ocenili kao 1A. Nažalost, poveske za jednokratnu upotrebu nisu široko rasprostranjene, posebno u nekim zemljama u razvoju ili nerazvijenim zemljama (53). Uprava bolnice treba da bude upoznata sa rizikom povezanim sa upotrebom višekratnih poveski i potencijalnom koristi od upotrebe jednokratnih poveski za bezbednost pacijenata i zdravstvenog osoblja.

6.4 Da bi se smanjio rizik od zastoja u venama, posebno ako se treba izvaditi krv u više epruveta, umesto poveski, mogu se koristiti uređaji za osvetljavanje i lociranje vena. Ovo je posebno korisno kod pacijenata sa venama u komplikovanom stanju. Pokazalo se da uređaji za osvetljavanje vena mogu poslužiti kao korisna alternativa za poveske kako bi se

izbegao venski zastoj i naknadne promene koncentracije različitih biohemijskih, hematoloških i koagulacionih parametara u krvi (54–56). Iako je potrebno više kliničkih dokaza pre nego što se može preporučiti široka primena, upotreba uređaja za osvetljavanje vena može biti dragocena perspektiva za budućnost.

6.5 Upozorite pacijenta da ne sme da stisne šaku ili da pumpa stiskanjem šake. Stiskanje šake i pumpanje mogu biti uzrok pseudohiperkalemije i promene nekih drugih biohemijskih i hematoloških parametara (57–62).

Korak 7. Odabir mesta venepunkcije (1B)

7.1 Da bi izabrali mesto za venepunkciju, ruku pacijenta treba istegnuti u poziciju na dole.

7.2 Ako je moguće trebalo bi uzeti u obzir najizraženije vene u kubitalnoj jami (cefalična, bazilična, medijalna kubitalna i medijalna antebrahijalna vena) (*Slika 1*). Kubitalna vena je najbolji izbor, jer je obično najistaknutija, ne okreće se ispod kože i može se naći na istom mestu kod većine pacijenata.

7.3 Dorzalne vene ruku mogu biti alternativa samo ako nije moguće izvaditi krv iz glavnih vena.

7.4 Vađenje krvi iz vena u zglobu šake nije preporučljivo.

7.5 Palpacija vene može pomoći u određivanju adekvatnog mesta venepunkcije.

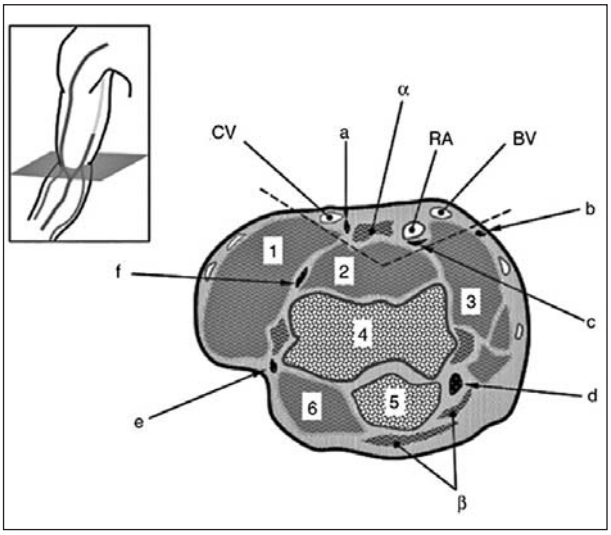
Grafički prikaz preseka kubitalne jame prikazan je na *Slici 2*. Razumevanje anatomije ovog područja pomaže u smanjenju rizika od povreda tokom postupka uzimanja krvi.

7.6 Ne vadite krv iz prethodno postavljenih perifernih venskih katetera, očvrslih vena, arteriovenoznog šanta, sa mesta hematoma, upale ili otekline, iz ruke sa vaskularnim bajpasom, paretičnih ruku ili ruku sa poremećajima limfne drenaže.

7.7 Obavezno dokumentujte kada koristite alternativna mesta za venepunkciju (npr. vene šake i stopala ili bilo koje drugo mesto osim gore navedenih).

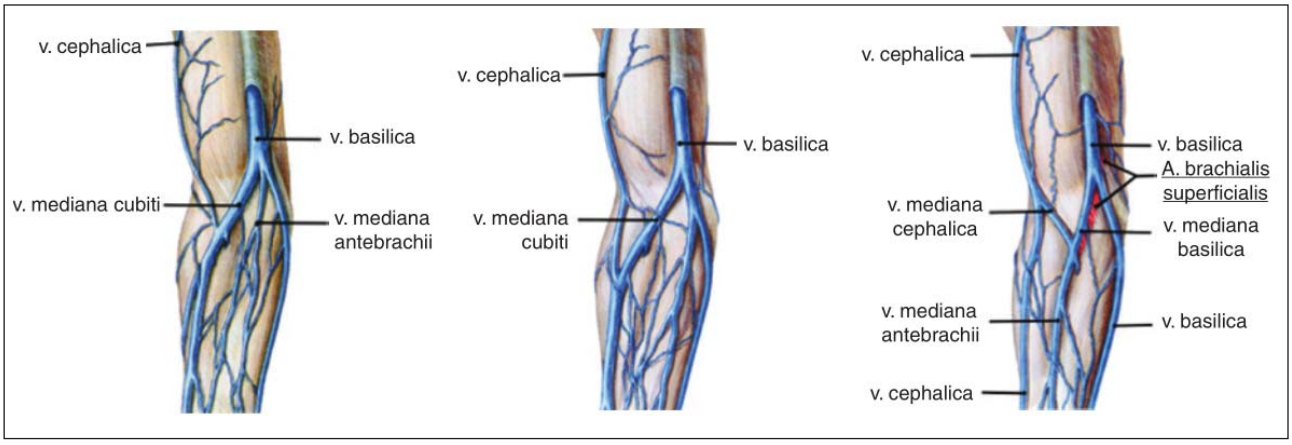
Preporuke 7.1–7.7 su preporuke razreda 1B. Moraju se primeniti na sve pacijente i u svakoj prilici, bez izuzetka.

Odabir najbolje vene i prepoznavanje najprikladnijeg mesta za uvođenje igle za vađenje venske krvi su važni za kvalitet uzorka, zadovoljstvo pacijenta, izbegavanje oštećenja nerva, izbegavanje arterijske



Slika 2 Topografska anatomija kubitalne jame (presek lakta).

Krvni sudovi: v. cephalica (VC), a.radialis; (AR), v. basilica (VB) Tetive: α, m. biceps brachii, tendo; β, m. triceps brachii tendo Nervi: a, n. cutaneus antebrachii lateralis; b, n. cutaneus antebrachii medialis; c, n. medianus; d, n. ulnaris; e, n. cutaneus antebrachii posterior; f, n. radialis. Mišići i kosti: 1, m. brachioradialis; 2, m. brachialis; 3, m. pronator teres; 4, trochlea humeri; 5, olecranon; 6, m. anconeus. Odštampano iz (59) uz dozvolu Hrvatskog društva za medicinsku biokemiju i laboratorijsku medicinu.



Slika 1 Najčešće varijacije vena podlaktice. Odštampano iz (63) uz odobrenje Elsevier GmbH.

punkcije, obezbeđivanje lakoće i brzine vađenja, i konačno, za uspeh same procedure vađenja krvi (59). Postoje brojni dokazi koji pokazuju da postupci vađenja krvi mogu uzrokovati ozbiljne povrede u slučaju neuspeha u pronalaženju vene za vađenje venske krvi (64, 65).

Korak 8. Čišćenje mesta uzorkovanja (1B)

8.1 Odabrano mesto venepunkcije treba očistiti 70% etil-alkoholom ili drugim odgovarajućim dezinfekcionim sredstvom pre uzimanja uzoraka krvi kako bi se sprečila kontaminacija kožnim patogenima. Čišćenje treba obaviti jednim brisanjem, a odabrano mesto treba ostaviti da se osuši. Nemojte dvaputa brisati mesto vađenja krvi istom gazom.

8.2 Za uzimanje krvnih kultura preporučujemo da se pridržavate uputstava koje daje bolničko odeljenje za mikrobiologiju i/ili informacija proizvođača sredstava za dezinfekciju. Preporučljiva je dvostruka dezinfekcija mesta za uzorkovanje sa dve različite gazne komprese. Neka se dezinfekciono sredstvo osuši najmanje 60 s (66, 67).

8.3 Ne dodirujte dezinfikovano mesto nakon čišćenja.

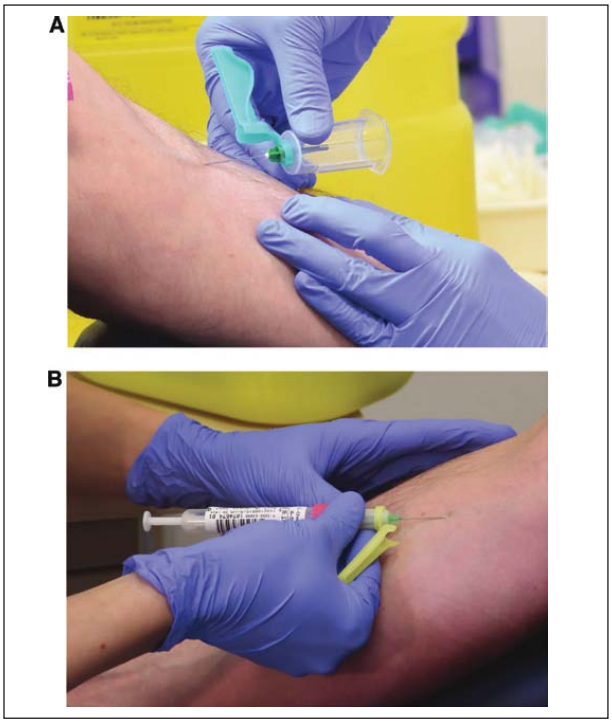
Dokazano je da tokom postupka vađenja krvi dolazi do kontaminacije krvi normalnom florom kože ako mesto venepunkcije nije pravilno očišćeno (68, 69),pa je čišćenje veoma važno ako se vadi krv za kulturu krvi.

Alkohol brzo isparava i već u roku od 10 sekundi količina alkohola se smanjuje za pola početne količine (70). Ako se alkohol ne osuši, to kod nekih pacijenata može izazvati svrab, ali neće ugroziti postupak vađenja krvi i kvalitet uzorka. Dokazano je da prisustvo alkohola (u slučaju da mesto venepunkcije nije osušeno) na mestu vađenja krvi nije uzrok lažne hemolize (71). (taviše, u idealnim uslovima za vađenje krvi, upotreba etanola pre vađenja venske krvi ne ometa merenje alkohola u krvi (72). Ipak, da bi se izbegao rizik od lažno pozitivnih rezultata na alkohol, predlažemo da se u slučaju vađenja krvi za testiranje forenzičkog alkohola ostavi da se alkohol osuši pre vađenja venske krvi. Alternativno, da bi se izbegao rizik od kontaminacije, može se koristiti odobreno bezalkoholno antiseptičko sredstvo za čišćenje.

Korak 9. Punkcija vene (*Slika 3*) (1A)

9.1 Ubodite venu pod kosim uglom, jer smanjujete bol i smanjujete rizik od perforacije zadnjeg venskog zida.

9.2 Sprečite okretanje vena tako što ćete zategnuti kožu pacijenta.



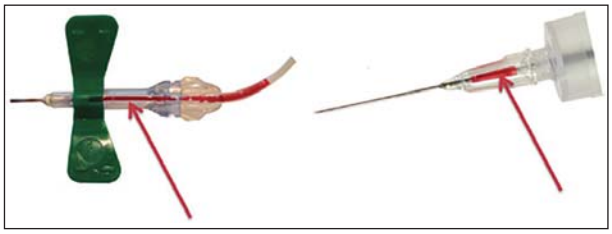
Slika 3 Iglu treba uvesti u krvni sud pod uglom od oko 5–30 stepeni, u zavisnosti od širine vene. (A) Uvođenje igle kada se koristi vakum epruveta i (B) Uvođenje igle za korisnike sistema za vađenje krvi pomoću tehnike aspiracije.

9.3 Odlučno i pažljivo uvedite iglu uzdužno u krvni sud pod uglom od oko 5–30 stepeni u zavisnosti od dubine vene tako da barem 0,5 cm igle uđe u krvni sud.

9.4 Čvrsto držite držač epruvete, a ruku pacijenta pridržavajte svojom šakom. (aka pacijenta mora da ostane otvorena i ne sme se stiskati šaka kada krv krene (8, 9, 73).

9.5 Ako se vena ne može locirati, lagano premeštanje igle (pomeranjem igle unazad ili prema napred) može pomoći u pronalaženju vene.

9.6 Upotreba uređaja sa vizuelizacijom može pomoći, posebno kod neiskusnog osoblja ili kod dece i pacijenata sa problematičnim venama. Ovi uređaji čine da vena postane vidljiva kada igla uđe u venu (*Slika 4*).



Slika 4 Uređaj za vađenje krvi sa vizualizacijom protoka krvi (leptir – levo), igla sa vidljivom protokom krvi (desno).

Korak 10. Vađenje krvi u prvu epruvetu (1A)

10.1 Izvadite krv: a) umetanjem epruvete u držač tako da se čep epruvete perforira i krv bude povučena (vakuumska tehnika); ili b) laganim povlačenjem klipa (tehnika aspiracije). Sledite EFLM preporučeni redosled vađenja (74). Pošto se tehnike vađenja krvi mogu razlikovati u zavisnosti od proizvođača, tokom vađenja krvi uvek treba poštovati konkretne preporuke proizvođača, zajedno sa preporukama u ovom dokumentu.

Preporučeni redosled vađenja je sledeći:

1. Epruveta za kulturu krvi,
2. Citratna epruveta,
3. Obična epruveta ili epruveta sa aktivatorom koagulacije,
4. Heparinska epruveta,
5. EDTA epruveta,
6. Epruveta sam inhibitorom glikolize,
7. Druge epruvete.

10.2 Kada se se krv izvadi u koagulacionu epruvetu kao u prvu ili jedinu:

– a za vađenje krvi se koristi prava igla, nije potrebna epruveta za odbacivanje (75, 76);

– kada se za vađenje koristi set za sa krilcima (leptir), mora se uzeti epruveta za odbacivanje kako bi se sprečilo

nedovoljno punjenje epruvete, a zatim i odstupanja u rezultatima testiranja (8).

10.3 Uverite se da su epruvete potpuno napunjene (do naznačenog nivoa na epruveti). Nedovoljno punjenje epruvete (epruvete ispunjene manje od 90% volumena) se nikako ne preporučuje i treba se izbegavati.

Iako neko može da tvrdi da neispravan redosled vađenja nije izvor kontaminacije kada se koriste zatvoreni sistemi za vađenje krvi (77, 78), postoje čvrsti dokazi koji pokazuju da se kontaminacija ipak javlja češće nego što se može očekivati i da ju je teško identifikovati (79–82). To je verovatno zato što se venepunkcija ne radi uvek u idealnim uslovima. Još uvek postoje klinička okruženja kao što su odeljenja za hitne slučajeve, gde se uzorkovanje krvi vrši u manje idealnim uslovima i gde se samo manji deo vađenja krvi vrši uz pomoć konvencionalne tehnike koja je propisana od strane proizvođača. Imajući u vidu gore objašnjene razloge, kao i toda praćenje redosleda vađenja ne uzrokuje očigledne probleme, preporučujemo da se redosled prati bez izuzetka tokom svakog vađenja krvi.

Korak 11. Uklanjanje poveske (1A)

11.1 Povesku treba ukloniti čim krv krene u prvu epruvetu.

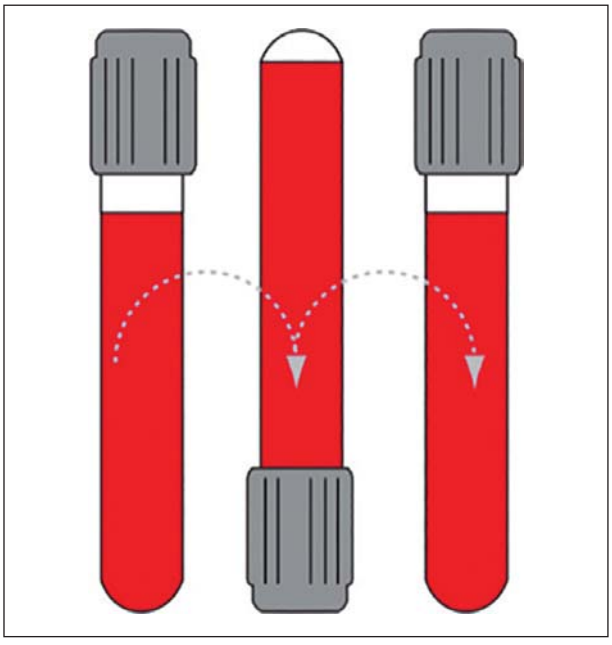
11.2 Ako je vađenje krvi neuspešno, povesku treba ukloniti i izvaditi krv na alternativnom mestu.

Poveskauzrokuje privremenu okluziju vena i privremeni zastoj. Ako se primenjuje tokom dužeg vremenskog perioda (duže od 1 min), poveska izaziva značajne varijacije u sastavu krvi usled ekstravazacije vode i malih molekula kao što su joni iz krvnog suda u subendotelni prostor. Tokom tog procesa, veliki molekuli kao što su lipoproteinske čestice, proteini i supstance vezane za proteine, ćelije i faktori koagulacije ostaju unutar krvnog suda, tako da se njihova koncentracija progresivno povećava. Većina ovih promena je zanemarljiva u roku od 1 minuta od primene poveske, ali kasnije može postati klinički značajna (84–86).

Korak 12. Lagano okrenite epruvete jednom odmah nakon vađenja krvi (1B)

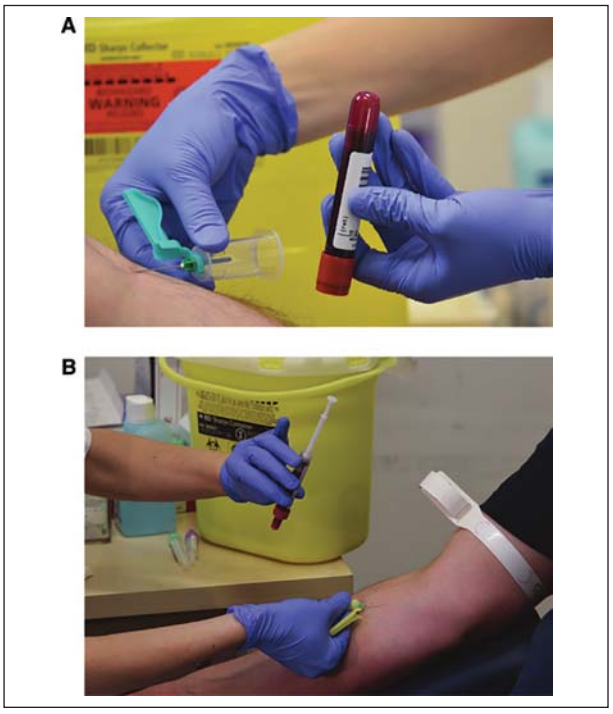
12.1 Sve epruvete treba promešati jednom odmah nakon što je krv izvađena. Svako kašnjenje može uticati na kvalitet uzorka.

12.2 Mešajte svaku epruvetu obrnuvši je jednom, pre nego što izvadite krv u sledeću epruvetu. Jedno okretanje uključuje okretanje epruvete vertikalno za 180° i vraćanje u početni položaj (*Slika 5*).



Slika 5 Jedan ciklus mešanja. Jedna inverzija uključuje okretanje epruvete vertikalno za 180° i vraćanje u početni položaj.

Odštampano (25) sa dozvolom Hrvatskog društva za medicinsku biokemiju i laboratorijsku medicinu.



Slika 6 Lagano okrenuti epruvetu jednom odmah nakon vađenja krvi. Držite iglu dominantnom rukom. Koristite uvek istu ruku tokom mešanja i punjenja dodatnih epruveta. (A) mešanje epruvete za korisnike vakumskih epruveta i (B) mešanje epruvete za korisnike sistema za vađenje krvi korišćenjem tehnike aspiracije.

12.3 Za držanje igle i držača tokom vađenja krvi treba koristiti dominantnu ruku da bi se zadržala kontrola. Takođe, ruku ne treba menjati tokom punjenja dodatnih epruveta (*Slika 6*).

12.4 Izbegavati snažno mešanje uzoraka (npr. trešenje, mućkanje) kako bi se sprečilo oštećenje krvnih ćelija, hemoliza, aktivacija trombocita ili koagulacija krvi (87).

12.5 Preporučuje se upotreba automatizovanih uređaja za mešanje, jer omogućava trenutno mešanje uzoraka bez angažovanja tehničara.

Adekvatno mešanje epruvete nakon vađenja krvi je važan korak koji obezbeđuje da se aditiv epruvete (antikoagulant, aktivator koagulacije itd.) adekvatno meša.Uzorci krvi su homogeni, te se održava kvalitet i integritet uzorka. Svesni smo da proizvođači daju svoje specifične preporuke o broju okretanja za određenu epruvetu, tj. da epruvete treba lagano okrenuti najmanje 5 do 10 puta, zavisno od tipa epruvete (8, 88, 89).

Tokom proteklih nekoliko godina vodila se rasprava o tome da li mešanje utiče ili ne utiče na kvalitet uzorka. Neke studije su pokazale da ukoliko se krv u primarnoj epruveti ne promeša, to najverovatnije neće dovesti do odstupanja u mnogim rezultatima testova. Objašnjenje ovih opažanja možda leži u tome da je turbulencija krvi koja je prouzrokovana standardnim vakuumskim pritiskom unutar primarnih epruveta dovoljna da sama po sebi omogući i solubilizaciju, i mešanje i stabilizaciju aditiva i krvi (90–92). Može se svakako desiti da pod optimalnim uslovima mešanje epruvete nakon uzimanja venske krvi ne mora biti obavezno (93–95). Međutim, u nekim graničnim uslovima i okolnostima, ukoliko se epruveta ne promeša, to može uticati na kvalitet uzorka i, na primer, dovesti do hemolize ili koagulacije uzorka. Imajući u vidu već navedene razloge, preporučujemo da se mešanje obavlja uvek i bez izuzetka.

U slučajevima kada je potrebno izvaditi više od jedne epruvete, praktično je nemoguće mešanje prve epruvete i stavljanje sledeće epruvete u držač u isto vreme, ukoliko flebotomičar drži držač jednom rukom a epruvetu meša drugom rukom. Ako flebotomičar odabere da prvo promeša jednu epruvetu (na primer 10 puta) i tek nakon toga da ostavi tu epruvetu, uzme sledeću i stavi je u držač, prosečno vreme potrebno za mešanje i stavljanje sledeće epruvete bi bilo najmanje 15 s (neobjavljena zapažanja). Ako je potrebno napuniti više epruveta, onda ukupno vreme tokom kojeg pacijent ima iglu u veni može biti bitno produženo. Da bi se ovo izbeglo i da bi sesmanjio osećaj nelagodnosti pacijenta, a da se pritom ne ugrozi značajno kvalitet uzoraka, preporučujemo da se, ako je neophodno napuniti više epruveta, svaka epruveta meša samo jednom punom inverzijom, i tek onda kada su sve epruvete napunjene, a igla uklonjena iz vene pacijenta, sve epruvetenaknadno promešaju još 4 puta (vidi korak 18).

Korak 13. Napunite dodatne epruvete u skladu sa preporučenim redosledom punjenja (1B)

13.1 Napunite sve naredne epruvete i lagano promešajte svaku epruvetu jednom (jedna puna inverzija), kao što je objašnjeno u prethodnom koraku (vidi korak 12).

13.2 Napunite epruvete po preporučenom redosledu punjenja (vidi korak 10).

Korak 14. Ulonite iglu iz vene i proverite da li je aktiviran sigurnosni mehanizam (1A)

Nakon izvlačenja zadnje epruvete stavite gazu na područje vađenja venske krvi bez pritiskanja. Pažljivo uklonite iglu trudeći se da ne izazovete bilo kakve povrede i pritisnite mesto punkcije gazom da biste izbegli krvarenje. Na tržištu postoje uređaji za vađenje krvi sa sigurnosnim dodacima koji se mogu razlikovati u načinu na koji se aktiviraju (npr. dok je igla još uvek unutar vene ili nakon što je igla uklonjena iz vene). U skladu sa Evropskom direktivom

2010/32 EU preporučujemo da se koriste samo uređaji sa sigurnosnim dodacima kako bi se sprečilo izlaganje zdravstvenih radnika i pacijenata kontaminiranoj igli (96). Treba pratiti preporuke proizvođača u zavisnosti od uređaja koji se koristi.

Korak 15. Odložite iglu (1A)

15.1 Odmah nakon aktiviranja sigurnosnog mehanizma, upotrebljeni uređaj za vađenje krvi treba odložiti u kontejner koji je otporan na probijanje.

5.2 Kontejneri za oštre predmete moraju biti nadohvat ruke. Odlazak do kontejnera za oštre predmete nije prihvatljiva praksa.

Korak 16. Previjte mesto punkcije (1C)

16.1 Proverite da li je krvarenje prestalo. Na ubodno mesto stavite suvi tufer ili gazu i fiksirajte flasterom ili zavojem.

Korak 17. Recite pacijentu da lagano pritisne ubodno mesto i da ne savija ruku (1C)

17.1 Pacijenta treba savetovati da blago pritisne mesto uboda i da ne savija ruku, kako bi se smanjio rizik od hematoma ili produženog krvarenja.

17.2 Podizanje ruke može pomoći da se zaustavi krvarenje na mestu uboda.

Treba vršiti blagi pritisak na mesto uboda sve dok se krvarenje ne zaustavi, što je obično period do 2 min za rutinska vađenja ili do 10 min za pacijente na antikoagulantnoj terapiji. Ako je vađenje bilo iz kubitalne vene, ruka pacijenta treba da bude ispružena. Iako jedna studija u Danskoj nije utvrdila razliku u riziku u pojavljivanju modrica bez obzira na to da li je ruka bila savijena ili ne (97), mnoge studije su pokazale da savijanje ruke može izazvati hematom (98, 99). Takođe, pokazalo se i da, ukoliko ne vršimo pritisak na mesto uboda dok krvarenje ne prestane, to povećava učestalost i ozbiljnost nastanka modrica (100).

Korak 18. Okrenite sve epruvete još najmanje 4 puta (1B)

18.1 Nakon što uklonite iglu iz vene i aktivirate sigurnosni mehanizam, okrenite sve epruvete najmanje još 4 puta, tako da je ukupan broj inverzija pet, tj. jednom odmah nakon punjenja epruvete a preostala 4 puta kada se napune sve epruvete (nakon uklanjanja igle iz vene). U idealnom slučaju, broj punih rotacija treba da odgovara instrukcijama proizvođača. Za informacije o pravilnom postupku mešanja pogledajte korak 12.

18.2 Ako se punisamo jedna epruveta, onda se ona okreće 5 puta odmah nakon vađenja.

18.3 Nakon postupka mešanja sve epruvete treba ostaviti u uspravnom položaju do dalje obrade.

Korak 19. Skinite rukavice (1A)

19.1 Pošto se upotrebljene rukavice mogu kontaminirati telesnim tečnostima i/ili mikroorganizmima, preporučujemo da se rukavice menjaju nakon svakog uzimanja venske krvi.

19.2 Preporučujemo sledeći postupak uklanjanja rukavica: skinite jednu rukavicu i okrenite je na spolja (*Slika 7*, levo), a zatim obuhvatite prvu rukavicu tako što ćete navućidrugu rukavicu preko nje (*Slika 7*, desno).

19.3 Odložite rukavice i očistite ruke (101).

Slika 7 Uklanjanje rukavica: skinite jednu rukavicu i okrenite je na spolja (levo),a zatim obuhvatite prvu rukavicu tako što ćete navući drugu rukavicu preko nje (desno).

III Procedura nakon uzimanja uzorka

Korak 20. Savetujte pacijenta da odmori 5 minuta (1B)

20.1 Savetujte pacijenta da se odmara 5 minuta ili da sačeka dok se krvarenje ne zaustavi (ako je duže od 5 min), pre nego što napusti prostor za vađenje krvi.

20.2 Budite empatični i pitajte pacijenta kako se oseća pre napuštanja objekta za vađenje krvi. Ovo može pomoći u identifikaciji pacijenata kod kojih postoji rizik od vrtoglavice ili čak sinkope (gubitka svesti).

20.3 Zahvalite se pacijentu i kažite mu/joj da će dobiti laboratorijske rezultate što je pre moguće. Ako vas pita o tačnom vremenu za podizanje laboratorijskih rezultata, obavestitega/je o tome ili posavetujte pacijenta gde da potraži tu informaciju (vidi Proceduru pre uzimanja uzorka, pod tačkom 4).

Ovim korakom želimo skrenuti pažnju na period nakon uzimanja uzorka krvi, tokom kojeg pacijenti mogu osećati vrtoglavicu ili čak nesvesticu zbog vazovagalne sinkope. Postoje pacijenti koji se plaše igala ili osećaju nelagodnost kada vide krv. Takvi pacijenti, posebno mladi, u nekim slučajevima mogu doživeti sinkopu tokom ili neposredno nakon vađenja krvi (102, 103). Sinkopa tokom ili nakon vađenja krvi se može pojaviti kao rezultat anksioznosti ili iznenadnog prestanka anksioznosti, kada se pacijent više ne oseća ugroženim (104). Stoga, da bismo bili sigurni da je pacijent dobro i da nema akutnih komplikacija, predlažemo da se pacijentu preporuči da se odmori u prostoriji za vađenje krvi ili u čekaonici najmanje 5 minuta ili duže dok se krvarenje ne zaustavi. Poželjno je da pacijenta prati ovlašćeno osoblje ili da ga ostavi da odmori, a da mu se pri tome skrene pažnja da treba da zatraži pomoć ako oseti damu je ona potrebna. Iako znamo da većina pacijenata ne pati od anksioznosti ili vrtoglavice nakon vađenja krvi, takođe smatramo da očigledna korist od poštovanja ovog koraka nadmašuje moguće teškoće u ispunjavanju ove preporuke.

Kao što je već ranije objašnjeno (u delu pod naslovom: Komunikacija sa pacijentom), empatična komunikacija sa pacijentom, koja mu uliva samopouzdanje, veoma je važna. Procena stepena straha od vađenja krvi može pomoći da se identifikuju pacijenti koji su pod povećanim rizikomod sinkope tokom ili nakon uzimanja uzoraka krvi (15, 105). Kod ovih pacijenata udobnost ili odvlačenje pažnje može ublažiti reakciju pacijenta na stres od vađenja krvi i smanjiti rizik od sinkope.

Tabela III Potencijalne prepreke i izazovi koje treba prevazići za uspešnu implementaciju smernica i preporuka.

Prepreke i izazovi	Rešenja
1. Pojedinac. a. Otpor pojedinca prema promeni b. Jezička barijera c. Nedostatak znanja, svesti i razumevanja neophodnosti primene preporuke	a. Upravljanje promenama (zajednička vizija i timski rad) b. Prevođenje dokumenta na vaš jezik c. Edukacija
2. Na nivou bolnice a. Finansijski razlozi b. Nedostatak osoblja koje bi moglo preuzeti odgovornost za sprovođenje promena c. Promena se smatra neprioritetnom od strane uprave	a. Prikazati upravi bolnice finansijske gubitke nastale usled lošeg kvaliteta b. Identifikujte »ambasadora« bolnice i izgradite tim c. Predstavite upravi koristi od promene (uštede, sigurnost pacijenata, prestiž bolnice itd.)
3. Na nacionalnom nivou a. Nedostatak svesti i razumevanja o neophodnosti sprovođenja preporuke b. Nedostatak profesionalnog tela koji bi moglo preuzeti odgovornost za sprovođenje c. Postojanje više od jedne profesionalne grupe čiji su članovi uključeni u proces vađenja krvi d. Preporuke su podržane samo ako dolaze od nacionalnog regulatornog tela e. Postojeće nacionalno zakonodavstvo je u suprotnosti sa ovim dokumentom f. Preporuku je teško sprovesti ako nije službeno odobrena ili čak uključena u neki međunarodno priznati regulatorni dokument (kao što su CLSI, ISO itd.)	a. Identifikujte nacionalnog »ambasadora« b. Uspostaviti nacionalnu radnu grupu za preanalitičku fazu c. Multidisciplinarna saradnja svih zainteresovanih strana d. Saradnja sa nacionalnim regulatornim telima e. Prilagoditi preporuke lokalnim pravilima i propisima f. EFLM radi na povezivanju sa međunarodnim regulatornim telima

IV Sprovođenje smernica

Potencijalne prepreke i izazovi

Uspešna implementacija smernica zavisi od prevazilaženja potencijalnih prepreka ili izazova. Da bi se napravio dobar i izvodljiv plan implementacije, prvo treba identifikovati sve prepreke i izazove i pažljivo razmotriti odgovarajuća rešenja (*Tabela III*).

Potencijalne prepreke i izazovi na individualnom nivou, koji mogu ugroziti uspešnu implementaciju ove preporuke, jesu otpor pojedinca prema promeni, jezička barijera, nedostatak znanja, svesti i razumevanja. Konačno, čak i ako postoji pozitivan stav prema promeni, takva promena može biti spora ako ne postoji niko ko je odgovoran za sprovođenje promene ili ako odgovorni pojedinac ima neke druge prioritete.

Prepreke i izazovi na nivou bolnice mogu biti finansijske prirode. Mogu postojati i problemi kao što su nedostatak osoblja koje bi moglo preuzeti odgovornost da sprovede promenu. Naravno, promena može biti teško sprovodljiva ako je uprava bolnice ne smatra prioritetnom.

Postoji i nekoliko mogućih prepreka koje bi mogle nastati na nacionalnom nivou. Kao što je slučaj na nivou pojedinačne bolnice, moguće prepreke na nacionalnom nivou mogu biti nedostatak svesti i razumevanja o neophodnosti primene preporuke, kao i nedostatak profesionalnog tela koje bi moglo preuzeti odgovornost za sprovođenje promene. Takođe, u nekim zemljama postoji više grupa zanimanja čiji su članovi uključeni u proces uzimanja uzoraka krvi. Postojanje takvih profesionalnih grupa može biti prepreka uspešnoj implementaciji preporuka ukoliko se one se ne slože da rade zajedno. U nekim zemljama preporuke bivaju podržane samo ako dolaze od regulatornog tela. Na kraju, ako je postojeće nacionalno zakonodavstvo u sukobu sa ovim dokumentom, to bi moglo predstavljati značajnu poteškoću za implementaciju ove preporuke.

Može se desiti da neke zemlje i nacionalna udruženja imaju poteškoće u sprovođenju preporuke ako ona nije zvanično odobrena ili čak uključena u neki međunarodno priznati regulatorni dokument (kao što su CLSI, ISO itd.).

S obzirom na sve navedene poteškoće u pronalaženju odgovarajućih kanala komunikacije ili ciljanju odgovornih subjekata u svakoj zemlji, prihvatanje i implementacija ove preporuke zaista mogu biti veliki izazov za sve članove EFLM i COLABIOCLI. Stoga predlažemo okvir za uspešnu implementaciju ove preporuke u nadi da on može olakšati ovaj proces tamo gde je to potrebno.

Okvir za uspešnu primenu ove preporuke

Neophodni uslovi za uspešnu implementaciju ove preporuke navedeni su u *Tabeli IV*. Ispod svakog uslova u tabeli dato je obrazloženje njegovog značaja. Postoji mnogo načina na koje možete reagovati u slučaju otpora pojedinca prema promeni (106). Verujemo da većina medicinskog osoblja brine za bezbednost i dobrobit pacijenata. Stoga je njihov otpor prema učenju i usvajanju nove procedure vađenja krvi u osnovi uzrokovan njihovim nerazumevanjem potencijalne štete koja može nastati kao posledica nepridržavanja preporučene procedure, kako za pacijenta tako i za samo osoblje. Edukacijom osoblja o potencijalnim rizicima za pacijenta prouzrokovanih lošom procedurom vađenja krvi podiže se svest o neophodnosti pridržavanja preporučene procedure (107–109). Edukacija podiže nivo poverenja i poboljšava kvalitet procedura (110). Ipak, efekti su obično kratkotrajni i zato edukacija treba da bude kontinuirana (111).

Postoji nizak nivo znanja i razumevanja nekih osnovnih preanalitičkih pitanja među učenicima/studentima biomedicine (Medicinska škola, Medicinski fakultet, Farmaceutski fakultet, Veterinarski fakultet) (1, 112). Edukacija o procedurama uzorkovanja krvi bi stoga trebalo da je dostupna medicinskom osoblju već tokom njihovog formalnog obrazovanja kako bi postali kvalifikovani u tom smislu (teoretski i praktično). Pošto se postupkom vađenja krvi bave različiti profili zanimanja u različitim evropskim zemljama, profesije koje bi trebalo da budu uključene u takvu vrstu edukacije variraju od zemlje do zemlje (113).

Edukacija o procedurama uzimanja uzoraka krvi takođe treba da bude dostupna novozaposlenom medicinskom osoblju koje je uključeno u uzimanje uzoraka krvi. Takođe, pored edukacije, koja je uglavnom teoretska, novozaposleno osoblje treba da prođe praktičnu obuku o postupku vađenja krvi. Praktična obuka bi po mogućnosti trebalo da bude sprovedena u laboratoriji koja prima ambulantne pacijente u periodu od jedne nedelje, tokom koje novo osoblje treba da pod nadzorom odgovornog osoblja obavi najmanje 100 venepunkcija. Tokom prvih pet i poslednjih pet vađenja krvi treba izvršiti opservacionu proveru kako bi se procenio stepen usklađenosti sa preporučenom procedurom i identifikovala potencijalna odstupanja.

Navedeni broj venepunkcija i trajanje praktične obuke su preporuka za minimalne kriterijume. Do ovih kriterijuma se došlo konsenzusom na osnovu iskustva i stručnosti autora ovog dokumenta. Minimalni broj venepunkcija može zavisiti od institucije, veštine i iskustva polaznika, složenosti kategorije pacijenta itd. Stoga je odgovornost na edukatoru i instruktoru da se odredi minimum znanja i iskustva koje treba prikazati tokom demonstracije procesa vađenja krvi.

Tabela IV Okvir za uspešnu implementaciju EFLM-COLABIOCLI preporuke za uzimanje uzoraka venske krvi.

Edukacija osoblja	Dostupna već tokom formalnog obrazovanja Dostupna svim novozaposlenim osobama Dostupna periodično (najmanje na 3 godine) Poželjno postojanje modula elektronskog učenja Uspostavljen sistem obuke trenera Test znanja se primenjuje pre i posle edukacije
Praktični trening zaposlenih	Dostupan već tokom formalnog obrazovanja Dostupan svim novozaposlenim osobama Dostupan periodično (najmanje na 3 godine) Po mogućnosti u laboratoriji (ambulantni pacijenti) Traje najmanje 1 sedmicu (najmanje 100 uzoraka)
Sertifikacija osoblja uključenog u uzimanje uzoraka krvi	Odnosi se na sve koji su uključeni u uzimanje uzoraka krvi Odobrava se novim članovima osoblja nakon uspešnog završetka: a) Početne edukacije i obuke b) Testiranja znanja i provere znanja Periodična resertifikacija
Provera primene procedure uzimanja uzoraka krvi	Uspostavljen je periodični sistem provere Ponovni trening se sprovodi kao korektivna mera Vrši se opservaciona provera uz korišćenje strukturirane kontrolne liste Tokom provere nadgleda se najmanje 20 vađenja krvi, koja su obavila najmanje tri različita flebotomičara Za praćenje kvaliteta uzorka koriste se pokazatelji kvaliteta Pokazatelji kvaliteta se koriste reagovanje i pokretanje korektivnih mera
Bolnički tim odgovoran za implementaciju	Postoji bolnički »ambasador« Postoji tim ključnih aktera u bolnici
Nacionalna društva	Postoji nacionalni »ambasador« U nacionalnom društvu postoji radna grupa za preanalitičku fazu Preporuka je prevedena na lokalni jezik Identifikovani su ključni akteri Implementacija se vrši u saradnji sa ključnim akterima Regulatorni i vladini organi podržavaju aktivnosti implementacije Sva nacionalna pravila i preporuke imaju prednost nad ovim dokumentom; postoji mehanizam za usaglašavanje modifikacija Urednici nacionalnih časopisa pomažu podizanjem svesti

Preporučujemo da svaka institucija uspostavi sopstveni sistem sertifikacije osoblja koje je uključeno u postupak uzimanja uzoraka krvi. Sertifikate treba dati svim novim članovima osoblja tek nakon uspešnog završetka početnog obrazovanja i obuke. Predlažemo da se kao uslov za dobijanje sertifikata sprovede testiranje znanja i opservaciona provera. Da bi dobio sertifikat, zaposleni treba da uspešno položi test znanja. Preporučujemo da se uspešnim testom smatra 80% tačnih odgovora, ali ostavljamo instituciji da definiše svoj minimalni standard.

Takođe, preporučujemo da svaka zdravstvena ustanova ima sistem kontinuirane provere znanja, ponovljene obuke i resertifikacije za sve zaposlene. Preporučujemo da se provera vrši u obliku opservacione provere koristeći standardizovanu strukturiranu kontrolnu listu (*Tabela V*). Opservacionu proveru treba vršiti periodično na svakom odeljenju klinike, najmanje jednom godišnje. Tokom svake opservacione provere treba ispratiti dovoljan broj postupaka vađenja krvi i broj flebotomičara. Preporučujemo da se tokom svake provere posmatra postupak obavljanja najmanje 20 venepunkcija od najmanje tri različita flebotomičara (najmanje tri na svakog flebotomičara). Opet, kao što je već rečeno, institucija je slobodna da definiše svoj minimalni standard.

Periodična edukacija (teorijska i praktična) bi trebalo da bude dostupna svim članovima osoblja nakon najmanje 3 godine. Ova edukacija se čak može organizovati kao onlajn učenje, ako postoje uslovi za tako nešto. S obzirom na to da edukacija i obuka mogu biti vremenski zahtevni i u okruženjima gde su

ljudski resursi ograničeni, preporučujemo da se uspostavi sistem za »obuku trenera", što znači da na svakom odeljenju postoji osoba (glavna medicinska sestra odeljenja) koja je odgovorna za edukaciju, obuku i kontrolu osoblja.

Preporučujemo da se za procenu nivoa znanja i razumevanja, kao i za podizanje svesti osoblja, pre nego što se krene sa edukativnim aktivnostima, koristi test znanja. Takođe, preporučujemo da se test znanja koristi i za procenu nivoa znanja i svesti osoblja nakon nastavnih aktivnosti. Test znanja treba da proceni razumevanje pitanja i činjenica navedenih u nastavku:

– najčešće greške u preanalitičkoj fazi
– uticaj preanalitičkih grešaka na kvalitet uzorka i rezultat
– kako pravilno pripremiti pacijenta za vađenje krvi?
– kako se definiše uzdržavanje od hrane i zašto je to važno?
– pravilna identifikacija pacijenta i postupak označavanja epruvete – vrste epruveta, aditivi
– redosled uzimanja uzoraka
– upotreba poveske
– adekvatan postupak mešanja
– zašto je važan odnos krvi i aditiva?
– hemoliza – uzroci i posledice
– koagulacija – uzroci i posledice
– bezbednost pacijenata i zdravstvenih radnika

Indikatori kvaliteta su efikasni alati za dobijanje informacija o riziku od grešaka, učestalosti grešaka i njihovoj distribuciji tokom celokupnog procesa testiranja (114). Preporučujemo da se indikatori kvaliteta koriste za praćenje kvaliteta uzoraka dobijenih u laboratoriji (115–117). Laboratorijama se preporučuje da prate učestalost nedovoljno napunjenih epruveta, koagulisanih uzoraka, hemoliziranih uzoraka, ID grešaka itd., jer su dobar alat za detekciju određenih »pikova" i ukazuju na neke specifične probleme tokom postupka vađenja krvi. Izbor pokazatelja kvaliteta koji će se koristiti zavisi od lokalnih zahteva i posebnih problema i problema na nivou svake bolnice. Te pokazatelje kvaliteta bi trebalo koristiti za delovanje i ispravljanje problema.

Da bi se prevazišla jezička barijera, preporuku treba prevesti na lokalni jezik i učiniti dostupnom svima koji su uključeni u proces uzimanja uzoraka krvi. Podstičemo nacionalna društva da pomognu u prevođenju ovog dokumenta.

Što se tiče načina prevazilaženja prepreka na nivou bolnice, potrebno je da budete u mogućnosti da ukažete na koristi od implementacije ove preporuke, kao što su troškovi koje nosi loš kvaliteta uzorka, potencijalne uštede, smanjenje posledica po pacijenta ili uticaj na zadovoljstvo i bezbednost pacijenta (118, 119). Osim toga, pokazano je da se pridržavanjem preporučene procedure vađenja krvi minimizira rizik od štete za pacijenta i učestalost pojavljivanja neodgovarajućih uzoraka (120). Ovaj važan bezbednosni aspekt se mora predstaviti rukovodstvu bolnice. Na kraju, rukovodstvo bolnice će verovatno biti zainteresovano za bilo koju intervenciju koja bi potencijalno mogla biti smatrana pitanjem prestiža među sličnim institucijama.

Za uspešnu implementaciju preporuke treba da postoji član osoblja odgovoran za sprovođenje promene na nivou bolnice (tzv. »ambasador«). Ova osoba treba da ima dovoljno vremena za obavljanje ovog zadatka.

Takođe, ova osoba treba da ima tim koji se sastoji od nekoliko ključnih osoba u bolnici, kao što su glavna sestra i eventualno predstavnici iz:

– laboratorije,
– kliničko osoblje (doktori medicine),
– laboratorijski tehničari,
– epidemiolozi,
– odeljenje za bolničke infekcije i bezbednost radnika,
– odeljenje za kontrolu kvaliteta,
– uprava bolnice.

Ovaj tim treba da se redovno sastaje, diskutuje i planira strategiju za uspešnu implementaciju i kontinuirano poboljšanje.

Na nacionalnom nivou takođe treba da postoji »ambasador« koji će preuzeti vodeću ulogu u procesu implementacije ove preporuke. Da bi se olakšalo sprovođenje preporuke, trebalo bi da postoji radna grupa za preanalitičku fazu ili neko drugo telo koji će biti odgovorno za aktivnosti edukacije i podizanje svesti među svim akterima i profesijama (iz istih ili različitih oblasti interesovanja i nivoa obrazovanja), a koji su uključeni u vađenje krvi zbog neophodnosti sprovođenja preporuke. Nacionalni časopisi i njihovi urednici se takođe ohrabruju da podignu svest o preanalitičkoj fazi i vađenju venske krvi, posebno koristeći svoj časopis kao efikasno i moćno sredstvo za razmenu znanja i informacija (121–123). Proces implementacije treba da bude urađen zajedničkim naporima uz blisku multidisciplinarnu saradnju svih zainteresovanih strana na nacionalnom nivou. Nacionalni »ambasadori« su odgovorni za identifikaciju i angažovanje ključnih zainteresovanih strana, kao što su nacionalna udruženja za negu, profesionalna društva laboratorijske medicine i po mogućnosti i pacijenti.

Bilo bi veoma dobro uključiti regulatorna tela, kao što su profesionalne komore, udruženja, nacionalna regulatorna tela, pa čak i vladina tela kao što je Ministarstvo zdravlja, da podrže aktivnosti implementacije.

Tabela V EFLM-COLABIOCLI formular za opservacionu proveru uzorkovanja venske krvi.

Ime posmatrača:						
Odeljenje[a]:						
Datum uzorkovanja:						
Ime / ID flebotomičara:						
Broj uzorka krvi	Uzorak 1		Uzorak 2		Uzorak 3	
Pitanje 1. Da li je flebotomičar pravilno identifikovao pacijenta?	da	ne	da	ne	da	ne
Pitanje 2. Da li je flebotomičar utvrdio da pacijent nije jeo i da je pravilno pripremljen za vađenje krvi?	da	ne	da	ne	da	ne
Pitanje 3. Da li je flebotomičar nabavio sve što mu je potrebno pre vađenja?	da	ne	da	ne	da	ne
Pitanje 4. Da li su epruvete obeležene u prisustvu pacijenta?	da	ne	da	ne	da	ne
Pitanje 5. Da li je flebotomičar stavio novi, nekorišćen par rukavica?	da	ne	da	ne	da	ne
Pitanje 6. Da li je poveska postavljena na četiri širine prsta (10 cm) iznad mesta venepunkcije?	da	ne	da	ne	da	ne
Pitanje 7. Da li je odabrano odgovarajuće mesto venepunkcije u skladu sa preporučenom praksom?	da	ne	da	ne	da	ne
Pitanje 8. Da li je mesto venepunkcije pravilno očišćeno i nedodirnuto nakon što je očišćeno?	da	ne	da	ne	da	ne
Pitanje 9. Da li je tehničar oslobodio povesku kada je krv počela da teče?	da	ne	da	ne	da	ne
Pitanje 10. Da li je prva epruveta (i sve naredne epruvete) odmah okrenuta jednom lagano?	da	ne	da	ne	da	ne
Pitanje 11. Da li je flebotomičar sledio ispravan redosled uzimanja krvi?	da	ne	da	ne	da	ne
Pitanje 12. Da li je odmah aktiviran sigurnosni element u sistemu za vađenje krvi?	da	ne	da	ne	da	ne
Pitanje 13. Da li je igla / sistem za vađenje bezbedno i odmah uklonjen?	da	ne	da	ne	da	ne
Pitanje 14. Da li je flebotomičar stavio čistu gazu na mesto venepunkcije?	da	ne	da	ne	da	ne
Pitanje 15. Da li je pacijentu rečeno da pritisne dok se krvarenje ne zaustavi i da ne savija ruku?	da	ne	da	ne	da	ne
Pitanje 16. Da li su sve epruvete za uzorke mešane još 4 puta?	da	ne	da	ne	da	ne
Pitanje 17. Da li je flebotomičar skinuo rukavice nakon završetka vađenja krvi?	da	ne	da	ne	da	ne
Pitanje 18. Da li je pacijentu savetovano da se odmara 5 minuta kako bi bili sigurni da je krvarenje prestalo, pre nego što napusti organizacionu jedinicu za vađenje krvi?	da	ne	da	ne	da	ne

[a]Dodatni generički podaci koji se odnose na instituciju, mogu biti neophodni kako bi se pravilno identifikovala i institucionalna jedinica iz koje su flebotomičari. To će zavisiti od institucionalne politike i organizacije, kao i od nekih specifičnih lokalnih okolnosti. Kriterijumi za isključenje: Pacijenti treba da budu svesni, da imaju više od 18 godina i krv ne sme da se uzima preko katetera. Koristite jedan formular po flebotomičaru. Svaki flebotomičar bi trebalo da bude praćen tokom tri naknadna uzastopna uzorkovanja.

Ako su neka nacionalna pravila u sukobu sa ovim dokumentom, treba da postoji mehanizam za postizanje dogovora o modifikaciji ovog dokumenta na nacionalnom nivou, a potom treba i prihvatiti revidiranu verziju za implementaciju.

Zaključci

Kao vodeće profesionalno telo uključeno u preanalitičku fazu, radna grupa EFLM-PRE se smatra odgovornom za obezbeđivanje okvira za uspešnu implementaciju ovog dokumenta na evropskom nivou (124, 125). Naš cilj je da podstaknemo Evropsku asocijaciju za akreditaciju da standardizuje ovaj dokument i podstakne njegovo korišćenje na nacionalnom nivou u svakoj evropskoj zemlji tokom procene akreditacije.

Kako bi se olakšala implementacija, EFLM WG-PRE je pripremio sledeće alate:

1. *Power Point* prezentacija koja opisuje neka osnovna pitanja vezana za uzimanje uzoraka venske krvi i celokupnu proceduru (koja će se koristiti tokom edukacije osoblja)
2. Video koji prikazuje celokupnu proceduru (koristi se tokom edukacije osoblja)
3. Test znanja za procenu nivoa znanja i podizanje svesti osoblja pre i nakon edukacije
4. Kontrolnu listu koja se koristi za proveru primene procedure uzimanja uzoraka krvi tokom periodičnih opservacionih revizija (*Tabela V*)
5. Postere sa ilustracijama koje opisuju ceo postupak (koji će se koristiti u prostorijama za vađenje krvi)

Ovi alati su besplatni i dostupni na veb-stranici EFLM (www.eflm.eu) pod EFLM Committees/ Science/WG: Preanalytical Phase, a onda pod Resources/Educational Material. Pozivamo profesionalni kadar da preuzme i koristi ove alate kako bi implementirali preporučenu proceduru za vađenje venske krvi i uspostavili sistem kvaliteta koji će održavati i kontinuirano poboljšavati kvalitet postupka.

Autorski prilozi: Svi autori su prihvatili odgovornost za celokupan sadržaj ovog dostavljenog rukopisa i odobrenog podneska.

Finansiranje istraživanja: Nema informacija.

Zapošljeni ili rukovodstvo: Nema informacija.

Honorari: Nema informacija.

Konkurentni interesi: Ne postoje organizacije koje su svojim finansiranjem imale ikakvu ulogu u izradi studije, u prikupljanju, analizi i interpretaciji podataka, u pisanju izveštaja ili u odluci da se izveštaj dostavi za objavljivanje.

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Dodatni materijal: Onlajn verzija ovog članka nudi dodatne materijale (https: //doi.org/10.1515/cclm-2018-0602).

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.**	

EUROPEAN FEDERATION OF CLINICAL CHEMISTRY
AND LABORATORY MEDICINE

RECOMMENDATION FOR VENOUS BLOOD SAMPLING

provided by the

EFLM Working Group: Preanalytical Phase (WG-PRE)

PRE-SAMPLING

Patient position should be unchanged for 15 minutes.
Positively identify the patient.
Verify patient is fasting and properly prepared.

SAMPLING (Vacuum-System)

1 Ensure appropriate conditions and supplies required for phlebotomy
2 Label and/or identify tubes
3 Clean hands in front of the patient
4 Put on gloves
5 Assemble appliances
6 Apply tourniquet
7 Select venepuncture site
8 Clean sampling site
9 Puncture the vein
10 Draw first tube
11 Release the tourniquet as soon as the blood flows into the first tube
12 Gently invert the tubes 1 time immediately after collection
13 Draw additional tubes following order of draw
14 Remove needle from the vein
15 Activate safety mechanism
16 Dispose of the needle
17 Ensure the bleeding has topped
18 Treat the puncture wound
19 Tell a patient to apply a pressure on the wound
20 Invert all tubes 4 times
21 Remove gloves
22 Clean hands

POST-SAMPLING

Advise patient to rest for 5 minutes and wait until the bleeding has stopped before leaving the blood collection facility.

Joint EFLM-COLABIOCLI Recommendation for venous blood sampling v 1.1, June 2018. CCLM, 2018: doi 10.1515/cclm-2018-0602

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EUROPEAN FEDERATION OF CLINICAL CHEMISTRY
AND LABORATORY MEDICINE

RECOMMENDATION FOR VENOUS BLOOD SAMPLING

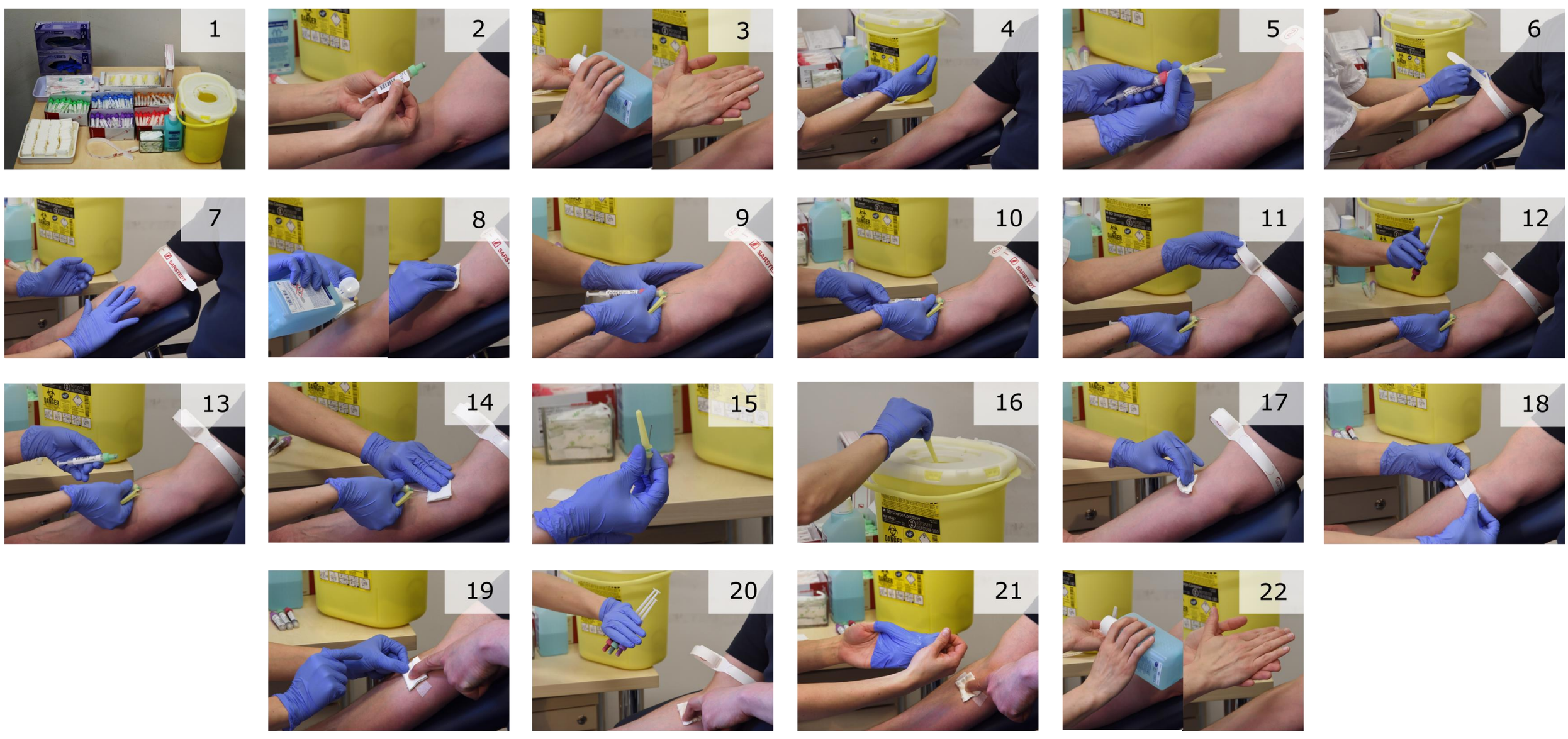
provided by the

EFLM Working Group: Preanalytical Phase (WG-PRE)

PRE-SAMPLING

Patient position should be unchanged for 15 minutes.
Positively identify the patient.
Verify patient is fasting and properly prepared.

SAMPLING (Aspiration System)



1 Ensure appropriate conditions and supplies required for phlebotomy
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10 Draw first tube
11 Release the tourniquet as soon as the blood flows into the first tube
12 Gently invert the tubes 1 time immediately after collection
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18 Treat the puncture wound
19 Tell a patient to apply a pressure on the wound
20 Invert all tubes 4 times
21 Remove gloves
22 Clean hands

POST-SAMPLING

Advise patient to rest for 5 minutes and wait until the bleeding has stopped before leaving the blood collection facility.

Joint EFLM-COLABIOCLI Recommendation for venous blood sampling v 1.1, June 2018. CCLM, 2018: doi 10.1515/cclm-2018-0602

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DE GRUYTER

Clin Chem Lab Med 2018; aop

EFLM Paper

EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

COLABIOCLI

Ana-Maria Simundic*, Karin Bölenius, Janne Cadamuro, Stephen Church, Michael P. Cornes, Edmée C. van Dongen-Lases, Pinar Eker, Tanja Erdeljanovic, Kjell Grankvist, Joao Tiago Guimaraes, Roger Hoke, Mercedes Ibarz, Helene Ivanov, Svetlana Kovalevskaya, Gunn B.B. Kristensen, Gabriel Lima-Oliveira, Giuseppe Lippi, Alexander von Meyer, Mads Nybo, Barbara De la Salle, Christa Seipelt, Zorica Sumarac and Pieter Vermeersch, on behalf of the Working Group for Preanalytical Phase (WG-PRE), of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and Latin American Working Group for Preanalytical Phase (WG-PRE-LATAM) of the Latin America Confederation of Clinical Biochemistry (COLABIOCLI)

Joint EFLM-COLABIOCLI Recommendation for venous blood sampling

v 1.1, June 2018

https://www.eflm.eu/site/page/a/1194

Version 1.1 / 2018

WHY DO WE NEED GUIDELINES?

Case #1

7:30 a.m.

Patient arrives at the laboratory outpatient unit. His last meal was at 21:00 on the previous day. In the morning he had coffee with milk (without sugar) and one cigarette. Routine chemistry and hematology tests are requested.

Is this patient properly prepared for blood tests?

a) Yes

b) No

Blood collection facts

Most common invasive procedure in the healthcare

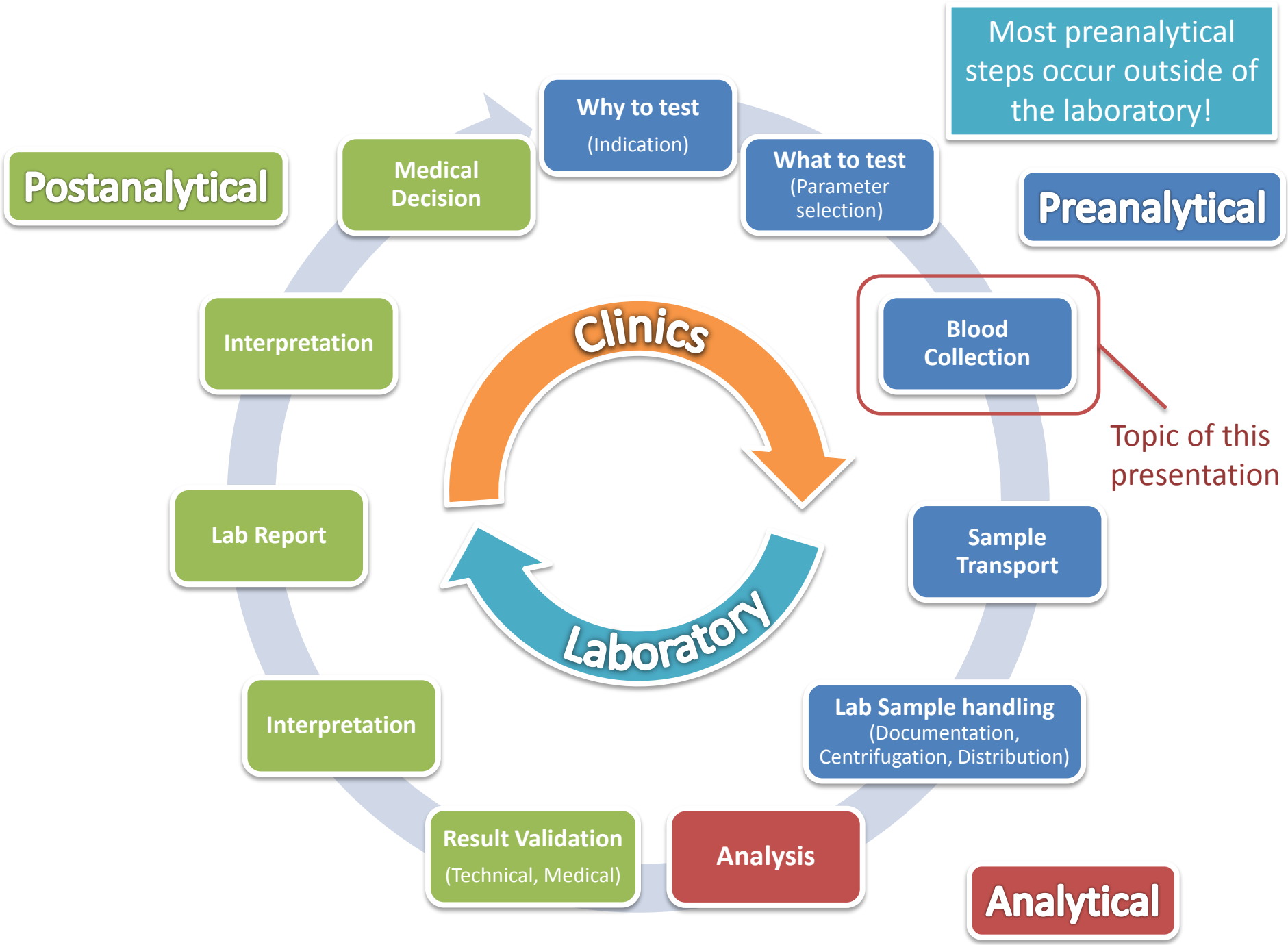
Available worldwide (Hospitals, Primary Health Care, Home Based Care)

Huge variations in technique, use of safety devices, disposal methods, reuse of devices and availability of post exposure prophylaxis.

Variations between countries, institutions, individuals

The most common source of preanalytical errors.

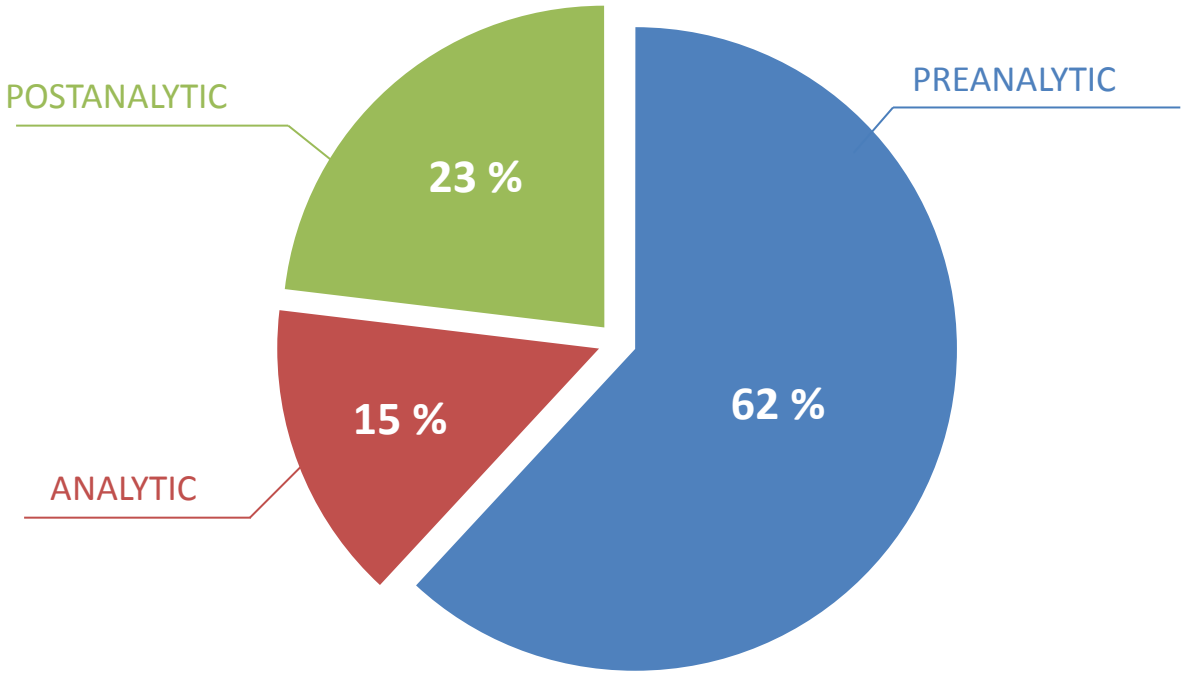
Errors often go unrecognized.


Most preanalytical steps occur outside of the laboratory!
Postanalytical
Preanalytical
Analytical
Why to test
(Indication)
What to test
(Parameter selection)
Blood Collection
Sample Transport
Lab Sample handling
(Documentation, Centrifugation, Distribution)
Analysis
Result Validation
(Technical, Medical)
Interpretation
Lab Report
Interpretation
Medical Decision
Clinics
Laboratory
Topic of this presentation

Errors within the total laboratory process

Error rate within the total laboratory process:
0.05% - 10 % of all samples

At what stage in the total laboratory process do these errors occur?



Lippi G,et al Clin Chem Lab Med 2009; 47:143-153; Carraro P, Plebani M. Clin Chem 2007; 53:1338-1342.

Consequences of preanalytical errors

Incorrect test results

Incorrect diagnosis

Unnecessary delays

Harm to the patient and phlebotomist

Unnecessary cost

Guidelines

CLSI GP41-A7 Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture

Clinical and Laboratory Standards Institute

WHO guidelines on drawing blood

World Health Organization

http://apps.who.int/iris/bitstream/10665/44294/1/9789241599221_eng.pdf

National - Only 7/28 European countries have guidelines

(Ireland, UK, Spain, Slovenia, Sweden, Italy and Croatia)

Results from a survey 2013

Different guidelines and different degrees of compliance

Simundic AM, et al. CCLM 2013;51(8):1585-93.

Case #2

7:00 a.m.

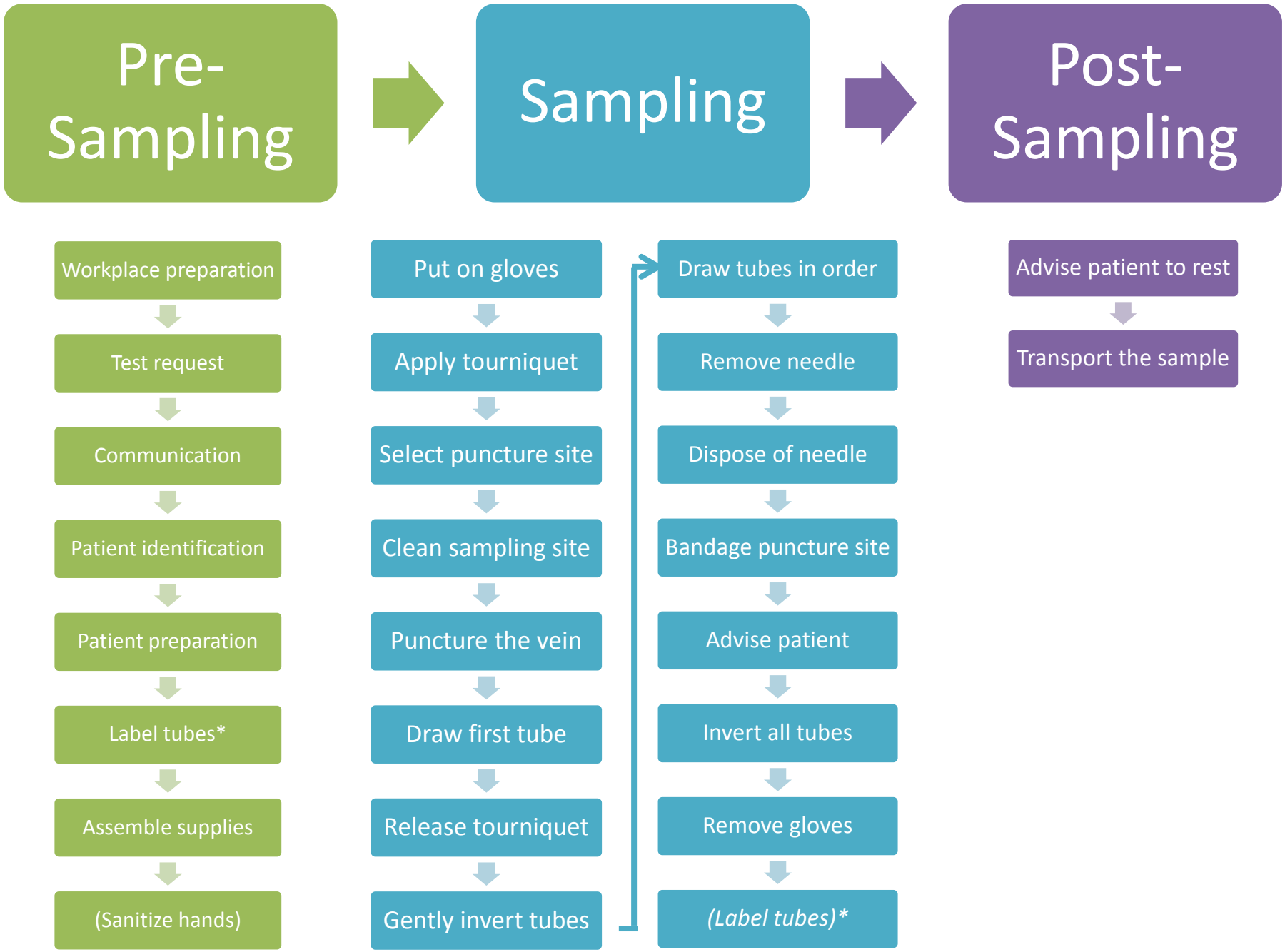
Patient is lying in his bed. Nurse arrives, asks the patient to sit upright in his bed, and draws one tube of blood. Serum proteins and cholesterol are requested.

Was it correct to ask the patient to sit upright?

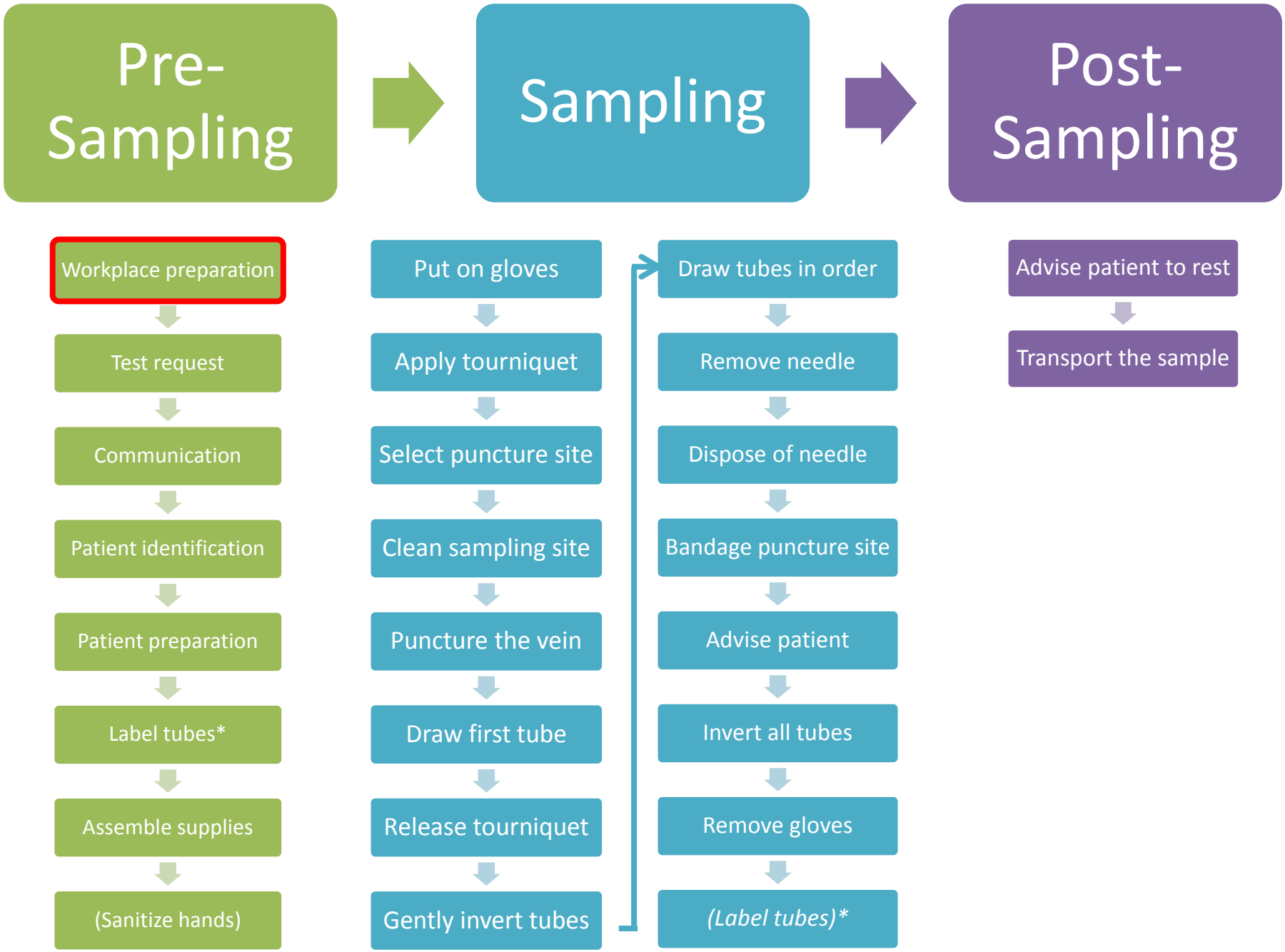
a) yes
b) no

EFLM-Guideline 2016

EFLM RECOMMENDED BLOOD COLLECTION PROCESS



* Depending on local risk assesment – see respective slide in this presentation



* Depending on local risk assesment – see respective slide in this presentation

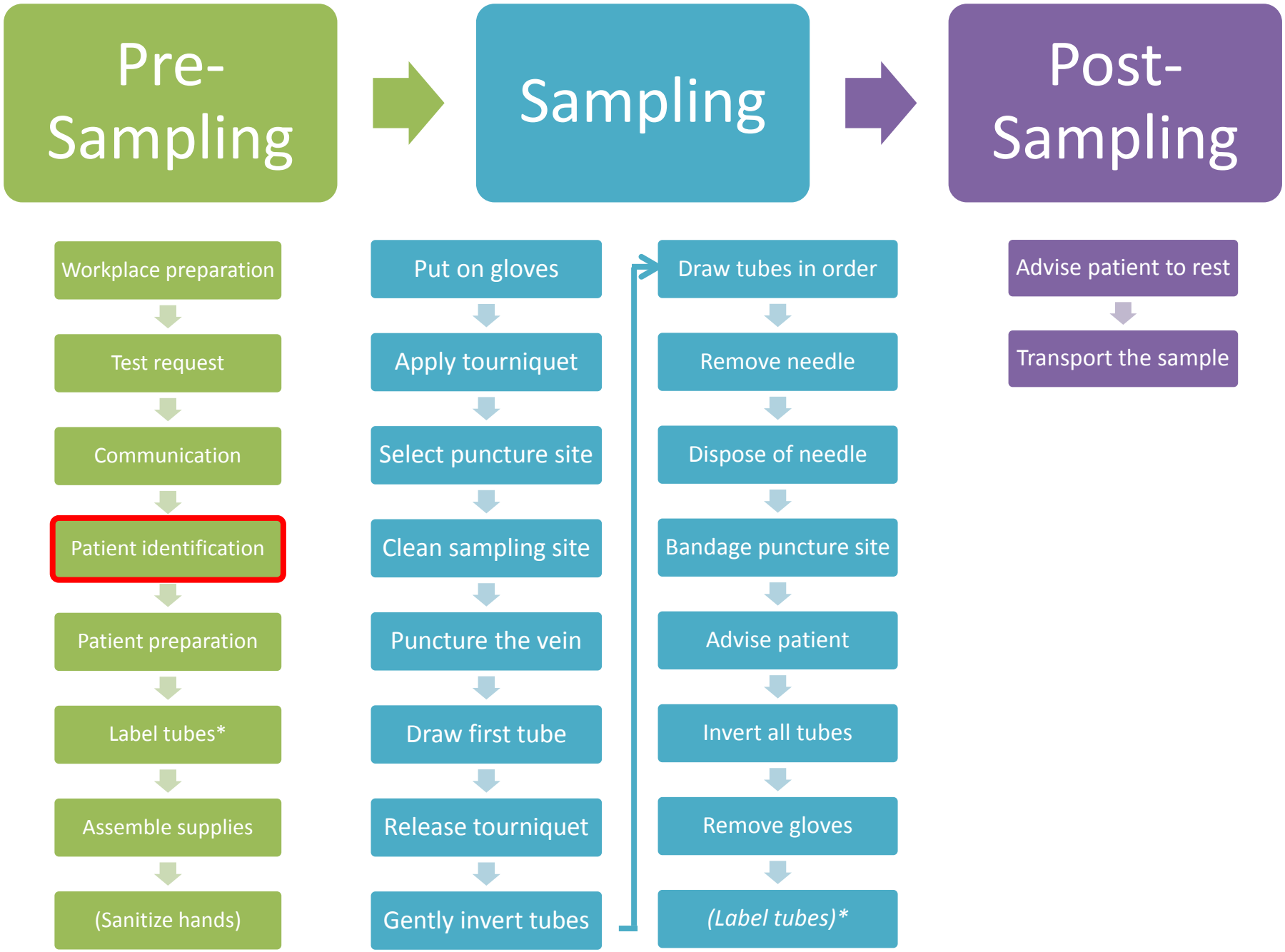
Workplace preparation

Ensure

- ✓ patient privacy
- ✓ continuous workflow
- ✓ undisturbed access to all necessary supplies.
- ✓ supplies within expiry date

Materials required

- ✓ blood collection tubes
- ✓ needles or winged blood collection sets with safety mechanism
- ✓ needle holders
- ✓ tourniquet
- ✓ gloves
- ✓ gauze pads, adhesive bandages, or tape
- ✓ puncture-resistant sharps container
- ✓ antiseptics: alcoholic and non-alcoholic disinfectants



* Depending on local risk assesment – see respective slide in this presentation

Patient Identification

ID errors are not rare!

- 0.1-1% in laboratory medicine
- 0.05% in transfusion medicine

Underreported (most go undetected)

Major healthcare issue

Potentially adverse consequences

ZERO TOLERANCE!

Any potentially mislabeled or misidentified specimen must and will be rejected.

Lippi G, et al. CCLM 2011;49(7):1113–1126

Patient Identification

At least two independent identifiers:

- ✓Patient full name (the first and the last name)
- ✓Date of birth

Preferably one additional identifier:

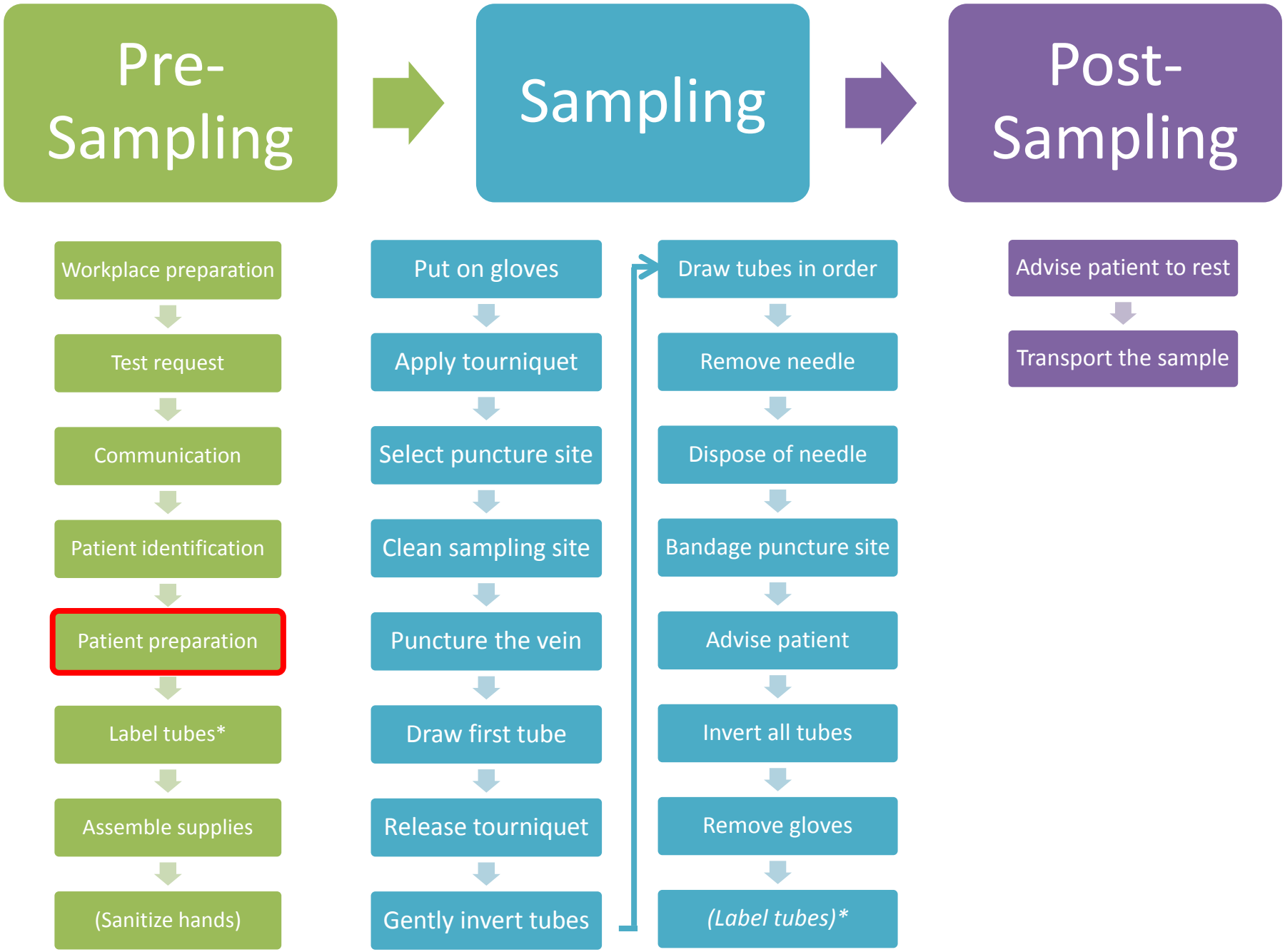
- ✓Address
- ✓Health insurance number
- ✓Patient identification number
- ✓ID card details or any other personal identifier

Use open questions: “What is your name?” and “What is your date of birth?”

Patient Identification

If any discrepancies are identified
do not collect samples
until issues are resolved!*

*Exceptions: Unconscious patients, Immigrants without ID number, etc.



* Depending on local risk assesment – see respective slide in this presentation

Patient preparation

Consider:

- Has the patient fasted
- Has the patient been involved in recent physical activity
- Patient positioning
- Patient medication / Infusion
- Time of day
- Test-specific requirements

Fasting

Blood for all tests should be drawn preferably in the morning from 7 to 9 a.m. after fasting

(before breakfast / medication)

Simundic AM et al. Clin Chim Acta 2014;432:33-7

Fasting

How long to wait before blood collection

Food and liquid (except water)	→	12 hours
Alcohol	→	24 hours
Smoking	→	Refrain on the day of blood sampling
Caffeine	→	

Special Situations: e.g.

Pineapple, Avocado, Banana, Kiwi, Tomato, etc → Serotonin ↑

Protein-rich meals → Homocysteine ↑

Simundic AM et al. Clin Chim Acta 2014;432:33-7 Nikolac N et al. Biochem Med 2013;23(3):242-54.

Fasting

Parameter	Relative Change 1-6h after standard meal
Triglycerides	10 – 21%
Total Cholesterol	1 – 8%
LDL Cholesterol	4 – 9%
HDL Cholesterol	0 – 6%

Nordestgaard BG et al.. Eur Heart J 2016.

Fasting

What to do if non-fasting blood collection is impossible?

Document that the patient was not fasting to guide later interpretation.

Kackov, S et al. Biochem Med 2013;23(3):326–31

Case #1
Result

7:30 a.m.

Patient arrives at the laboratory outpatient unit. His last meal was at 21:00 on the previous day. In the morning he had coffee with milk (without sugar) and one cigarette. Routine chemistry and hematology tests are requested.

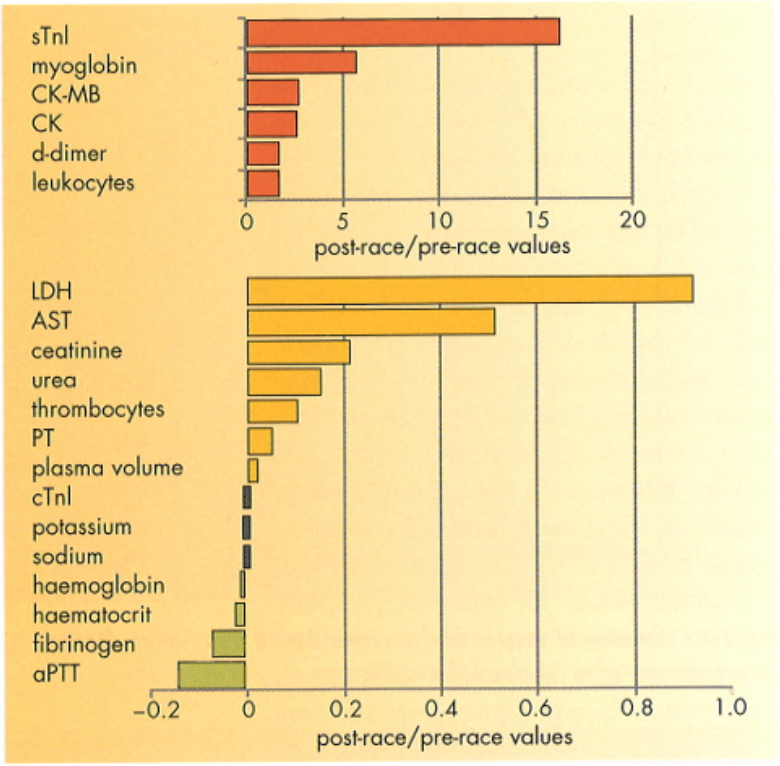
Is this patient properly prepared for blood tests?

a) Yes

b) No

Physical activity

Effects of marathon running



Even moderate exercise (e.g. running to the doctor's office) can influence laboratory parameters

Blood collected 1-3 days before and 1 hour after finishing the race

Guder WG, Narayanan S, Wisser H, Zawta B: Diagnostic Samples: From the Patient to the Laboratory, 4th ed.2009

What to ask the patient

When was your last meal?

When was your last drink?

What was it?

Have you performed any unusal physical activity in the last 24 hours?
(„Unusual“ for that specific patient)

Patient Positioning

Patient should be sitting in a comfortable chair with arms to provide support in case the patient faints

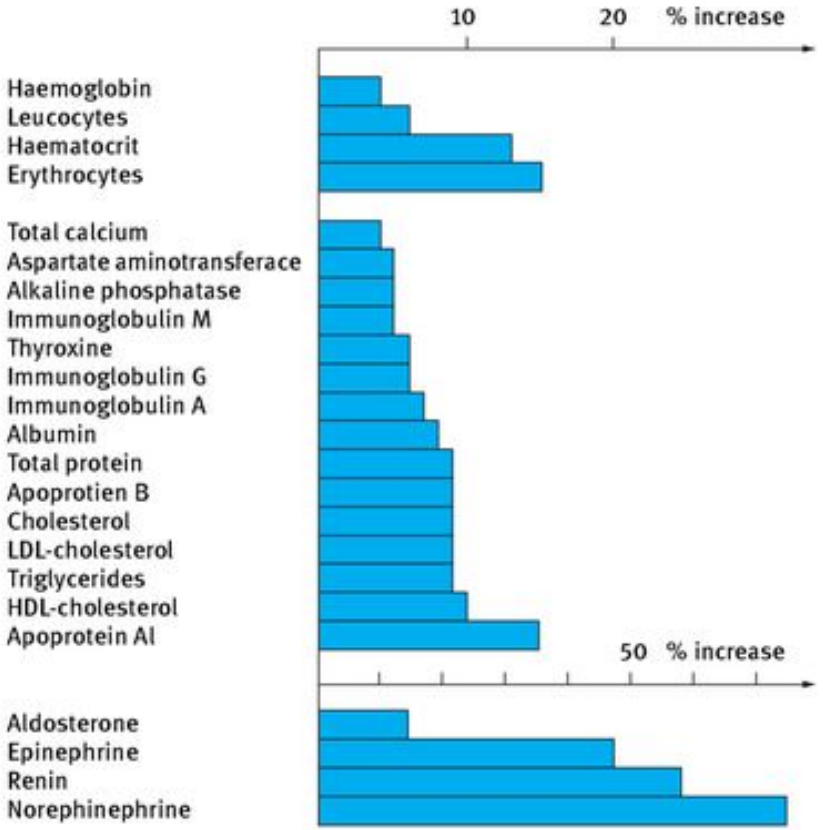
If necessary, patient may lie down

Do not change position before blood sampling!

(if possible)

Patient Positioning

Change from supine to upright position



Blood collection preferably after 15 minutes rest in one position

Guder WG, Narayanan S. Pre-Examination Procedures in Laboratory Diagnostics. 1st ed. DeGruyter, Berlin 2015

Case #2

7:00 a.m.

Patient is lying in his bed. Nurse arrives, asks the patient to sit upright in his bed, and draws one tube of blood. Serum proteins and cholesterol are requested.

Was it correct to ask the patient to sit upright?

a) yes

b) no

Medication / Infusion

Therapeutic drug monitoring

Always after steady state has been reached

Always document / inform the lab:

- WHAT (drug did the patient receive)?
- HOW MUCH (of the drug did the patient receive)?
- WHEN (was the last intake)?

Medication / Infusion

Many medications interfere (in-vivo / in-vitro) with laboratory tests.

Examples:

Medication	Parameter affected
Anticoagulant therapy	Coagulation testing
Aspirin	Platelet function
Supplements containing iron within the last 10 days	Iron
Insulin	Glucose
Levethyroxine	T4/fT4

If not avoidable: Blood collection immediately prior to taking the next dose of the drug including information on WHAT? / WHEN? / HOW MUCH?

Nikolac N et al. Biochem Med 2013;23(3):242-54.

Blood collection using an IV catheter

Whenever possible avoid drawing blood through an IV catheter.

Catheter collection can impact sample quality through the creation of significantly more hemolysis in samples, sample dilution and contamination of samples

If unavoidable only collect after from a newly inserted catheter, and ideally not after/during infusion, use manual aspiration technique or partial draw blood collection tubes*

*Partial draw tubes are tubes which are designed not be filled completely (e.g. 16x100mm / 4ml)

Medication / Infusion

Turn off any infusion before blood collection if possible

Blood collection always on the other arm or distal to the infusion site

Recommendation:

Infusion	Earliest time of blood sampling after infusion has been stopped
Lipid	8 hours
Glucose	1 hour
Electrolytes	1 hour
Protein	1 hour

Adapted from Guder W et al, Diagnostic Samples: From the Patient to the Laboratory, 4th ed.,Wiley-Blackwell, Weinheim, 2009

Medication / Infusion

Tab. 7-1 Infusions/transfusions as interfering factors and/or contaminants of laboratory diagnostic tests

Infusion/transfusion	Analyte affected	Trend	Comments, mechanism
Dextran	Thrombin time, reptilase time	↓	5–10 seconds slower
	von Willebrand factor	↓	
	Total protein in serum, plasma	↑	Biuret, method-dependent
			(turbidity, flocculation, greenish coloration)
	Urea, serum	↓	
	Blood grouping serology		Pseudoagglutination
γ-Globulin	Serological determinations during virus-mediated and bacterial infections		False positive
Electrolytes	Potassium, sodium, magnesium	↑	Contamination
Glucose	Glucose	↑	Contamination
Glucose	Inorganic phosphate, potassium,	↓	Insulin
	Amylase, bilirubin	↓	Up to 15%, particularly in neonates
Fructose	Uric acid	↑	Metabolic effect
Citrate (blood transfusion!)	pH value in blood	↓	
	Coagulation tests	↓↑	Inhibition

Guder WG, Narayanan S, Wisser H, Zawta B: Diagnostic Samples: From the Patient to the Laboratory, 4th ed.2009

Time of day

Blood for all tests should be drawn preferably in the morning from 7 to 9 a.m.

(before breakfast / medication)

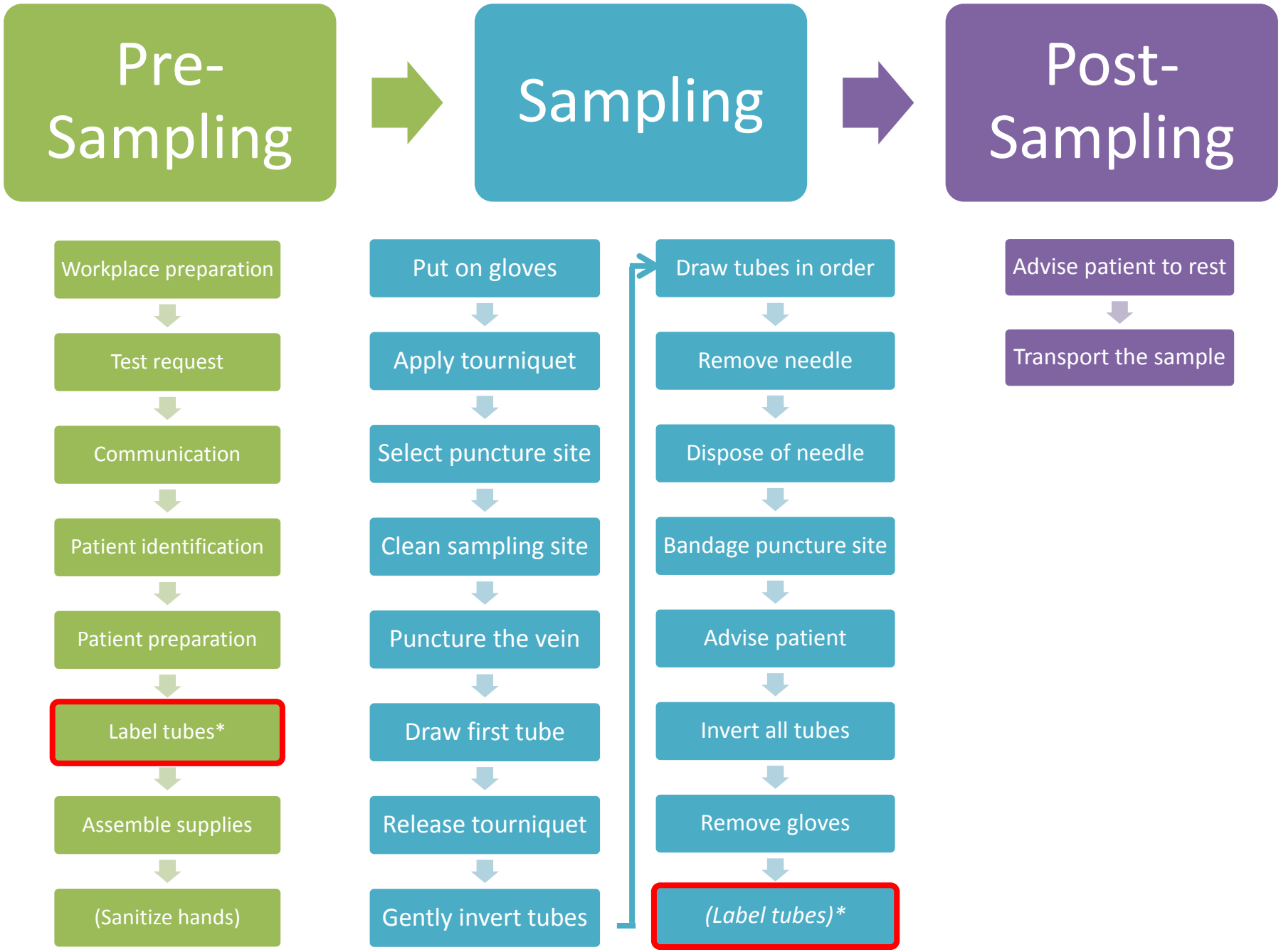
Time of day

Tab. 6-1 Diurnal variation of selected analytes (P = plasma; U = urine) (305)

Analytes	Maximum (time of day)	Minimum (time of day)	Amplitude (percentage of daily mean)	Analytes	Maximum (time of day)	Minimum (time of day)	Amplitude (percentage of daily mean)
ACTH	6–10	0–4	150–200	Norepinephrine (P,U)	9–12	2–5	50–120
Cortisol (P,U)	5–8	21–3	180–200	Haemoglobin	6–18	22–24	8–15
Testosterone	2–4	20–24	30–50	Eosinophils	4–6	18–20	30–40
TSH	20–2	7–13	5–15	Iron (P)	14–18	2–4	50–70
Thyroxine	8–12	23–3	10–20	Potassium (P)	14–16	23–1	5–10
Somatotropin	21–23*	1–21	300–400	Phosphate (P)	2–4	8–12	30–40
Prolactin	5–7	10–12	80–100	Sodium (U)	4–6	12–16	60–80
Aldosterone	2–4	12–14	60–80	Phosphate (U)	18–24	4–8	60–80
Renin	0–6	10–12	120–140	Volume (U)	2–6	12–16	60–80
Epinephrine (P)	9–12	2–5	30–50	Body temperature	18–20	5–7	0.8–1.0 °C

* Start of sleeping phase

Guder WG, Narayanan S, Wisser H, Zawta B: Diagnostic Samples: From the Patient to the Laboratory, 4th ed.2009



* Depending on local risk assesment – see respective slide in this presentation

Label tubes

Tube labelling or tube cross-identification must be done in the presence of the patient. Labelling before or after blood collection should be based on a prospective risk analysis of the blood collection process in each institution.

Tube information should <u>at least</u> contain:

- Patient first and last name
- Date of birth
- ID number

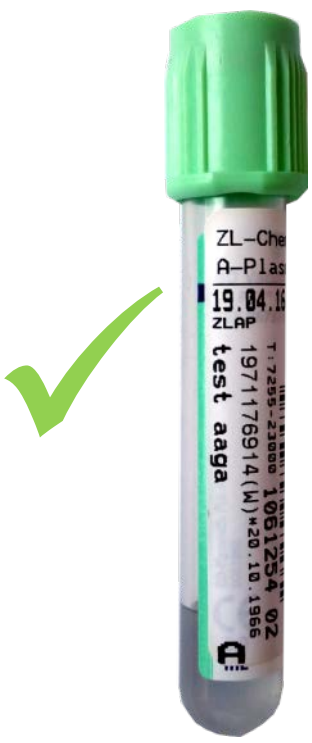
Preferable additional information on the tube:

- Date
- Time (if necessary, e.g. for TDM)
- ID of the phlebotomist
  (or there should be a mechanism to identify a phlebotomist)

If this information is not printed directly on the label, a mechanism must be in place to identify this information for example through IT systems (e.g. laboratory/hospital information systems)

Label tubes

- ✓ Visible fill line
- ✓ Labelled straight vertically
- ✓ Labelled high



Labelled too low

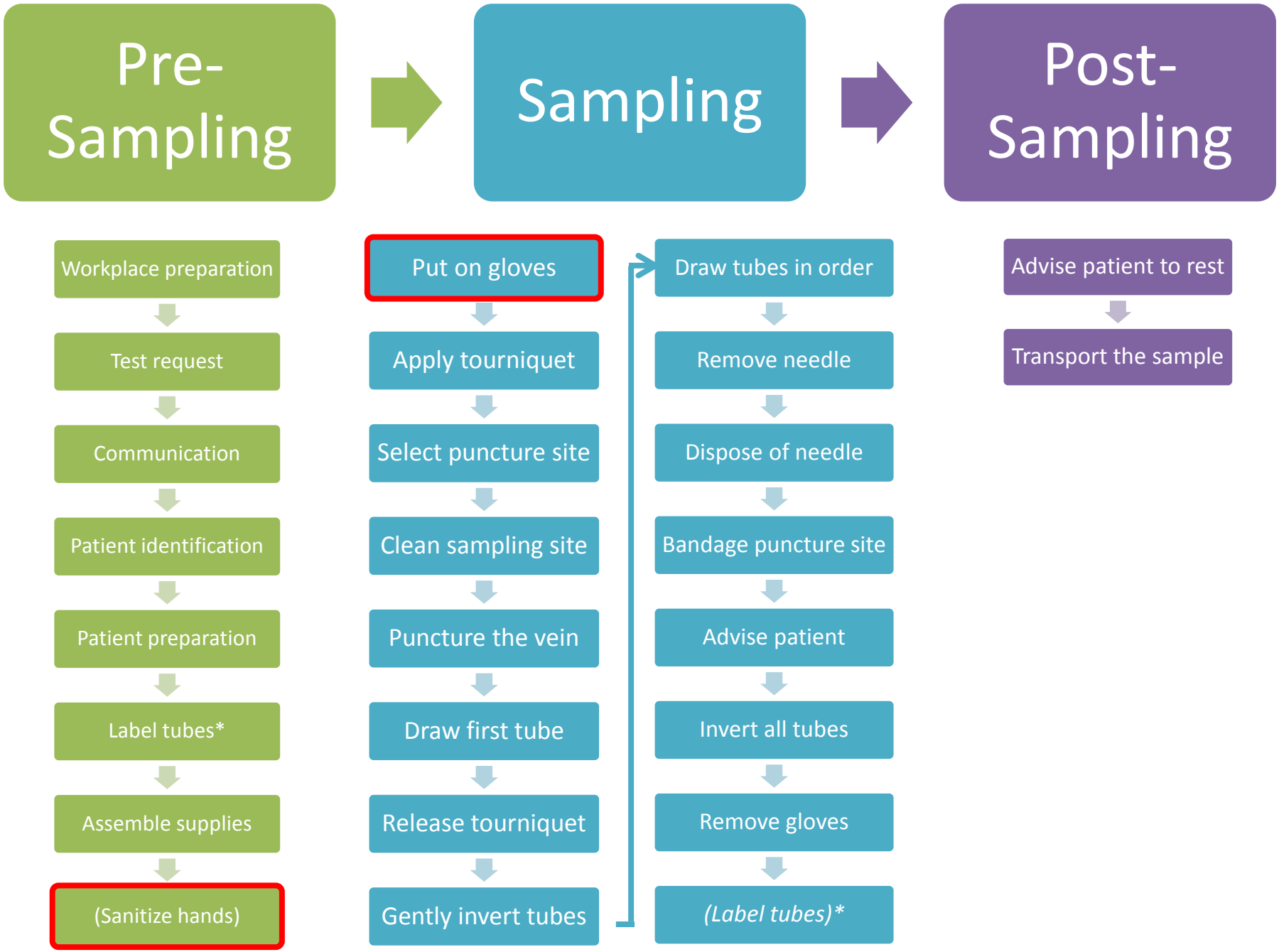
Labelled horizontally

Labelled all around
(Fill line not visible)

Labelled askew

Label tubes

Avoid contact of the label with disinfectant



* Depending on local risk assesment – see respective slide in this presentation

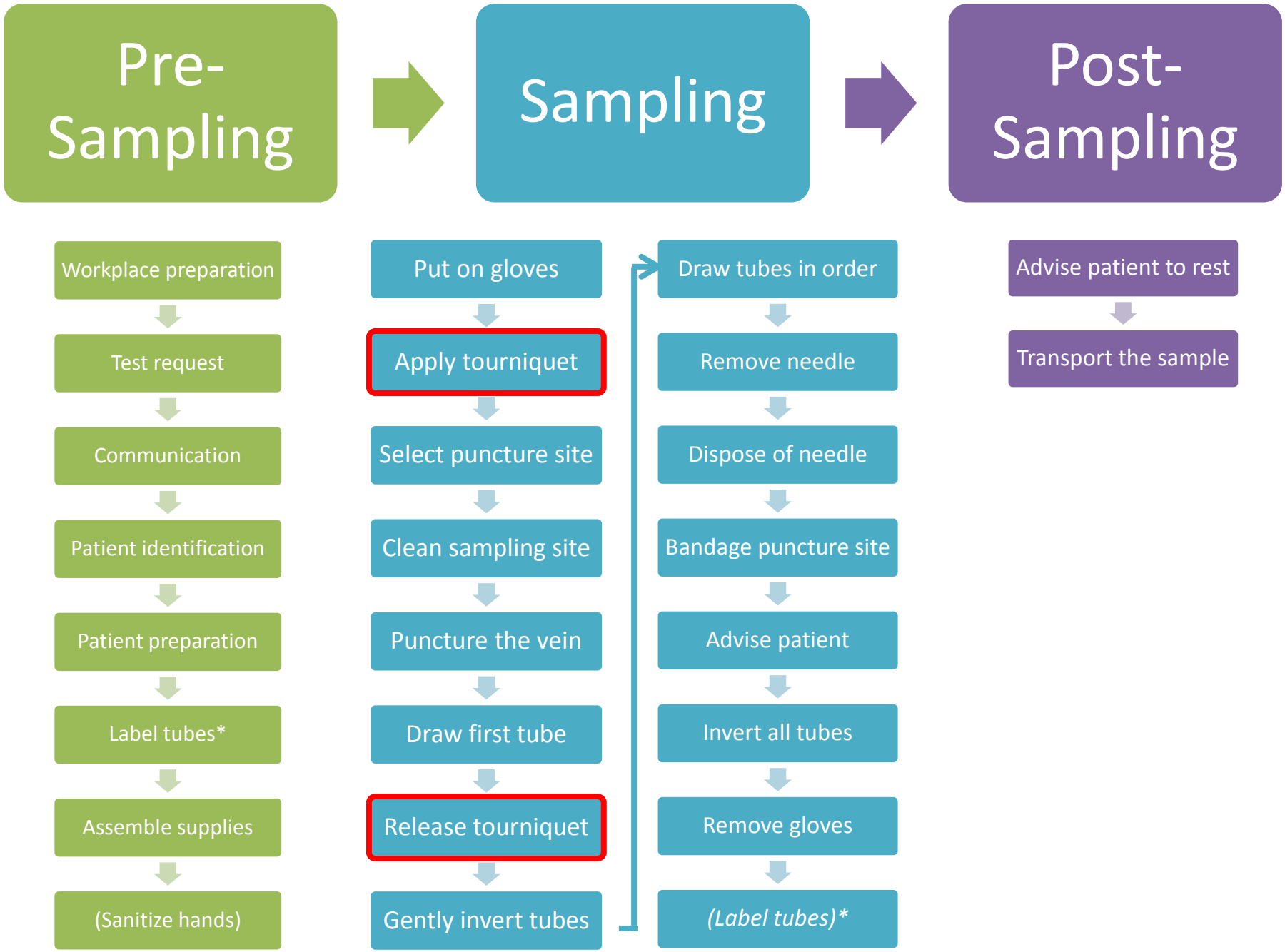
Put on gloves / Sanitize hands

Cleaning of hands in front of patients is also important in reassuring a patient.

To minimize blood stasis it is recommended putting on gloves prior to tourniquet application.

Always use a new pair of gloves for each patient.

Lima-Oliveira G, et al. Biochemia Medica 2012;22(3):342-51.



* Depending on local risk assesment – see respective slide in this presentation

Apply tourniquet

Apply tourniquet only if necessary.

EFLM-recommendation: Collect blood without tourniquet whenever possible.

Try to minimize the use of a tourniquet for the following collections:

- lactate
- ammonia
- albumin
- calcium

Tourniquets are a source of MRSA

(Through poor hand hygiene. Therefore use single-use devices!)

Apply tourniquet

When using a tourniquet:

7 - 10 cm (4–5 finger width) proximal to the puncture site

Release ≤ 1 minute (If > 1 minute, release and reapply after 2 min)

Pumping (fist clenching) should not be done!

Apply tourniquet

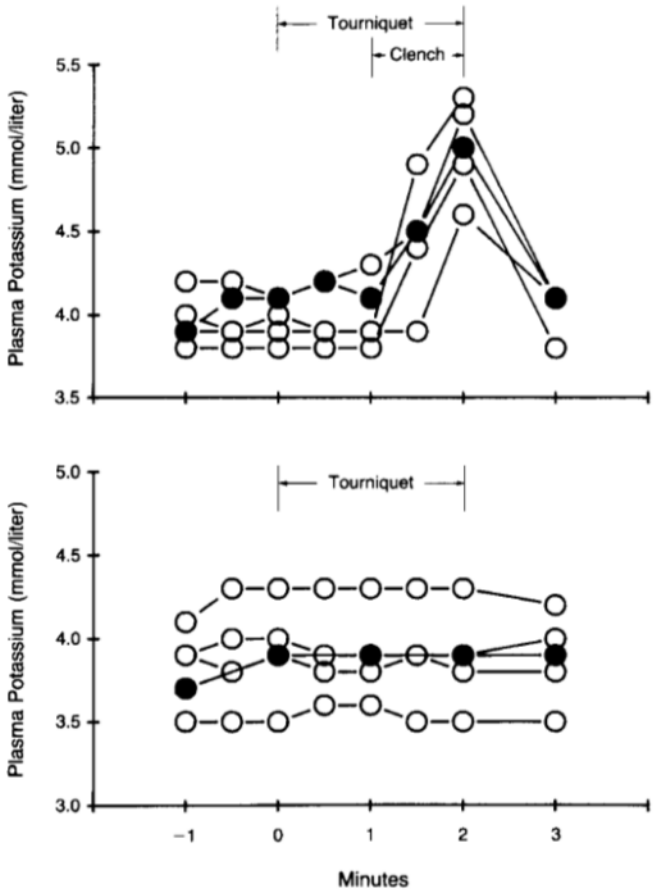


Figure 1. Effects of the Application of a Tourniquet plus Fist Clenching (Upper Panel) and Tourniquet Alone (Lower Panel) on Plasma Potassium Concentrations.

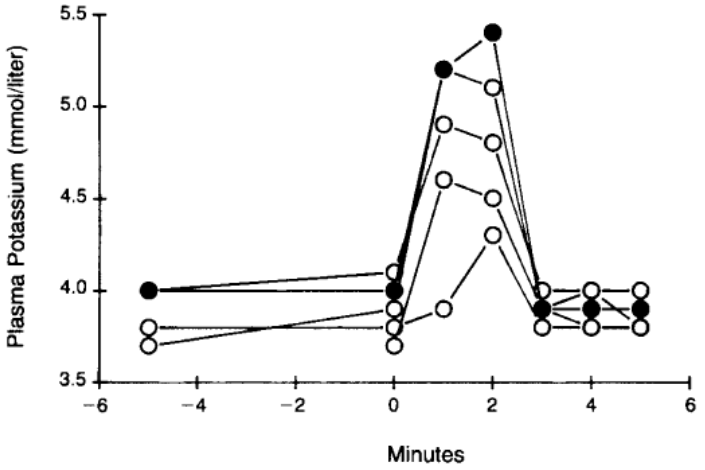


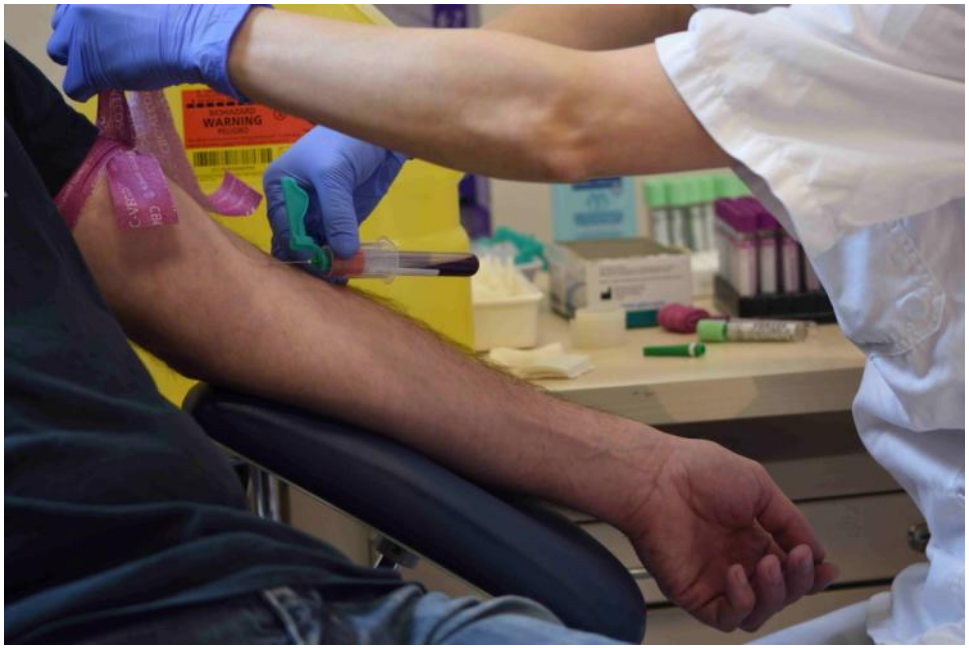
Figure 2. Effect of Handgrip Exercise on Plasma Potassium Concentrations.

Fist clenching leads to an increase in **potassium** !!

Don BR et al. N Engl J Med 1990;322(18):1290-2.

Release Tourniquet

As soon as possible after the blood begins to flow into tube

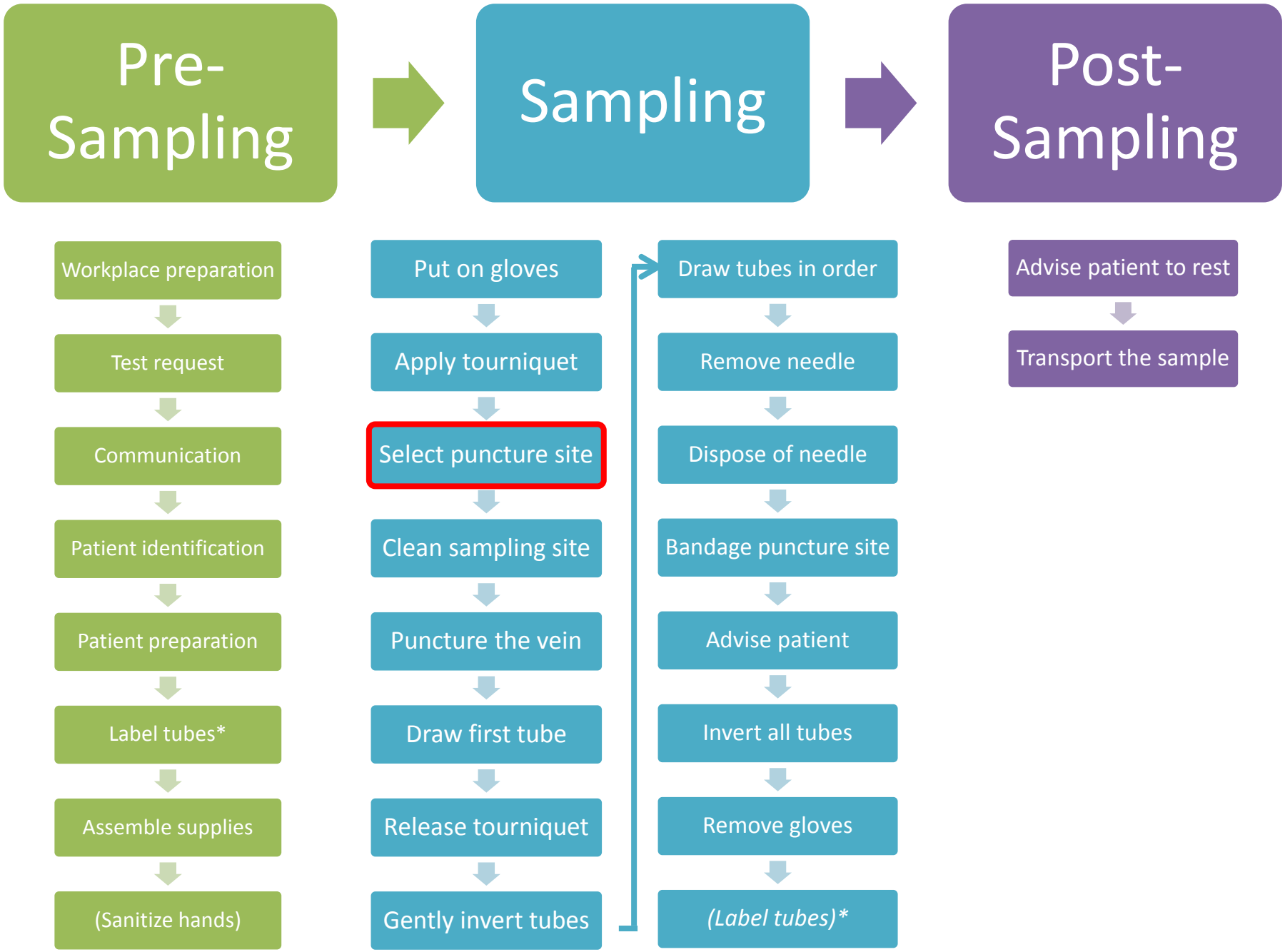


Helpful tools

Vein illumination device

for better vizualisation of the veins

Vein Viewer® Flex – Greiner BioOne



* Depending on local risk assesment – see respective slide in this presentation

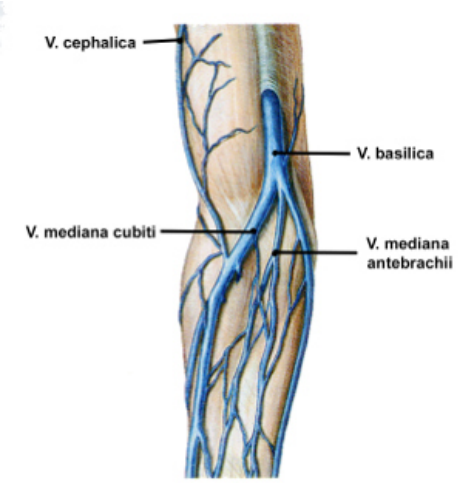
Select a puncture site

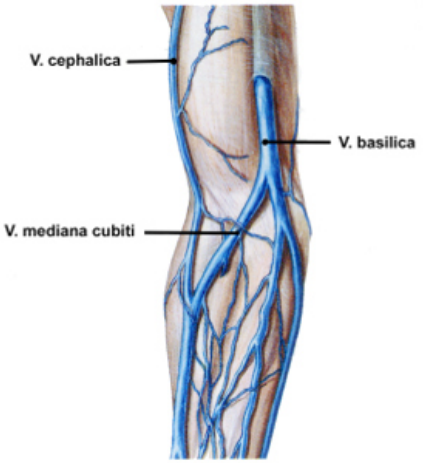
Selecting the best vein for venipuncture is important:

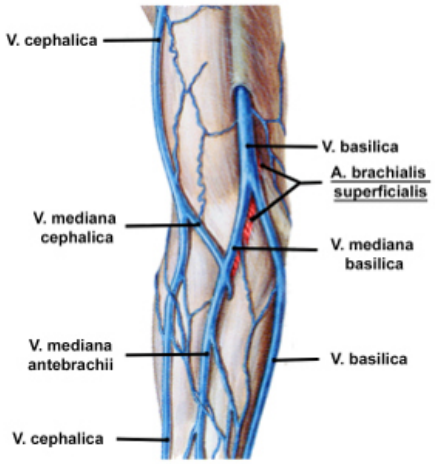
- sample quality,
- patient satisfaction,
- to avoid nerve damage,
- to avoid arterial puncture,
- ease and speed of collection

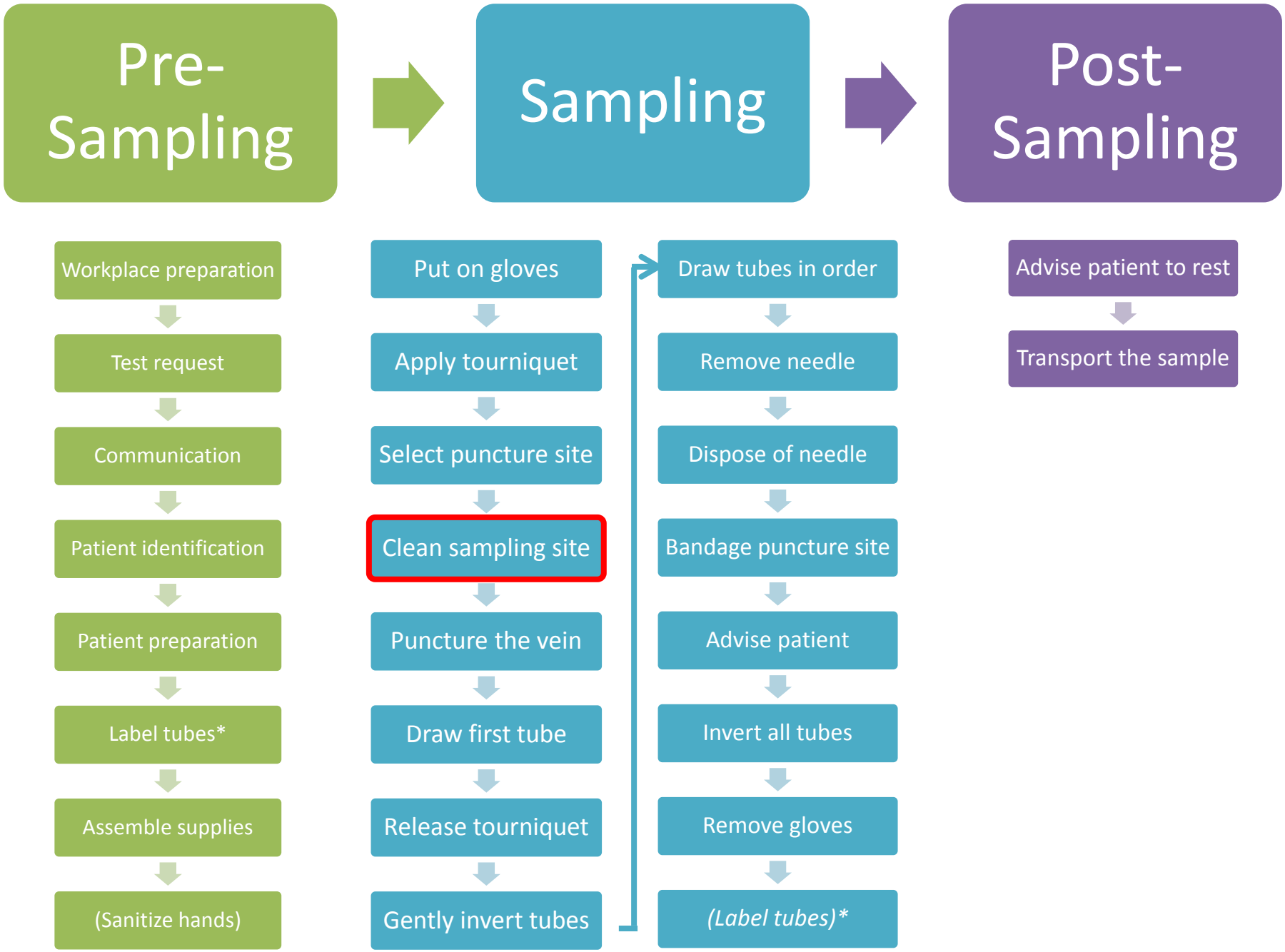
Do not collect blood from:

- previously placed peripheral venous catheters
- indurated veins
- paretic arm
- arms with lymphatic drain disorders









* Depending on local risk assesment – see respective slide in this presentation

Clean sampling site

CLSI GP41-A7 guideline recommends that the puncture site must be cleaned to prevent contamination of a patient or a sample

- Use 70% ethyl alcohol
- For blood culture collection let alcohol dry for a minimum of 60 seconds
- When collecting a sample for alcohol concentration measurements, the use a non-alcoholic disinfectant is preferable.

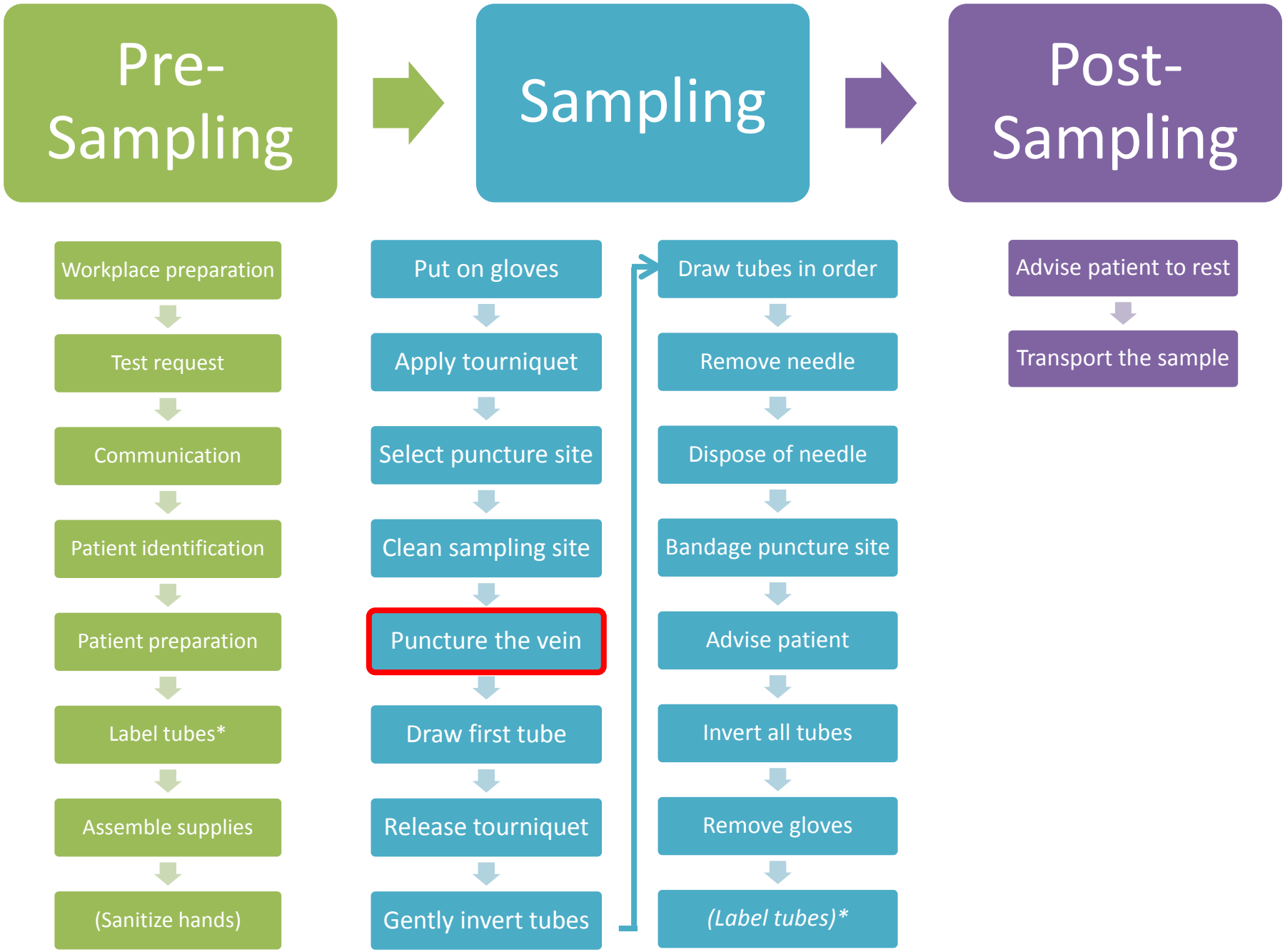
Lippi G et al. Biochem Med 2017; 27(2):398-403

Clean site with on wipe and let it dry.

- ~~To prevent hemolysis~~
- To prevent patient experiencing a burning sensation during puncture
- To allow the alcohol to sterilise the puncture site

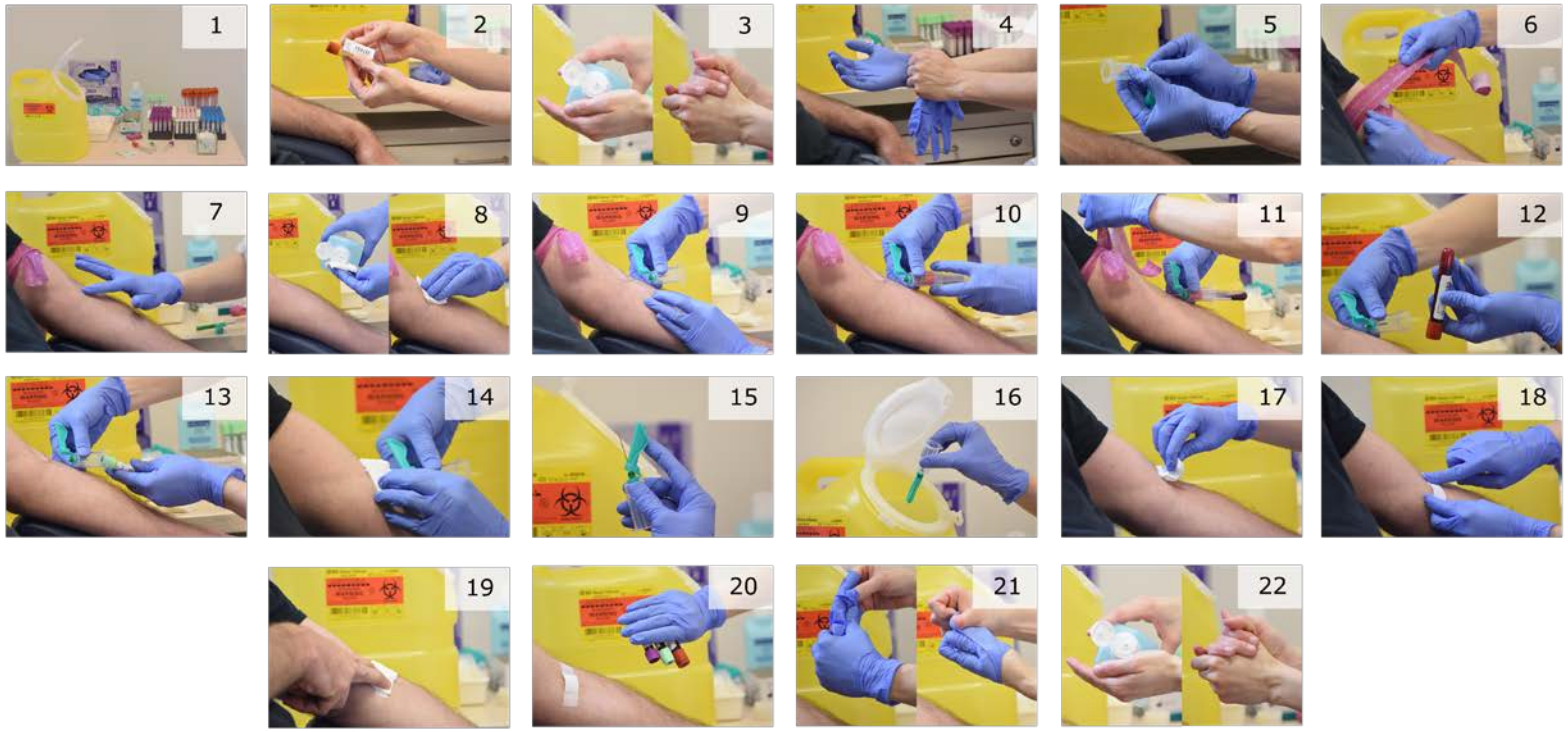
Failure to let alcohol dry is not associated with sample hemolysis !

Salvagno GL et al. Biochem Med 2013;23(2):201-5.



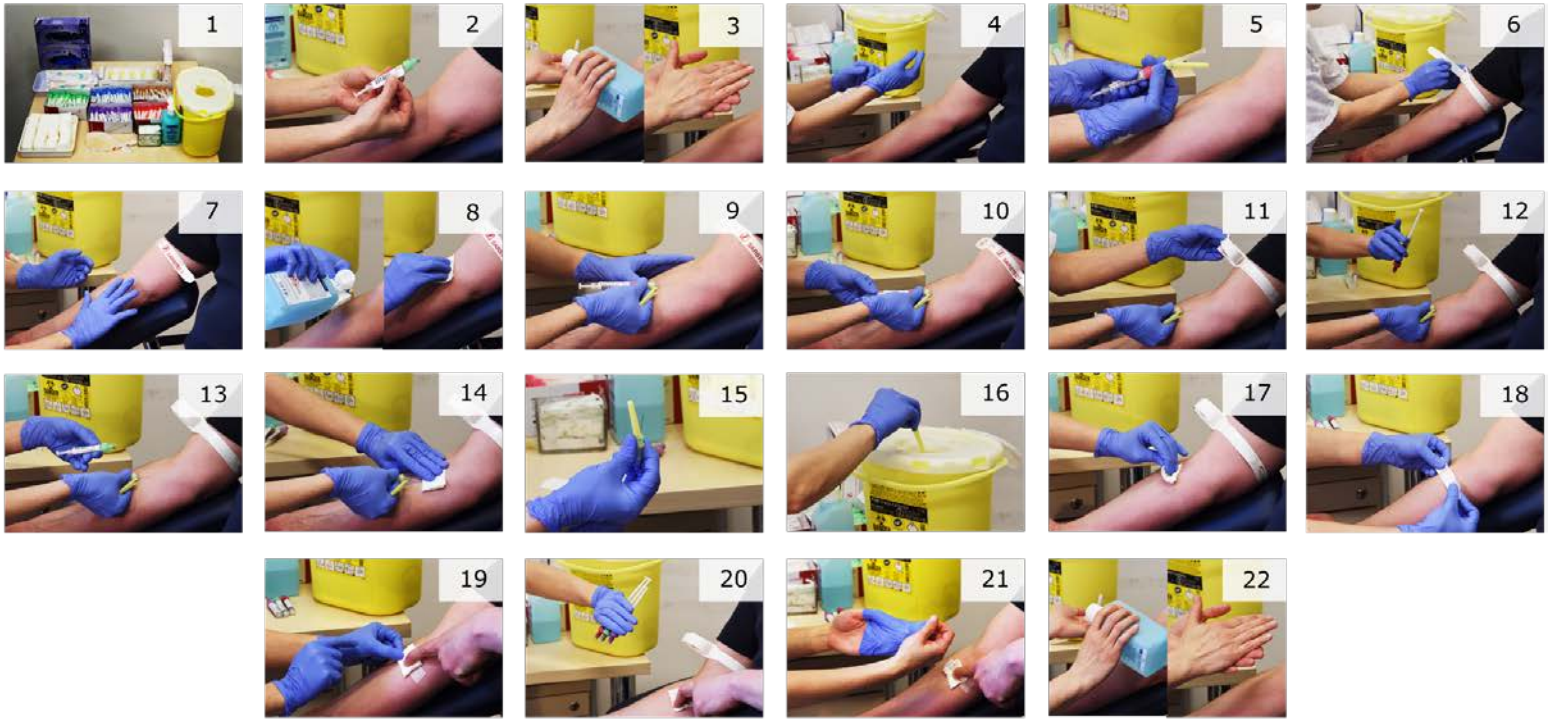
* Depending on local risk assesment – see respective slide in this presentation

Puncture the vein - Vacuum System



1 Ensure appropriate conditions and supplies required for phlebotomy
2 Label and/or identify tubes
3 Clean hands in front of the patient
4 Put on gloves
5 Assemble appliances
6 Apply tourniquet
7 Select venepuncture site
8 Clean sampling site
9 Puncture the vein
10 Draw first tube
11 Release the tourniquet as soon as the blood flows into the first tube
12 Gently invert the tubes 1 time immediately after collection
13 Draw additional tubes following order of draw
14 Remove needle from the vein
15 Activate safety mechanism
16 Dispose of the needle
17 Ensure the bleeding has stopped
18 Treat the puncture wound
19 Tell a patient to apply a pressure on the wound
20 Invert all tubes 4 times
21 Remove gloves
22 Clean hands

Puncture the vein - Aspiration System



1 Ensure appropriate conditions and supplies required for phlebotomy
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6 Apply tourniquet
7 Select venepuncture site
8 Clean sampling site
9 Puncture the vein
10 Draw first tube
11 Release the tourniquet as soon as the blood flows into the first tube
12 Gently invert the tubes 1 time immediately after collection
13 Draw additional tubes following order of draw
14 Remove needle from the vein
15 Activate safety mechanism
16 Dispose of the needle
17 Ensure the bleeding has stopped
18 Treat the puncture wound
19 Tell a patient to apply a pressure on the wound
20 Invert all tubes 4 times
21 Remove gloves
22 Clean hands

Puncture the vein

Puncture the vein with the bevel up, as it minimizes the pain and reduces the risk of perforation of the back wall of the vein

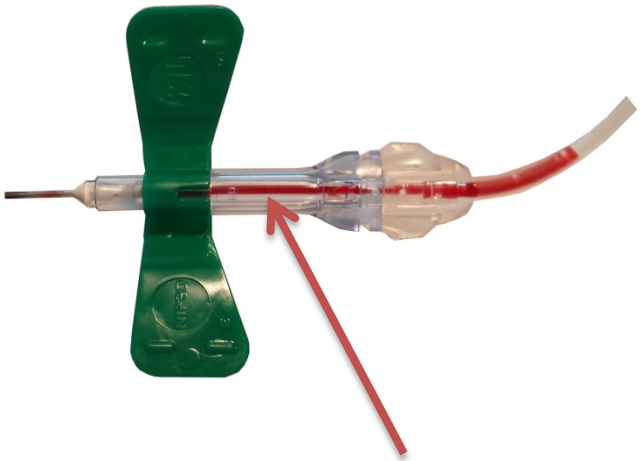
If the first blood collection attempt is unsuccessful, the second attempt should be made on the other arm.

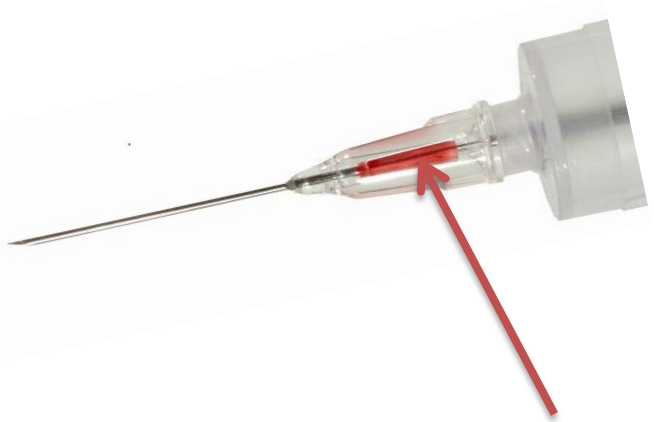
If a third attempt should be necessary, it should be performed distal to the previous puncture sites. Also consider calling a more experienced colleague.

Helpful tools

Sharps device with flash visualisation

Needle & wingsets are available that either through design or as part of the method of operation that will provide a visible flash indication when the needle has penetrated the vein





Blood borne pathogens

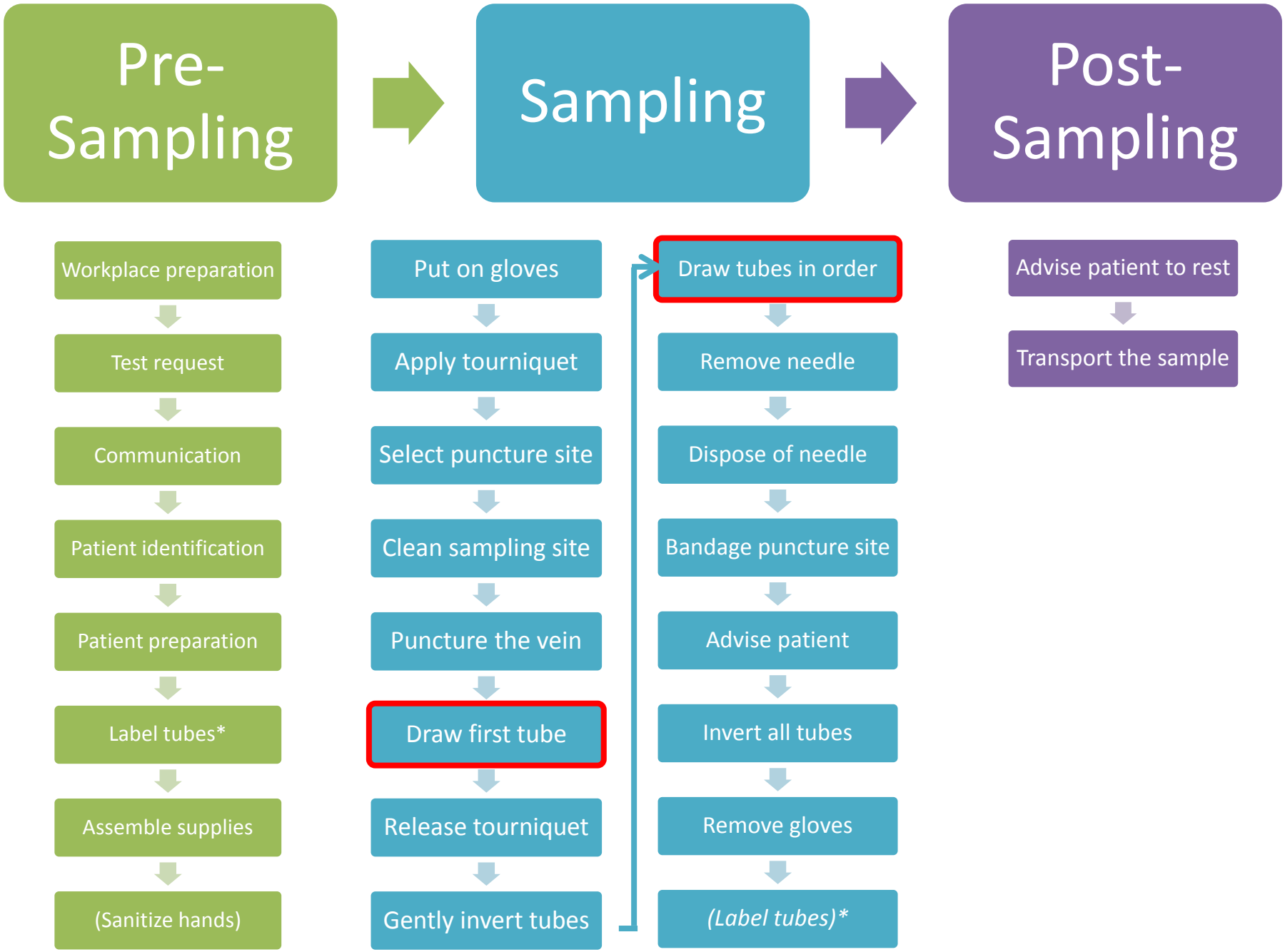
Possible transmission of a variety of pathogens including HIV, Hepatitis B + C, and other

Use medical devices incorporating a safety-engineered protection mechanism

Place effective disposal procedures and clearly marked and technically safe sharps containers

Use Personal Protective Equipment (Gloves)

NEVER recap a used needle



* Depending on local risk assesment – see respective slide in this presentation

Case #3

Nurse needs to draw EDTA, serum and citrate tubes from a patient. Which is the correct order of draw?

a) Coagulation (citrate) > EDTA > Serum
b) EDTA > Coagulation (citrate) > Serum
c) Coagulation (citrate) > Serum > EDTA
d) The order of draw does not matter. It is not important.

Order of draw

Important to:

- assure sample quality
- avoid cross-contamination of additives between tubes

Evidence shows that it occurs and may affect the quality of results

Cornes MP et al. Clin Chem Lab Med 2013; 51:e285 - e285.

Order of draw

Coagulation tube as first tube?

When using a winged safety blood collection set, a discard tube must be used to prevent underfilling.

No discard tube is needed when straight needles are used for blood collection.

Image with kind permission of Greiner Bio-One©

Order of draw

EFLM WG-PRE Recommendation

In agreement with ISO 6710:1995 Preview
Single-use containers for venous blood specimen collection

Blood culture	
Citrate tube	ESR*
Serum tube with or without barrier	
Heparin tubes with or without barrier	
EDTA tubes	
Glucose tubes	
Other tubes (e.g. trace elements)	

Cap colors in your hospital might differ, please refer to your laboratory

*Erythrocyte sedimentation rate

Case #3

Nurse needs to draw EDTA, serum and citrate tubes from a patient. Which is the correct order of draw?

a) Coagulation (citrate) > EDTA > Serum
b) EDTA > Coagulation (citrate) > Serum
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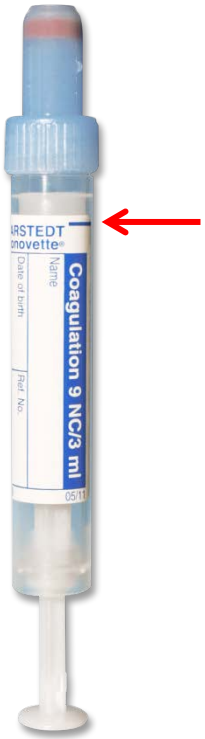
d) The order of draw does not matter. It is not important.

Tube filling



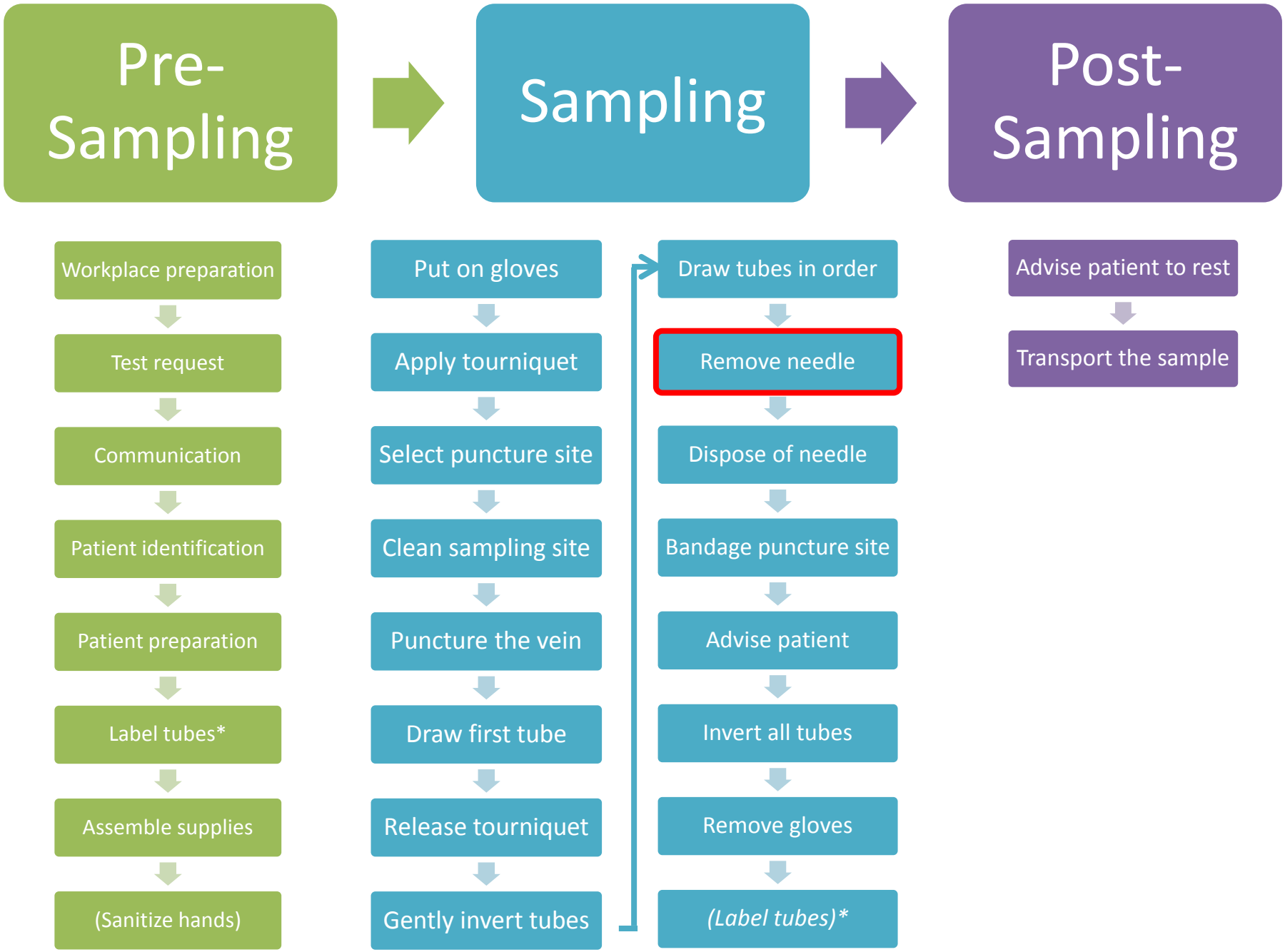
Consequence of underfilled coagulation tube:

Too much citrate per ml blood
→ Incorrect coagulation results

Even slightly underfilled tubes may lead to erroneous coagulation results

Tube filling

Never transfer blood from a syringe or another blood collection tube !!!!



* Depending on local risk assesment – see respective slide in this presentation

Remove needle from the vein

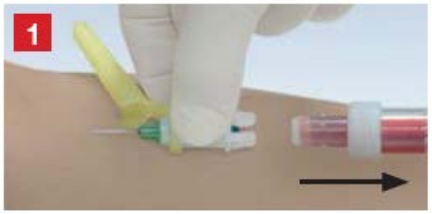
1. After disconnecting the last tube place a gauze on the venipuncture area, without applying pressure.

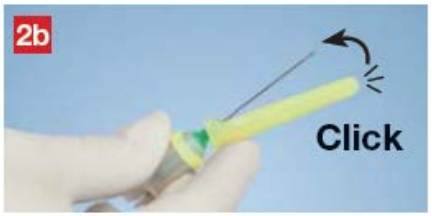
2. Gently remove the needle and immediately activate the safety mechanism

3. Apply pressure to the puncture site with the gauze to prevent bleeding

Activate Safety Device and dispose needle

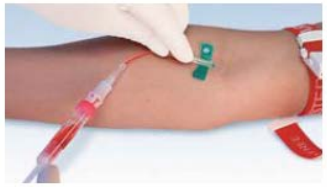
Aspiration system

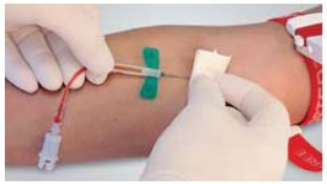


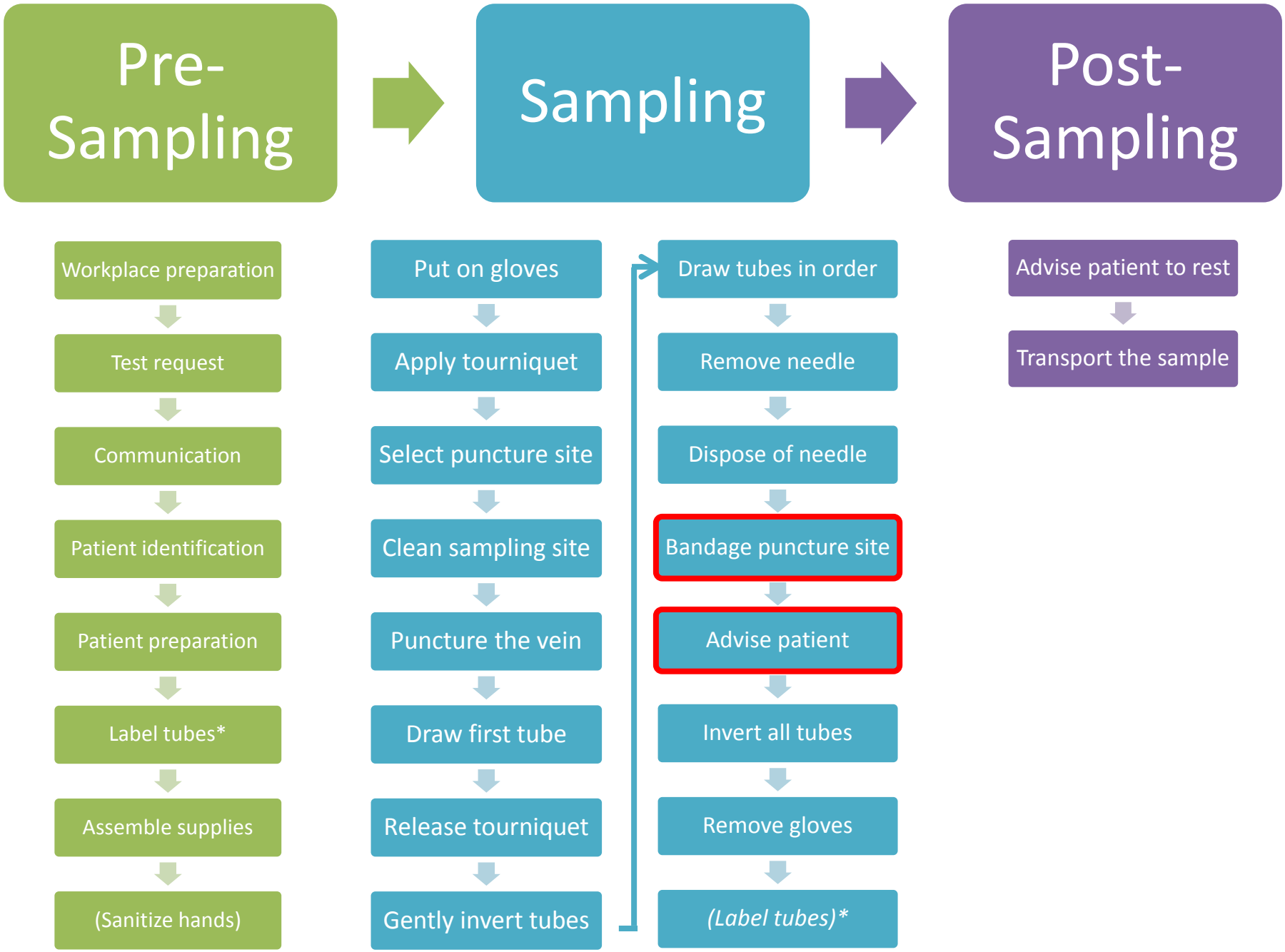


Evacuated blood collection system

Butterfly



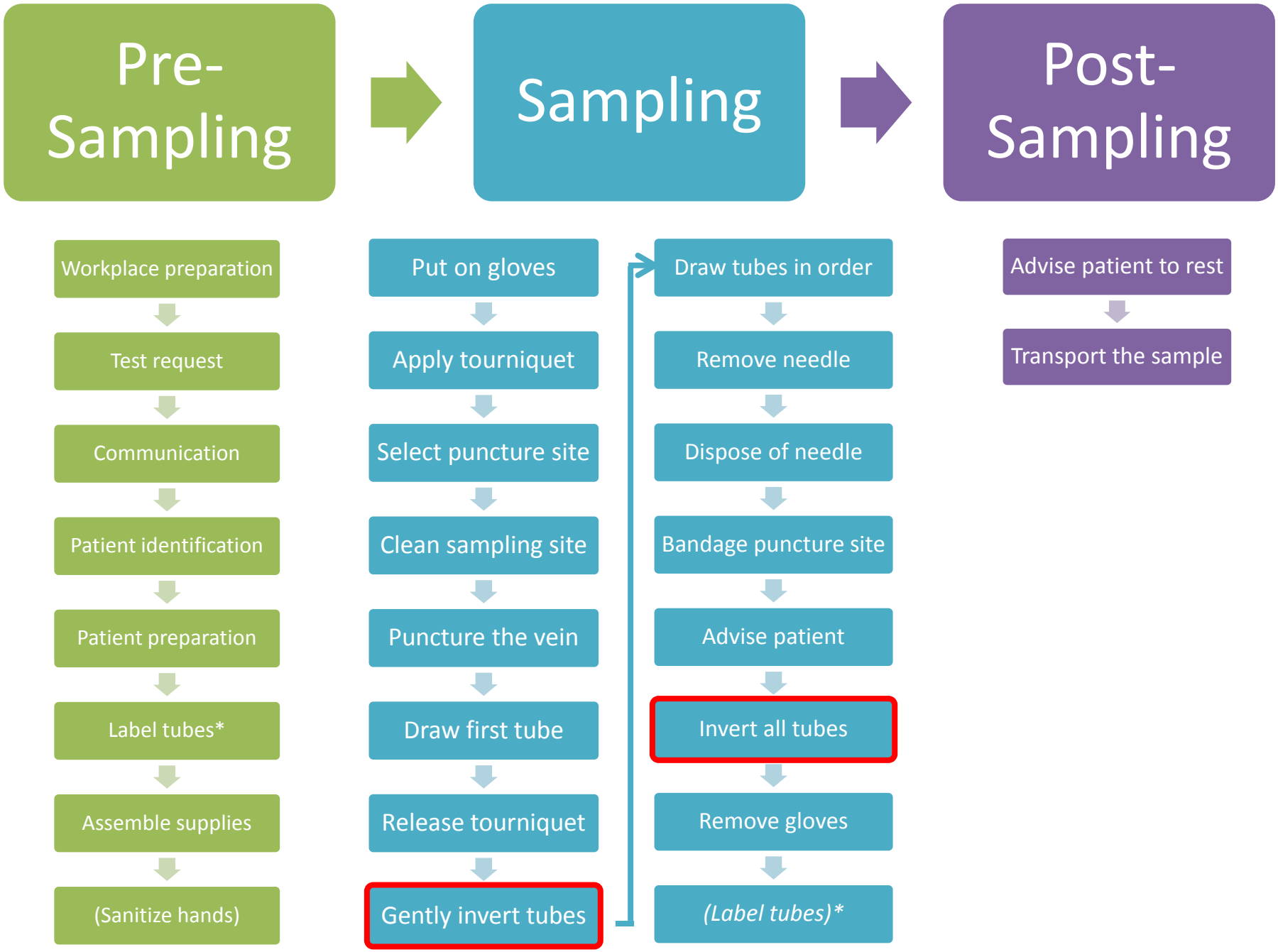




* Depending on local risk assesment – see respective slide in this presentation

Bandage puncture site and advise Patient

- **Check** that the **bleeding has stopped**. **Apply** an adhesive bandage securely over a dry pad/gauze square.
- Ask the patient to apply pressure for at least 2 minutes for routine draws and up to 10 minutes for patients on anticoagulation.
- If cephalic basilic vein is used, ask the patient not to bend the arm



* Depending on local risk assesment – see respective slide in this presentation

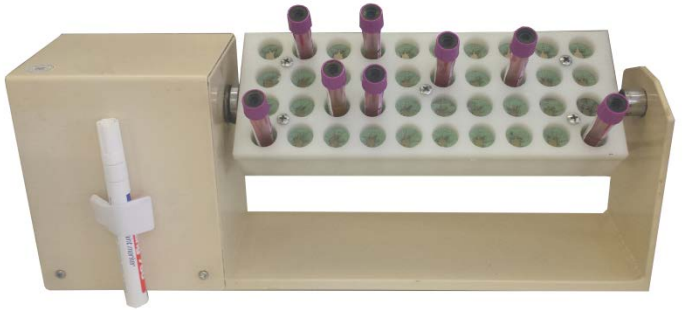
Invert tubes

Blood must be mixed with anticoagulant

Invert tubes gently 1x directly after collection *and*

4x after collection of all tubes

If only one tube is collected, invert 5 x directly after collection.



No mixing → Risk of clotted sample and latent clotting in serum samples

Do NOT shake the sample → sample hemolysis !

Sample hemolysis

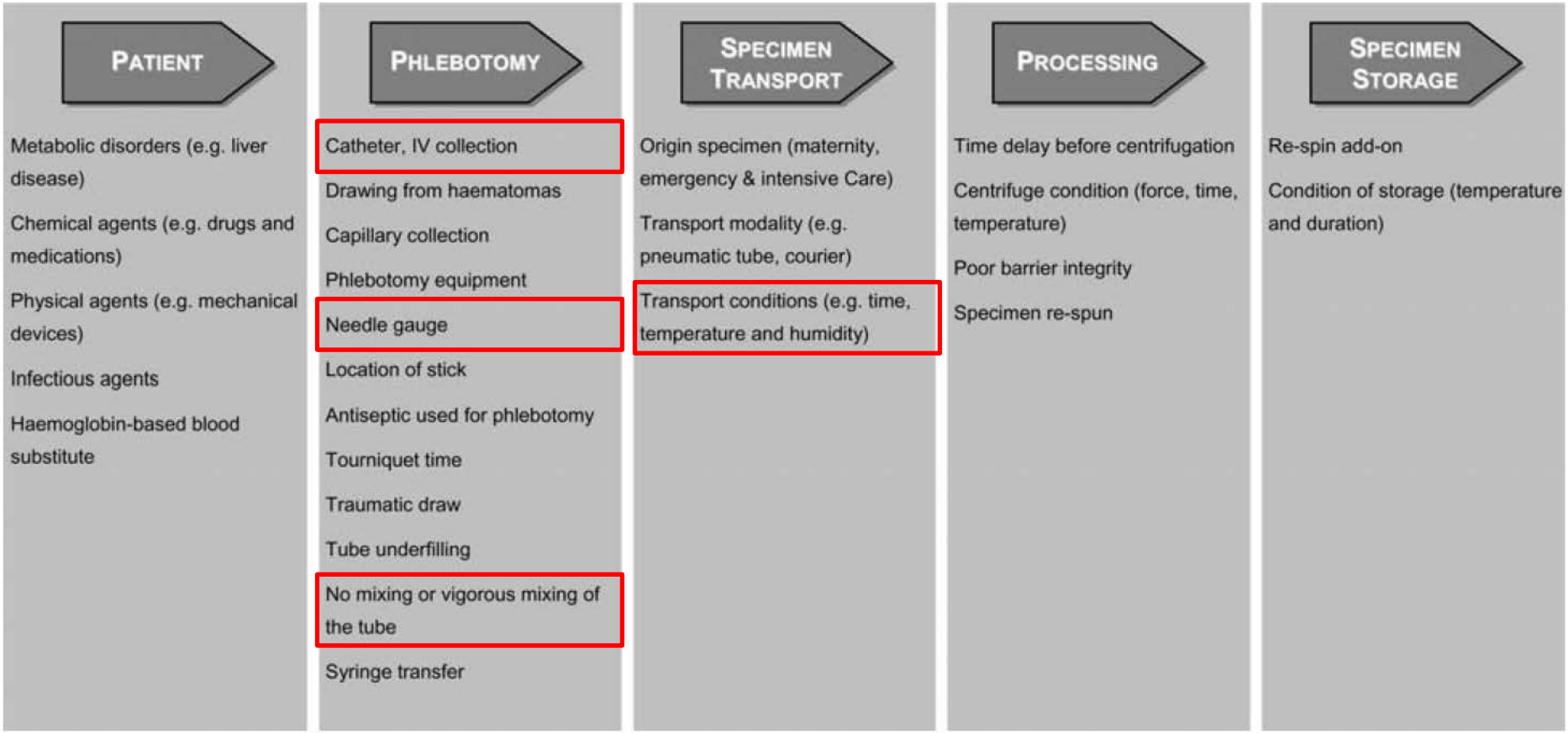


Figure 1 Major causes of haemolytic specimens in clinical laboratories (European Preanalytical Scientific Committee, EPSC. Available at: www.specimencare.com).

Lippi G, et al. Clin Chem Lab Med 2008; 46:764-772.

Sample hemolysis

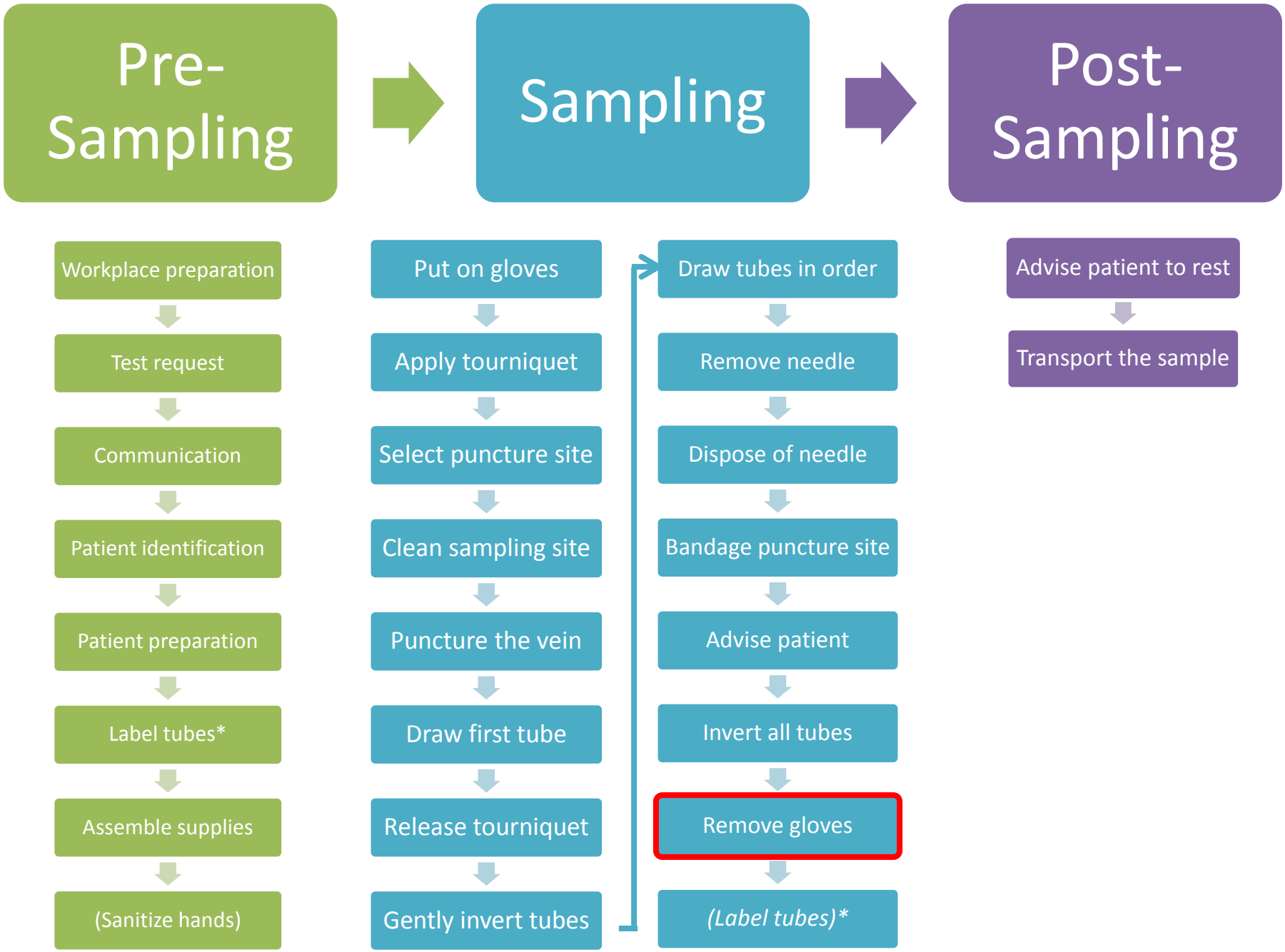
Consequences

- Interference with chromatic measurements
- Release of intracellular components after erythrocyte rupture

Table 1 Laboratory parameters affected by haemolysis and/or blood cell lysis in the specimen.

Parameter	Bias	Cause
Adrenocorticotropic hormone	Negative	Proteolysis
Activated partial thromboplastin time	Negative	Release of thromboplastic substances
Antithrombin	Negative	Analytical interference
Aspartate aminotransferase	Positive	Cellular release
Alanine aminotransferase	Positive	Cellular release
Albumin	Negative	Dilution
Alkaline phosphatase	Negative	Analytical interference
Bilirubin (neonatal)	Variable	Analytical interference
Bilirubin (total)	Negative	Analytical interference
Calcitonine	Positive	Proteolysis
Chloride	Negative	Dilution
Cortisol	Negative	Analytical interference
Creatine kinase	Positive	Analytical interference
Creatinine	Positive	Analytical interference
D-dimer	Positive	Release of thromboplastic substances
Fibrinogen	Negative	Release of thromboplastic substances
Folate	Positive	Cellular release
γ-Glutamyltransferase	Negative	Analytical interference
Gastrin	Negative	Proteolysis
Glucagon	Negative	Proteolysis
Glucose	Negative	Dilution
Haptoglobin	Negative	Analytical interference
Homocysteine	Negative	Analytical interference
Insulin	Negative	Proteolysis
Iron	Positive	Analytical interference
Lactate dehydrogenase	Positive	Cellular release
Lipase	Positive	Analytical interference
Magnesium	Positive	Cellular release
Parathormon	Negative	Proteolysis
Phosphorus	Positive	Cellular release
Potassium	Positive	Cellular release
Prostate specific antigen	Positive	Analytical interference
Prothrombin time	Positive	Release of thromboplastic substances
Sodium	Negative	Dilution
Urea	Positive	Cellular release
Testosterone	Negative	Analytical interference
Troponin I	Positive	Analytical interference
Troponin T	Negative	Analytical interference
Vitamin B12	Negative	Analytical interference

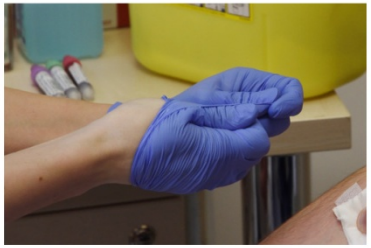
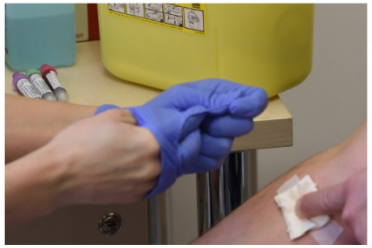
Lippi G, et al. Clin Chem Lab Med 2008; 46:764-772.



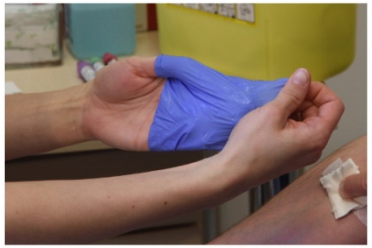
* Depending on local risk assesment – see respective slide in this presentation

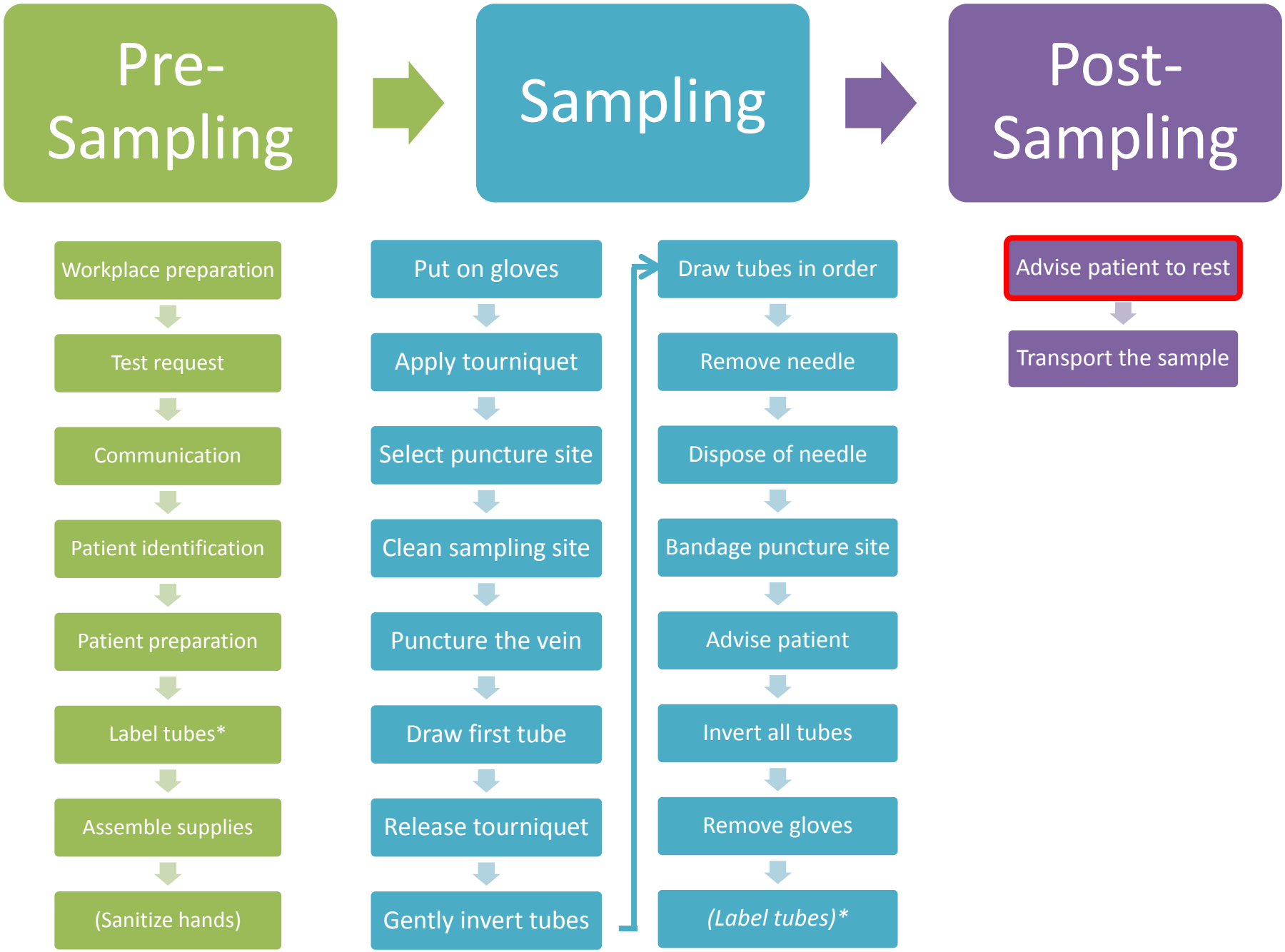
Remove gloves

Always remove gloves by turning them inside out.
Before removing the second glove place the first one in your fist.
Thereby you should have one bundle with all potentially infectious substances facing inwards.



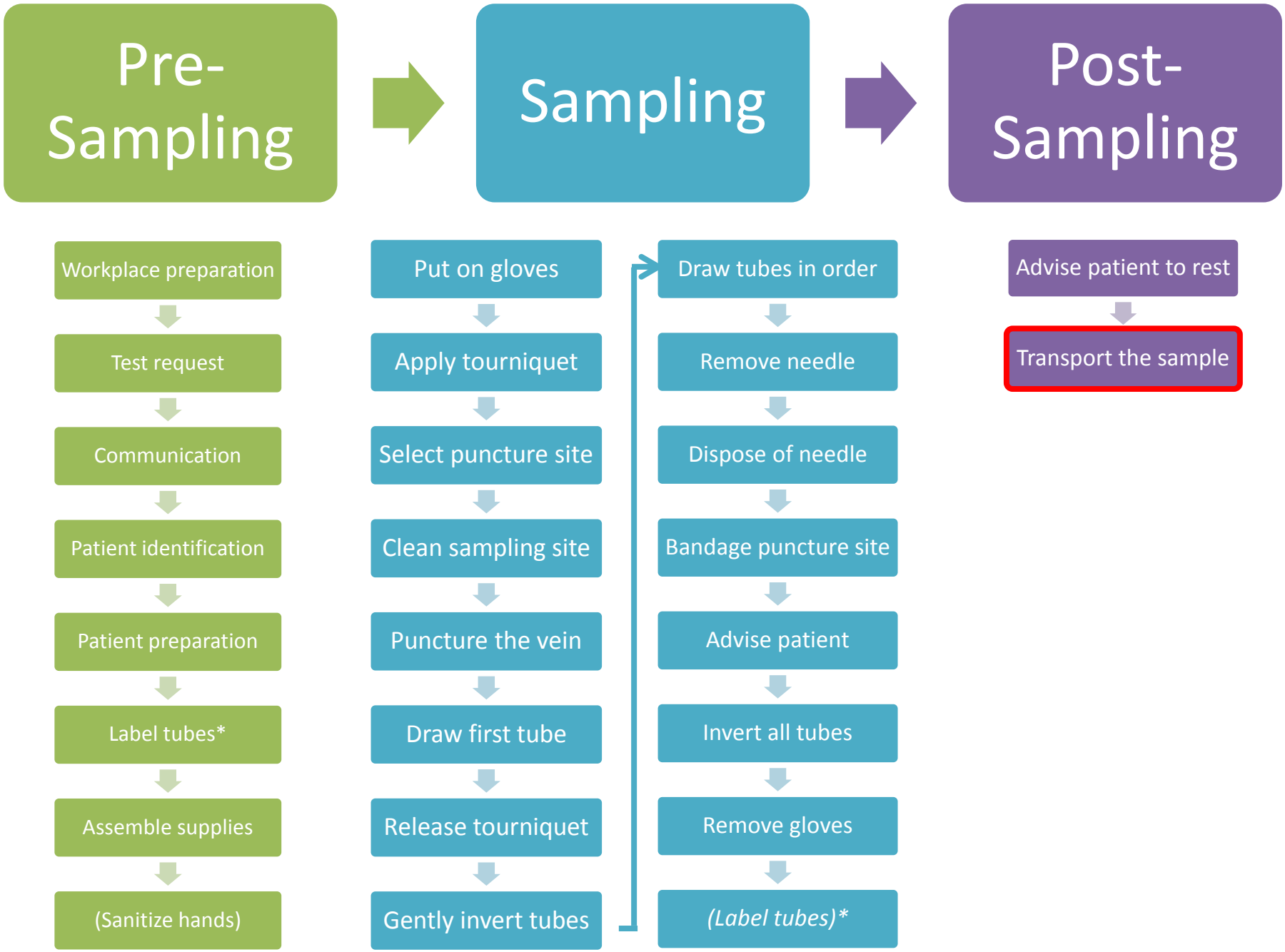




* Depending on local risk assesment – see respective slide in this presentation

Advise patient to rest

Advise patient to rest for 5 minutes and ensure bleeding has stopped before leaving the area where blood collection took place



* Depending on local risk assesment – see respective slide in this presentation

Sample transportation

The laboratory should be asked for advice on proper transport conditions.

You are in charge of the prompt and proper transportation of the samples you collected.

Special handling of specimens	Source	Comments
Light sensitive analytes		
Amphotericin B	(55)	Transport specimens wrapped in a foil immediately after collection and store protected from the light until analysis.
Bilirubin	(10)	
Carotene	(55)	
Chlordiazepoxide	(55)	
Chlorpromazine	(55)	
Isoniazid	(55)	
Methotrexate	(56)	
Porphobilinogen	(55)	
Porphyrins	(10)	
Pyridoxal 5-phosphate	(55)	
Rifampin	(55)	
Thioridazine	(55)	
Trifluoperazine	(55)	
Vitamin A	(55)	
Vitamin B1	(55)	
Vitamin B2	(55)	
Vitamin B3 (niacin)	(55)	
Vitamin C	(55)	
Vitamin E	(55)	
Vitamin K1	(55)	
Specimen Chilling		
Ammonia	(10)	To chill a specimen, place it immediately in a mixture of ice and water (ice slurry not big ice cubes). Do not put the specimen in direct contact with ice or dry ice to avoid hemolysis. Chilling whole blood specimens for longer than two hours is contraindicated for determination of potassium levels.
Lactate	(10)	
Pyruvate	(10)	
Gastrin	(10)	
Homocysteine	(29)	
Renin	(57)	
Parathyroid hormone	(10)	
Catecholamines	(10)	
Adrenocorticotropic hormone	(57)	
Free fatty acid	(57)	
Acetone	(57)	
ACE		
Specimen Transportation at 37 °C		
Cold agglutinin	(10)	For determination of cold agglutinins, an EDTA tube should be used. For cryofibrinogen and cryoglobulins, use tubes that do not contain any additives, all collection supplies must be pre-warmed, keep the sample at water bath heated at 37°C until serum can be separated from the cells, separate the serum from the cells within 1 hour of collection.
Cryofibrinogen	(10)	
Cryoglobulins	(10)	

Nikolac N et al. Biochem Med 2013;23(3):242-54.

The quality of laboratory analyses depends to a large degree on correct preanalytical blood collection practices and sample handling for which you are responsible.

Deviation from the proposed Guideline might lead to false laboratory reports and potentially harms the patient!

Contact your laboratory if you are in any doubt or if you have any questions.

For more information (knowledge test, observation sheet, videos, …) visit the website of the

EFLM Working Group „Preanalytical Phase“

https://www.eflm.eu/site/page/a/1156

EUROPEAN FEDERATION OF CLINICAL CHEMISTRY
AND LABORATORY MEDICINE

DE GRUYTER Clin Chem Lab Med 2018; aop

EFLM Paper

EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

COLABIOCLI

Ana-Maria Simundic*, Karin Bölenius, Janne Cadamuro, Stephen Church, Michael P. Cornes, Edmée C. van Dongen-Lases, Pinar Eker, Tanja Erdeljanovic, Kjell Grankvist, Joao Tiago Guimaraes, Roger Hoke, Mercedes Ibarz, Helene Ivanov, Svetlana Kovalevskaya, Gunn B.B. Kristensen, Gabriel Lima-Oliveira, Giuseppe Lippi, Alexander von Meyer, Mads Nybo, Barbara De la Salle, Christa Seipelt, Zorica Sumarac and Pieter Vermeersch, on behalf of the Working Group for Preanalytical Phase (WG-PRE), of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and Latin American Working Group for Preanalytical Phase (WG-PRE-LATAM) of the Latin America Confederation of Clinical Biochemistry (COLABIOCLI)

Joint EFLM-COLABIOCLI Recommendation for venous blood sampling

v 1.1, June 2018

https://www.eflm.eu/site/page/a/1194

Version 1.1 / 2018

Knowledge test

for

“Joint EFLM-COLABIOCLI Recommendation for venous blood sampling”

Correct answers are marked in red (Please choose only one answer option per question)

To what degree are preanalytical variables responsible for errors within the total testing process?

1. ~20%
2. ~40%
3. ~60%
4. ~90%

Most preanalytical steps occur:

1. In the laboratory reception process
2. During sample processing in the laboratory
3. Outside of the laboratory
4. During the reporting process

Do preanalytical errors have an impact on patient outcome and safety?

1. Yes
2. No

Preanalytical errors affect patient outcome and safety by:

1. Causing delays in reporting results
2. Affecting lab test results
3. Causing incorrect diagnosis
4. All of the above

Are preanalytical errors currently identified by the laboratory and unsuitable samples excluded from analyses?

1. Yes, all of them
2. No, never
3. Yes, but only a minor proportion of them
4. No, but doctors can easily detect preanalytical errors

Which information <u>cannot</u> be used for patient identification?

1. Patient full name (for- and surname)
2. Date of birth

3. Telephone number
4. Health insurance number or equivalent

How many identifiers are needed for a correct identification of the patient and his/her sample?

1) at least one
2) at least two
3) at least three
4) at least four

How do you confirm the patient's name?

1) "What is your name?"
2) "Are you Mr. Smith?"
3) "Who is Mr. Smith?" *(when entering a room with more than one patient)*
4) "Is your name Walter Smith?"

When should blood sampling preferably be performed?

1) 7 - 9 a.m.
2) Before 12 a.m.
3) If patient is fasting, even the afternoon is acceptable.
4) Any time during the day.

How many hours before blood sampling should the patient refrain from <u>food and liquid intake</u> (except water)?

1. No fasting required
2. Refrain on the day of blood sampling
3. 12 hours
4. 24 hours

How many hours before blood sampling should the patient refrain from <u>smoking</u> or drinking <u>caffeine</u> containing drinks (coffee, tea, etc)?

1. No smoking/caffeine free interval required
2. Refrain on the day of blood sampling
3. 12 hours
4. 24 hours

How many hours before blood sampling should the patient refrain from drinking alcohol?

1. No alcohol free interval required
2. Refrain on the day of blood sampling
3. 12 hours
4. 24 hours

For how long should you wait before venous blood specimen collection after the patient has received an intravenous lipid infusion?

1. At least 8 hours
2. At least 1 hour
3. At least 30 minutes
4. There is no need to wait

When should intravenous glucose infusion have been terminated prior to venous blood specimen collection for glucose determination?

1. 30 minutes
2. 60 minutes
3. 5 minutes
4. There is no need to wait

Concentration of iron:

1. Is constant during the day
2. Is higher in the morning and lower in the afternoon
3. Is lower in the morning and higher in the afternoon
4. Fluctuates randomly during the day

When should you release the tourniquet?

1. As soon as possible after the blood begins to flow into the tube
2. After the last tube is drawn
3. After removing the needle from the vein
4. Before you puncture the vein

Why should patients not clench their fist during blood collection?

1. Swelling/reddening of the skin
2. Increased risk of bruising
3. Test results may be affected

4. Increased risk of infection

When should collection tubes be labeled?

1) Always before phlebotomy.
2) Consistently either immediately before or after phlebotomy but always in the presence of the patient.
3) Always after phlebotomy
4) At any time, as long as you are sure that the correct labels are used.

When should samples be mixed?

1. Mixing of samples is done by the laboratory
2. After collection of all tubes
3. Directly after collection *and* after collection of all tubes
4. Only coagulation tubes need mixing directly after collection

How should samples be mixed?

1. Mixing of samples is done by the laboratory
2. By inverting at least 5 times in total
3. By shaking the sample
4. By inverting the sample once

Which statements regarding the order of draw are correct?

1. Blood culture tubes should always be collected first
2. EDTA tubes should be collected after heparin or serum tubes
3. Coagulation tubes should be collected after blood culture tubes
4. All of the above

Why is it important to follow the recommended order of draw?

1. The most important tests are conducted on the first tube, so it is important to ensure complete filling
2. To avoid any risk of additive contamination
3. The first tube taken requires longer for the additives to work
4. To standardize processes, so that no tube is missed during phlebotomy

When is it allowed to recap a used needle?

1. When no safe sharp container is in your vicinity.
2. Always
3. Never
4. When the safety-feature which should cover the needle is broken

A transmission of which viruses is possible after a needle stick injury with a used needle?

1. HIV
2. Hepatitis C
3. Hepatitis B
4. All of the above

Which recommendations should you follow during phlebotomy to avoid the risk of sharps injuries?

1. Use medical devices incorporating a safety-engineered protection mechanism
2. Display effective disposal procedures and clearly marked and technically safe sharps containers
3. Use Personal Protective Equipment
4. All of the above

Which factors can potentially lead to hemolytic blood samples?

1. Blood collection through an IV-Catheter collection with high vacuum collection systems
2. Small needle gauges
3. Vigorous mixing of the tube
4. All of the above

Which laboratory parameters are potentially affected by hemolysis?

1. Potassium
2. Asparate aminotransferase (AST / GOT)
3. Lactate dehydrogenase (LDH)
4. All of the above

Which factors can potentially lead to clotted blood samples?

1. No mixing of tubes after collection
2. Very slow blood flow into the tube
3. Prolonged sample transportation time before centrifugation
4. All of the above

Does exercise prior to blood collection affect laboratory parameters?

1. No
2. Yes, but only heavy exercise (e.g. marathon or excessive training)
3. Yes, even moderate exercise (e.g. running to the doctor's office)
4. Yes, but only some rare laboratory parameters are affected

Is the body posture of the patient affecting laboratory parameters?

1. No
2. Yes, but only if the posture changed within 15 minutes before blood collection (e.g. from the supine to the upright position)
3. Yes, the patient always has to lie down during phlebotomy
4. Yes, but only some rare laboratory parameters are affected

Does underfilling of a coagulation tube affect coagulation parameters?

1. No
2. Yes, but only if it is severely underfilled
3. Yes, even slight underfilling (i.e., less than 90% the nominal filling volume)
4. Yes, but only some rare coagulation parameters are affected