Management of Instruments, Consumables, and Reagents in Blood Banks

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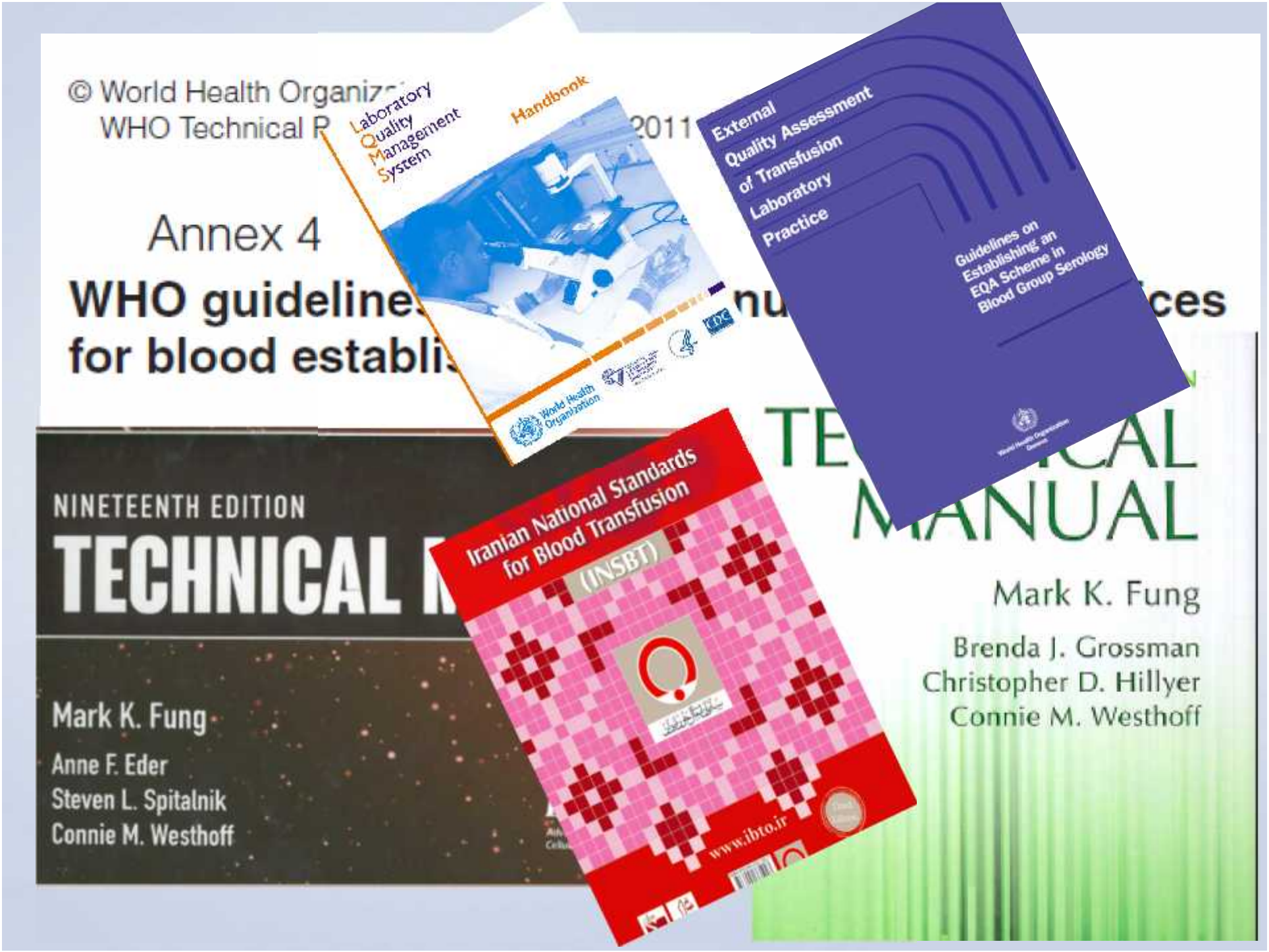
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WHO Technical R 2011
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for blood establis
Laboratory Quality Management System
Handbook
World Health Organization
External Quality Assessment of Transfusion Laboratory Practice
Guidelines on Establishing an EQA Scheme in Blood Group Serology
NINETEENTH EDITION
TECHNICAL M
Mark K. Fung
Anne F. Eder
Steven L. Spitalnik
Connie M. Westhoff
Iranian National Standards for Blood Transfusion
(INSBT)
www.ibto.ir
TE CAL
MANUAL
Mark K. Fung
Brenda J. Grossman
Christopher D. Hillyer
Connie M. Westhoff

Specificities and Requirements

- ✓ The Blood Transfusion Service (BTS)/ laboratories must define acceptance specifications and requirements for critical supplies.
- ✓ BTS/ laboratories must develop procedures to control and prevent the inadvertent use of materials that do not meet specifications.
- ✓ Critical material should be received under quarantine and then evaluated for acceptability.
- ✓ Corrective action may include returning the material to the vendor or destroying it.

General Specifications

- laboratory infrastructure
- desired characteristics of the test (antigen, antibody)
- simplicity of test procedure
- equipment necessary to perform the test
- performance time
- shelf-life of the reagents after opening and preparation
- Duration of shelf-life (Long)
- storage conditions
- technical skill of laboratory staff
- laboratory logistics (continuous supply of kits, maintenance of equipment, spare parts, availability of service, etc.).
- price

Receipt and quarantine

- Incoming critical materials should be physically or administratively quarantined immediately after receipt and until they are released for use.
- Where the quarantine status is ensured by storage in separate areas, these areas should be clearly marked and their access restricted to authorized personnel.
- Any system replacing physical quarantine (e.g. a computerized system) should provide equivalent security.

Sampling

- The flow of products is broken into discrete batches called lots.
- A random sample is one in which each unit in the lot has an equal chance of being included in the sample.
- If a sample is random, it is likely to be representative of the lot.
- As the percentage of lots in samples is increased:
  - the sampling and sampling costs increase

Evaluation

Appropriate checks on received goods in order to confirm that they correspond to the order and meet the specifications:

- Packaging
- Country of Origin
- Attached certificates
- Manufacturer
- Expiry date
- Lot number
- Ref/Catalogue No.
- Monitoring the temperature during transportation (According the type of medical device)
- Storage Temperature and humidity
- Quantity
- Physical defects (Damaged containers should be carefully checked to detect possibly affected materials.)

- Antisera must be of high quality with a shelf life of at-least one year of use and should be received in cold chain
- Select the reagent with high specifications-reference preparation has been established for ABO, Rh and anti-human globulin (AHG)
- Should contain a preservative to minimize contamination.
- Should be stored in the refrigerator at 2-8°C
- Should be used according to manufacturer's instructions
- Must comply with the standards laid down for potency (titer and avidity) and specificity
- New reagents should not be introduced into routine work until internal QC testing have confirmed that they are satisfactory
- Should be clearly labeled with :

❖ Batch number
❖ Expiry date
❖ Storage temperature

QC reports

- Identification of personnel performing the test.
- Identification of reagents (including lot numbers and expiration dates).
- Identification of equipment.
- Testing date and, when applicable, time.
- Results.
- Interpretation (eg, meets or fails to meet established criteria).
- Reviews.

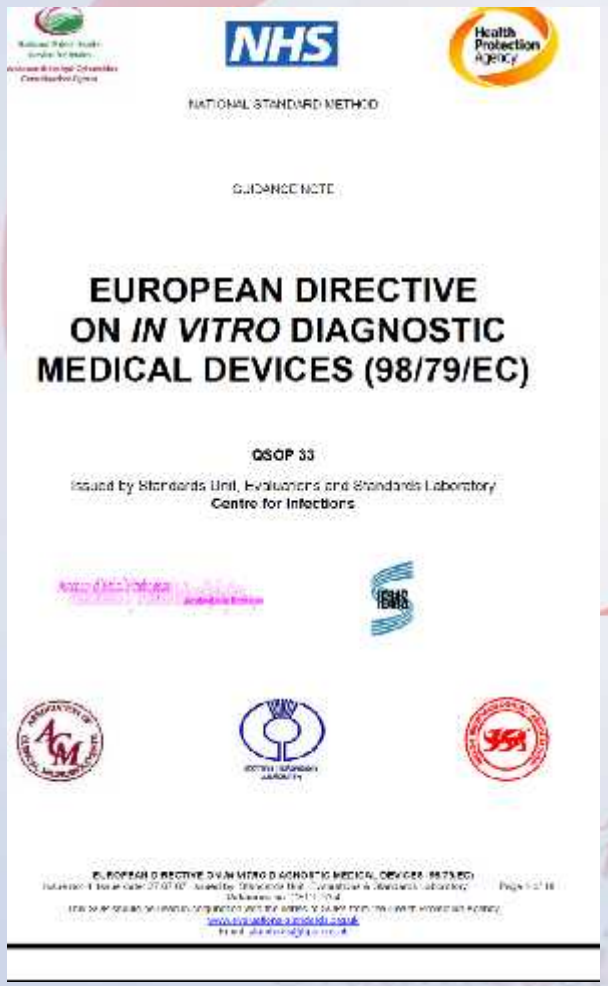
Release

- After acceptability has been determined, the materials should be released by an authorized person for use in blood transfusion centers/laboratories.
- The actual release may be performed by an authorized person or under the guidance of a validated computer system.
- The minimum criteria for the release should be the availability — and check of — certificates or other acceptability records generated by the manufacturer and containing sufficient information to determine product acceptance.

Release

Each new lot of testing kits should be evaluated by the laboratory to check compliance with predetermined performance standards before release for routine analysis.

98/79/EC
Annex II, List A



NHS

Health Protection Agency

NATIONAL STANDARD METHOD

GUIDANCE NOTE

EUROPEAN DIRECTIVE ON *IN VITRO* DIAGNOSTIC MEDICAL DEVICES (98/79/EC)

QSOP 33

Issued by Standards Unit, Evaluations and Standards Laboratory
Centre for Infections

Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: ABO system, rhesus (C, c, D, E, e) anti-Kell,

reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D.

Equipment (1)

A great deal of thought and planning should go into equipment management. As the laboratory puts an equipment management programme in place, the following elements should be considered:

- Selection and purchasing—When obtaining new equipment, what criteria should be used to select equipment? Should equipment be purchased or would it be better to lease? (URS)

Equipment, Qualification (2)

- Installation: For new equipment or relocation, what are the installation requirements and who will install the new instrument?
- Operation: For new equipment or relocation, OQ can simply be defined as a series of tests which ensure that equipment and its sub-systems will operate within their specified limits consistently and dependably.
- Performance: For new equipment or relocation or new reagents, a collection of test cases used to verify that a system performs as expected under simulated real-world conditions. The performance qualification tests requirements defined in the User Requirements Specification (or possibly the Functional Requirements Specification).

Equipment (3)

- Calibration and performance evaluation—What is needed to calibrate the equipment and validate that it is operating correctly? How will these important procedures be conducted for both old and new instruments?
- Maintenance, What maintenance schedule is recommended by the manufacturer? Will the laboratory need additional preventive maintenance procedures? Are current maintenance procedures being conducted properly?
- Troubleshooting, Is there a clear procedure for troubleshooting for each instrument?
- Service and repair, What is the cost? Can the laboratory obtain the necessary service and repair in its geographical area?
- Retiring and disposing of equipment, What must be done to dispose of old equipment, When it needs to be replaced?

کنترل کیفی Quality Control

انجام آزمایش و مشاهده واکنش‌های ذیل، روزانه (۲۴ ساعت) برای هر یک از معرف‌های استفاده شده با شماره Lot مشخص الزامی است:

۱- معرف Anti-A با گلبول قرمز گروه A_1 واکنش(4^+) و با گلبول قرمز گروه B واکنش منفی می‌دهد.

۲- معرف Anti-B با گلبول قرمز گروه B واکنش(4^+) و با گلبول قرمز A_1 واکنش منفی می‌دهد.

* **مهم :** در صورت عدم دسترسی به گلبول قرمز A1 یا B شناخته شده مقداری از گلبول قرمز دو گروه A یا B را مخلوط نموده و در صورت مشاهده واکنش (+4) قابل استفاده می‌باشد.

سازمان انتقال خون ایران

معاونت تضمین کیفیت و کنترل کیفی

« فرم ارزیابی روزانه آنتی سرم های گروه های خونی»

استان: پایگاه: مسئول بخش سرولوژی :

تاریخ	Reagent Specificity														مسئول آزمایش
	A_1 cell		B cell		Rh(D^+) / cell	Rh (d) / cell									
	Anti-A	Lot No: EXP Date: Manufacture:	Anti-B	Lot No: EXP Date: Manufacture:	Anti-D	Anti-D				Lot No: EXP Date: Manufacture:					
						IS	37°C	AHG	CC*						

۱- برای کنترل آنتی سرمها از سوسپانسیون سلولی ۵-۲٪ می توان استفاده کرد.

۲- در صورتیکه هر یک از آنتی سرمها واکنش آگلوتیناسیون مورد انتظار (3+ to 4+) را عدم آگلوتیناسیون برای Rh(D)- Neg cell) دیده نشده آنتی سرم مورد نظر از سیستم کاری خارج و جهت ارزیابی مجدد ایزوآسیون به واحد کنترل کیفی ارسال گردد.

۳- لازم به ذکر است این فرم فقط برای ارزیابی روزانه هر آنتی سرم تهیه شده است .

CC*=Check cells

۴. آنتی‌سرم گروه خون:

- کنترل کیفی آنتی سرم های گروه بندی خون روزانه قبل از مصرف :

- □ آنتی A (۱) امتیاز
- □ آنتی B (۱) امتیاز
- □ آنتی AB (۱) امتیاز
- □ آنتی D (۱) امتیاز

- بررسی آنتی سرم های گروه بندی خون روزانه

- آنتی A : □ تاریخ مصرف: دارد (۱) امتیاز □ عدم تغییر رنگ و عدم وجود رسوبات (۱) امتیاز
- آنتی B : □ تاریخ مصرف دارد (۱) امتیاز □ عدم تغییر رنگ و عدم وجود رسوبات (۱) امتیاز
- آنتی D : □ تاریخ مصرف دارد (۱) امتیاز □ عدم تغییر رنگ و عدم وجود رسوبات (۱) امتیاز

کنترل کیفی آنتی سرم های گروه خون روزانه قبل از مصرف با گلبول قرمزی که درآزمایشات روز قبل واکنش ۴ پلاس داشته است صورت می گیرد.

۵. آنتی هیومن‌گلوبولین:

□ تاریخ مصرف دارد (۱) امتیاز

□ عدم تغییر رنگ و عدم وجود رسوبات (۱) امتیاز

۶. آلبومین:

□ تاریخ مصرف دارد (۱) امتیاز

□ عدم تغییر رنگ و عدم وجود رسوبات (۱) امتیاز

۷. مستندات مبنی بر کنترل کیفی کلیه آنتی سرمها بر اساس هر Lot. No :

- بررسی تیترآنتی سرم:

□ دارد (۱) امتیاز

□ ندارد (۰) امتیاز

- درصد اختصاصی بودن آنتی سرم:

□ دارد (۱) امتیاز

□ ندارد (۰) امتیاز

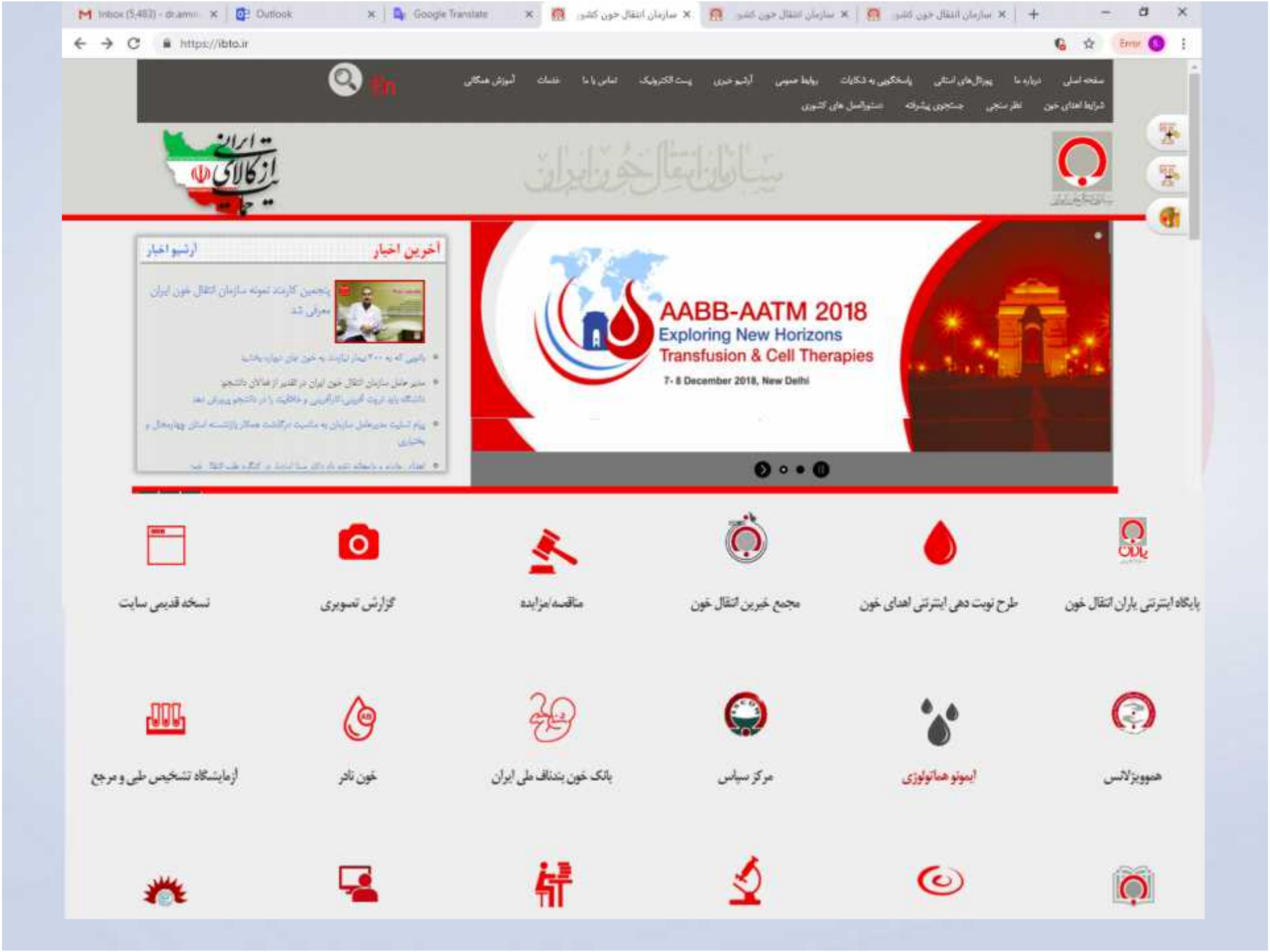
- چک قدرت واکنش:

□ دارد (۱) امتیاز

□ ندارد (۰) امتیاز

مشاهدات و توضیحات:

*** امتیاز نهایی اخذ شده در قسمت ج:(۴۱) .....**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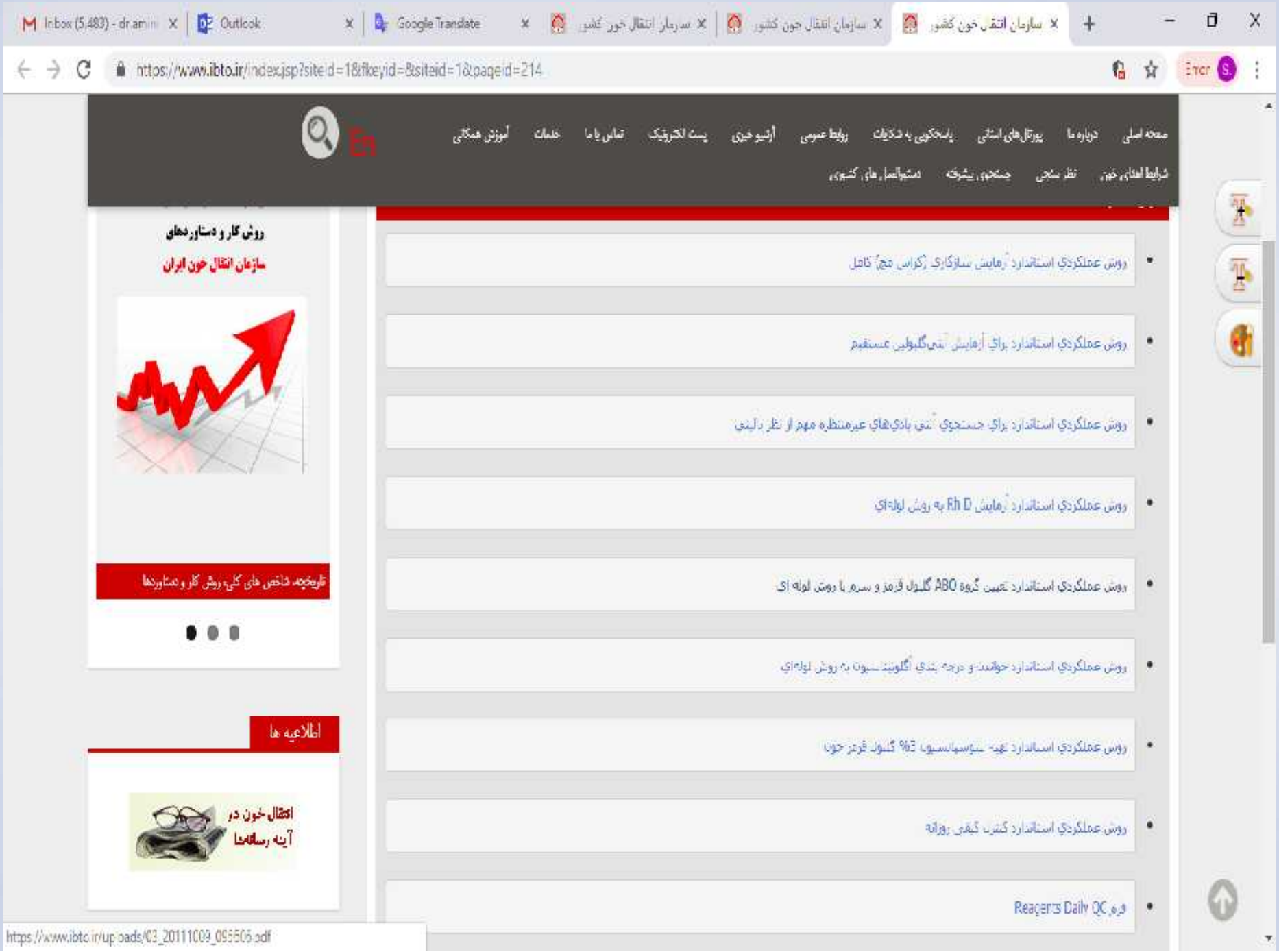
آزمایشگاه تشخیص طبی و مرجع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آموزش همگانی
شرایط اهدای خون
نظر سنجی
جستجو پیشرفته
دستاوردهای کشوری
روش عملکردی استاندارد آزمایش سازگاری کراس مچ کامل
روش عملکردی استاندارد برای آزمایش آنتی‌گلوبولین مستقیم
روش عملکردی استاندارد برای جستجوی آنتی بادی‌های غیرمنتظره مهم از نظر بالینی
روش عملکردی استاندارد آزمایش Rh D به روش لوله‌ای
روش عملکردی استاندارد تعیین گروه ABO گلبول قرمز و سرم یا روش لوله ای
روش عملکردی استاندارد حواندن و درجه بندی آگلوتیناسیون به روش لوله‌ای
روش عملکردی استاندارد تهیه سوسپانسیون 3% گلبول قرمز خون
روش عملکردی استاندارد کنترل کیفی روزانه
فرم Reagents Daily QC
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تاریخچه، شاخص های کلی، روش کار و دستاوردها
اطلاعیه ها
انتقال خون در آینه رسانه‌ها
https://www.ibto.ir/uploads/03_20111009_095505.pdf

External Quality Assurance

- The internal QC should be complemented by regular external quality assurance e.g. : participation in a proficiency testing program
- Proficiency program test, coded “normal” and “problem” blood samples are distributed from national or regional reference laboratory to the participants usually 2x to 4x a year.
- The exercise limited to compatibility testing-ABO-grouping, Rh-typing and phenotyping and alloantibody detection

Conclusion

- Quality control (QC) includes the activities from the suppliers, through production, and to the customers.
- Incoming materials are examined to make sure they meet the appropriate specifications.
- The quality of partially completed products are analyzed to determine if production processes are functioning properly.
- Finished goods and services are studied to determine if they meet customer expectations.

Restrictive Blood Transfusion

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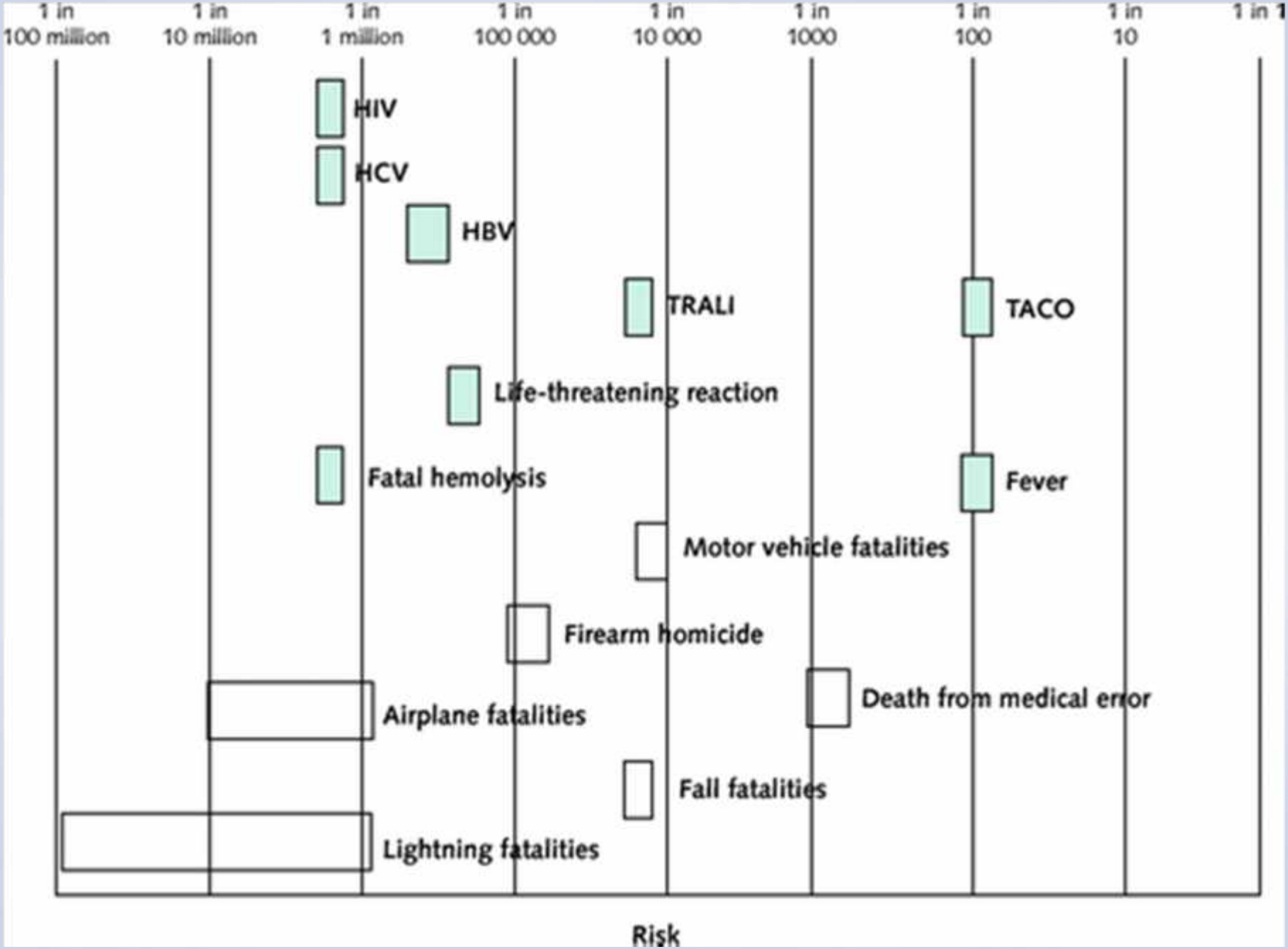
Risks of Blood Transfusion

- Transfusion-transmitted pathogens (HIV, HBV, HCV, CMV, bacteria, parasites)
- Allergic and Immunologic Reactions
- Transfusion Associated Circulatory Overload (TACO)
- Transfusion Related Acute Lung Injury (TRALI)
- Electrolyte abnormalities, hyperkalemia, citrate toxicity (metabolic alkalosis or ionized hypocalcemia)
  - Consider giving Calcium prophylactically with massive transfusion


1 in 100 million
1 in 10 million
1 in 1 million
1 in 100 000
1 in 10 000
1 in 1000
1 in 100
1 in 10
1 in 1
HIV
HCV
HBV
TRALI
TACO
Life-threatening reaction
Fatal hemolysis
Fever
Motor vehicle fatalities
Firearm homicide
Death from medical error
Airplane fatalities
Fall fatalities
Lightning fatalities
Risk

- Blood transfusion is not benign and should be ordered judiciously.
- Most patients with chronic anemia can compensate oxygen delivery by increasing cardiac output.
- Generally avoid transfusion for Hg>7 for most stable patients without active cardiovascular disease or active bleeding.
- Fever and TACO are the most common complications occurring about 1 in 100 transfusions.

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journal homepage: www.tmreviews.com

Patient Blood Management Bundles to Facilitate Implementation

Patrick Meybohm [a,*], Toby Richards [b], James Isbister [c], Axel Hofmann [d], Aryeh Shander [e], Lawrence Tim Goodnough [f], Manuel Muñoz [g], Hans Gombotz [h], Christian Friedrich Weber [a], Suma Choorapoikayil [a], Donat R. Spahn [i], Kai Zacharowski [a]

More than 30% of the world's population are anemic. Anemia is increasingly recognized as a risk factor for a number of adverse outcomes, including hospitalization, morbidity, and mortality.

Patient blood management (PBM), as defined by the Society for the Advancement of Blood Management, refers to "the timely application of evidence based medical and surgical concepts designed to **maintain haemoglobin concentration**, **optimise haemostasis** and **minimise blood loss** in an effort to improve patient outcome."

Four principle of patient Blood Management (PBM), by empowered multidisciplinary team

The first principle or strategy is to manage the patient's anemia, which primarily involves instituting methods of early detection and using nutritional and pharmaceutical treatments to support erythropoiesis, if it is not mainly genetic or cancer related. While actively treating anemia, the physiologic tolerance of anemia can be enhanced by minimizing oxygen consumption and/or enhancing delivery.

The second PBM strategy involves optimizing coagulopathy. This involves determining the patient's current coagulation status and assessing those medications that affect this, correcting any abnormalities and, if present, rapidly assessing the cause of bleeding.

The third guiding PBM principle entails using interdisciplinary blood conservation modalities. Physicians can adhere to this principle by ensuring that their surgical techniques are precise enough to minimize blood loss. Intraoperative and postoperative blood conservation techniques should be used, including autologous conservation modalities. Attention should be given to phlebotomy volume and frequency with the intent to minimize or eliminate this common source of iatrogenic blood loss, which can either induce or exacerbate anemia.

The fourth principle that also especially embodies the overall PBM approach, and optimal blood use is the concept of patient centered decision making. This involves thorough communication with the patient regarding his/her treatment. It is necessary to effectively communicate the risks and benefits of the various potential interventions and to decide on the right course of action together with the patient.

Patient Blood Management Bundles

A comprehensive PBM program may include more than 100 different measures/tasks, divided into 4 bundle blocks according to the aforemen- tioned four PBM strategies completed by 2 additional blocks providing important information about general PBM project management and PBM-related metrics.

Block 1: PBM Project Management Involvement of Key PBM Stakeholders

Table 1
Patient Blood Management project management

Block 1: General PBM project management	
Transfusion medicine specialists/transfusion committee [prevention of blood wastage, optimal blood use, changes in donor blood management]	0☐ 1☐ 2☐
Central laboratory/laboratory scientists [smaller blood collecting tubes]	0☐ 1☐ 2☐

Block 2: First Strategy-Manage Patient's Anemia

Preoperative management of anemia (subgroup of surgical patients)	
Diagnosis of anemia	
Identification of anemic patients (screening)	0 ☐ 1 ☐ 2 ☐
Diagnosis of iron deficiency anemia (eg, blood count, ferritin, transferrin saturation, calculation of the individual iron deficit)	0 ☐ 1 ☐ 2 ☐
Diagnosis of vitamin B12 or folic acid deficiency	0 ☐ 1 ☐ 2 ☐

Block 3: Second Strategy- Optimizing Coagulopathy Preoperative Management of Coagulopathy

Point-of-care diagnostic in coagulopathy	
Coagulation system (eg, viscoelastic methods)	0 ☐ 1 ☐ 2 ☐
Platelet function (eg, aggregometric methods)	0 ☐ 1 ☐ 2 ☐

Block 4: Third Strategy-Interdisciplinary Blood Conservation Modalities Reduction of Diagnostic and Surgery

Reduction of Diagnostic-Associated Blood Loss

A key element of PBM is prevention of blood being unnecessarily removed from the patients, particular by reducing phlebotomy blood loss within daily laboratory analyses (Table 4). This can be achieved in several ways. First, as mentioned above, early preoperative anemia screening is instrumental in reducing the need for phlebotomy when the patient is hospitalized or postsurgery. Second, when sampling blood, phlebotomists should use the smallest collection tube size that is practical for the required analysis. In addition, reducing unnecessary laboratory tests, unnecessary blood culture draws, the frequency of sampling, the "discard" volume when samples are obtained from indwelling lines, and the blood waste by the use of closed in-line flush blood sampling devices for arterial and central venous lines are recommended [51,52,79]. In addition to the medical benefits of this approach, patients will also appreciate fewer painful blood draws.

Reduction of diagnostic-associated blood loss	
Reduced size of blood collection tubes	
EDTA tube	0☐ 1☐ 2☐
Citrate tube	0☐ 1☐ 2☐
Lithium-heparin/serum tube	0☐ 1☐ 2☐
Type and screen tubes	0☐ 1☐ 2☐
Restrictive frequency of blood collection	0☐ 1☐ 2☐
Appropriate timing of postoperative blood tests and not daily judicious use/"weekend" plan	0☐ 1☐ 2☐
Reduced sampling for blood cultures in daily routine (limit to established indications)	0☐ 1☐ 2☐
Closed in-line flush devices (arterial pressure transducer systems, central venous blood collection)	0☐ 1☐ 2☐

Block 5: Fourth Strategy- Optimal Blood Use With Patient-Centered Decision Making

Single-unit policy (RBC units, platelet concentrate)	0 ☐ 1 ☐ 2 ☐
Intelligent electronic ordering system for blood products (including patient's lab results, alert function)	0 ☐ 1 ☐ 2 ☐
Use of dosage for blood components instead of units	0 ☐ 1 ☐ 2 ☐

Block 6: PBM-Related Metrics, Patient's Outcome, Benchmark Patient Blood Management–Related Metrics

Patient Blood Management

- Protect the patient from unnecessary or excessive transfusions
- Inform transfusion decisions not simply by hemoglobin, but by patient symptoms and comorbidities
- Utilize restrictive transfusion strategies
- Reduce iatrogenic anemia through reduction in both the volume and frequency of blood draws
- Avoid arbitrary 2 unit transfusions
- Consider transfusion alternatives for anemia management

Carson JL, Terrin ML, Noveck H, et al. *Liberal or restrictive transfusion in high-risk patients after hip surgery.* N Engl J Med. 2011;365:2453-62.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 29, 2011 VOL. 365 NO. 26

Liberal or Restrictive Transfusion in High-Risk Patients after Hip Surgery

Jeffrey L. Carson, M.D., Michael L. Terrin, M.D., M.P.H., Helaine Noveck, M.P.H., David W. Sanders, M.D., Bernard R. Chaitman, M.D., George G. Rhoads, M.D., M.P.H., George Nemo, Ph.D., Karen Dragert, R.N., Lauren Beaupre, P.T., Ph.D., Kevin Hildebrand, M.D., William Macaulay, M.D., Courtland Lewis, M.D., Donald Richard Cook, B.M.Sc., M.D., Gwendolyn Dobbin, C.C.R.P., Khwaja J. Zakriya, M.D., Fred S. Apple, Ph.D., Rebecca A. Horney, B.A., and Jay Magaziner, Ph.D., M.S.Hyg., for the FOCUS Investigators*

Hebert PC, Wells G, Blajchman MA, et al. *A multicenter, randomized, controlled clinical trial of transfusion requirements in critical care*. N Engl J Med 1999;340:409-417.

The New England
Journal of Medicine

VOLUME 340 FEBRUARY 11, 1999 NUMBER 6

A MULTICENTER, RANDOMIZED, CONTROLLED CLINICAL TRIAL OF TRANSFUSION REQUIREMENTS IN CRITICAL CARE

PAUL C. HÉBERT, M.D., GEORGE WELLS, PH.D., MORRIS A. BLAJCHMAN, M.D., JOHN MARSHALL, M.D., CLAUDIO MARTIN, M.D., GIUSEPPE PAGLIARELLO, M.D., MARTIN TWEEDDALE, M.D., PH.D., IRWIN SCHWEITZER, M.SC., ELIZABETH YETISIR, M.SC., AND THE TRANSFUSION REQUIREMENTS IN CRITICAL CARE INVESTIGATORS FOR THE CANADIAN CRITICAL CARE TRIALS GROUP*

A Difference of Opinion, Liberal or Restrictive blood Transfusion

How high should Hgb be in the ICU and postoperative patient?

- LIBERAL (higher Hgb goals)
  - Hgb 10-12
- RESTRICTIVE (transfusion approach)
  - Hgb 7-9

Doesn't the LIBERAL approach deliver more O2 to the tissues and improve outcome?

Red Blood Cell Transfusion: A Clinical Practice Guideline From the AABB*

- Restrictive transfusion in hospitalized stable patient

➢ Transfuse if Hgb < 7-8

- Restrictive transfusion in hospitalized patient with CV disease

➢ Transfuse if symptomatic or Hgb ≤ 8

- Transfusion decisions guided by symptoms and Hgb
- No data for guide in hospitalized stable ACS patient

Liberal or Restrictive Transfusion in High-Risk Patients after Hip Surgery

- Patients > age 50
  - Known or at risk for cardiovascular disease
  - Hip fracture surgery
- Liberal: transfuse if Hgb< 10
- Restrictive: transfuse if anemia symptoms or Hgb<8
- No difference in:
  - Mortality
  - Morbidity
  - Functional capacity at 60 days postop

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Should Transfusion Trigger Thresholds Differ for Critical Care Versus Perioperative Patients? A Meta-Analysis of Randomized Trials

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CONCLUSIONS

Evidence suggests that the safety of restrictive transfusion thresholds differs for critically ill patients versus perioperative patients. In critical care patients, a restrictive transfusion strategy (transfusion trigger ~ 7–8 g/dL) reduces the risk of overall mortality, stroke/TIA, transfusion reactions, length of stay, and allogeneic blood exposure. In contrast, for perioperative patients, current evidence suggests a restrictive transfusion strategy may increase the risk of mortality, particularly with transfusion triggers of 7–7.5 g/dL. While the evidence base is sufficiently robust to provide definitive conclusions for critically ill patients due to large accumulated sample size, the existing evidence base for the perioperative population remains less robust due to insufficiently accumulated sample size. Consequently, further research is encouraged in perioperative patients to define safe transfusion thresholds, especially for cardiac surgical patients or high-risk patients undergoing noncardiac surgery.

Patient Blood Management

- A series of ‘rights’
  - Right Patient
    - Right Product
      - Right Reason
        - » Right Time
- Who defines ‘right’?
  - Clinical decision informed by evidence
    - Not all hypotension is due to anemia
      - Not all hypoxia is due to reduced red cell mass
        - » Not all who are anemic require red cell transfusion

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