NMDA321
Nutritional Physiology Research

Session 1

Nutritional Medicine Department

Evidence based approach to nutritional medicine practice
Introduction to NMDA321

Learning Outcomes

1. Develop an answerable clinical question relating to a specific disease or associated biological process.
2. Conduct a literature review bearing on the clinical question.
3. Demonstrate knowledge of the current and emerging nutritional physiology research.
4. Critically evaluate, analyse, synthesise and consolidate current nutritional science research methodology and findings.
5. Apply evidence-based practice principles, complementary medicine understandings and philosophy, critical thinking, creativity and judgement to determine nutritional interventions for acute and chronic disease.
Prescribed Text

- This subject requires students to search the literature using research databases to discover and evaluate the best recent articles on their topic of investigation. Guidance on conducting searches will be provided in class.
Session 1

- Evidence Informed Practice
- Combining traditional knowledge and evidence-based practice
- Hierarchy of evidence versus clinical relevance and application
Evidence Informed Practice
Evidence Base Practice

- Evidence does, of course, have a very important role to play in practice.
- Clinical practice is as much an ‘art’ as it is a ‘science’, and as much a dialogue as it is an application of empirical findings to clients’ unique characteristics and context.
- The wisdom appropriate to it is practical wisdom rather than strictly scientific rationality.

(Nevo L, et al. 2011)
Evidence Informed Practice

- Evidence Based Practice describes the clinical decision-making process that utilises current available evidence to make decisions about the analysis and treatment of individual patients.

  +

  - Integration of the most current knowledge with our philosophical interpretation of the case while considering each client's unique health history.
3 Phase Approach in EBP

http://guides.mclibrary.duke.edu/c.php?g=158201&p=1036021
Evidence Informed Practice

Integrating 3 phases EBP = EIP

1. Best external clinical evidence from systematic research which goes beyond simply using whatever research evidence you happen to obtain from a few journals

2. Individual clinical expertise – proficiency and judgement individual clinicians acquire through clinical experiences and practice

3. Thoughtful identification and compassionate use of individual patients’ predicaments, rights and preferences in making clinical decisions about their care
Evidence Informed Practice

Best external clinical evidence

- Encourages explicit and conscientious attempts in locating the best evidence from research

- Understanding what the different study designs can and cannot identify

- Locate the type of study design best suited to the type of information required to make a clinical decision

- Studies which have not been designed well reduce the confidence in their conclusions therefore quality is important

(Hoffman et al. 2013)
Evidence Informed Practice

Individual clinical expertise

• Evidence Informed Practice recognises that research evidence alone is not sufficient for addressing the complex nature of professional practice

• Clinical or professional expertise and experience is central in the translation of research into a practice context

• Expertise develops as an individual gains greater knowledge, understanding and mastery in their practice.

(Hoffman et al. 2013)
Evidence Informed Practice

Individual patients’ outcomes are dependent on a range of factors which need to be considered within their treatment:

- The nature of their health
- Types of treatments or services available to and accessible by the client
- Practices of health professionals working in those services
- The nature and quality of interaction between client and health professional
- Attitudes of the client towards the recommendations
- The client’s own conceptualisation of the health problem
- The ease any recommendations may be carried out by the client in the broader context of their life

(Hoffman et al. 2013)
Evidence Informed Practice

- Evidence-informed practice (EIP) should be understood as leaving ample room for the constructive and imaginative judgement and knowledge of practitioners and clients who must be in constant interaction and dialogue with one another for most interventions to succeed.
  - In particular, research findings should not override, or take precedence over, clinical experience and clients’ wishes, values and knowledge.
  - Rather, research evidence is better regarded as one component in the mutual and constantly changing journey of client and practitioner.

(Nevo L, et al. 2011)
A qualitative study conducted among 12 Australian naturopaths found there are tensions between research and traditional knowledge (Steel and Adams, 2011a). Some practitioners:

1. describe using science to explain traditional approaches. Strengthening perceived validity of their traditional knowledge.
2. perceived a focus on modern research weakens the value practitioners place on traditional knowledge.
A qualitative study conducted among 12 Australian naturopaths found there are tensions between research and traditional knowledge (Steel and Adams, 2011a). Some practitioners:

3. described poor research design as affecting the value they place on research through limiting the transferability into practice.

4. When research was perceived to take direction from traditional knowledge, the research was described as being more valuable.
Combining traditional knowledge and evidence-based practice

- How can these tensions between research and tradition be overcome in clinical practice?
- Does this resistance hinder evidence-informed practice?
- How can we work toward providing the most efficacious, ethical and safe treatments for our patients?
Evidence for lifestyle and nutritional medicine

- Some problems with research translation exist
- Heterogeneity in trials
- Variability of quality from one trial to another
- Mixed results and conclusions – especially meta-analysis; pooled analysis – if some studies support the null hypothesis, the studies with positive outcomes may be overlooked!
- Some not trialled, or no efficacy found, level of current research—doesn’t mean they aren’t effective in practice

Associate Professor Vicki Kotsirilos, ACNEM Conference, 2016
When considering any therapy

- It is important to understand:
  - The risks
  - The benefits
  - The evidence
  - The costs
  - Patient choice
  - The alternatives
    - E.g. other therapies/ doing nothing


Associate Professor Vicki Kotsirilos, ACNEM Conference, 2016
Balance clinical decision making

- Consider
- Patient choice – respect beliefs
- Expertise?
  - Who is the best person to treat?
- Evidence-based?
- Clinically effective?
  - For this particular health problem?
- Safe in this particular clinical situation?
  - Is patient at risk if denying other Rx’s
  - Monitor and follow up patient, reflect on practice

• Associate Professor Vicki Kotsirilos, ACNEM Conference, 2016
Scientific evidence for NM

- Be clear which Rx’s are supported by scientific evidence and which are not.
- Record in case notes if treatment is clinically effective, based on your clinical observations.
- If no evidence but may be effective, is it harmful?

Associate Professor Vicki Kotsirilos, ACNEM Conference, 2016
Adverse reactions to Complementary Medicine and Nutritional Medicine AUST 2009

- Level of adverse report for CM is LOW
- Aust TGA data adverse events 2004-2008
- CMs < 2%
- 656 total reports with 7 possible death outcomes
- Prescription and registered products ≈ 98%
- 38,337 total reports with 1014 possible death outcomes

- Statistics provided by the Office of Medicines Safety Monitoring at the Therapeutic Good Administration, 25th March, 2009

Associate Professor Vicki Kotsirilos, ACNEM Conference, 2016
Strategies to close the evidence practice gap

• Interventions to strengthen translation and application
  – Practitioner meetings
  – Practitioner social media groups
  – Educational meetings
  – Seminars and conferences
  – Computerised reminders and alerts
  – A collaborative healthcare team
  – Journal clubs

  – (Webb S, 2013, Translation of evidence into practice – pushing or pulling? 2nd Annual NHMRC Research Translation Faculty Symposium, From Bench to Bourke.)
Decision Making in Practice

- 5 Steps to Follow
Evidence Based Practice

- 5 stages EBP information cycle –
  - **ASK** a question
  - **ACQUIRE** the information
  - **APPRAISE** the articles founds
  - **APPLY** the information
  - **AUDIT** or **ANALYSE**

Hoffman et al 2013
Evidence Based Practice

**ASK** convert your information needs into an answerable clinical question.

- When in consultation with patients, we aim to assess their clinical problems in order to devise an adequate treatment.
- Once a case has been taken, we identify key issues which may be functioning within the patient.
- We should then acknowledge any knowledge gaps in order to inform what further knowledge we require to effectively treat the patient.
  - Background questions ask general knowledge about a condition or thing
  - Have two essential components:
    1. A question root (who, what, where, when, how, why) and a verb
    2. A disorder, test, treatment, or other aspect of health care
      e.g. Does a low fat diet benefit heart disease

Hoffman et al 2013
Evidence Based Practice

**ASK** convert your information needs into an answerable clinical question.

- Foreground Questions - ask for specific knowledge to inform clinical decisions or actions
- Have four essential components: (PICO)
  1. **Patient**, population and/or problem – describes ones you come in contact with and are relevant to your practice (*among _____*)
  2. **Intervention** (or exposure) – therapies, environmental factors, patient education or diagnostic tests (*does _______*)
  3. **Comparison**, if relevant – may be standard therapy, placebo, alternative treatment, exposure or diagnostic test (*versus___*)
  4. **Outcomes**, including time if relevant – spend some time working out exactly what outcome is important to you, your patient and an appropriate time-frame (*affect_____*)

Hoffman et al 2013
Evidence Based Practice

- An example of applying PICO to a clinical question would be:

  In adults with hypertension (P), would consuming a low salt diet (I) compared to a high plant based diet (C) reduce morbidity or mortality from stroke (O)?

Hoffman et al 2013
Evidence Based Practice

**ACQUIRE** - Find the best evidence to answer your clinical question.

- Construct a search strategy and prioritise given time constraints.
- Search for information from reliable databases.
- Check other sources to verify information.

**Endeavour databases:**

EBSCO-host—CINAHL – MEDLINE – Proquest – PubMed – ScienceDirect - Cochrane

Hoffman et al 2013
Evidence Based Practice

**APPRAISE** critically appraise the evidence for its validity, impact and applicability.

- Is the information from a reliable source?
- Has the research been done well?
- Are the results statistically significant?

Do you know about any RCTs that provide evidence that we should use RCTs?

Hoffman et al 2013

Image: http://freshspectrum.com/6-rct-randomista/
Evidence Based Practice

**APPLY** integrate the evidence with clinical expertise, the patient’s values and circumstances, and information from the practice context.

- Are the results clinically relevant?
- Are the results related to your patient?
- Is the treatment translatable to your clinical practice?

Hoffman et al 2013
Audit or Analyse

- **AUDIT** evaluate the effectiveness and efficiency with which steps 1-4 were carried out and think about ways to improve your performance next time.

- Separate to this but also extremely important to guide future practice is to measure patient health outcomes over time.
  - What outcome measures are important for this patient?
  - Did the treatment achieve expected outcomes?
  - Were there any obstacles, problems encountered?

Hoffman et al 2013
Clinically Relevant Outcome Measures

- **General**
  - Health-related quality-of-life (QoL)
  - Satisfaction with care or treatment
  - Dimensions of patient experience
    - E.g., depression and anxiety

- **Disease-specific**
  - Health status assessment
  - Symptom reporting
  - Biological assessments
Health research questions

- **Intervention:** Does the treatment work?
- **Diagnosis:** Does a test diagnose a condition?
- **Prognosis:** What is the outcome of a condition?
- **Aetiology:** What is the cause of a condition?
- **Screening:** Should we test everyone for a condition?
- **Experiences:** How do people feel about a condition?
In clinical practice we most frequently look for intervention effectiveness

- Intervention studies involve quantitative research methods
- Answers the question as to whether an intervention works
- An intervention is anything that can have a cause and effect but usually means a treatment
Research that is able to answer this question has high validity

- Internal validity entails both PRECISION and ACCURACY (i.e. does a study provide a truthful answer to the research questions?)

- Validity has a group of related meanings:
  - Truth
  - Rigour
  - Quality
  - Believability
  - Clinical usefulness

- Quantitative research aims to have all of these

- If validity is weak in one or several of these criteria the proof will be limited.
Threats to validity are biases...

- Systematic errors which affect results.
- Internal validity is the term for validity in research design.
- Some types of research have more bias, or threat to validity than other types.
- These are ranked by order of internal validity and are referred to as ‘levels of evidence’ or ‘hierarchy of evidence’.
- The level of evidence is decided by the number and types of threats to internal validity.
Hierarchy of evidence versus relevance and application
Levels of Evidence

The Evidence Pyramid

Useful evidence or not?

- Question…

- You have given a new treatment (magnesium) to five clients and measured their mood before and after treatment based on self-report questionnaire. On average they get 36% better following 6 weeks of treatment. Therefore the effect size is 36%.

- This sounds impressive!

- Is this strong evidence that the treatment works?
Strength of evidence

- Answer...

- It is good clinical practice and this is how we monitor patient health outcomes over time.
- However, it **is not strong evidence** that the treatment is effective.

- Why?
Why is this not strong evidence?

1. Placebo effect – the ritual of the intervention, being cared for. About 1:3 people will get better due to placebo effect. Watch video on placebo effect.
   • https://www.youtube.com/watch?v=yfRVCaA5o18

2. Hawthorne effect – Hawthorne Works commissioned Harvard University to study the lighting effects in their factory on productivity. Productivity improvements occurred because workers were being studied.

3. Natural Recovery – many conditions improve irrespective of treatments, people often seek treatment when conditions are at their worst.
Why is this not strong evidence?

4. Statistical regression to the mean – a natural phenomenon; patients with episodic disease present when condition is most severe but from there fluctuations likely to be less severe.

5. Assessor bias – selection bias, measurement bias

6. Recall bias – extreme cases feature most prominently in memory—optimistic bias


8. There are many others….
A **control group** is the solution of this problem

- Treatment under investigation is taken by the experimental group and the control group is treated in the same way but are not taking the intervention being studied.
- At the outset the experimental group and controls need to be as similar as possible i.e. randomised
- Control group may take placebo, no treatment or usual care i.e. best existing treatment.
Experiences are the same in the treatment group and control group i.e.

- Placebo effect
- Hawthorne effect
- Natural recovery
- Regression to the mean
- Assessor bias
- Process of treatment

Plus either

- New treatment
- Control treatment

Therefore the only difference between the two groups must be due to the intervention.
Randomisation

- **Randomisation** means assigning at random a patient (or a study unit) to their intervention groups.
- Random allocation should be ‘unpredictable, uncontrolled and unbiased by either the subjects or the researchers’ (Clegg and Bannigan, 1997)
- Over large numbers, randomisation minimises the risk of bias but this does not always hold true for small samples.

- Randomisation is probably the most important element in a controlled experiment.
Blinding

- Blinding means not knowing who is receiving the true intervention, and who is receiving the control.
- Researchers must be blinded.
- Participants must be blinded if possible (double blinded).
- Therapists (those administering the treatment) must be blinded if possible. This can be difficult with some treatments.

Dalmeets.com
Attrition – drop outs, lost of follow up ? ?

- For the controlled experiment to work, it should include data from as many people as possible at the end of the study.
- Internal validity is threatened if too many people drop-out. Ideally 85% completion and certainly not more than 20% drop out.
- Analyse data by intention-to-treat i.e. analyse all data according to the group they were allocated. This is for people who have changed groups or dropped out.
Facts!

- Studies **without random allocation** tend to show **greater effects** (e.g. improvement) than those with random allocation.
- Studies **without blinding** tend to show **greater effects** than those with concealment.
- Studies which **exclude drop-outs in analysis** tend to show **greater effects** than those which include them.
Hierarchy by Study Design
Let’s revisit the hierarchy of evidence

- Levels of evidence
- As you work up the hierarchy
- The potential for bias is reduced
- The internal validity is increased
- And therefore strength of evidence is increased

- When searching for evidence we start with the best evidence and work our way down as needed.
Hierarchy of Evidence

- Clinical Guidelines, Summaries
- Systematic Reviews
- Randomised Clinical Trials
- Non-randomised Clinical Trial
- Cohort Studies
- Case-control Studies
- Longitudinal Studies
- Cross Sectional Surveys
- Case Series / Time Series
- Case Reports
- Expert Opinions – Literature Reviews
- Animal Studies
- In Vitro Experiments
Level may be graded **DOWN** on the basis of:

- Study quality
- Imprecision
- Indirectness (study question does not directly match your questions relevant to your enquiry),
- Inconsistency between studies
- The absolute effect size is very small

  - Level may be graded **UP** if there is a large or very large effect size.
  - As always, a meta-analysis or systematic review is **generally** better than an individual study.

  Oxford Centre for Evidence-Based Medicine 2011
# Oxford Centre for Evidence-Based Medicine 2011

## Levels of Evidence

<table>
<thead>
<tr>
<th>Question</th>
<th>Step 1 (Level 1*)</th>
<th>Step 2 (Level 2*)</th>
<th>Step 3 (Level 3*)</th>
<th>Step 4 (Level 4*)</th>
<th>Step 5 (Level 5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How common is the problem?</td>
<td>Local and current random sample surveys (or censuses)</td>
<td>Systematic review of surveys that allow matching to local circumstances**</td>
<td>Local non-random sample**</td>
<td>Case-series**</td>
<td>n/a</td>
</tr>
<tr>
<td>Is this diagnostic or monitoring test accurate? (Diagnosis)</td>
<td>Systematic review of cross sectional studies with consistently applied reference standard and blinding</td>
<td>Individual cross sectional studies with consistently applied reference standard and blinding</td>
<td>Non-consecutive studies, or studies without consistently applied reference standards**</td>
<td>Case-control studies, or &quot;poor or non-independent reference standard&quot;**</td>
<td>Mechanism-based reasoning study</td>
</tr>
<tr>
<td>What will happen if we do not add a therapy?</td>
<td>Systematic review of inception cohort studies</td>
<td>Inception cohort studies</td>
<td>Cohort study or control arm of randomized trial*</td>
<td>Case-series or case-control studies, or poor quality prognostic cohort study</td>
<td>n/a</td>
</tr>
</tbody>
</table>

### Prognosis

<table>
<thead>
<tr>
<th>Does this intervention help? (Treatment Benefits)</th>
<th>Systematic review of randomized trials or n-of-1 trials</th>
<th>Randomized trial or observational study with dramatic effect</th>
<th>Non-randomized controlled cohort/follow-up study**</th>
<th>Case-series, case-control studies, or historically controlled studies**</th>
<th>Mechanism-based reasoning</th>
</tr>
</thead>
</table>

### Harm

| COMMON harms? (Treatment Harms)                                         | Systematic review of randomized trials, systematic review of nested case-control studies, n-of-1 trial with the patient you are raising the question about, or observational study with dramatic effect | Individual randomized trial, or (exceptionally) observational study with dramatic effect | Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)** | Case-series, case-control, or historically controlled studies** | Mechanism-based reasoning |
|-------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|==================================================================================|-----------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|-----------------------------|

### Detection

<table>
<thead>
<tr>
<th>Is this (early detection) test worthwhile? (Screening)</th>
<th>Systematic review of randomized trials</th>
<th>Randomized trial</th>
<th>Non-randomized controlled cohort/follow-up study**</th>
<th>Case-series, case-control, or historically controlled studies**</th>
<th>Mechanism-based reasoning</th>
</tr>
</thead>
</table>

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Study Designs

https://irb.research.chop.edu/study-design
Intervention Studies versus Observational Studies

- Intervention studies are used to determine the effectiveness of an intervention or the effectiveness of a health service delivery.
- They can also establish safety, cost-effectiveness and acceptability of an intervention.
- Two types of intervention studies: randomised controlled trials (RCTs) and non-randomised or quasi-experimental trials.
- RCT is considered to be the ‘gold standard’ of clinical research because it is the only known way to avoid selection and confounding biases.
Intervention Studies versus Observational Studies

- Analytical observational studies (i.e. cohort and case control studies) look at the relationships between risk factors or characteristics of patients and their likelihood of getting a particular disease.
Before we get started, let’s review basic concepts that help identify study type

Study Factor – Exposure or Intervention

- The *exposure* of interest may be associated with either an increased or a decreased occurrence of disease or other specified health outcome, and may relate to the environment, lifestyle etc. The term risk factor is often used to describe an exposure variable.

Outcome Factor

- The *outcome* of a study is a broad term for any defined disease, state of health, health-related event or death. In some studies, there may be multiple outcomes (e.g. BP, HbA1C etc.)
Systematic Reviews

- Combines more than one primary study for any of the research questions
- For interventions these will mostly be randomised controlled trials (RCTs)

A systematic review
- Uses explicit methods to search for existing research
- Critically appraises these studies
- And if possible combines the studies statistically which is called a meta-analysis

Tends to find the least exciting results! Bias has been minimised so effect sizes are not exaggerated.
Meta-analysis

- Meta-analysis – pooled results from more than 1 RCT, less bias and will have more power to measure effect
  - Need to check of heterogeneity
    - Is the study question similar in each study?
    - Is the effect either positive or negative mainly derived from one large study?
Randomised Controlled Trial (RCT)

- Control over Study Factor
- Experiments provide strong evidence of cause and effect
- The most rigorous by design – protected from confounding
- May not always be ethical
Observational Studies

- In observational studies, the researcher observes and systematically collects information, but does not try to change the people being observed.
- Does not provide proof but helps to generate a hypothesis.
- Prospective or Retrospective
  - **Cohort studies** – subject with reference to their exposure status – also known as follow-up or incidence studies.
  - **Case control studies** – subjects are selected with reference to their disease state.
  - **Cross-sectional studies** – subjects are selected at random.
Cohort Study

- Exposure to study factor determined by subject e.g. smoker or non-smoker; take multi-vitamin and mineral supplement daily etc.
- Can be prospective and retrospective
- Next best observational study – less subject to bias than case control study
Cohort Study

Group of interest (e.g. smokers)

Follow over time

Comparison group (e.g. non-smokers)

Follow over time

Compare outcomes
Case Control Study

- The outcome of interest already known i.e. disease
- Retrospective review of exposures to determine causal relationship i.e. high prevalence of lung cancer in smokers
- Toughest part of case-control design: defining the study base and selecting controls who represent the base
- Almost as good as cohort study if well defined study base
Case Control Study

Group of interest (e.g. cancer patients)

Comparison group (e.g. non-patients)

Take histories

Draw conclusions

Compare histories

Take histories
Case Reports / Series

- A single case or group of single cases may be described.
- Case reports and case series are descriptive studies.
- A case report typically describes a single patient. It is normally the report of something that has happened or has been observed.
- Case reports normally focus on the manifestations, clinical course, and prognosis or outcome for the patient.
- In a case series, the researcher may describe a set of patients that they have seen who show similar symptoms or outcomes.
Animal Studies (In Vivo studies)

- Provide controlled insight into disease/diet or behaviour relationships and mechanisms of disease
- Requires a good animal model
- Hypothesis generating
- Preliminary research precedes human trials
In Vitro Studies

- In vitro methods reduce the use of animal models.
- Are usually the methods of choice for large-scale production by the pharmaceutical industry because of the ease of culture for production, compared with use of animals, and for economic reasons.
- Avoid or decrease the need for laboratory personnel experienced in animal handling.
- Provide insight into mechanism of action of therapeutic ingredient.
- Results from in vitro experiments need to be interpreted cautiously as may or may not yield the same results in human trials.
By the end of this Session you should:

- Be familiar with the Subject Outline, Learning Outcomes, Reading List and Assessment Tasks for this Subject.
- Be able to clearly differentiate between interventional and observational studies.
- Be able to identify the study type, study factor and outcome factor in research papers.
- Understand the context of how evidence is applied in practice.
Tutorial
Tutorial – EBP model

In groups of 2 or 3 consider the following questions. Once you have discussed your answers, contribute back to the wider group:

- What is your understanding of the term ‘evidence’?
- Do you think EBP should be used by practitioners within your discipline?
- What do you believe are the main barriers to the uptake of EBP within your discipline? How do you think these obstacles should be addressed?
Tutorial – EBP Case example

- A 66 year old client comes to you with a diagnosis of moderate depression. He has read about a product containing 500mg of Curcumin being effective for depression and wants to try it. His GP has advised against this option and would like him to go on an SNRI anti-depressant. The client is a pensioner.

- In groups consider the following:

- Clinical evidence:
  - Is the treatment clinically effective as a single active treatment?
  - What is the level of evidence to support it?
  - Is the treatment safe?
Tutorial – EBP Case example

○ Consumer Perspective
  • Is the treatment suitable according to client preferences and beliefs
  • Are there client-related factors that could interact with or contra indicate treatment?

○ Economic Justification
  • Is the treatment cost-effective for the client?
  • Is the treatment cost-prohibitive for the client?

○ Professional expertise
  • Does the treatment sit within your scope of practice?
  • Is your experience with the intervention and condition suitable for providing treatment?
Tutorial – EBP Case example

- CAM Philosophy
  - Is the research design compatible with the philosophy of CAM?
  - Does the research design reflect the complexities of CAM practice?

- Factors that might help with your discussion:
  - RCT - Curcumin for treatment of major depression
  - Cost of product - $75 per month

- Come to a conclusion about your findings as a group.
- Discuss your group’s willingness to apply the findings for this client.
References

  [http://annonc.oxfordjournals.org/content/23/8/2198.full](http://annonc.oxfordjournals.org/content/23/8/2198.full)
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References

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