A nurses’ guide to the hierarchy of research designs and evidence

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KEY WORDS

Evidence based practice (EBP). Case reports, Cross-Sectional Studies, Cohort Studies, Random Control Trials, Systematic Reviews, Meta-analysis

ABSTRACT

Objective
This article provides a breakdown of the components of the hierarchy, or pyramid, of research designs. Its intention is to simplify the components of the hierarchy to enable novice readers of research to better understand the differing approaches and levels of evidence.

Primary Argument
Evidence-based Practice (EBP) is the integration of the best research evidence with clinical expertise and the patient’s unique circumstances. This includes respect of patient values, and their needs, whilst delivering high-quality, cost effective health care. Understanding the differing levels of evidence, and their reliability, is paramount to making correct and appropriate health care decisions. Nurses are required to use evidence-based practice as they are responsible for a significant amount of judgments and decisions every day, and therefore, they must use research literature as part of their clinical decision-making.

Conclusion
The content, or levels of evidence, of the hierarchy will be discussed in a systematic, logical order from the base to the apex of the pyramid. A comparative grid at the end may lead the nurse to better understand the differing components of the seven levels of evidence or, depending on the source, eight.
INTRODUCTION

The nursing research pyramid, or nursing research hierarchy of evidence, provides a visual and systematic depiction of forms of research from the least reliable (base) to the most reliable (apex). The pyramid includes both qualitative and quantitative paradigms. Pyramids vary slightly from source to source which can be confusing. To further add to the varying hierarchies “there is currently no universally agreed upon hierarchy of evidence for study types that seek to answer questions about patient’s experiences and concerns (Del Mar et al 2013 p.29). Figures 1 and 2 are discussed in the main part of this article.

At the Base of the Pyramid (Level 7): Ideas, Opinions, Anecdotes and Editorials

The least reliable evidence comes from ideas, opinions, anecdotes and editorials. Our knowledge comes from varying places and our practices can be from tradition and custom, with many practices ritualistic. We can accept those practices with little questioning (Usher and Fitzgerald 2008 p.7). Whilst personal ideas, opinions and experience can be useful, they may not be transferrable or easily explained. They are akin to anecdotal evidence which is based on, or consists of, reports or observations of usually unscientific observers (Merriam Webster Dictionary 2015).

Editorials are usually in the form of a newspaper or magazine article that give the opinion of the editor or publisher (Merriam Webster Dictionary 2015). They are printed and available for public view and scrutiny but cannot be used as scientific evidence.

Another form of evidence not mentioned in the pyramid is instinct which is a ‘hunch’ or ‘gut feeling’ which is closely tied to personal experience (Usher and Fitzgerald 2008 p.10). Benner (1984) believes this is often deep knowledge derived from many hours, even years, of observation and experience, and acknowledges its importance, but it remains under-researched (Usher and Fitzgerald 2008 p.10) and cannot be quantified. It is, however, an important tool in nursing practice and part of nurses’ synergistic response to patients and events (Center for Spirituality & Healing and Charlson Meadows 2015).

Case Controlled Studies, Case series and Case Reports (Level 6)

A case controlled study, or a case report, can be defined as an in-depth research study of an individual unit which may include, for example, one person, one family, a group or other social unit (Burns and Grove, 2009; Jackson and Borbasi 2008 p.154). A case study generally combines both qualitative and quantitative data (Jackson and Borbasi, 2008). This is further described by Wilczynski and McKibbon (2013 p.43) as an original study but specifically one study only. Jirawong and Pepper (2013 p.156) suggest that case controlled studies have subjects with a disease or condition (cases) or don’t (controls). Information is obtained about their previous exposure/non-exposure to the intervention or factor under study (NHMRC (National Health and Medical Research Council) 2009). Comparisons can then be made by the researchers. There is a potential for bias in recalling information and the quality may be affected if the information is collected retrospectively (Jirojwong and Pepper 2013).

A case series is defined as a report on a series of patients, or cases, who have an outcome of interest or may have received some intervention (Del Mar et al 2013) whereas the NHMRC (2009) state it is a single group of people exposed to a intervention (factor under study). Whilst pre and post tests are recorded, there is no control group (Del Mar et al 2013 p.28). Due to the individual nature of these studies, with limited ability to extrapolate to a wider audience, they remain at the lower part of the pyramid.

Cohort Studies (Level 5)

Cohort Studies are defined by Jirawong and Pepper (2013 p.156) as a study which categorises participants according to the level of exposure to risk factors who are then followed over a period of time to observe the
possible occurrence of a disease. This is further clarified by Del Mar et al (2013 p.25) as a longitudinal, observational study where differences in outcome are observed and related to the initial differences. The NHMRC (2009 p.9) state that those under study are then compared to a group not exposed to the risk factor.

Cohort studies can be prospective or retrospective. The NHMRC (2009 p.9) explain that prospective cohorts are observed at a point in time to be exposed or not exposed to an intervention whereas retrospective studies are usually done from medical records.

Observational studies are good at answering questions about prognosis, diagnosis, frequency and aetiology but not questions regarding the effect of an intervention (Del Mar et al 2013 p.24). Random Controlled Trials are able to quantify the effects of intervention hence they are higher up the pyramid than Cohort studies.

Random Control Trials (Level 4)
Random Control Trials, or RCT’s, are the gold standard but Meta‑analyses (discussed below) combine many RCT’s. RCT’s are considered to provide the best evidence (Koch et al 2008 p.233). This is an experimental form of research where participants are randomised (randomly allocated) in to two, or more, different groups with each group receiving a different intervention. At the end of the trial the effects of the different interventions are then measured (Del Mar et al 2013 p.25). The results are gathered and decisions can be made once it is evident that one intervention is more effective than another.

RCT’s are routinely used to test new forms of medication because the design has the three major characteristics of an experiment, namely randomisation, a control group and manipulation (Jirojwong and Pepper 2013 p.153). This style is considered very reliable because the replication of a trial is possible and the study protocols have to be well defined and clearly described (Rose 2013).

Critically-Appraised Individual Articles (Article Synopses) (Level 3)
Critical appraisal is a term used to assess the outcomes for evidence with regard to an individual research study’s effectiveness (Jirojwong, Johnson and Welch 2013). Authors of critically-appraised individual articles evaluate and synopsise individual research studies (Harvey Cushing/John Hay Whitney Medical Library 2015; Walden University 2015; Glover et al 2006). A synopses is the evidence of an individual article with an expert telling you its strengths (Wilczynski and McKibbon 2013 p.43). This is less reliable than Critically Appraised Topics as there is less evidence on single articles than in a synthesis of a topic using several papers.

Critically Appraised Topics (Evidence Syntheses) (Level 2)
Several journals have sections where they highlight critically appraised papers (Wilczynski and McKibbon 2013) and tell you how strong the evidence is. Authors of critically-appraised topics evaluate and synthesise multiple research studies (Harvey Cushing/John Hay Whitney Medical Library 2015; Walden University 2015; Glover et al 2006).

These are also called Synopses of Syntheses which have structured abstracts, or brief overviews, of published systematic reviews that have been screened for methodological rigour (Wilczynski and McKibbon 2013 p.46). Synthesising research publications entails categorising a series of related studies, analysing and interpreting their findings and then summarising those findings in to unified statements. The potential lack of standardisation can undermine the validity. However, if properly conducted, it is a systematic approach that can integrate qualitative and quantitative strategies (Shi 2007).

The Apex of the Pyramid (Levels 1a/1b Figures 1 and 2): Systematic Reviews and Meta-analysis
Systematic reviews can be defined as a compilation of all scientific studies on a particular topic according to predetermined criteria (Fernandez et al 2013 p.348). More specifically, it is a method to “review existing literature on a particular question by identifying, appraising, selecting and synthesising all high quality research
evidence relative to that question” (Jirojwong et al 2013 p.405). Systematic reviews differ from literature reviews in that they involve rigorous review of all the available evidence on an aspect of health care (Koch et al 2008). The quality of the research is appraised and then the evidence is ranked in terms of reliability (Koch et al 2008). Authors of a Systematic review ask a specific clinical question, perform a comprehensive literature search, eliminate the poorly done studies and attempt to make practice recommendations based on the well-done studies (Harvey Cushing/John Hay Whitney Medical Library 2015; Walden University 2015; Glover et al 2006).

Fernandez et al (2013) and the NHMRC (2009) state that Systematic reviews are recognized as the highest form of evidence as they include all available evidence with conclusions based on rigorous critical appraisal. Literature reviews, by comparison, a much simpler and are a summary of available theoretical and research literature on a selected topic (Borbasi et al 2008 p.105). This helps to place the research problem in a context of what is already known and can help support the need for the study. Systematic reviews may summarise results from qualitative, quantitative or combination studies, that is, Mixed methods research (Bennett et al 2013).

A Meta-analysis is also at the highest part of the pyramid because it is a pooled analysis of several randomised controlled trials (DelMar et al 2013 p.24). Some sources place Systematic reviews alongside Meta-analyses whereas others place Meta-analyses above Systematic reviews. The Meta-analysis differs from Systematic reviews in that the results of two or more individual quantitative studies are typically summarised using the measure of effect that allows for statistics to be compared and combined to form the Meta-analysis (Bennett et al 2013 p.284). A Meta-analysis is a systematic review that combines all the results of all the studies into a single statistical analysis of results (Harvey Cushing/John Hay Whitney Medical Library 2015; Walden University 2015; Glover et al 2006). Sometimes the results of the RCT’s cannot be combined because the interventions, or outcomes, may be too diverse to combine and the results are then synthesised narratively (Bennett et al 2013 p.284). Higgins and Green (2011) support this stating if studies are clinically diverse then a meta-analysis may be meaningless, and genuine differences in effects may be obscured.

An example of a body who performs both Systematic reviews and Meta-analyses is the Cochrane Collaboration (Cochrane Community 2015). Cochrane Reviews are Systematic reviews, or Meta-analyses, of primary research into human health care and health policy. They are recognised internationally as the highest standard in evidence-based care (Cochrane Community 2015; Jirojwong and Welch 2013 p.284). Their role is to investigate effects of interventions for prevention, treatment and rehabilitation. They also assess the accuracy of a diagnostic test for a given condition in a specific patient group and setting (Cochrane Community 2015).

CONCLUSION

An understanding of the pyramid of evidence will lead the nurse to appreciate and identify which levels of research are more reliable. Nurses need to be competent in evaluating the strengths and weaknesses of research studies and the applicability of them in relation to their working environment (Jirojwong and Welch 2013 p.5; Levett-Jones 2013; Nursing and Midwifery Board of Australia 2013; Stevens 2013). Nurses have a responsibility to contribute to the development of the profession’s knowledge through research.
### Comparative Grid of the Seven Levels of Evidence

<table>
<thead>
<tr>
<th>Level</th>
<th>Type</th>
<th>Reliability &amp; Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 7</td>
<td>Base</td>
<td>Least reliable. Basically anecdotal. Unscientific reports and observations (Usher and Fitzgerald 2008)</td>
</tr>
<tr>
<td>Level 6</td>
<td>Case Series and Case Reports</td>
<td>Slightly more reliable but there is a potential for bias in recalling information and the quality may be affected if the information is collected retrospectively (Jirojwong and Pepper 2013).</td>
</tr>
<tr>
<td>Level 5</td>
<td>Cohort Studies</td>
<td>Becoming more reliable. Observational studies are good at answering questions about prognosis, diagnosis, frequency and aetiology but not questions regarding the effect of an intervention (Del Mar et al 2013 p.24).</td>
</tr>
<tr>
<td>Level 4</td>
<td>Middle</td>
<td>Very Reliable/ Gold Standard. Random Controlled Trials are able to quantify the effects of intervention hence they are higher up the pyramid than Cohort studies (Koch et al 2008)</td>
</tr>
<tr>
<td>Level 3</td>
<td>Critically-Appraised Individual Articles (Article Synopses)</td>
<td>Increasing reliability of findings. A synopses is the evidence of an individual article with an expert telling you its strengths (Wilczynski and McKibbon 2013 p.43). This is less reliable than Critically Appraised Topics as there is less evidence on single articles than in a synthesis of a topic using several papers.</td>
</tr>
<tr>
<td>Level 2</td>
<td>Critically Appraised Topics (Evidence Syntheses)</td>
<td>Very high reliability. Synthesising research publications entails the categorising of a series of related studies, analysing and interpreting their findings and then summarising those findings in to unified statements. The potential lack of standardisation can undermine the validity.</td>
</tr>
<tr>
<td>Level 1a/1b</td>
<td>Apex</td>
<td>The most reliable of all. Systematic reviews, and Meta-analyses, of primary research into human health care and health policy are recognised internationally as the highest standard in evidence-based care (Cochrane Community 2015; Jirojwong and Welch 2013 p.284).</td>
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REFERENCE LIST


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