European Statements of Hospital Pharmacy: glossary

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This glossary (table 1) has been produced to accompany the European Statements of Hospital Pharmacy agreed at a summit in Brussels on 15 May 2014.

In the process of refining the statements in workshops with attendees at the summit on 14 May 2014, it was recognised that there was a clear need for a glossary to accompany the statements. This was to enable readers of the statements who did not partake in the May discussions, to have a common understanding of key terms used in the statements.

Communication is challenging. Not only are the statements in English, which is not the first language for many readers, but words and phrases have different meanings in different countries. In addition, the practice of pharmacy is very different in different member states. The glossary seeks to prevent misunderstandings related to the technical terms used in the statements.

All authors of the glossary were facilitators or observers in the Delphi process, and three (NM, RF, JU) were facilitators in the World Café process (*see page 264*); David Preece was a note-taker in the World Café process. All were familiar with the technical terms in the European statements for hospital pharmacy which generated discussions about terminology during both processes. Such discussions were the starting point for identifying words and phrases which would form a glossary to accompany the statements. If not identified in discussions, potential sources of the required definitions of terminology were identified through PubMed or internet search engines. When required, snowballing of references was employed. The determinant of the most appropriate sources for the glossary was relevance to the technical discussions which took place in the Delphi and World Café processes.

Contributors NM, in correspondence with DP, developed the approach for the production of the glossary. DP produced a first draft which was added to and refined by NM. RF and JU reviewed and made further suggested amendments which DP incorporated. A final version was then developed by NM. All authors reviewed and approved the final manuscript.

Competing interests NM and JU are employed part time by the National Institute for Health and Care Excellence. RF is President of the European Association of Hospital Pharmacists. DP has no competing interests to declare.

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Table 1 Glossary of terms

Term	Definition	Source	Notes
Administration of medicines	Administration of medicines involves checking the patient's identity, ensuring the patient is not allergic to the medicine, ensuring the medicine's use is in line with its normal dosage, side effects, precautions and contra-indications, and is in line with the patient's plan of care (care plan or pathway), the medicine is in date, and that the method of administration, route and timing are appropriate, and ensuring that a clear, accurate and immediate record of all medicine administered, intentionally withheld or refused by the patient is made.	Adapted from UK Nursing & Midwifery Council: http://www.nmc-uk.org/Documents/NMC-Publications/NMC-Standards-for-medicines-management.pdf	
Adverse drug reactions	Any undesirable experience that has happened to the patient while taking a drug which is suspected to be caused by the drug or drugs.	MHRA: http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme/Informationforhealthcareprofessionals/Adversedrugreactions/index.htm	
Best practice quality requirements	These principles maximise efficiency, effectiveness, safety, access, reduction in inappropriate variation, and sustainability.	Adapted from UNITE FOR SIGHT: http://www.uniteforsight.org/global-health-course/module1	
Clinical incident reporting system (CIRS)	Reporting of errors, injuries, non-harmful errors, equipment malfunction, process errors or other hazards by the doctor, nurse or other provider within the hospital or healthcare organisation, and by the organisation to a broader audience through a system-wide, regional or national reporting system. This can help target improvement efforts and systems changes to reduce the likelihood of future harm to patients. Reporting systems are non-punitive and may also be designed to receive reports from patients, families and consumer advocates.	Adapted from the World Health Organization: http://www.who.int/patientsafety/events/05/Reporting_Guidelines.pdf	Also called critical incident reporting system. The two terms appear to be used interchangeably.
Clinical management options	A competent clinician formulates appropriate management plans in line with best practice and varies the management options in response to changing circumstances. S/he refers appropriately, co-ordinates care with other professionals, and provides continuity of care for the patient rather than just the problem.	Adapted from the RCGP: http://www.wpba4gps.co.uk/fileadmin/user_upload/secure/mindmaps/PDF_files_for_Competency/Clinical_Management.pdf	
Clinical trials	Participants in clinical trials receive specific interventions according to the research plan or protocol created by the investigators. Clinical trials may compare a new medical approach to a standard one that is already available or to a placebo that contains no active ingredients, or to no intervention.	Adapted from ClinicalTrials.gov: https://clinicaltrials.gov/ct2/about-studies/learn	Also called interventional studies.
Competence	The knowledge, skills, behaviours and attitudes that an individual accumulates, develops and acquires through education, training and work experience.	FIP: http://www.ajhp.org/content/66/5_Supplement_3/s67.full	
Competency framework	A competency framework is a collection of competencies thought to be central to effective performance. Development of competencies should help individuals to continually improve their performance and to work more effectively.	Whiddett S, Hollyforde, S. *The Competencies Handbook*. London: Institute of Personnel and Development, 1999. See http://www.fip.org/files/fip/PharmacyEducation/GbCF%20booklet.pdf	
Compounding (of medicines)	Pharmacy compounding is the process of preparing personalised medications for patients.	Adapted from PCAA: http://www.pccarx.com/what-is-compounding	See also 'Extemporaneous preparation'.
Computerised decision support	Computer decision support systems are computer applications designed to aid clinicians in making diagnostic and therapeutic decisions in patient care. They can simplify access to data needed to make decisions, provide reminders and prompts at the time of a patient encounter, assist in establishing a diagnosis when prescribing and reviewing medication, and alert clinicians when new patterns in patient data are recognised.	Adapted from: Payne TH. Computer decision support systems. *Chest* 2000;**118**:47S–52S. http://www.ncbi.nlm.nih.gov/pubmed/10939999	
Counterfeit (relating to medicines)	A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging.	World Health Organization: http://www.who.int/medicines/services/counterfeit/overview/en/	

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Table 1 Continued

Term	Definition	Source	Notes
Dispensing (of medicines)	To label from stock and supply a clinically appropriate medicine to a patient or caregiver, usually against a written prescription, for self-administration or administration by another professional, and to advise on safe and effective use.	FIP: http://www.ajhp.org/content/66/5_Supplement_3/s67.full	
Disposal (of medicines)	Medicines that are no longer to be administered to a patient, and for whatever the reason, should normally be returned to the relevant pharmacy or dispensing doctor for safe disposal.	Adapted from the Royal Pharmaceutical Society (UK): http://www.rpharms.com/support-pdfs/safsechandmeds.pdf	
Distribution (of medicines)	The process for the consistent storage, transportation and handling under suitable conditions of medicines as required by the marketing authorisation or product specification.	Adapted from MHRA: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodDistributionPractice/	
Drug and therapeutics committees	A forum to bring together all stakeholders involved in decisions about drug use; they may exist at any level within the healthcare system—at district level (overseeing primary healthcare facilities), in hospitals, or at the national level.	World Health Organization: http://apps.who.int/medicinedocs/en/d/Js4882e/3.1.html	
Efficacy (of medicines)	The ability of an intervention to produce the desired beneficial effect in expert hands and under ideal circumstances, for example in clinical trials.	Modified from *Dorland's Medical Dictionary for Health Consumers*: http://medical-dictionary.thefreedictionary.com/efficacy	
Effectiveness (of medicines)	The degree to which an intervention achieves the intended health result under normal or usual circumstances.	Modified from *Mosby's Dental Dictionary*, 2nd edn, 2008: http://medical-dictionary.thefreedictionary.com/effectiveness	
e-Health	e-Health is the transfer of health resources and health care by electronic means. It encompasses three main areas: ▶ The delivery of health information, for health professionals and health consumers, through the internet and telecommunications ▶ Using the power of IT and e-commerce to improve public health services, e.g. through the education and training of health workers ▶ The use of e-commerce and e-business practices in health systems management.	World Health Organization: http://www.who.int/trade/glossary/story021/en/	
Evidence-based practice	The conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. Expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate acknowledgement of individual patient's predicaments, rights and preferences in making clinical decisions about their care.	Sackett DL, Rosenberg WMC, Muir Gray JA, *et al.* Evidence based medicine: what it is and what it isn't. *BMJ* 1996;**312**:71. http://www.bmj.com/content/312/7023/71	The term 'evidence-based practice' is now preferred to 'evidence-based medicine'.
Extemporaneous preparation	A product which is dispensed immediately after preparation and not kept in stock	FIP: http://www.ajhp.org/content/66/5_Supplement_3/s67.full	See also 'Compounding (of medicines)'.
External quality assessment accreditation programme	A regional (or potentially national) process voluntarily entered into by service provider organisations for the improvement of the organisation and delivery of health services assessed against explicit, published standards by peer-group teams moderated by a non-partisan authority involving (but impartial to) users, providers, purchasers and government.	Shaw CD. External quality mechanisms for health care: summary of the ExPeRT project on visitatie, accreditation, EFQM and ISO assessment in European Union countries. *Int J Qual Health Care* 2000;**12**:169–7. http://www.ncbi.nlm.nih.gov/pubmed/10894187	
Formulary	The output of processes to support the managed introduction, utilisation or withdrawal of healthcare treatments within a health economy, service or organisation.	Developing and updating local formularies. NICE Medicines Practice Guidelines 2012: http://www.nice.org.uk/guidance/MPG1/chapter/1-background#definition-of-a-local-formulary	
Guideline (clinical)	Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances	Field M, Lohr K; Committee to Advise the Public Health Service on Clinical Practice Guidelines, Institute of Medicine. *Clinical Practice Guidelines: Directions for a New Program*. Washington, DC: National Academies Press, 1990.See http://www.sign.ac.uk/guidelines/fulltext/50/section1.html	
Hazardous (related to medicines)	Drugs considered hazardous include those that exhibit one or more of the following six characteristics in humans or animals:	NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012: http://www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf	

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Table 1 Continued

Term	Definition	Source	Notes
	▶ Carcinogenicity ▶ Teratogenicity or other developmental toxicity ▶ Toxicity ▶ Reproductive toxicity ▶ Organ toxicity at low doses ▶ Genotoxicity.		
Healthcare setting	The location in which health or social care is provided for an individual.	See https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/212915/Care-Setting-Definitions.pdf for detailed definitions	
High risk medicines	High risk medicines are medicines that are most likely to cause significant harm to the patient, even when used as intended.	Patient Safety First: http://www.patientsafetyfirst.nhs.uk/ashx/Asset.ashx?path=/How-to-guides-2008-09-19/Medicines%201.1_17Sept08.pdf	
Labelling (of medicines)	The safe use of all medicines depends on users reading the labelling and packaging carefully and accurately and being able to assimilate and act on the information presented. The primary purpose of medicines labelling and packaging is the clear unambiguous identification of the medicine and the conditions for its safe use.	MHRA: http://www.mhra.gov.uk/home/groups/pl-a/documents/websiteresources/con157150.pdf	
Manufacture (of medicines)	Activities for which the authorisation referred to in Article 40(1) and (3) of Directive 2001/83/EC or the authorisation referred to in Article 13(1) of Directive 2001/20/EC is required.	Commission Directive 2003/94/EC: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2003_94/dir_2003_94_en.pdf	
Marketing authorisation	Medicines which meet the standards of safety, quality and efficacy are granted a marketing authorisation (previously a product licence), which is normally necessary before they can be prescribed or sold.	MHRA: http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Marketingauthorisations/	
Medical device	Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: ▶ diagnosis, prevention, monitoring, treatment or alleviation of disease ▶ diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap ▶ investigation, replacement or modification of the anatomy or of a physiological process ▶ control of conception and which does not achieve its principal intended action on or in the human body by pharmacological, immunological or metabolic means but which may be assisted in its function by such means.	European Union: http://ec.europa.eu/health/medical-devices/files/revision_docs/2007-47-en_en.pdf	
Medication error	Medication errors are unintentional errors in the prescribing, dispensing, administration or monitoring of a medicine while under the control of a healthcare professional, patient or consumer.	EMA: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000570.jsp	
Medicinal product	Any substance or combination of substances presented as having properties for treating or preventing disease in human beings, or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis.	European Union: http://www.wipo.int/wipolex/en/details.jsp?id=13063	Synonymous with 'medicine'.
Medication error reporting systems (MERS)	An incident reporting system which allows front-end clinicians to have easy access for reporting an incident with an understanding that their report will be handled in a non-punitive manner, and that it will lead to enhanced learning regarding the causes of the incident and systemic changes which will prevent it from recurring.	Mahajan RP. Critical incident reporting and learning. *Br J Anaesth* 2010;**105**:69–75. http://bja.oxfordjournals.org/content/105/1/69.abstract	

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Table 1 Continued

Term	Definition	Source	Notes
Medicine use process	Medication use is a complex process that comprises the sub-processes of medication prescribing, order processing, dispensing, administration, and effects monitoring.	Institute for Safe Medication Practices: http://www.ismp.org/faq.asp#Question_3	
Medicines management policies	A system of processes and behaviours that determines how medicines are used by patients and by healthcare systems.	Adapted from National Prescribing Centre: http://www.npc.nhs.uk/developing_systems/intro/resources/library_good_practice_guide_mmmbook1_2002.pdf	
Medicines optimisation	Medicines optimisation ensures people obtain the best possible outcomes from their medicines while minimising the risk of harm. Medicines optimisation requires evidence-informed decision making about medicines involving effective patient engagement and professional collaboration to provide an individualised, person-centred approach to medicines use within the available resources.	NICE: http://www.nice.org.uk/guidance/gid-cgwave0676/resources/medicines-optimisation-draft-scope2	
Medicines shortages	A situation in which the total supply of all clinically interchangeable versions of a medicine is inadequate to meet the current or projected demand at the user level. Medicine shortages can occur for many reasons, such as manufacturing difficulties or problems affecting the quality of medicines that can impact on patient care	Adapted from the FDA: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffPoliciesandProcedures/ucm079936.pdfandEMA: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000588.jsp&mid=WC0b01ac05807477a5	
mHealth	Medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs) and other wireless devices.	World Health Organization: http://www.who.int/goe/publications/goe_mhealth_web.pdf	
Mixing (of medicines)	The combination of two (or more) active pharmaceutical ingredients in a single formulation or of two or more medicines administered at the same time.	National Prescribing Centre: http://www.npc.nhs.uk/improving_safety/mixing_meds/resources/mixing_of_medicines.pdf	
Multidisciplinary	Combining or involving several academic disciplines or professional specialisations in an approach to a topic or problem.	Oxford Dictionaries: http://www.oxforddictionaries.com/definition/english/multidisciplinary	
Near miss (related to medication error)	An event, situation or error that took place but was captured before it affected the patient.	Institute for Safe Medication Practices:https://www.ismp.org/newsletters/acutecare/articles/20090924.asp	
Outsource	Obtain goods or a service by contract from an outside supplier	Oxford Dictionaries: http://www.oxforddictionaries.com/definition/english/outsource	
Patient care teams	Care of patients by a multidisciplinary team usually organised under the leadership of a physician; each member of the team has specific responsibilities and the whole team contributes to the care of the patient.	MeSH term. See The Health Foundation: http://www.health.org.uk/public/cms/75/76/313/579/Patient%20Care%20Teams.pdf?realName=jsrQqb.pdf	
Patient safety	The prevention of errors and adverse effects to patients associated with health care.	World Health Organization: http://www.euro.who.int/en/health-topics/Health-systems/patient-safety	
Patient's health record	A collection of clinical information pertaining to a patient's physical and mental health, compiled from different sources.	*Segan's Medical Dictionary 2012*: http://medical-dictionary.thefreedictionary.com/health+record	
Pharmacy preparation	All operations of purchase of materials and products, production, quality control, release, storage, delivery of medicinal products, and related controls.	PIC/S Guide to Good Practices for the Preparation ofMedicinal Products in Healthcare Establishments: http://www.picscheme.org/bo/commun/upload/document/pe-010-4-guide-to-good-practices-for-the-preparation-of-medicinal-products-in-healthcare-establishments-1.pdf	
Pharmacoeconomic evaluation	Pharmacoeconomics is the scientific discipline that evaluates the clinical, economic and humanistic aspects of pharmaceutical products, services and programmes, as well as other healthcare interventions to provide healthcare decision makers, providers and patients with valuable information for optimal outcomes and the allocation of healthcare resources.	International Society for Pharmacoeconomics and Outcomes Research: http://www.ispor.org/Terminology/Default.asp	
Pharmacovigilance programmes	The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.	World Health Organization: http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/	
Pharmacy practice	The mission of pharmacy practice is to contribute to health improvement and to help patients with health problems to make the best use of their medicines.	FIP/WHO: http://www.fip.org/files/fip/WHO/GPP%20guidelines%20FIP%20publication_final.pdf	
Point of care (systems)	Laboratory and other services provided to patients at the bedside. These include diagnostic and laboratory testing using automated information entry.	MeSH term: http://www.ncbi.nlm.nih.gov/mesh?term=Point-of-Care%20Systems	

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Table 1 Continued

Term	Definition	Source	Notes
Procurement	Providing a fast, effective supply service to patients, of the right medicines at the right price, while achieving cost-effective purchasing for the local, regional or national healthcare system. This may involve a complex network of business, operational, IT and quality control and risk management systems. Prescribing advice, formulary guidance and issues of clinical governance should be observed and adhered to.	British Journal of Medicines Procurement: http://www.medicinesprocurement.co.uk/	
Protocol	A procedure for carrying out a scientific experiment or a course of medical treatment.	Oxford Dictionaries: http://www.oxforddictionaries.com/definition/english/protocol	
Quality assurance	The maintenance of a desired level of quality in a service or product, especially by means of attention to every stage of the process of delivery or production.	Oxford Dictionaries: http://www.oxforddictionaries.com/definition/english/quality-assurance	
Quality control	A system of maintaining standards in manufactured products by testing a sample of the output against the specification	Oxford Dictionaries: http://www.oxforddictionaries.com/definition/english/quality-control?q=quality+control	
Reconstitution (of medicines)	Manipulation to enable the use or application of a medicinal product with a marketing authorisation in accordance with the instructions given in the summary of product characteristics in the patient information leaflet.	PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments: http://www.picscheme.org/bo/commun/upload/document/pe-010-4-guide-to-good-practices-for-the-preparation-of-medicinal-products-in-healthcare-establishments-1.pdf	
Responsible use of medicines	A situation where health-system stakeholder activities and capabilities are aligned to ensure that patients receive the right, cost-effective medicines at the right time, use them appropriately, and benefit from them. Bringing the right medicines to patients who need them requires the engagement of all actors, including governments, and a vision on how to integrate public and private interests and mobilise resources.	Adapted from FIP: http://www.fip.org/centennial/files/static/REPORT_MINISTERS_SUMMIT_-_English_version_final.pdf	
Review (of medication)	A structured, critical examination of a patient's medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems, and reducing waste.	National Prescribing Centre: http://www.npc.nhs.uk/review_medicines/intro/resources/room_for_review.pdf	
Risk assessment	A systematic process of evaluating the potential risks that may be involved in a projected activity or undertaking.	Oxford Dictionaries: http://www.oxforddictionaries.com/definition/english/risk-assessment	
Seamless care	Seamless care is a smooth and safe transition of a patient within or between care settings including from hospital to home.	Adapted from Spehar AM, Campbell RR, Cherrie C, et al. *Seamless Care: Safe Patient Transitions from Hospital to Home*.http://www.ncbi.nlm.nih.gov/books/NBK20459/	
Stakeholders (related to health care)	Persons or groups who have a vested interest in a clinical decision and the evidence that supports that decision. Stakeholders may be patients, caregivers, clinicians, researchers, advocacy groups, professional societies, businesses, policymakers or others. Each group has a unique and valuable perspective.	AHRQ: http://www.ahrq.gov/research/findings/evidence-based-reports/stakeholderguide/chapter3.html	
Traceability	The ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration.	GS1http://www.gs1.org/docs/healthcare/GS1_article_PMPS.pdf	
Transcription (related to prescriptions)	The act of making an exact copy usually in writing. This means that there must always be an original from which the transcribed copy is made. For medicines, the act of transcribing is usually performed so that prescription details and other communications are available to the professionals caring for a patient.	Adapted from UKMi: http://www.medicinesresources.nhs.uk/upload/documents/Communities/SPS_E_SE_England/Transcribing%20guidance%20Vs%201%20Feb11%20DG.pdf	

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Table 1 Continued

Term	Definition	Source	Notes
Treatment pathway	Anticipated care placed in an appropriate time frame, written and agreed by a multidisciplinary team.	Welsh National Leadership and Innovation Agency for Healthcare guide to integrated care pathways: http://www.wales.nhs.uk/sitesplus/Documents/829/integratedcarepathways.pdf	Also known as care pathways, critical pathways, integrated care pathways, or care maps.
Use of a medicine outside of its marketing authorisation	There are clinical situations when the use of unlicensed medicines or the use of medicines outside the terms of the licence (i.e., 'off-label') may be judged by the prescriber to be in the best interests of the patient on the basis of available evidence. Such practice is particularly common in certain areas of medicine: for instance, in paediatrics where difficulties in the development of age-appropriate formulations mean that many medicines used in children are used off-label or are unlicensed. Healthcare professionals may regard it as necessary to prescribe or advise on the use of an unlicensed medicine when no licence suitable alternative is available, or when a medicine is prepared in a pharmacy by, or under the supervision of, a pharmacist, or the use of a licence medicine outside the terms defined by the licence (e.g., outside defined indications, doses, routes of administration, or contrary to listed warnings). Compassionate-use programmes are for patients who have a disease with no satisfactory authorised therapies or cannot enter a clinical trial. They are intended to facilitate the availability to patients of new treatment options under development.	Adapted from MHRA: http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON087990andEMA: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000293.jsp	