Label Claims

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Purpose of a health claim

- Legitimate: To inform the consumer the benefit of the product or ingredient

- Illegitimate: To mislead the consumer to believe that the product/ingredient in the product provides a benefit- when it is not true

A qualitative claim

- Product with an ingredient that gives a implied health benefit by its mere presence / absence
- Eg NO ADDED SUGAR
- Or CONTAINS Probiotics

Specific Structure Function Claims

- Presence of a ingredient with established health benefit
- Eg : Rich in calcium – builds strong bones
- Or
- Omega 3 – good for heart health

Quantitative claims/ Nutrient content claims

- Low in sugar – good for weight conscious
- Rich source of fiber- low glycemic
- Rich source if > 30 % RDA/DV
- Good source if > 15% RDA/DV

Health Claim

- Product beneficial in a disease state-FSDU.FSMP
- Eg – Shown to be beneficial for growth of children
- (qualified claim)
- Or – proven to promote growth in children
- (authorized claim)

Health Claim – not specific to a disease

- Improves appetite
- Good for growing children
- Promotes immunity
- Eye vitamins and minerals supplement
- Dietary Supplement – promotes urinary tract health/ digestive health/ heart health..

Why health claims were allowed at all

- A Case in US

in the case of Pearson v. Shalala , the court concluded that First Amendment protection of commercial speech does not permit FDA to reject health claims that it determines are potentially misleading . As a result of this ruling, FDA began to allow commercial speech about health claims rather than impose an outright ban on such claims,

Claudine et al: JNCI: Journal of the National Cancer Institute, Volume 99, Issue 14, 18 July 2007,

Scientific evidence

" FDA's determination of significant scientific agreement represents the agency's best judgment as to whether qualified experts would likely agree that the scientific evidence supports the substance–disease relationship that is the subject of a proposed health claim.

The significant scientific agreement standard is intended to be a strong standard that provides a high level of confidence about the validity of a substance–disease relationship.

Claudine et al: JNCI: Journal of the National Cancer Institute, Volume 99, Issue 14, 18 July 2007

What is an Evidence-Based Review System?

Systematic science-based evaluation of the strength of the evidence to support a statement.

The evaluation process involves

- Assess scientific studies and other data,
- Eliminate those from which no conclusions about the substance/disease relationship can be drawn,
- Rate the remaining studies for methodological quality

Types of health claims based on scientific strength (USFDA)

- Authorized health claims- Strong undisputed evidence

- Qualified Health Claims- less robust but acceptable level of evidence

Recommended reading

The U.S. Food and Drug Administration's Evidence-Based Review for Qualified Health Claims: Tomatoes, Lycopene, and Cancer
Claudine J. Kavanaugh Paula R. Trumbo Kathleen C. Ellwood
JNCI: Journal of the National Cancer Institute, Volume 99, Issue 14, 18 July 2007, Pages 1074–1085, https://doi.org/10.1093/jnci/djm037

Identifying Studies That Evaluate the Substance/Disease Relationship

Stages in review

- A literature search, that are relevant to the proposed health claim
- Individual relevant articles on human studies from other types of data and information.
- Review primarily on articles reporting human intervention and observational studies

Have the studies specified and measured the substance that is the subject of the claim?

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Have the studies appropriately specified and measured the specific disease or health-related condition that is the subject of the claim?

randomized, controlled intervention studies provide the strongest evidence of whether or not there is a relationship between a substance and a disease

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Study Specificity

- Studies shall be specific to the population for whom the claim is targeted

- Eg The evidence consists of studies showing an association between intake of a substance and reduced risk of juvenile diabetes, then such studies should not be extrapolated to the risk of diabetes in adults.

Observational studies

- In contrast to intervention studies, even the best-designed observational studies cannot establish cause and effect between an intervention and an outcome
- Cohort studies are considered to be the most reliable observational study design
- Case-control studies are considered to be less reliable than cohort studies
- Nested-case control or case-cohort studies are considered less reliable than cohort studies but more reliable than case-control studies.

Cross sectional studies

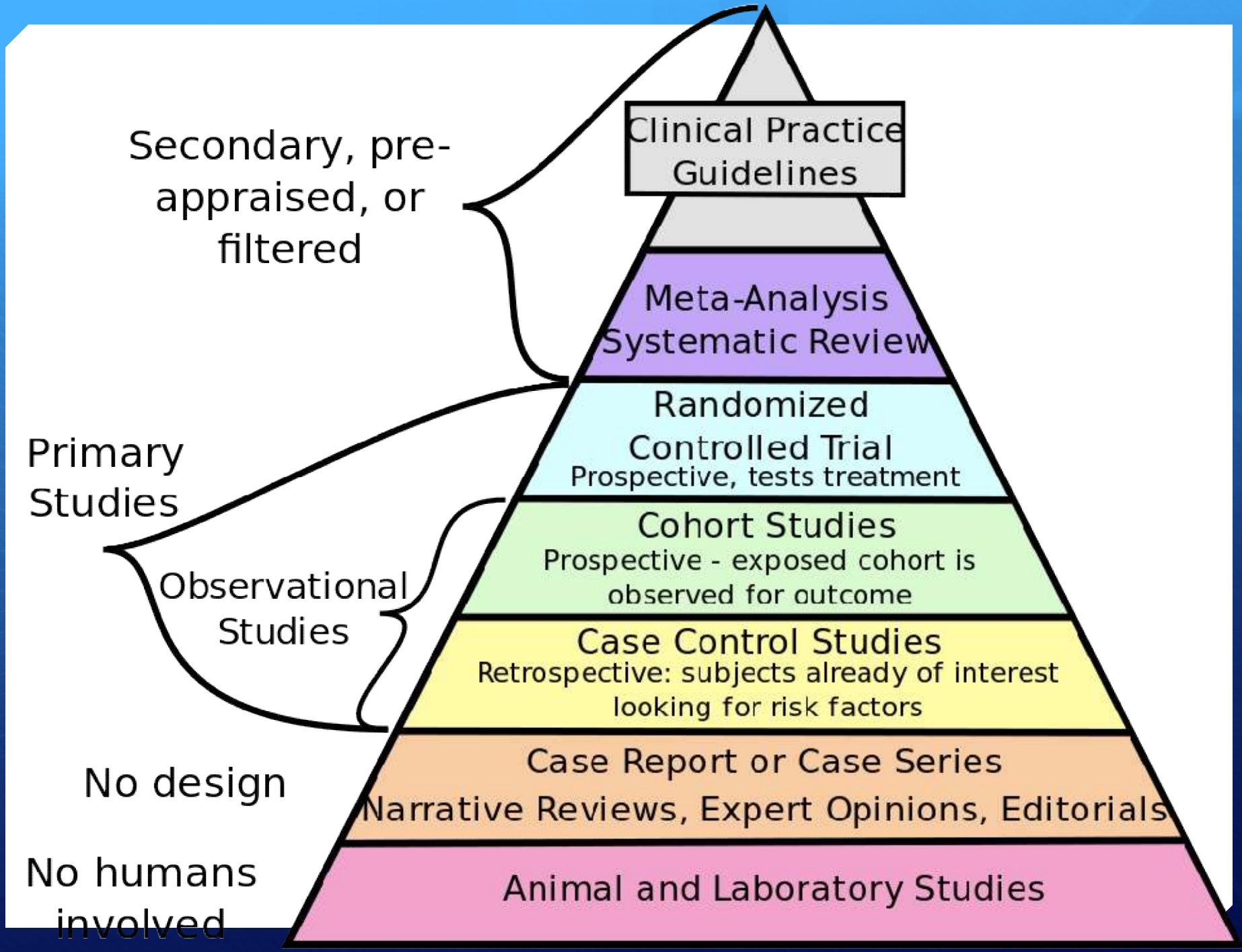
- Cross-sectional studies are considered to be a "relatively weak method of studying diet-disease associations"
- Subject to significant potential measurement error regarding dietary intake due to inaccuracy of survey methods used and limited ability to control for dietary intake variations
- Cross-sectional studies are considered to be less reliable than cohort and case-control studies

The Gold Standard

- FDA, intends to consider as part of its health claim review process a meta-analysis that reviews all the publicly available studies on the substance/disease relationship.

Animal and *in vitro* Studies

- use animal and *in vitro* studies as background information regarding mechanisms that might be involved in any relationship between the substance and disease.


Secondary, pre-appraised, or filtered
Clinical Practice Guidelines
Meta-Analysis
Systematic Review
Primary Studies
Randomized Controlled Trial
Prospective, tests treatment
Observational Studies
Cohort Studies
Prospective - exposed cohort is observed for outcome
Case Control Studies
Retrospective: subjects already of interest looking for risk factors
No design
Case Report or Case Series
Narrative Reviews, Expert Opinions, Editorials
No humans involved
Animal and Laboratory Studies

Identifying Surrogate Endpoints of Disease Risk

- Surrogate endpoints are risk biomarkers that have been shown to be valid predictors of disease risk and therefore may be used in place of clinical measurements of the onset of the disease in a clinical trial

- Plasma Cholesterol ? Biomarker for heart disease – NOT ANYMORE

Checklist for evaluation of supporting studies

- *Were the study subjects healthy or did they have the disease that is the subject of the health claim*
- *Was the disease that is subject of the claim measured as a "primary" endpoint?*
- *Did the study include an appropriate control group?*
- *Was the study designed to measure the independent role of the substance in reducing the risk of a disease?*

Checklist ……

- *Were the relevant baseline data (e.g., on the surrogate endpoint) significantly different between the control and intervention group?*
- *How were the results from the intervention and control groups statistically analyzed?*
- *What type of biomarker of disease risk was measured?*
- *How long was the study conducted?*
- Eg HbA1c

Checklist……..

- *If the intervention involved dietary advice, was there proper follow-up to ascertain whether the advice resulted in altered intake of the substance?*
- *Where were the studies conducted?*

Diverse populations cannot be compared due to different nutritional status and different dietary intakes

checklist

- *What type of information was collected?*
- *Were scientifically acceptable and validated dietary assessment methods used to estimate intake of the substance?*
- *Did the observational study evaluate the relationship between a disease and a food or a food component?*

Methodological Quality of Studies

- *Were the studies randomized and blinded and was a placebo provided?*
- *Were inclusion/exclusion criteria and key information on the characteristics of the study population provided?*
- *Was subject attrition (subjects leaving the study before the study is completed) assessed, explained in the article reporting the study, and reasonable?*
- *How was compliance with the study protocol verified?*

Methodological Quality

- *Was statistical analysis conducted on baseline data for the all subjects initially enrolled in the study or only those who completed the study?*
- *Did the study measure disease incidence or a surrogate endpoint of disease risk?*
- *How was the onset of a disease determined?*
- *Was there an adequate adjustment for confounders of disease risk?*

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Totality of Scientific Evidence

- *Number* of studies and number of subjects per group
- *Methodological quality* (high, moderate, or low).

Totality of Scientific Evidence

- *Outcome* (beneficial effect, no effect, adverse effect) of the studies within each study

Totality of Scientific Evidence

- In general, the greater the *consistency* among the studies in showing a beneficial relationship, the greater the level of confidence that a substance/disease relationship exists.
- Conflicting results do not disprove an association (because the elements of the study design may account for the lack of an effect in negative studies) but tend to weaken confidence in the strength of the association

Totality of Scientific Evidence

- The greater the magnitude of the beneficial effect, the more likely the association may exist.
- *Relevance* to the general population
- *Did the studies only include subjects with unique lifestyles (e.g., smokers, vegetarians)?*
- *Do the studies suggest that the intake level of the substance that provides a benefit significantly exceeds usual intakes in the country*

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Conclusion

"It is science and science alone that can provide the evidence of a consumer benefit and permit a health claim… Who indeed could afford to ignore science today? At every turn we have to seek its aid… The future belongs to science and to industry that make friends with science."

Misquoting Pandit Jawaharlal Nehru –first PM of India

Truth shall triumph

thank you!