



Rare-bestpractices project. A platform for sharing best practices for the management of rare diseases

Glossary

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About RARE-Bestpractices project

RARE-Bestpractices, a platform for sharing best practices for the management of rare diseases is a four-year project (January 2013-December 2016) funded by the Seventh Framework Programme of the European Union (FP7/2007-2013).

The National Centre for Rare Diseases (CNMR) of the Istituto Superiore di Sanità acts as coordinator, bringing together a team of highly qualified experts in the area of guidelines, systematic reviews, health technology assessments, health policy, rare disease epidemiology, public health and patient organisations coming from 9 countries across Europe. The project aims to improve the management of rare diseases:

- 1) Create reliable procedures for the development and evaluation of clinical practice guidelines for rare diseases
- 2) Build a comprehensive publicly searchable database of high quality clinical practice guidelines ranging from diagnostic tests and treatments to organization of care to help professionals, patients, policy makers access the best and most up to date information
- 3) Produce mechanisms to identify rare disease clinical research needs to optimize as well as redefine the clinical research agenda taking into consideration both patients' and clinicians' needs and interests
- 4) Set up training activities targeted at key stakeholders to disseminate processes and tools for developing and evaluating clinical practice guidelines.

More information are available at www.rarebestpractices.eu



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1 Introduction

The following glossary contains definitions of key terms used in the RARE-Bestpractices project. The aim of the glossary is to ensure consistent use and understanding of core terminology relating to rare diseases, evidence-based medicine and healthcare delivery throughout the lifecycle of this multidisciplinary pan-European collaboration.

This glossary is composed of definitions of 20 key terms released by HIS (Jan Manson and Michele Hilton Boon), on October 1st 2013, and 41 new key term definitions released by AREAS-CCI used in the RARE-Bestpractices project with the collaboration of ISS (Cristina Morciano, Paola Laricchiuta), HIS (Karen Ritchie and Lorna Thompson), LSE (Panos Kanavos), FUNCIS (Pedro Serrano-Aguilar) and ISCIII (Manuel Posada) who revised and integrated some definitions.

To minimise duplication of effort, a number of existing glossaries were examined for suitable descriptions which could be adopted or modified for the purpose of this document:

- <http://htaglossary.net/HomePage>
- <http://effectivehealthcare.ahrq.gov/index.cfm/glossary-of-terms/>
- http://whqlibdoc.who.int/wkc/2004/WHO_WKC_Tech.Ser._04.2.pdf
- <http://www.ebm.med.ualberta.ca/Glossary.html>
- <http://www.cochrane.org/glossary>
- <http://www.nice.org.uk/website/glossary/glossary.jsp>
- <http://www.ncbi.nlm.nih.gov/books/NBK55850/>
- <http://www.guideline.gov/about/glossary.aspx>
- <http://grants.nih.gov/grants/glossary.htm>
- A Dictionary of Epidemiology – M. Porta et al (eds). © International Epidemiological Association, 2014
Publisher: Oxford University Press Print Publication Date: 2008 Print ISBN-13: 9780195314496
Published online: 2014 Current Online Version: 2014 DOI: 10.1093/acref/9780195314496.001.0001
eISBN: 9780199338931

When the definition of a specific key term was not found in any of the resources above or when it was found but additional information was needed a further search in Google has been conducted to search for definitions of the term in other glossaries or relevant websites, or it has been considered the definition reported in the RARE-Bestpractices project (www.rarebestpractices.eu).

An initial list of proposed terms was circulated to the RARE-Bestpractices beneficiaries for consultation and the finalised definitions contained within this document have been agreed through consensus.

References to any sources used for each key term are provided as footnotes. The following glossary has been uploaded in the “Training tools” webpages of the RARE-Bestpractices website (www.rarebestpractices.eu), with possibility to browse the glossary of terms by alphabetical letter.

2 Glossary

2.1 Adaptive pathway (formerly known as 'adaptive licensing')

Preamble

The term was found in the European Medicine Agency (EMA) website¹. Adaptive pathway is particularly relevant for medicines with the potential to treat serious conditions with an unmet medical need, and may reduce the time to a medicine's approval or to its reimbursement for targeted patient groups. It involves balancing the importance of timely patient access with the need for adequate, evolving information on a medicine's benefits and risks.

The adaptive pathways approach builds on regulatory processes already in place within the existing European Union legal framework. These include:

- scientific advice;
- compassionate use;
- the conditional approval mechanism (for medicines addressing life-threatening conditions);
- patient registries and pharmacovigilance tools that allow collection of real-life data and development of the risk-management plan for each medicine.

Developing the approach involves early discussion between a wide range of stakeholders to explore ways of optimising development pathways. These include organisations such as EMA and other medicines regulators, the pharmaceutical industry, health-technology-assessment (HTA) bodies, organisations issuing clinical treatment guidelines, patient and consumer organisations, healthcare professionals, researchers and academics.

Definition

An initial approval of a treatment in a well-defined patient subgroup with a high medical need and subsequent widening of the indication to a larger patient population, or an early regulatory approval (e.g. conditional approval) which is prospectively planned, and where uncertainty is reduced through the collection of post-approval data on the medicine's use in patients.

¹ http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000601.jsp

2.2 Advisory board

Preamble

The term definition was not found in any of the resources consulted. In the RARE-Bestpractices project² the 'Advisory Board' is composed of international experts representing the major stakeholders involved in the clinical management of patients with rare diseases, in evidence-based medicine, and in developing evidence-based health care policies. The Advisory Board gives advice to the General Assembly on major topics and evaluates the project advancements and the sustainability plan. Moreover it improves contacts with relevant stakeholders.

Definition

A group of people formed of international experts representing the major stakeholders involved in the clinical management of patients with rare diseases, in evidence-based medicine, and in developing evidence-based health care policies.

(As described in www.rarebestpractices.eu)

² RARE-Bestpractices. <http://www.rarebestpractices.eu/>. [last accessed 10/03/2015]

2.3 AGREE II instrument

Preamble

Only the NICE Glossary provides the definition of AGREE and the AGREE II instrument: “An international collaboration of researchers and policy makers whose aim is to improve the quality and effectiveness of practice guidelines. The AGREE II instrument, developed by the group, is designed to assess the quality of clinical guidelines.”³

The AGREE Enterprise website was also consulted. The AGREE II instrument is the result of the efforts made to improve the usability, validity and reliability of the original AGREE instrument released in 2003. AGREE II instrument is composed of 23 items, each targeting various aspects of practice guideline quality. The items are organized into six domains. Through two final overall assessment items appraisers can express the overall judgment of the practice guideline, considering how they rated the 23 items.⁴

The following definition has been adapted from the AGREE Enterprise web site.

Definition

AGREE II is a reliable and validated tool to assess the methodological rigour and transparency in which a guideline is developed.

³ <http://www.nice.org.uk/Glossary?letter=A> [last accessed 30/04/2015]

⁴ <http://www.agreetrust.org/about-the-agree-enterprise/introduction-to-agree-ii/> [last accessed 30/04/2015]

2.4 Best available evidence

Preamble

A term ubiquitous in the EBM literature, 'best available evidence' was defined in only two of the examined glossaries.

The proposed definition has been adapted from the NICE definition:

"The strongest, best-quality research evidence available on the topic being investigated".⁵

Definition

The evidence which is judged to be strongest and the most reliable for any given topic.

(Adapted from NICE, 2011, as above)

⁵ National Institute for Health and Care Excellence (NICE). Glossary. 2011.
<http://www.nice.org.uk/website/glossary/glossary.jsp> [last accessed 29/04/2013].

2.5 Best practice statement

Preamble

This definition is adapted from Healthcare Improvement Scotland (HIS) which actively produces documents of this type.

“Focusing specifically on nursing, midwifery & allied health professions, BPSs describe best and achievable practices in specific areas of care emphasising delivering care that is patient centred, feasible and fair, and an attempt to reduce existing variations in practice. Best practice statements are endorsed by the Chief Nursing Officer and are recommended good practice for NHS Scotland.”⁶

Definition

A statement to direct the best achievable practice in specific areas of care emphasising the delivery of care that is patient centred, feasible and fair.

(Adapted from HIS, 2006, as above)

⁶ Healthcare Improvement Scotland. NHS QIS and NICE Advice – definitions and status. 2006.
http://www.healthcareimprovementscotland.org/previous_resources/process_documentation/nhs_qis_nice_advice.aspx
[last accessed 29/04/2013]

2.6 Carer

Preamble

WHO, NICE and HTAglossary.net list definitions for carer or caregiver and recognise that this role can be carried out on a formal or informal basis. The adaption of the following HTAglossary.net definition captures the range of people who might fulfil this role.

“1) A duly trained and paid person who provides a person with a disease or disability with care. 2) A person (often a family member or friend), paid or unpaid, who regularly provides a person with a disease or disability with any form of care.”⁷

Definition

A person, paid or unpaid, who regularly provides care to a person because they are ill, frail or have a disability.

(Adapted from HTAGlossary.net, as above)

⁷ HTAGlossary.Net. <http://htaglossary.net/HomePage> [last accessed 29/04/2013].

2.7 Case-control study

Preamble

The term definition was found in the HTA glossary, NCBI, NICE, Cochrane Glossary, Ualberta web sites.

The case-control study is a study to find out the cause(s) of a disease or condition. This is done by comparing a group of patients who have the disease or condition (cases) with a group of people who do not have it (controls) but who are otherwise as similar as possible (in characteristics thought to be unrelated to the causes of the disease or condition). This means that the researcher can look for aspects of their lives that differ to see if they may cause the condition.

For example, a group of people with lung cancer might be compared with a group of people the same age that do not have lung cancer. The researcher could compare how long both groups had been exposed to tobacco smoke. Such studies are retrospective because they look back in time from the outcome to the possible causes of a disease or condition.⁸

This design is particularly useful where the outcome is rare and past exposure can be reliably measured. Case-control studies are usually retrospective.⁹

Definition

A study that compares people with a specific disease or outcome of interest (cases) to people from the same population without that disease or outcome (controls), and which seeks to find associations between the outcome and prior exposure to particular risk factors.

(From Cochrane Collaboration Glossary⁹)

⁸ National Institute for Health and Care Excellence (NICE). Glossary. 2011.
<http://www.nice.org.uk/website/glossary/glossary.jsp> [last accessed 09/03/2015]

⁹ Cochrane Collaboration Glossary. <http://www.cochrane.org/glossary> [last accessed 09/03/2015]

2.8 Case-series study

Preamble

The term definition was found in the HTA, Ualberta and Cochrane Glossary web sites.

A collection of subjects (usually, patients) with common characteristics used to describe some clinical, pathophysiological, or operational aspect of a disease, treatment, exposure, or diagnostic procedure. A case series does not include a comparison group and is often based on prevalent cases and on a sample of convenience⁷. Case series may be prospective or retrospective, depending on whether participants are recruited before any intervention and followed into the future, or are identified from past records; it can be consecutive or non-consecutive, depending on whether all cases presenting to the reporting authors over a period were included, or only a selection.¹⁰

Definition

A study reporting observations on a series of individuals, usually all receiving the same intervention, with no control group.

(From Cochrane Collaboration Glossary¹¹)

¹⁰ A Dictionary of Epidemiology – M. Porta et al (eds). © International Epidemiological Association, 2014
Publisher: Oxford University Press Print Publication Date: 2008 Print ISBN-13: 9780195314496 Published online: 2014
Current Online Version: 2014 DOI: 10.1093/acref/9780195314496.001.0001 eISBN: 9780199338931

¹¹ Cochrane Collaboration Glossary. <http://www.cochrane.org/glossary> [last accessed 10/03/2015]

2.9 Classification of diseases

Preamble

This definition is taken from the WHO glossary of terms for healthcare and services for older people.

Classification of diseases is useful in efforts to achieve standardization in the methods of presenting mortality and morbidity data from different sources and, therefore, in comparability. It may include a systematic numerical notation for each disease entry. Examples include the International Statistical Classification of Diseases, Injuries and Causes of Death.

Definition

Grouping of diseases with common characteristics.

(As described in WHO, 2004¹²)

¹² World Health Organisation (WHO). 2004. A glossary of terms for community health care and services for older persons http://whqlibdoc.who.int/wkc/2004/WHO_WKC_Tech.Ser._04.2.pdf [last accessed 25/02/2015].

2.10 Clinical recommendation

Preamble

The following definition is adapted from NICE.¹³ Clinical recommendations on how healthcare and other professionals should care for people with specific conditions are systematically-developed in clinical guidelines:

“Healthcare and other professionals in the NHS are expected to take clinical recommendations fully into account when exercising their professional judgment. However, the recommendation does not override the responsibility of healthcare professionals and others to make decisions appropriate to the circumstances of each patient. These decisions should be made in consultation with, and with the agreement of, the patient and/or their guardian or carer. Healthcare professionals and others should record their reasons for not following clinical recommendations”.

Definition

Clinical recommendations provide guidance on how healthcare and other professionals should care for people with specific conditions.

(Adapted from NICE, as above)

¹³ National Institute for Health and Care Excellence (NICE). Glossary. 2011.
<http://www.nice.org.uk/website/glossary/glossary.jsp> [last accessed 02/03/2015].

2.11 Clinical research

Preamble

The National Institutes of Health (NIH) defines “clinical research” as research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. In vitro studies that utilize human tissues that cannot be linked to a living individual are excluded from this definition.

Clinical research includes:¹⁴

- Patient-oriented research – This type of research involves a particular person or group of people, or uses materials from humans. This research can include 1) mechanisms of human disease, 2) therapeutic interventions, 3) clinical trials, and 4) development of new technologies
- Epidemiological and behavioral studies – These types of studies examine the distribution of disease, the factors that affect health, and how people make health-related decisions.
- Outcomes and health services research – These studies seek to identify the most effective and most efficient interventions, treatments, and services.

Definition

Research conducted with human subjects.
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(As described in NIH¹⁵)

¹⁴ http://keck.usc.edu/en/Research/Clinical_Research/Definition.aspx [last accessed 27/02/2015].

¹⁵ <http://grants.nih.gov/grants/glossary.htm> [last accessed 02/03/2015].

2.12 Cochrane Collaboration

Preamble

The term definition was found in the NICE, NCBI and Cochrane Collaboration Glossary Web Site. A further search of the term definition was done on the Cochrane Collaboration¹⁶ web site.

Cochrane is a global independent network of researchers, professionals, patients, careers, and people interested in health.

Cochrane contributors from more than 120 countries work together to produce credible, accessible health information that is free from commercial sponsorship and other conflicts of interest. Many of their contributors are world leaders in their fields - medicine, health policy, research methodology, or consumer advocacy - and our groups are situated in some of the world's most respected academic and medical institutions.

Its mission is to promote evidence-informed health decision-making by producing high-quality, relevant, accessible systematic reviews and other synthesized research evidence.

Cochrane's work is based on ten key principles:

- 1) Collaboration by fostering global co-operation, teamwork, and open and transparent communication and decision-making.
- 2) Building on the enthusiasm of individuals by involving, supporting and training people of different skills and backgrounds.
- 3) Avoiding duplication of effort by good management, co-ordination and effective internal communications to maximize economy of effort.
- 4) Minimizing bias through a variety of approaches such as scientific rigour, ensuring broad participation, and avoiding conflicts of interest.
- 5) Keeping up-to-date by a commitment to ensure that Cochrane Systematic Reviews are maintained through identification and incorporation of new evidence.
- 6) Striving for relevance by promoting the assessment of health questions using outcomes that matter to people making choices in health and health care.
- 7) Promoting access by wide dissemination of our outputs, taking advantage of strategic alliances, and by promoting appropriate access models and delivery solutions to meet the needs of users worldwide.
- 8) Ensuring quality by applying advances in methodology, developing systems for quality improvement, and being open and responsive to criticism.
- 9) Continuity by ensuring that responsibility for reviews, editorial processes, and key functions is maintained and renewed.
- 10) Enabling wide participation in our work by reducing barriers to contributing and by encouraging diversity.

Cochrane Reviews are prepared and updated by collaborating authors using explicitly defined methods to minimize the effects of bias; where appropriate and feasible, meta-analysis is used.¹⁷

¹⁶ Cochrane Collaboration. <http://www.cochrane.org/> [last accessed 02/03/2015]

Definition

An international organization of clinicians, epidemiologists, other professionals, and patients that aims to help people make well informed decisions about health care by preparing, maintaining, and ensuring the accessibility of systematic reviews of the effects of healthcare interventions.

(From Cochrane Collaboration glossary¹⁸)

¹⁷ A Dictionary of Epidemiology – M. Porta et al (eds). © International Epidemiological Association, 2014 Publisher: Oxford University Press Print Publication Date: 2008 Print ISBN-13: 9780195314496 Published online: 2014 Current Online Version: 2014 DOI: 10.1093/acref/9780195314496.001.0001 eISBN: 9780199338931

¹⁸ Cochrane Collaboration Glossary. <http://www.cochrane.org/glossary> [last accessed 10/03/2015]

2.13 Cohort study

Preamble

The term definition was found in the HTA Glossary, AHRQ, NCBI, NICE, Cochrane Glossary¹⁹, Ualberta²⁰ web sites. A 'prospective' cohort study recruits participants before any intervention and follows them into the future. A 'retrospective' cohort study is conducted by reconstructing data about persons at a time or times in the past. This method uses existing records about the health or other relevant aspects of a population as it was at some time in the past and determines the current (or subsequent) status of members of this population with respect to the condition of interest. Record linkage systems are often used in historical cohort studies. A common feature of a cohort study is comparison of incidences in groups that differ in exposure levels.²¹²²

Definition

A observational study that begins with the gathering of two matched groups (the cohorts), one which has been exposed to a prognostic factor, risk factor or intervention and one which has not (or it is exposed at different levels). The groups are then followed forward in time (prospective) to measure the development of different outcomes. In a retrospective cohort study, cohorts are identified at a point of time in the past and information is collected on their subsequent outcomes.

(Adapted from Cochrane Glossary and Ualberta)

¹⁹ Cochrane Collaboration Glossary. <http://www.cochrane.org/glossary> [last accessed 05/03/2015]

²⁰ <http://www.ebm.med.ualberta.ca/Glossary.html> [last accessed 08/03/2015]

²¹ <http://ccg.cochrane.org/non-randomised-controlled-study-nrs-designs> [last accessed 03/03/2015]

²² A Dictionary of Epidemiology – M. Porta et al (eds). © International Epidemiological Association, 2014 Publisher: Oxford University Press Print Publication Date: 2008 Print ISBN-13: 9780195314496 Published online: 2014 Current Online Version: 2014 DOI: 10.1093/acref/9780195314496.001.0001 eISBN: 9780199338931

2.14 Compassionate use

Preamble

The term was found in the European Medicine Agency (EMA) website²³. Compassionate-use programmes are for patients in the European Union (EU) 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. Compassionate-use programmes are often governed by legislation in individual EU Member States, to make medicines available on a named-patient basis or to cohorts of patients.

Definition

A treatment option that allows the use of an unauthorised medicine.

²³ http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000601.jsp

2.15 Consensus process

The term definition was found in the HTA, AHRQ, WHO²⁴, NICE²⁵ and National Guideline Clearinghouse web sites and modified by the RARE-Bestpractices Consortium.

Consensus process is part of the development of health care guideline (as defined as in paragraph 2.32). The multidisciplinary group is often required to reach an agreement on various issues in the guideline development process. For example when defining the scope of the guideline and the key questions, when selecting the inclusion/exclusion criteria of the studies and the relevant outcomes, and when the recommendations have to be formulated. Furthermore with the aim “to ensure that group processes fundamentally encourage inclusion of all opinions and grant adequate hearing to all arguments” (IOM, 2011) formal consensus methods (Delphi method, Nominal Group Technique) can be adopted and included as part of the guideline development process.

In this glossary the definition of health care guideline given in the paragraph 2.32 and the explanation about the use of consensus process in guideline development given above intends to provide clarification about the use of the term guideline and the use of consensus process in the guideline. This is also to underline what distinguishes the healthcare guidelines by other form of guidance (protocol, consensus statement, consensus conferences) that do not follow rigorous transparent development process.

The process of reaching an agreement can be informal, i.e. an approach to consensus development that lacks structure. Participants publicly express their views, the aggregate of which may be summarized by the group's leader and considered the final decision. Formal strategy can be adopted such as the nominal group and Delphi techniques.

Brief description of formal consensus techniques

The Delphi method, which originated in 1948, is an attempt to obtain expert opinion in a systematic manner. Experts who participate in a Delphi are polled individually and anonymously, usually with self-administered questionnaires. The survey is conducted over three or four "rounds," but after each one, the results are elicited, tabulated, and then reported to the group. A Delphi is considered complete when there is a convergence of opinion or when a point of diminishing returns is reached.

The nominal group technique is a structured meeting that attempts to provide an orderly procedure for obtaining qualitative information from target groups who are most closely associated with a problem area.

The first step in the nominal group process is to assemble all participants and ask them to list, individually and without discussion, their own ideas on a specific topic or question. At the completion of a given period of time, each individual, in round-robin fashion, presents the most important idea on his or her list. The process is repeated until all lists are exhausted. The ideas are recorded on a chart so that everyone present

²⁴ World Health Organisation (WHO). 2004. A glossary of terms for community health care and services for older persons http://whqlibdoc.who.int/wkc/2004/WHO_WKC_Tech.Ser.04.2.pdf [last accessed 25/02/2015].

²⁵ National Institute for Health and Care Excellence (NICE). Glossary. 2011. <http://www.nice.org.uk/website/glossary/glossary.jsp> [last accessed 02/03/2015].

can see the composite list. In the next phase, a highly structured discussion of the ideas on the composite list occurs. Participants evaluate each idea separately and, when necessary, clarify the ideas. After the discussion, each participant, privately and in writing, ranks or rates the idea's worth; next, the group's views are assessed.²⁶

Definition

In health care guideline consensus process is an approach that enable the multidisciplinary group to reach an agreement on a particular issue (e.g. decide on the relevant outcomes, on the inclusions and exclusion criteria of the study, the recommendations).

(Based on WHO, NICE, National Guideline Clearinghouse glossary and modified by the RARE-Bestpractices consortium)

²⁶ Fink A, , Kosecoff J, Chassin M , et al. Consensus Methods: Characteristics and Guidelines for Use Am J Public Health 1984; 979-983.

2.16 Consumer

Preamble

This definition is taken from the WHO glossary of terms for healthcare and services for older people.

Definition

A person who is receiving or may receive services.

(As described in WHO, 2004²⁷)

²⁷ World Health Organisation (WHO). 2004. A glossary of terms for community health care and services for older persons http://whqlibdoc.who.int/wkc/2004/WHO_WKC_Tech.Ser._04.2.pdf [last accessed 12/04/2013].

2.17 Cost-benefit analysis

Preamble

A cost-benefit analysis is a type of economic evaluation, that is, the comparison of at least two alternative technologies in terms of costs and benefits, where the benefits are measured in financial terms. Other types of economic evaluations use different type of outcomes.

Definition

An economic evaluation which compares costs and benefits of at least two technologies where the benefits or outcomes are measured in financial terms.

(From the HTA glossary²⁸)

²⁸ <http://htaglossary.net/cost-benefit+analysis>.

2.18 Cost-effectiveness analysis

Preamble

A cost-effectiveness analysis is a type of economic evaluation, that is, the comparison of at least two alternatives technologies in terms of costs and benefits, where the benefits are measured in natural units. Other types of economic evaluations use different type of outcomes.

Definition

An economic evaluation which compares costs and benefits of at least two technologies where the benefits or outcomes are measured in natural units (e.g. life years gained).

(From the HTA glossary²⁹)

²⁹ <http://htaglossary.net/cost-benefit+analysis>.

2.19 Critical appraisal

Preamble

The term definition was found in the HTA, Cochrane and NICE web sites. Critical appraisal is the process of - applying the rules of evidence to a study for carefully and systematically examining research to judge its trustworthiness, and its value and relevance in a particular context. It is an essential skill for evidence-based medicine because it allows clinicians to find and use research evidence reliably and efficiently.³⁰

Definition

The process of assessing and interpreting scientific research results by systematically analysing their validity, clinical and statistical significance, and clinical relevance.

(From HTA Glossary³¹)

³⁰ http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/what_is_critical_appraisal.pdf

³¹ HTAGlossary.Net. <http://htaglossary.net/HomePage> [last accessed 29/02/2015].

2.20 Cross-sectional study/prevalence study

Preamble

The term definition was found in the NICE and Cochrane Glossary web sites.

The purpose of this study is mainly descriptive, often in the form of a survey. Usually there is no hypothesis as such, but the aim is to describe a population or a subgroup within the population with respect to an outcome and a set of risk factors.

The purpose of the study is to find the prevalence of the outcome of interest, for the population or subgroups within the population at a given time-point.

It is a study that examines the relationship between diseases (or other health outcomes) and other variables of interest as they exist in a defined population at one particular time. The presence or absence of disease and the presence or absence of the other variables (or, if they are quantitative, their level) are determined in each member of the study population or in a representative sample at one particular time.

The relationship between a variable and the outcome can be examined (1) in terms of the prevalence of the outcome in different population subgroups defined according to the presence or absence (or level) of the variables and (2) in terms of the presence or absence (or level) of the variables in the individuals with and without the outcome. Note that disease prevalence rather than incidence is normally recorded in a cross-sectional study. The time order of cause and effect cannot necessarily be determined in a cross-sectional study³².

Cross-sectional studies are sometimes carried out to investigate associations between risk factors and the outcome of interest (analytical cross-sectional studies). They are limited, however, by the fact that they are carried out at one time point and give no indication of the sequence of events - whether exposure occurred before, after or during the onset of the disease outcome. It is therefore not possible to infer causality³³.

Definition

A study measuring the distribution of some characteristic(s) in a population at a particular point in time. Also called: prevalence study.

(From Cochrane Collaboration Glossary³⁴ modified by the RARE-Bestpractices consortium)

³² A Dictionary of Epidemiology – M. Porta et al (eds). © International Epidemiological Association, 2014 Publisher: Oxford University Press Print Publication Date: 2008 Print ISBN-13: 9780195314496 Published online: 2014 Current Online Version: 2014 DOI: 10.1093/acref/9780195314496.001.0001 eISBN: 9780199338931

³³ <http://www.nature.com/ebd/journal/v7/n1/full/6400375a.html> [last accessed 08/03/2015]

³⁴ Cochrane Collaboration Glossary. <http://www.cochrane.org/glossary> [last accessed 08/03/2015]

2.21 DALY (Disability-adjusted life year)

Preamble

This content and definition are taken from the WHO "Health statistics and information systems"³⁵. DALYs for a disease or health condition are calculated as the sum of the Years of Life Lost (YLL) due to premature mortality in the population and the Years Lost due to Disability (YLD) for people living with the health condition or its consequences. DALY is calculated as:

$$\text{DALY} = \text{YLL} + \text{YLD}$$

The YLL basically correspond to the number of deaths multiplied by the standard life expectancy at the age at which death occurs. The basic formula for YLL (without including other social preferences), is the following for a given cause, age and sex:

$$\text{YLL} = \text{N} \times \text{L}$$

where:

N = number of deaths

L = standard life expectancy at age of death in years

Because YLL measure the incident stream of lost years of life due to deaths, an incidence perspective has also been taken for the calculation of YLD in the original Global Burden of Disease Study for year 1990 and in subsequent WHO updates for years 2000 to 2004.

To estimate YLD for a particular cause in a particular time period, the number of incident cases in that period is multiplied by the average duration of the disease and a weight factor that reflects the severity of the disease on a scale from 0 (perfect health) to 1 (dead). The basic formula for YLD is the following (without applying social preferences):

$$\text{YLD} = \text{I} \times \text{DW} \times \text{L}$$

where:

I = number of incident cases

DW = disability weight

L = average duration of the case until remission or death (years).

Definition

One DALY can be thought of as one lost year of "healthy" life. The sum of these DALYs across the population, or the burden of disease, can be thought of as a measurement of the gap between current health status and an ideal health situation where the entire population lives to an advanced age, free of disease and disability.

³⁵ http://www.who.int/healthinfo/global_burden_disease/metrics_daly/en/

2.22 Database

Preamble

A database is an organized set of data or collection of files that can be used for a specified purpose³⁶. WHO, HTAglossary.net list definitions for 'bibliographic database' as an indexed computerized or printed source of citations, describing documents such as journal articles and scientific reports; the citations typically include the name(s) of the author(s), the title, the source, an abstract and, where applicable, related information (including the full text in some cases) as example: MEDLINE and EMBASE. WHO defines also 'factual database' and 'database (or register)'.

Definition

Any of a wide variety of repositories (often computerized) for observations and related information about a group of individuals, a disease, an intervention or other events or characteristics, typically organized for easy search and retrieval.

(As described in WHO, 2004³⁷)

³⁶ A Dictionary of Epidemiology – M. Porta et al (eds). © International Epidemiological Association, 2014 Publisher: Oxford University Press Print Publication Date: 2008 Print ISBN-13: 9780195314496 Published online: 2014 Current Online Version: 2014 DOI: 10.1093/acref/9780195314496.001.0001 eISBN: 9780199338931

³⁷ World Health Organisation (WHO). 2004. A glossary of terms for community health care and services for older persons http://whqlibdoc.who.int/wkc/2004/WHO_WKC_Tech.Ser.04.2.pdf [last accessed 03/03/2015]

2.23 Diagnostic test

Preamble

The proposed definition has been derived from the Agency for Healthcare Research and Quality (AHRQ) Glossary:

“A procedure to provide information about a person's condition that helps health care providers to make a diagnosis. Diagnostic tests provide information about whether a person does or does not have a particular disease.”³⁸

A diagnostic test can have three roles: replacement, triage, and add-on.³⁹

- A new replacement test can replace the existing ones because it may be more accurate, less invasive, easier to do, less risky, less uncomfortable for patients, quicker to yield results, technically less challenging, or more easily interpreted.
- A new triage test is used before the existing test or testing pathway, and only patients with a particular result on the triage test continue the testing pathway. Triage tests may be less accurate than existing ones and may not be meant to replace them. They have other advantages, such as simplicity or low cost.
- A new add-on test may be positioned after the existing pathway. The use of these tests may be limited to a subgroup of patients—for example, when the new test is more accurate but otherwise less attractive than existing tests.

Definition

A procedure to provide information about a person's condition that helps health care providers to make a diagnosis.

(As reported by AHRQ)

³⁸ Agency for Healthcare Research and Quality (AHRQ). Glossary. <http://effectivehealthcare.ahrq.gov/index.cfm/glossary-of-terms/> [last accessed 28/02/2015].

³⁹ Bossuyt PM, Irwig L, Craig J, Glasziou P. *BMJ*. 2006;332(7549):1089-92.

2.24 Dissemination

Preamble

Similar definition of the term was found in two resources: HTAglossary.net and WHO.

Definition

Any process by which information is transmitted (made available or accessible) to intended audiences or target groups.

(As described in WHO, 2004⁴⁰)

⁴⁰ World Health Organisation (WHO). 2004. A glossary of terms for community health care and services for older persons http://whqlibdoc.who.int/wkc/2004/WHO_WKC_Tech.Ser._04.2.pdf [last accessed 03/03/2015]

2.25 Economic Evaluation

Preamble

An economic evaluation is a type of study that offers the results as costs per additional (unit of outcomes) gained. Depending on whether the consequences are expressed as monetary, physical or qualitative variables, the analysis may be a cost-benefit, cost-effectiveness or cost-utility analysis⁴¹.

Definition

The comparative analysis of the costs and consequences of two or more possible options.

(From the Health-Technology-Assessment Glossary)

⁴¹ <http://htaglossary.net/economic+evaluation>

2.26 Efficacy and Effectiveness

Preamble

Several definitions of efficacy and effectiveness are available. Despite the sometimes substantial differences among the various interpretations of efficacy, four critical factors form a comprehensive view of the concept. The factors are: (i) Benefit to be achieved; (ii) Medical problem giving rise to use of the intervention; (iii) Population affected, and (iv) Conditions of use under which the intervention is applied.⁴² Clinical trials that assess efficacy are sometimes called explanatory trials and are restricted to participants who fully co-operate. Clinical trials that assess effectiveness are sometimes called pragmatic or management trials.

Definition

<p>Efficacy: The extent to which an intervention produces a beneficial result under ideal conditions. Effectiveness: The extent to which a specific intervention, when used under ordinary circumstances, does what it is intended to do.</p>

(From Cochrane Collaboration Glossary⁴³)

⁴² <https://www.princeton.edu/~ota/disk3/1978/7805/780504.PDF> [last accessed 09/04/2015]

⁴³ <http://www.cochrane.org/glossary> [last accessed 09/04/2015]

2.27 Epidemiology

Preamble

The term definition was found in many of the resources consulted (HTA glossary.net, effectivehealthcare.ahrq.gov, WHO, Cochrane, NICE and NCBI). NICE defines epidemiology as follow: “the study of the causes, distribution, control and prevention of disease. Epidemiologists collect and examine medical data and spot health trends to establish which diseases are on the increase and where, which treatments and other activities work and which do not. (This includes activities to prevent disease and to improve health and wellbeing). They consider the possible risk factors for a whole population or area, not just for individual patients.

The Dictionary of Epidemiology defines epidemiology as the study of the occurrence and distribution of health-related events, states, and processes in specified populations, including the study of the determinants influencing such processes, and the application of this knowledge to control relevant health problems. Study includes surveillance, observation, screening, hypothesis testing, analytic research, experiments, and prediction. Distribution refers to analysis by time, place (or space), and population (i.e., classes or subgroups of persons affected in an organization, population, or society, or at regional and global scales). Determinants are the geophysical, biological, behavioral, social, cultural, economic, and political factors that influence health. Health-related events, states, and processes include outbreaks, diseases, disorders, causes of death, behaviors, environmental and socioeconomic processes, effects of preventive programs, and use of health and social services. In the past 90 years, the definition has broadened from concern with communicable disease epidemics to include all phenomena related to health in populations. Therefore, epidemiology is much more than a branch of medicine treating of epidemics⁴⁴.

Definition

The study of the causes, distribution, control and prevention of disease.
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(As described in NICE⁴⁵)

⁴⁴ A Dictionary of Epidemiology – M. Porta et al (eds). © International Epidemiological Association, 2014 Publisher: Oxford University Press Print Publication Date: 2008 Print ISBN-13: 9780195314496 Published online: 2014 Current Online Version: 2014 DOI: 10.1093/acref/9780195314496.001.0001 eISBN: 9780199338931

⁴⁵ National Institute for Health and Care Excellence (NICE). Glossary. 2011.
<http://www.nice.org.uk/website/glossary/glossary.jsp> [last accessed 25/02/2015].

2.28 European commission

Preamble

The proposed definition is taken from the website of the European Union⁴⁶:

“The European Commission (EC) is the executive body of the European Union responsible for proposing legislation, implementing decisions, upholding the EU treaties and managing the day-to-day business of the EU Commissioners. The EC is composed of the College of Commissioners of 28 members, including the President and Vice-Presidents. The Commissioners, one from each EU country, are the Commission's political leadership during a 5-year term.

The Directorate-General for Research and Innovation defines and implements European Research and Innovation (R&I) policy with a view to achieving the goals of the Europe 2020 strategy and its key flagship initiative, the Innovation Union. The DG contributes to the European Semester by analyzing national R&I policies, by assessing their strengths and weaknesses, and by formulating country specific recommendations where necessary. It monitors and contributes to the realization of the Innovation Union flagship initiative and the completion of the European Research Area. It funds excellent Research and Innovation through Framework Programmes taking a strategic programming approach.”

Definition

The executive body of the European Union.
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⁴⁶ http://ec.europa.eu/index_en.htm [last accessed 4/03/2015]

2.29 Evidence-based practice

Preamble

The term “evidence-based practice” was not specifically defined in the resources consulted for this glossary. The proposed definition is taken from Dr. David Sackett⁴⁷:

“EBP is the integration of clinical expertise, patient values, and the best research evidence into the decision making process for patient care. Clinical expertise refers to the clinician’s cumulated experience, education and clinical skills. The patient brings to the encounter his or her own personal preferences and unique concerns, expectations, and values. The best research evidence is usually found in clinically relevant research that has been conducted using sound methodology.”

Definition

Decisions about patient care based on clinical expertise, patient values, and the best research evidence available.

⁴⁷Sackett, D. *Evidence-based Medicine: How to Practice and Teach EBM*. 2nd edition. Churchill Livingstone, 2000

2.30 General assembly

Preamble

The 'general assembly' definition was not found in any of the resources consulted. In the RARE-Bestpractice project⁴⁸ the General Assembly is constituted by a representative for each Beneficiary (project's participants); it is in charge for contractual issues.

Definition

A group of people constituted by a representative for each Beneficiary (project's participants) in charge for contractual issues.
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(Adapted from www.rarebestpractices.eu)

⁴⁸ RARE-Bestpractices. <http://www.rarebestpractices.eu>. [last accessed 11/03/2015]

2.31 GRADE approach

Preamble

The term definition was found only in the NICE⁴⁹ web site. A systematic and explicit approach to making judgments such as these can help to prevent errors, facilitate critical appraisal of these judgments, and can help to improve communication of this information. Since the 1970's a growing number of organizations have employed various systems to grade the quality (level) of evidence and the strength of recommendations. Unfortunately, different organizations use different systems to grade evidence and recommendations. One of the aims of the GRADE Working Group⁵⁰ is to reduce unnecessary confusion arising from multiple systems for grading evidence and recommendations.

Definition

A systematic and explicit approach to grading the quality of evidence and the strength of recommendations.

(Adapted from NICE and Grade Working Group)

⁴⁹ National Institute for Health and Care Excellence (NICE). Glossary. 2011.
<http://www.nice.org.uk/website/glossary/glossary.jsp> [last accessed 06/03/2015]

⁵⁰ <http://www.gradeworkinggroup.org/> [last accessed 06/03/2015]

2.32 Health care guideline

Preamble

The following definition is adapted by the RARE-Bestpractices consortium from the World Health Organisation (WHO) and the Institute of Medicine (IOM) existing definitions.

“Guidelines are systematically developed evidence-based statements which assist providers, recipients and other stakeholders to make informed decisions about appropriate health interventions. Health interventions are defined broadly to include not only clinical procedures but also public health actions. Guidelines are formal advisory statements which should be robust enough to meet the unique circumstances and constraints of the specific situation to which they are being applied. The basic nature and intent of guidelines have also been expressed under other formats variously labelled as protocols, best practice, algorithms, consensus statements, expert committee recommendations, and integrated care pathways. This document refers to all formats with the basic nature and intent of guidelines.”⁵¹

“Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.”⁵²

Definition

Health care guidelines are systematically developed statements by a systematic review of evidence and an assessment of the benefits and harms of alternative care options, which assist providers, patients and stakeholders to make informed decisions about appropriate health care for specific circumstances, including clinical interventions, public health activities, or government policies. Health care guidelines provide recommendations that describe in detail what the recommended action is and under what circumstances it should be performed.

(Based on WHO and IOM as above and modified by the RARE-Bestpractices consortium)

⁵¹ World Health Organisation (WHO). Guidelines for WHO guidelines. 2003.

http://whqlibdoc.who.int/hq/2003/EIP_GPE_EQC_2003_1.pdf [last accessed 09/05/2013].

⁵² Institute of Medicine of the National Academies. Clinical practice guidelines we can trust. 2011.

http://www.nap.edu/openbook.php?record_id=13058&page=1 [last accessed 09/05/2013].

2.33 Health care policies

Preamble

This definition is taken from the WHO glossary of terms for healthcare and services for older people.

Definition

A formal statement or procedure within an institution (notably government) which defines goals, priorities and the parameters for action in response to health needs, within the context of available resources.

(As described in WHO, 2004.⁵³)

⁵³ World Health Organisation (WHO). 2004. A glossary of terms for community health care and services for older persons http://whqlibdoc.who.int/wkc/2004/WHO_WKC_Tech.Ser._04.2.pdf [last accessed 26/02/2015].

2.34 Health care provider

Preamble

Existing definitions refer to health care workers and are inclusive to all levels of training, expertise and areas of responsibilities. The proposed definition has been taken from the National Guideline Clearing House glossary⁵⁴.

Definition

Individuals working in the provision of health services, whether as individual practitioners or employees of health institutions and programs, whether or not professionally trained, and whether or not subject to public regulation. Also includes those institutions or programs that offer health services.

⁵⁴ National Guideline Clearing House (NGCH). Glossary. <http://www.guideline.gov/about/glossary.aspx> [last accessed 12/04/2013].

2.35 Health technology assessment (HTA)

Preamble

The formal evaluation of technologies used in health care, including medicine, and in public health. It explicitly involves not only efficacy but also cost-effectiveness, cost-utility, and all other aspects of technology that may be important for society. HTA supports evidence-based decision-making in health care policy and practice⁵⁵

The proposed definition has been derived from the HTAGlossary.net web resource:

“The systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies. Note: HTA is conducted by interdisciplinary groups that use explicit analytical frameworks drawing on a variety of methods.”⁵⁶

Definition

The systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies.

⁵⁵ A Dictionary of Epidemiology – M. Porta et al (eds). © International Epidemiological Association, 2014 Publisher: Oxford University Press Print Publication Date: 2008 Print ISBN-13: 9780195314496 Published online: 2014 Current Online Version: 2014 DOI: 10.1093/acref/9780195314496.001.0001 eISBN: 9780199338931

⁵⁶ HTAGlossary.Net. <http://htaglossary.net/HomePage> [last accessed 29/04/2013].

2.36 Health utilities

Preamble

The term definition was found in “what are health utilities?” Health economics, second edition, 2009 www.whatisseries.co.uk. In health economics, utilities are cardinal values that reflect an individual’s preferences for different health outcomes. They are measured on an interval scale with zero reflecting states of health equivalent to death and one reflecting perfect health. In health economics, utilities are typically combined with survival estimates and aggregated across individuals to generate quality-adjusted lifeyears (QALYs) for use in cost–utility analyses of healthcare interventions.

Definition

Utilities are cardinal values that represent the strength of an individual’s preferences for specific health-related outcomes.

(As described in <http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/Health-util.pdf>)⁵⁷

⁵⁷ <http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/Health-util.pdf>

2.37 Horizon scanning

Preamble

The proposed definition has been adapted from the INAHTA glossary entry:

“The systematic identification of technologies in development that could have important effects on health care, and which might be considered for Health Technology Assessment”⁵⁸

Definition

The systematic identification of health care interventions in development that could have important effects on future health care delivery.

(Adapted from the INAHTA glossary, as above)

⁵⁸ International Network of Agencies for Health Technology Assessment (INAHTA) health technology assessment glossary. <http://www.inahta.net/> [last accessed 12/04/2013].

2.38 Implementation

Preamble

The term definition was not found in any of the resources consulted. The term was used by NICE in combination with the term 'consultants' and 'tools'⁵⁹. NICE produces various 'tools' to help the National Health System, local authorities and other organisations in the public, private, voluntary and community sector put our guidance into practice. These tools can cover audit, costing, and information to support education and learning for practitioners. Further research of the term definition was conducted in Google.

Definition

Methods to promote the uptake of research findings into routine healthcare in clinical, organisational or policy contexts.

(From <http://www.implementationscience.com/>)

⁵⁹ National Guideline Clearing House (NGCH). Glossary. <http://www.guideline.gov/about/glossary.aspx> [last accessed 15/02/2015].

2.39 Indirect comparison

Preamble

The term definition was found in “what is...series” Health economics , second edition , 2009..1. Indirect comparison refers to a comparison of different healthcare interventions using data from separate studies, in contrast to a direct comparison within randomised controlled trials. Indirect comparison is often used because of a lack of, or insufficient, evidence from head-to-head comparative trials to estimate the relative effects of different treatments. In contrast to direct within-trial comparison, indirect comparison means a between-study comparison of different interventions.⁶⁰

Definition

A comparison of different healthcare interventions using data from separate studies.

(As described in www.medicine.ox.ac.uk/bandolier/painres/download/whatis/What_is_ind_comp.pdf)

⁶⁰ http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/What_is_ind_comp.pdf

2.40 Meta-analysis

Preamble

The term definition was found in the HTA Glossary, AHRQ, Alberta, Cochrane Collaboration Glossary, Nice, NCBI web sites. A statistical analysis of results from separate studies, examining sources of differences in results among studies, and leading to a quantitative summary of the results if the results are judged sufficiently similar or consistent to support such synthesis.⁶¹ In statistics, meta-analysis comprises statistical methods for contrasting and combining results from different studies in the hope of identifying patterns among study results, sources of disagreement among those results, or other interesting relationships that may come to light in the context of multiple studies.⁶²

The motivation of a meta-analysis is to aggregate information in order to achieve a higher statistical power for the measure of interest, as opposed to a less precise measure derived from a single study. In performing a meta-analysis, an investigator must make choices many of which can affect its results, including deciding how to search for studies, selecting studies based on a set of objective criteria, dealing with incomplete data, analyzing the data, and accounting for or choosing not to account for publication bias.⁶³

Definition

A statistical method that consists of systematically combining results from different studies to obtain a quantitative estimate of the overall effect of a particular intervention or variable.

(From HTA Glossary⁶⁴)

⁶¹ A Dictionary of Epidemiology – M. Porta et al (eds). © International Epidemiological Association, 2014 Publisher: Oxford University Press Print Publication Date: 2008 Print ISBN-13: 9780195314496 Published online: 2014 Current Online Version: 2014 DOI: 10.1093/acref/9780195314496.001.0001 eISBN: 9780199338931

⁶² Greenland S, O' Rourke K: Meta-Analysis. Page 652 in Modern Epidemiology, 3rd ed. Edited by Rothman KJ, Greenland S, Lash T. Lippincott Williams and Wilkins; 2008. [last accessed 06/03/2015]

⁶³ WALKER, E.; HERNANDEZ, A. V.; KATTAN, M. W. (1 June 2008). "Meta-analysis: Its strengths and limitations". Cleveland Clinic Journal of Medicine 75 (6): 431–439. doi:10.3949/ccjm.75.6.431. [last accessed 05/03/2015]

⁶⁴ <http://htaglossary.net/HomePage> [last accessed 06/03/2015]

2.41 Non-randomised studies

Preamble

The term definition was found in the Cochrane Collaboration Glossary⁶⁵ web site.

Non-randomized clinical trials arise from situations in which it is impossible or difficult to assign subjects to treatment by chance. Unlike randomized control studies, non-randomised trials are vulnerable to bias because of the inability to control the balance of prognostic factors between the treatment groups.⁶⁶

There are many possible types of non-randomised intervention study, including cohort studies, case control studies, controlled before and after studies, interrupted time series studies and controlled trials that do not use appropriate randomisation strategies (sometimes called quasi randomised studies).

Definition

Any study that does not use randomisation to allocate units to comparison groups (including studies where 'allocation' occurs in the course of usual treatment decisions or peoples' choices, i.e. studies usually called 'observational') estimating the association between an exposure (e.g. an intervention or a risk factor) and the effect of exposure (e.g. harm, benefit, or incidence of disease) against some control intervention (or no intervention).

(Adapted from Cochrane Collaboration Glossary)

⁶⁵ Cochrane Collaboration Glossary <http://www.cochrane.org/glossary> [last accessed 10/03/2015]

⁶⁶ Li, Z. 2007. Non-Randomized Trial. Wiley Encyclopedia of Clinical Trials. 1–8.

2.42 Orphan drug

Preamble

A number of terms are used interchangeably for orphan drugs, including "orphan medicines", "orphan medicinal products", with some terms preferentially associated with particular agencies, for example EMA and FDA tend to use "orphan medicinal products" or "orphan medicines", while NICE tends to use "orphan drugs". For the purposes of this report, it would be prudent to use the term and definition from REGULATION (EC) No 141/2000) and it is the following:

An orphan medicinal product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the Community when the application is made.

Definition

An orphan medicinal product (also known as orphan drug and orphan medicine) is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the Community when the application is made.

2.43 Palliative care

Preamble

The term definition was found in the WHO website. Palliative care: provides relief from pain and other distressing symptoms; affirms life and regards dying as a normal process; intends neither to hasten or postpone death; integrates the psychological and spiritual aspects of patient care; offers a support system to help patients live as actively as possible until death; offers a support system to help the family cope during the patients illness and in their own bereavement; uses a team approach to address the needs of patients and their families, including bereavement counselling, if indicated; will enhance quality of life, and may also positively influence the course of illness; is applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy or radiation therapy, and includes those investigations needed to better understand and manage distressing clinical complications.

Definition

An approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.

(As described in www.who.int/cancer/palliative/definition/en/)

2.44 Partner

Preamble

The definition was not found in any of the resources consulted. The definition was extracted from the Oxford dictionaries.

Definition

A person who takes part in an undertaking with another or others, especially in a business or firm with shared risks and profits.

(From <http://www.oxforddictionaries.com/definition/>)

2.45 Patient

Preamble

The INAHTA glossary does not include an entry for patient and instead refers users to the definition of 'customer'. In the majority of the consulted resources it is accepted that 'patient' refers to a person making contact with a health provider in some way.

The proposed definition is that of the Agency for Healthcare Research and Quality (AHRQ).⁶⁷

Definition

An individual seeking or receiving medical care.

⁶⁷ Agency for Healthcare Research and Quality (AHRQ). Glossary. <http://www.guideline.gov/about/glossary.aspx> [last accessed 12/04/2013]

2.46 Platform infrastructure

Preamble

The term ‘Platform infrastructure’ was not specifically defined in the resources consulted for this glossary.

The RARE-Bestpractices project (www.rarebestpractices.eu) offers separate descriptions for both ‘platform’ and ‘infrastructure’; these were amalgamated to provide the proposed definition reported below.

‘Platform’: “a web repository supporting the collection of standardized and validated data and efficient exchange of knowledge and reliable information on rare diseases (RD). The platform is conceived for health care providers, experts, patients, policy makers and best practice guideline developers with outcomes that support closure of healthcare gaps among countries and improved clinical management of RD patients globally.”

‘Infrastructure’: “Systems and services used to:

1. develop, implement and maintain a project website that enables the network to publicise its activities/results and communicate the availability and purpose of the network’s resources
2. set up, implement and maintain an online database facilitating collection, development, dissemination, and revision of BP guidelines, enabling access
3. develop, implement and maintain an online database that enables collection, prioritisation and communication of research recommendations, enabling access
4. develop and maintain a web community for developing the pilot guideline

Definition

A web system and services developed, implemented and maintained to enable collection, access and exchange of knowledge and information to intended audiences and or target groups.

(As adapted from the RARE-Bestpractices project⁶⁸)

⁶⁸ RARE-Bestpractices project. <http://www.rarebestpractices.eu/>. [last accessed 10/03/2015]

2.47 Policy maker

Preamble

None

Definition

A person responsible for or involved in formulating policies.

2.48 Quality of care

Preamble

A level of performance or accomplishment that characterizes the health care provided. Measures of the quality of care depend upon value judgments, but there are ingredients and determinants of quality that can be measured objectively. Such factors were classified by Donabedian into measures of structure (e.g., manpower, facilities), process (e.g., diagnostic and therapeutic procedures), and outcome (e.g., case fatality rates, disability rates, and levels of patient satisfaction with the service)⁶⁹

This definition is from IOM (1990).⁷⁰ Rationale for this definition is from “*Assuring the quality of health care in the European Union. A case for action. Legido Quigley et al. World Health Organization 2008, on behalf of the European Observatory on Health Systems and Policies.*”

This definition:

- includes a measure of scale;
- encompasses a wide range of elements of care with reference to health services;
- identifies both individuals and populations as targets for quality assurance efforts;
- is goal oriented, making a distinction within the health care goals depending on whether they emanate from government, patients, administrators, health care practitioners or other participants in the health care system;
- recognises the importance of outcomes without specifying for whom, thus allowing the possibility of differing perspectives on which values of quality are most important;
- highlights the importance of individual patients’ and society’s preferences and values and implies that the patients have been taken into account in health care decision and policy-making;
- underlines the constraints placed on professional performance by the state of technical, medical and scientific knowledge, implying that the State is dynamic and that the health care provider is responsible for using the best knowledge base available.

It shifts the focus from patients to individuals and populations, hence allowing quality of care also to incorporate health promotion and disease prevention and not just cure and rehabilitation.

It also adds “desired outcomes” to the definition so as to emphasize the need to consider the perspective of the recipients of services, and by highlighting that care should be “consistent with current professional knowledge” it implies that the standards of the service also need to be defined.

⁶⁹ A Dictionary of Epidemiology – M. Porta et al (eds). © International Epidemiological Association, 2014 Publisher: Oxford University Press Print Publication Date: 2008 Print ISBN-13: 9780195314496 Published online: 2014 Current Online Version: 2014 DOI: 10.1093/acref/9780195314496.001.0001 eISBN: 9780199338931

⁷⁰ IOM (1990). Medicare: A strategy for quality assurance, Vol.1. Washington, DC, National Academy Press

Definition

Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

2.49 Quality of evidence

Preamble

The term definition was found only on the HTA⁷¹ web site.

The levels of evidence were originally described in a report by the Canadian Task Force on the Periodic Health Examination in 1979. The report's purpose was to develop recommendations on the periodic health exam and base those recommendations on evidence in the medical literature. The levels of evidence were further described and expanded by Sackett in 1989⁷². The hierarchies rank studies according to the probability of bias. RCTs are given the highest level because they are designed to be unbiased and have less risk of systematic errors.

Since the introduction of levels of evidence, several other organizations and journals have adopted variation of the classification system, e.g. Centre for Evidence-based medicine (CEBM) for treatment⁷³.

The GRADE approach introduced a new scheme in order to create one single system to avoid confusion. The single system should avoid shortcomings of other systems and include their strengths. Some grading systems are based on study design alone without explicit consideration of other important factors in determining quality of evidence. Some systems are excessively complex.⁷⁴

Grading of Recommendations Assessment, Development and Evaluation (GRADE)⁷⁵

Code	Quality of Evidence	Definition
A	High	Further research is very unlikely to change our confidence in the estimate of effect. <ul style="list-style-type: none">• Several high-quality studies with consistent results• In special cases: one large, high-quality multi-centre trial
B	Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. <ul style="list-style-type: none">• One high-quality study• Several studies with some limitations
C	Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. <ul style="list-style-type: none">• One or more studies with severe limitations

⁷¹ HTAGlossary.Net. <http://htaglossary.net/HomePage> [last accessed 10/03/2015].

⁷² Sackett DL. Rules of evidence and clinical recommendations on the use of antithrombotic agents. Chest. 1989 Feb; 95(2 Suppl):2S-4S.

⁷³ Centre for Evidence-Based Medicine, <http://www.cebm.net>. [last accessed 02/03/2015]

⁷⁴ Grade Working Group <http://www.gradeworkinggroup.org/> [last accessed 02/03/2015]

⁷⁵ Balshem H, Helfand M, Schünemann HJ, Oxman AD, Kunz R, Brozek J, Vist GE, Falck-Ytter Y, Meerpohl J, Norris S, Guyatt GH. GRADE guidelines: 3. Rating the quality of evidence. J Clin Epidemiol. 2011 Apr;64(4):401-6

D	Very Low	<p>Any estimate of effect is very uncertain.</p> <ul style="list-style-type: none"> • Expert opinion • No direct research evidence • One or more studies with very severe limitations
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Factors that might decrease quality of evidence:

- Study limitations
- Inconsistency of results
- Indirectness of evidence
- Imprecision
- Publication bias

Factors that might increase quality of evidence:

- Large magnitude of effect
- Plausible confounding, which would reduce a demonstrated effect
- Dose-response gradient

Definition

In the context of a systematic review, the ratings of the quality of evidence reflect the extent of our confidence that the estimates of the effect are correct. In the context of making recommendations, the quality ratings reflect the extent of our confidence that the estimates of an effect are adequate to support a particular decision or recommendation.

(From Balshem H et al. GRADE guidelines: 3. Rating the quality of evidence. J Clin Epidemiol. 2011 Apr;64(4):401-6)

2.50 Quality standard

Preamble

Healthcare Improvement Scotland (HIS) actively produce quality standard statements and have already provided a description of this type of output with reference to the provision of healthcare in Scotland:

“Standards are statements of levels of performance that patients should expect from NHS Scotland. They are based on evidence relating to clinical practice, feasibility and service provision that is responsive to patients’ needs and views. They cover the key issues relating to the provision of safe, effective and patient-focused care and treatment.”⁷⁶

The Royal College of Nursing (RCN) glossary definition further emphasises the use of standards as tools to assess the quality of healthcare delivery:

“A standard is a level of quality against which performance can be measured. It can be described as 'essential'- the absolute minimum to ensure safe and effective practice, or 'developmental', designed to encourage and support a move to better practice.”⁷⁷

Definition

A statement, against which performance can be measured, on the standard of care patients should expect from a health care service.

(Adapted from HIS and RCN, as above)

⁷⁶ Healthcare Improvement Scotland. NHS QIS and NICE Advice – definitions and status. 2006. http://www.healthcareimprovementscotland.org/previous_resources/process_documentation/nhs_qis_nice_advice.aspx [last accessed 29/04/2013]

⁷⁷ Royal College of Nursing. Glossary. http://www.rcn.org.uk/development/practice/clinical_governance/glossary [last accessed 02/05/2013].

2.51 Randomised controlled trial

Preamble

The term definition was found in the HTA Glossary, AHRQ⁷⁸, Ualberta⁷⁹, Cochrane Collaboration, NICE, NCBI web sites. Random allocation in real trials is complex, but conceptually, the process is like tossing a coin. After randomisation, the two (or more) groups of subjects are followed in exactly the same way, and the only differences between the care they receive, for example, in terms of procedures, tests, outpatient visits, and follow-up calls, should be those intrinsic to the treatments being compared. The most important advantage of proper randomisation is that it minimizes allocation bias, balancing both known and unknown prognostic factors, in the assignment of treatments.⁸⁰

RCTs are generally regarded as the most scientifically rigorous method of hypothesis testing available in epidemiology and medicine. Nonetheless, they may suffer lack of generalizability due, for example, to the non-representativeness of patients who are ethically and practically eligible, chosen, or consent to participate⁸¹

Definition

An experimental comparison study in which participants are allocated via a randomisation mechanism (by chance) to either an intervention/treatment group or a control /placebo group, then followed over time and assessed for the outcomes of interest. Participants have an equal chance of being allocated to either group.

(Adapted from AHRQ and Ualberta)

⁷⁸ <http://effectivehealthcare.ahrq.gov/index.cfm/glossary-of-terms/> [last accessed 02/03/2015]

⁷⁹ <http://www.ebm.med.ualberta.ca/Glossary.html> [last accessed 08/03/2015]

⁸⁰ Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG (2010). "CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials". Br Med J 340: c869. doi:10.1136/bmj.c869. PMC 2844943. PMID 20332511

⁸¹ A Dictionary of Epidemiology – M. Porta et al (eds). © International Epidemiological Association, 2014 Publisher: Oxford University Press Print Publication Date: 2008 Print ISBN-13: 9780195314496 Published online: 2014 Current Online Version: 2014 DOI: 10.1093/acref/9780195314496.001.0001 eISBN: 9780199338931

2.52 Rare disease

Preamble

The following definition is taken from the RARE-Bestpractices project summary documentation⁸².

Definition

A disease characterised by low prevalence. In Europe this is defined as a disease affecting no more than 5 in 10,000 persons.

⁸² RARE-Bestpractices. <http://www.rarebestpractices.eu/>. [last accessed 02/05/2013]

2.53 Registry

Preamble

The term definition was found in the HTA Glossary. A definition of specialized register was found in the Cochrane Glossary. When specialised registers only contain reports of controlled trials (such as randomised controlled trials, or controlled clinical trials), they are sometimes referred to as trials registers⁸³.

Definition

A file in which is registered, on an ongoing basis, information concerning all cases of a given disease or other problem in a defined population, such that the cases may be related to the database concerning that population.

(As described in htaglossary.net.⁸⁴)

⁸³ www.cochrane.org/glossary [last accessed 06/05/2015]

⁸⁴ www.htaglossary.net/HomePage [last accessed 06/05/2015]

2.54 Research recommendation

Preamble

The term “research recommendation” was reported by the Cochrane Collaboration Handbook⁸⁵ that adopted a proposed format for reporting research recommendations (‘EPICOT’), as follows⁸⁶

- E (Evidence): What is the current evidence?
- P (Population): Diagnosis, disease stage, co-morbidity, risk factor, sex, age, ethnic group, specific inclusion or exclusion criteria, clinical setting.
- I (Intervention): Type, frequency, dose, duration, prognostic factor.
- C (Comparison): Placebo, routine care, alternative treatment/management.
- O (Outcome): Which clinical or patient-related outcomes will the researcher need to measure, improve, influence or accomplish? Which methods of measurement should be used?
- T (Time stamp): Date of literature search or recommendation.

Other factors that might be considered in recommendations include the disease burden of the condition being addressed, the timeliness (e.g. length of follow-up, duration of intervention), and the study type that would best suit subsequent research.

Definition

Statements that explicitly outline uncertainties identified through the systematic review of scientific literature and encourage research in relevant topics.

(As described in <http://www.lindalliance.org/pdfs/BMJEpicotarticle2006.pdf>)

⁸⁵ Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [updated March 2011]. Chapter 12: Interpreting results and drawing conclusions. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org (accessed 24 March 2015)

⁸⁶ <http://www.lindalliance.org/pdfs/BMJEpicotarticle2006.pdf>

2.55 Screening

Preamble

The term definition was found in the HTA Glossary, AHRQ⁸⁷, WHO⁸⁸ web sites.

For many diseases (for example, cancers), starting treatment earlier leads to better results. The purpose of screening is to find the disease so that treatment can be started as early as possible.

The presumptive identification of unrecognized disease or defect by the application of tests, examinations, or other procedures which can be applied rapidly. Screening tests sort out apparently well persons who probably have a disease from those who probably do not. A screening test is not intended to be diagnostic. Persons with positive or suspicious findings must be referred to their physicians for diagnosis and necessary treatment. Screening may identify risk factors, genetic predisposition, and precursors, or early evidence of disease.⁸⁹

Definition

Using tests or other methods of diagnosis to find out whether or not an apparently well person has a specific disease or condition before it causes any symptoms.

(Adapted from WHO and AHRQ)

⁸⁷ <http://effectivehealthcare.ahrq.gov/index.cfm/glossary-of-terms/> [last accessed 07/03/2015]

⁸⁸ World Health Organisation (WHO). 2004. A glossary of terms for community health care and services for older persons http://whqlibdoc.who.int/wkc/2004/WHO_WKC_Tech.Ser._04.2.pdf [last accessed 03/03/2015]

⁸⁹ A Dictionary of Epidemiology – M. Porta et al (eds). © International Epidemiological Association, 2014 Publisher: Oxford University Press Print Publication Date: 2008 Print ISBN-13: 9780195314496 Published online: 2014 Current Online Version: 2014 DOI: 10.1093/acref/9780195314496.001.0001 eISBN: 9780199338931

2.56 Systematic review

Preamble

The term definition was found in the HTA Glossary , AHRQ, Cochrane Collaboration Glossary , Nice, NCBI web sites. A systematic review attempts to collate all empirical evidence that fits pre-specified eligibility criteria in order to answer a specific research question. It uses explicit, systematic methods that are selected with a view to minimising bias, thus providing more reliable findings from which conclusions can be drawn and decisions. The key characteristics of a systematic review are:

- a clearly stated set of objectives with pre-defined eligibility criteria for studies;
- an explicit, reproducible methodology;
- a systematic search that attempts to identify all studies that would meet the eligibility criteria;
- an assessment of the validity of the findings of the included studies, for example through the assessment of risk of bias;
- and a systematic presentation, and synthesis, of the characteristics and findings of the included studies.

Many systematic reviews contain meta-analyses. Meta-analysis is the use of statistical methods to summarize the results of independent studies. By combining information from all relevant studies, meta-analyses can provide more precise estimates of the effects of health care than those derived from the individual studies included within a review (see Chapter 9, Section 9.1.3). They also facilitate investigations of the consistency of evidence across studies, and the exploration of differences across studies.⁹⁰ Systematic reviews differ from traditional narrative reviews, which tend to be mainly descriptive, do not involve a systematic search of the literature, and thus can suffer from selection bias.⁹¹

Definition

A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyze data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyze and summarize the results of the included studies.

(From Cochrane Collaboration⁹²)

⁹⁰ Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org. [last accessed 04/03/2015]

⁹¹ A Dictionary of Epidemiology – M. Porta et al (eds). © International Epidemiological Association, 2014 Publisher: Oxford University Press Print Publication Date: 2008 Print ISBN-13: 9780195314496 Published online: 2014 Current Online Version: 2014 DOI: 10.1093/acref/9780195314496.001.0001 eISBN: 9780199338931

⁹² Cochrane Collaboration Glossary <http://www.cochrane.org/glossary> [last accessed 06/03/2015].

2.57 Stakeholder

Preamble

The proposed definition is taken from the WHO glossary of terms for healthcare and services for older people.

Definition

People or groups who have an involvement or interest in a project.⁹³

⁹³ World Health Organisation (WHO). 2004. A glossary of terms for community health care and services for older persons http://whqlibdoc.who.int/wkc/2004/WHO_WKC_Tech.Ser._04.2.pdf [last accessed 12/04/2013].

2.58 Standard

Preamble

Something that serves as a basis for comparison; a technical specification or written report drawn up by experts based on the consolidated results of scientific study, technology, and experience, aimed at optimum benefits and approved by a recognized and representative body.⁹⁴

The proposed definition is taken from the WHO glossary of terms for healthcare and services for older people. Standard, in this example, is described in a context wider than healthcare delivery.

Definition

A quality, measure or reference point established as a rule or model by authorities, custom or general consent, against which things can be evaluated or should conform.⁹⁵

⁹⁴ A Dictionary of Epidemiology – M. Porta et al (eds). © International Epidemiological Association, 2014 Publisher: Oxford University Press Print Publication Date: 2008 Print ISBN-13: 9780195314496 Published online: 2014 Current Online Version: 2014 DOI: 10.1093/acref/9780195314496.001.0001 eISBN: 9780199338931

⁹⁵ World Health Organisation (WHO). 2004. A glossary of terms for community health care and services for older persons http://whqlibdoc.who.int/wkc/2004/WHO_WKC_Tech.Ser.04.2.pdf [last accessed 12/04/2013]

2.59 Steering committee

Preamble

The term definition was not found in any of the resources consulted. In the RARE-Bestpractice project (www.rarebestpractices.eu) the Steering Committee is constituted by the Project Coordinator, the Project Manager and Work Package leaders. It is responsible for:

- ensuring good practice in planning, management, dissemination and implementation of activities;
- overseeing the work and progress of individual WP, especially milestones and deliverables and reviewing progress against objectives and timetable to ensure successful delivery of the project outputs;
- planning the annual project meetings;
- making recommendations regarding any other project issue, including evolution of the partnership composition;
- solving any issues that cannot be clarified or agreed at a lower level (WP teams), in particular the resolution of disputes and matters relating to allocation of funding.

Definition

A group of people constituted by the Project Coordinator, the Project Manager and Work Package leaders.

(From www.rarebestpractices.eu⁹⁶)

⁹⁶ RARE-Bestpractices project, www.rarebestpractices.eu [last accessed 06/03/2015]

2.60 Strength of recommendations

Preamble

The term definition was not found in any of the resources consulted.

Recommendations to administer, or not administer, an intervention, should be based on the tradeoffs between benefits on the one hand, and risks, burden and, potentially, costs on the other. If benefits outweigh risks and burden, experts will recommend that clinicians offer a treatment to typical patients. The uncertainty associated with the tradeoff between the benefits and risks and burdens will determine the strength of recommendations.

Many organizations developed various grading system of the strength of recommendation.⁹⁷

For example:

Agency for Healthcare Research and Quality:

A:	There is good research-based evidence to support the recommendation.
B:	There is fair research-based evidence to support the recommendation.
C:	The recommendation is based on expert opinion and panel consensus.
X:	There is evidence of harm from this intervention.

USPSTF Guide to Clinical Preventive Services:

A:	There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination.
B:	There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination.
C:	There is insufficient evidence to recommend for or against the inclusion of the condition in a periodic health examination, but recommendations may be made on other grounds.
D:	There is fair evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.
E:	There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.

One of the aims of the GRADE Working Group is to reduce unnecessary confusion arising from multiple systems for grading evidence and recommendations. GRADE has only two levels: strong and weak recommendations.

⁹⁷ http://www.essentialvidenceplus.com/product/ebm_loe.cfm?show=guidelines [last accessed 10/03/2015]

Strong recommendation: Based on the available evidence, if clinicians are very certain that benefits do, or do not, outweigh risks and burdens they will make a strong recommendation.

Weak recommendation: Based on the available evidence, if clinicians believe that benefits and risks and burdens are finely balanced, or appreciable uncertainty exists about the magnitude of benefits and risks, they must offer a weak recommendation. In addition, clinicians are becoming increasingly aware of the importance of patient values and preferences in clinical decision making. When, across the range of patient values, fully informed patients are liable to make different choices, guideline panels should offer weak recommendations.

Factors that panels should consider in deciding on a strong or weak recommendation.

- Uncertainty in the estimates of likely benefit, and likely risk, inconvenience, and costs
- Importance of the outcome that treatment prevents
- Magnitude of treatment Effect
- Precision of estimate of treatment Effect
- Risks associated with therapy
- Burdens of Therapy
- Risk of target event
- Costs
- Varying Values.

Definition

The strength of a recommendation is defined as the extent to which one can be confident that the desirable consequences of an intervention outweigh its undesirable consequences.

(From Andrews J, et al. GRADE guidelines: 14. Going from evidence to recommendations: the significance and presentation of recommendations. J Clin Epidemiol. 2013 Jul;66(7):719-25⁹⁸)

⁹⁸ Andrews J et al., Guyatt G, Oxman AD, Alderson P, Dahm P, Falck-Ytter Y, Nasser M, Meerpohl J, Post PN, Kunz R, Brozek J, Vist G, Rind D, Akl EA, Schünemann HJ. GRADE guidelines: 14. Going from evidence to recommendations: the significance and presentation of recommendations. J Clin Epidemiol. 2013 Jul;66(7):719-25.

2.61 Web community

Preamble

The term definition was not found in any of the resources consulted. The proposed definition is taken from Flake et al.⁹⁹

Definition

A web community is a web site (or group of web sites) where specific content or links are only available to its members. A web community may take the form of a social network service, an Internet forum, a group of blogs, or another kind of social software web application.

⁹⁹ <http://courses.cs.washington.edu/courses/cse522/05au/communities-flake.pdf> [last accessed 11/03/2015]