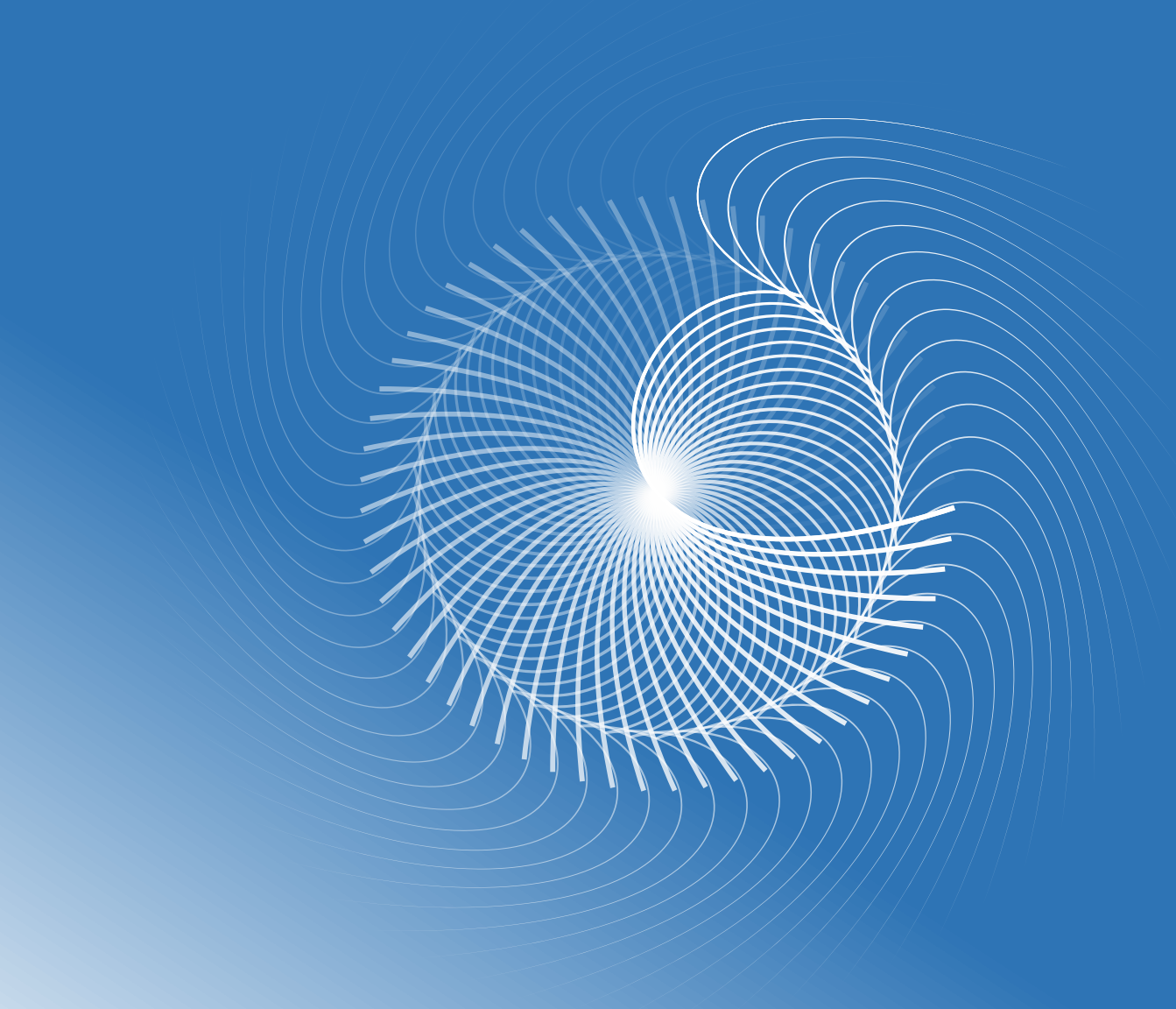
Standards of Evidence

General Requirements for Evidence – Part 1: Vocabulary



Standard of Evidence 1 Part 1 (StEv 1-1:2016)

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Technical foreword

Information about this document

This standard is published by HACT and drafted by Jim Vine. It came into effect on 2 February 2016.

National and international standards bodies have established conventions for the drafting of standards. As far as is practicable, HACT has adopted these conventions in the drafting of this standard. For the avoidance of doubt, the adoption of these conventions does not constitute a claim that any such body has overseen the creation of this standard.

> *[REFERENCES: ISO/IEC Directives, Part 2, 2011. http://www.iec.ch/members_experts/refdocs/iec/isoiec-dir2%7Bed6.0%7Den.pdf. Rules for the structure and drafting of UK standards, 2012. http://www.bsigroup.com/Documents/standards/guide-to-standards/BSI-Guide-to-standards-2-standard-structure-UK-EN.pdf]*

This standard is a vocabulary, a type of standard that is concerned with defining terms, principally for use in other standards. A vocabulary is used to support the aim that the requirements and recommendations of standards should be clear and unambiguous. One part of this is to ensure that there is clarity over the meanings of terms used. Another part is ensuring consistency in the use of terms. As far as possible the consistency is intended to work in both directions: each term should be used to only refer to one concept and also each concept should consistently be referred to by the same term wherever it occurs.

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Great thanks are also due to all of those who have acted as a Correspondence Group for the project of developing the standard,

contributing their thoughts in ways that have very much improved the final output, and to Peter Molyneux, who chaired meetings of the working group that led to the standard. Any errors that remain are, of course, the responsibility of the author.

The Correspondence Group included representatives of the following organisations: Academy of Medical Royal Colleges; Alliance for Useful Evidence; Care and Repair England; Centre for Mental Health; Chartered Institute of Housing; Children and Young People's Mental Health Coalition; Department for Communities and Local Government (DCLG); EDF; Economic and Social Research Council (ESRC); Homeless Link; Housing LIN; Joseph Rowntree Foundation (JRF); London School of Hygiene and Tropical Medicine; MDRC; National Housing Federation; National Institute for Health and Care Excellence (NICE); Place2Be; Royal College of Psychiatrists; University College London; University of Chicago; University of Durham; University of Glasgow; University of Stirling; University of Warwick; University of York; and Youth Access.

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a standard cannot confer immunity from legal obligations.

Contents

1 Scope

This Standard of Evidence defines terms relating to producing, reviewing and using evidence.

2 Terms and definitions

For the purposes of this standard, the following terms and definitions apply.

[NOTE: Terms are grouped thematically rather than listed alphabetically.]

2.1 evidence

outputs of studies that are intended to support conclusions

[NOTE: This type of evidence might be labelled "research evidence" or "empirical evidence" in contexts where it is necessary to distinguish it from theoretical evidence, experiential evidence or contextual evidence. In the context of producing evidence of the effectiveness of interventions it is safe to simply refer to "evidence", which has been adopted in the interests of readability.]

2.1.1 evidence of effectiveness

evidence intended to address the question of 'what works' (plus extension to related questions such as 'what works, for whom, in what circumstances, at what costs, how and why?')

[SEE ALSO: effective]

2.1.2 evidence users

community of practitioners and decision makers who could make use of the evidence to inform decisions about their practice

2.2 effective

contributing in a causal sense to the achievement of an outcome

2.2.1 causal

resulting in an increased probability that an outcome will occur

[NOTE: A causal relationship in this context does not imply an entirely deterministic link between an intervention and some outcome, with the outcome occurring in 100% of cases where the intervention is applied.]

2.2.2 correlation

relationship identified between an intervention and an outcome that does not on its own prove that the intervention caused the outcome

2.2.3 non-causal design

design of a study that is not able to offer a robust estimate of the counterfactual, and hence can at best detect a relationship or correlation between the intervention and an outcome, not provide convincing evidence that the intervention caused the outcome

2.2.4 counterfactual

knowledge of what would have happened to study participants who received an intervention if they had simultaneously not received the intervention

[NOTE: We cannot actually observe a counterfactual: it is impossible for the same participants to simultaneously both receive and not receive an intervention. Study designs that seek to establish causal evidence are those that attempt to create a robust approximation to the actual counterfactual. ADAPTED FROM: Shadish, Cook and Campbell (2002), p5.]

2.2.5 causal chain map

any one of several techniques intended to identify processes by which interventions might contribute to outcomes by assembling a series or network of steps that are believed to be plausibly causally linked

[NOTE: The family of techniques that might be considered causal chain mapping techniques include: logic model, programme logic, programme theory, theory of change, causal model, results chain, and intervention logic. SOURCE: List of synonyms from Rogers (n.d.).]

2.3 intervention

activity that is delivered with the intention of achieving one or more outcomes

[NOTE: This includes any format of activity, including ongoing services, provision and use of products, one-off projects, back-end business processes, and specific interactions. It also includes any variant or adjusted design of an activity.]

2.4 outcome

variable of interest in the study

[ADAPTED FROM: CONSORT glossary http://www.consort-statement.org/resources/glossary]

2.4.1 primary outcome

the outcome of greatest importance

[ADAPTED FROM: CONSORT glossary http://www.consort-statement.org/resources/glossary]

2.4.2 secondary outcome

outcomes measured to evaluate additional effects of the intervention

2.4.3 direct outcome measure

measure intended to directly reflect an outcome of interest

2.4.4 surrogate outcome measure

measure intended to act as a proxy for an outcome that is hard to measure directly

2.4.5 minimum practically important difference

smallest amount of difference in an outcome that would matter for comparing the intervention to the alternative

[NOTE: A difference or change in this outcome measure below this level would be considered negligible, unimportant or irrelevant.]

2.4.6 intermediate outcome

outcome that is not an outcome of particular practical interest but that represents a point along the causal chain between the intervention and an outcome of interest

2.4.7 adverse outcome

outcome that is undesirable

2.5 study

project intended to use systematic, replicable methods to produce evidence regarding one or more interventions

2.5.1 pragmatic study

study in which the intention is to establish whether the intervention is likely to work in real practice, and where delivery of the intervention is designed to resemble as closely as possible the situation that would exist in normal practice

2.5.2 explanatory study

study in which the intention is to establish whether the intervention is able to work in ideal conditions, and where delivery of the intervention is under tight controls

2.5.3 randomised controlled trial (RCT)

study design in which participants are allocated at random into a variety of groups (typically a control group plus one or more intervention groups)

2.5.4 study site

location at which the study is being conducted

[NOTE: In a study with multiple organisations or branches within an organisation providing the intervention each organisation or branch might be considered to be a study site.]

2.5.5 context

range of conditions and factors affecting the participants, either in a study as a whole or for some of the participants, such as those at a particular study site

2.5.6 participants

individual units that participate in the study, whether in an intervention or comparison group, and on which data are collected

[NOTE: These are typically individual people, but other units, such as households or neighbourhoods are possible.]

2.5.7 attrition

proportion of participants who commence the study but do not progress to completion

2.5.8 non-compliance

actions of participants during the study that differs from the intended actions as specified in the intervention design

2.5.9 arms

groups in a study that are compared to each other, typically including a comparison group and one or more intervention groups

2.5.10 intervention group

group of participants receiving an intervention that is being studied to assess its effectiveness

2.5.11 comparison group

group of participants receiving some service other than the intervention(s) being studied

[NOTE: The service received by a comparison group may include no service, the business-as-usual service, or a service of existing known effectiveness.]

2.5.12 control group

type of comparison group where the members of the group are selected from the overall population of participants in the study using a robust randomised process

2.5.13 eligibility criteria

criteria used to establish whether any given potential participant from a population may become a participant in the study

[NOTE: Eligibility criteria were historically often grouped as separate inclusion and exclusion criteria. As criteria can typically be framed either in

the positive or the negative it is now generally preferred to produce a combined set of eligibility criteria.]

2.6 protocol

document specifying how a study will be conducted

2.6.1 registration

publishing a study's protocol in a registry

2.7 analysis

processing data collected in a study in order to produce findings

2.7.1 post hoc analysis

analysis that was not specified in the protocol

2.8 academic publishing

publishing in journals predominantly targeted at an academic audience and typically characterised by peer review

2.8.1 open access

academic publishing outputs made available online for access without payment or other restrictions

[NOTE: This is distinct from the previously standard form of publishing, where access to journal articles was typically dependent upon an institutional subscription to the journal or high fees to access individual articles.]

2.8.2 gold open access

articles made open access through the journal publishing them

2.8.3 green open access

articles made open access by lodging in a central accessible repository

2.9 process evaluation

evaluation undertaken with the intention of increasing understanding of how an intervention is implemented, why it seems to work or not, and what contextual factors are affecting it

*[NOTE: This is distinguished from the task of assessing **whether** an outcome was achieved (the effectiveness of the intervention).]*

2.10 economic evaluation

comparative analysis of alternative courses of action in terms of both their costs and consequences

[SOURCE: Drummond et al (2015, p4)]

2.10.1 cost minimisation

type of economic evaluation intended to examine which of two (or more) interventions that cause the same outcome does so for the lowest cost

2.10.2 cost-effectiveness analysis

type of economic evaluation that compares the costs of delivering an intervention to the amount of its outcome it achieves, in order to derive a cost-effectiveness ratio, which is expressed in terms of the cost for each unit of the outcome

2.10.3 cost-benefit analysis

type of economic evaluation that places monetary values on the benefits as well as the costs, in order to report a ratio that is expressed in the same terms (e.g. £2 of benefits for every £1 of expenditure)

[NOTE: This also enables different outcomes to be compared on the same scale, as they are all converted into the same units (money).]

2.10.4 cost-utility analysis

type of economic evaluation that converts various outcomes to a measure of 'utility', allowing the comparison of different outcomes on a common scale

[NOTE: This technique is commonly used in health sectors, where the common measure of utility is the Quality Adjusted Life Year, QALY.]

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