

## List of Essential Medicines: how do haemo- and pharmacovigilance cohabitate?



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**Sanquin, Amsterdam**  
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## WHO Model Lists of Essential Medicines

The WHO Model Lists of Essential Medicines has been updated every two years since 1977. The current versions are the 17th WHO Essential Medicines List and the 3rd WHO Essential Medicines List for Children updated in March 2011.

### CURRENT LISTS

ADULTS -- 17th edition (March 2011)

[English \[pdf 432 kb\]](#) | [French \[pdf 452 kb\]](#)

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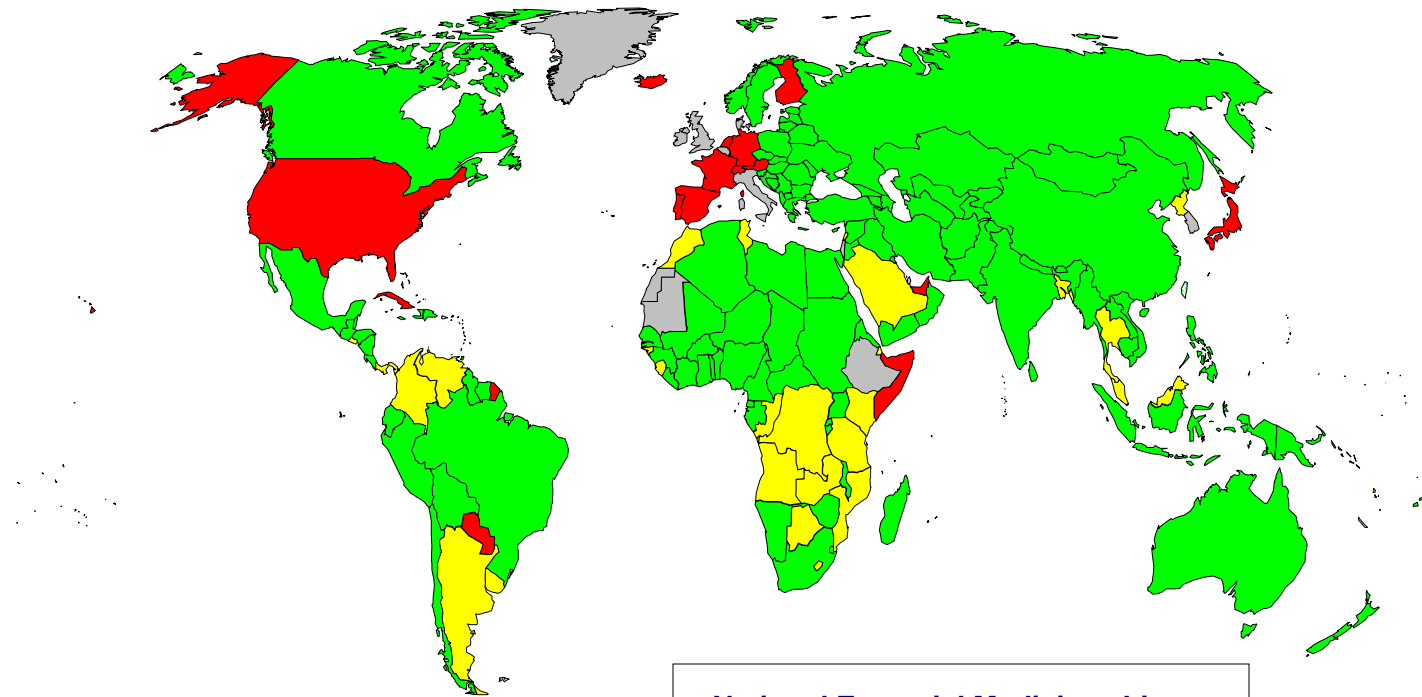
## Lists of Essential Medicines

**Principle:** A limited range of carefully selected essential medicines leads to better health care, better medicines management, and lower costs

**Definition:** Essential medicines are those that satisfy the priority health care needs of the population





**Selection:** Selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness.

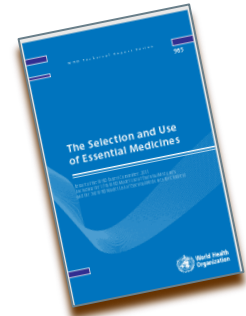
## Countries with a national List of Essential Medicines



**156 countries with EMLs**  
**1/3 within 2 years**  
**3/4 within 5 years**

### National Essential Medicines List

	< 5 years	(127)
	> 5 years	(29)
	No NEML	(19)
	Unknown	(16)



## WHO Model List of Essential Medicines (I)

- The WHO Model List of Essential Medicines provides guidance to Member States on optimization of a national formulary to assure adequate and cost-effective use of medicines in the context of public health
- Basic criteria for listing of an essential medicine include availability, public health relevance, safety and effectiveness versus comparators, cost and cost-effectiveness, and regulatory status

# WHO Model List of Essential Medicines: Criteria for Consideration (I)

Effective and safe medicine

- Based on clinical trials data, post marketing surveillance, pharmacovigilance, regulatory approvals

Regulatory approval in a number of countries

- Indicates availability, efficacy, safety

Available in most parts of the world and ease of use in different settings

- Necessary for access

## **WHO Model List of Essential Medicines: Criteria for Consideration (II)**

### Public health need

- Indicated by burden of disease, populations served, annual estimates of use, guideline recommendations

### Affordable for most health care systems

- Costs comparisons, cost benefit

### Recommended in Guidelines especially by WHO programmes

- Indicates public health need, efficacy, safety

## Essential medicines selection

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### Whole blood and red blood cells (Addition) -- Adults and Children

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19th Expert Committee on the Selection and Use of Essential Medicines

#### Drug information

Section 11: Blood products and plasma substitutes

#### Formulation:

#### Application prepared by:

AABB (formerly the American Association of Blood Banks), the American Red Cross, Canadian Blood Services and the International Society of Blood Transfusion

Application for the inclusion of Whole blood and Red blood cells  
pdf, 2.06Mb

#### Comments from:



## **Essential medicines connects to the basic functions of blood establishments**

Quality and safety for:

- Collection
- Testing
- Processing
- Storage
- Distribution

of human blood and blood components

***Directive 2002/98/EC***

## Quality management and regulatory oversight is needed for improvements ....



# Additional functions of blood establishments

## Patient blood management

- Knowledge of the primary process of the client
- Sufficient supply of blood
- Optimal usage of blood
- Client relations
- Creating of customer intimacy
- **Haemovigilance**
- Research
- Offering excellent services to the customers

## JOURNAL OF BLOOD SERVICES MANAGEMENT

### Synergies between blood center and hospital quality systems

*Jennifer E. Rhamy*

Blood centers have expertise in following federally mandated standards and establishing rigorous quality systems. Medicare participating hospitals and their laboratories must be compliant with the requirements of the Centers for Medicare and Medicaid Services. Following standards and experiencing unannounced surveys allow blood centers and hospitals to organize and strengthen their patient safety efforts and achieve

Blood centers, hospitals, and laboratories follow various regulations contained in the Code of Federal Regulations and administered by different divisions of the federal government's Department of Health and Human Services. Blood centers are primarily held to the regulations overseen by the US Food and Drug Administration (FDA).<sup>1</sup> Hospitals must meet the minimum health and safety requirements specified in the Centers for Medicare and Medicaid Services (CMS) Hospital

*Rhamy JF, JBSM 2010, 50: 2793-2797*

## **Essential medicines will help to improve evidence-based transfusion medicine**

- **Is the treatment correct?**  
How can be explained the huge differences in treatment ?
- **What do we know about the products?**  
Specifications of the products well defined?  
Products with the same name really the same?  
What about aging, volume, type and product treatment ?
- **Individual reactions ?**  
Are age, sex, hereditary factors, underlying disease, pre-existent disorder, clinical condition, acute or chronic disease, disturbance in haematopoietic, humeral or cellular systems, of importance or taken into account?

## National Regulation of Blood Components as Medicines

Blood is regulated as a medicine in many jurisdictions, either directly or indirectly, e.g.

- o In the US, Canada, and Germany, blood and components are directly regulated as biologic medicines
- o In Japan, blood and blood products are regulated as safety measures by the “Pharmaceutical Affairs Law” and under the “Law on Securing a Stable Supply of Safe Blood Products”
- o In Australia, blood component manufacturers are subject to licensing to assure that the products meet standards as per the Council of Europe “Guide”

Common to all blood component regulations are requirements to assure that blood components meet product standards through controls on manufacturing, often explicitly stated as Good Manufacturing Practice requirements



SPECIAL ARTICLE

## Emergency Hospitalizations for Adverse Drug Events in Older Americans

Daniel S. Budnitz, M.D., M.P.H., Maribeth C. Lovegrove, M.P.H.,  
Nadine Shehab, Pharm.D., M.P.H., and Chesley L. Richards, M.D., M.P.H.

ABSTRACT

**BACKGROUND**

Adverse drug events are important preventable causes of hospitalization in older adults. However, nationally representative data on adverse drug events that result in hospitalization in this population have been limited.

**METHODS**

We used adverse-event data from the National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance project (2007 through 2009) to estimate the frequency and rates of hospitalization after emergency department visits for adverse drug events in older adults and to assess the contribution of specific medications, including those identified as high-risk or potentially inappropriate by national quality measures.

ORIGINAL INVESTIGATION

## Frequency of and Risk Factors for Preventable Medication-Related Hospital Admissions in the Netherlands

Anne J. Leendertse, PharmD; Antoine C. G. Egberts, PhD; Lennart J. Stoker, PharmD;  
Patricia M. L. A. van den Bemt, PhD; for the HARM Study Group

## European Commission estimation

- 5% of all hospital admissions due to Adverse Drug Reactions (ADRs)
- 5% of all hospital patients experience an ADR
- ADRs 5th most common cause of hospital death
- 197,000 deaths per year in EU caused by ADRs
- Total societal cost €79 billion

# What is Pharmacovigilance?

- Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem
- Underlying objectives are:
  - preventing harm from adverse reactions in humans arising from the use of medicines; and
  - promoting the safe and effective use of medicines, in particular through providing timely information about the safety of medicines to patients, healthcare professionals and the public.



# Adverse Event vs Adverse Drug Reaction

## **Adverse Event (AE)**

Any untoward medical occurrence in a patient or clinical trial subject administered a medicine and which does not necessarily have a causal relationship with this treatment

## **Adverse Drug Reaction (ADR)**

A response to a medicine which is noxious and unintended

## Adverse reaction

- Adverse reaction characterized by the fact that a causal relationship between a medicine and an occurrence is suspected.

## Seriousness Criteria

- Death
- Life-threatening
- Requires hospitalization/prolongation
- Persistent/significant disability/incapacity
- Congenital birth defect
- Medical important event
- \*Transmission of infectious disease is considered a serious event

## Special situation-case reports

- Use of a medicine during pregnancy or breastfeeding
- Use of a medicine in a paediatric or elderly population
- Lack of therapeutic efficacy
- Reports of overdose, abuse, off-label use, misuse, medication error or occupational exposure

## Potential Sources of Adverse Events: Solicited

Reports from organised data collection systems, i.e.:

- clinical trials,
- non-interventional studies,
- registries,
- post-authorisation named-patients use programmes,
- other patient support and disease management programmes,
- surveys of patients or healthcare providers or
- information gathering on efficacy or patient compliance.
  - Exception: AEs originating from certain compassionate use or named patient use where AEs are not actively sought.

## Potential Sources of AEs: Spontaneous

- Through **calls, conversation, social settings, faxes**
- From consumers or healthcare professionals

Consumer: Person who is not a healthcare professional such as a patient, lawyer, friend or relative/parent/child of a patient

Primary Source (Reporter): Person who reports the facts.

- Several primary sources may provide information on the same case such as healthcare professionals and/or a consumer.
- All the primary sources' details, including the qualifications, should be provided

## Potential Sources of AEs: Spontaneous

- **Legal claims, complaints or medical information**
- **Literature reports:** Reports of suspected adverse reactions from the scientific and medical literature, including relevant published abstracts from meetings and draft manuscripts.
- **Reports from other sources**
  - lay press or other media
- Information on suspected adverse reactions from the **internet** or **digital media**
  - MAHs should regularly screen internet or digital media under their management or responsibility, for potential reports of suspected adverse reactions. (Digital media is considered to be company sponsored if it is owned, paid for and/or controlled by the marketing authorisation holder.)

## Summary

- Addition of blood components to the WHO Model List of Essential Medicines will promote the global availability of safe blood for transfusion, advancing global health
- Government attention to establishing and maintaining National Blood Systems to assure supply and safety
- Recognition of the need for blood regulation
- Protection of donors (donor vigilance)
- Assurance of blood quality and safety
- Listing of Whole Blood and RBC would be especially important to address unmet needs for effective treatment of hemorrhage and anemia in many developing countries
- Whether under haemovigilance or pharmacovigilance, whole blood and red cells will cohabitate well as both are directed to safety biologic medicines





## Questions?

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