# Dissertation Module: Research Skills Program
# Topic 1: What is Research?

## What is Research?

The question we want to discuss here is how does research in the health sciences work. There is a theoretical framework guiding all studies in the health sciences which we will introduce in the following. This process is embedded in the principles of acquiring new knowledge in general. It addresses the question how research (in the health sciences but also in other disciplines) should be conducted.

**Definition of Research**

**Research** is understood as "a class of activities designed to develop or contribute to generalizable knowledge; generalizable knowledge consists of theories, principles, or relationships, or the accumulation of information on which these are based, that can be corroborated by acceptable scientific methods of observation, inference, and/or experiment."

Or shorter: **Research** "is an organised quest for new knowledge based on curiosity or perceived needs".

Hence, research is about finding new knowledge; knowledge that can be generalised. Research tries to answer questions, such as: How knowledgeable are children in the areas of physical fitness, diet and exercise?; Is obesity in children on the rise in Uganda?; Does the consumption of soft drinks add to rising obesity in the USA?; Will a musical intervention reduce aggressive behaviour in demented elderly?; Are people who are afraid of going to the dentist ending up with worse teeth?; Can a dietary supplementation intervention for mothers improve health outcomes for babies in Cambodia?; etc.

New knowledge is acquired by "acceptable" methods.

Source: Porta, M. 2014.

Research is conducted to contribute to knowledge by means of "acceptable" scientific methods. This means we cannot just go about research as we please, but have to adhere to certain standards. The scientific method specifies these standards. It tells us:

- ✓ How knowledge should be acquired;
- ✓ The form in which knowledge should be stated; and
- ✓ How truth or falsity of the knowledge should be evaluated.

The scientific method as it is understood and carried out today, developed over a period of several centuries, concomitantly with the growth of modern scientific research. Before the era of enlightenment (17$^{th}$ to 18$^{th}$ century), philosophy, mathematics, and meta-physics were seen as the main scientific disciplines, developed by means of deductive reasoning. In the 17$^{th}$ century René Descartes and others established a framework for scientific enquiry based on observations and measurements. As a consequence scientific disciplines such as physics, chemistry, biology, and later medicine which are all based on observations and which use inductive logic gained importance (for more details please see: http://en.wikipedia.org/wiki/Scientific_method).

There are three basic elements of the scientific method:

- **Scepticism**
  *Refers to the notion that any proposition or statement, even when made by great authorities, is open to doubt and analysis*. Scepticism implies that every authority can be questioned. This was not always the case. In former times, people would very much rely on authority and some "scientific" dogma would remain standard principle of thinking or practice just because the dogma originated from a famous authority.
- **Determinism**
  *Refers to the notion that events in the world occur according to regular laws and causes*. The scientific community believes that there are laws which govern our universe and science is trying to unravel those laws. For example, the law of gravity attracts two objects with mass. We observe and experience gravity as a force which keeps us earth-bound. Laws of biology and chemistry guide medical processes.
- **Empiricism**
  *Refers to the notion that enquiry ought to be conducted through observation and verified through experience*. Observations are fundamental to all empirical sciences such as physics, chemistry, biology and medicine. We observe and measure objects or people and based on these observations we develop our understanding of the world.

## The Research Cycle

The scientific method in its most simplified version is depicted in Figure 1.

**Figure 1:** The scientific method


The hypothesis is of essential importance in science and forms the core of each scientific enquiry. The accepted principle of the scientific method is **falsification**. Hence, a scientifically acceptable hypothesis has to be stated in such a way that it will be falsifiable. This principle goes back to the Austrian philosopher Karl Popper (1902-1994) who stated: "A theory is scientific if it is falsifiable" (Popper, K. 1959). In a critical sense, Popper's understanding of science, formulated in his "Theory of Demarcation", was based upon his understanding of a logical asymmetry which holds between verification and falsification. It is logically impossible to conclusively verify a universal proposition by reference to experience (that is, by induction), but a single counter-instance conclusively falsifies the corresponding universal law. The example usually given is the hypothesis that "all swans are white". In order to verify this hypothesis one would need to look at all swans – a rather tedious, impractical, even impossible proposition. However, if we know about one black swan, we have conclusively falsified the hypothesis.

Popper's famous statement was that "The failure to falsify a falsifiable hypothesis is the best support for its verity." Therefore, a hypothesis which we failed to falsify will be accepted as true for the time being, until a future study or observation proves the hypothesis wrong. This understanding of the scientific approach stresses the fact that science is in a continuous flux. Having proposed a hypothesis, one needs to ask whether there is sufficient evidence to justify that it is plausible and whether it is capable of being tested, that is, falsified.

Please note not all statements are falsifiable and thus not all statements can be scientifically assessed. For example, your perception of the colour blue might be completely different from mine. But we both call it blue (by convention) although what I see might be actually your red. The hypothesis that we perceive colour in the very same way cannot be falsified. The development of meaningful and at the same time falsifiable hypotheses is one of the main tasks of science.

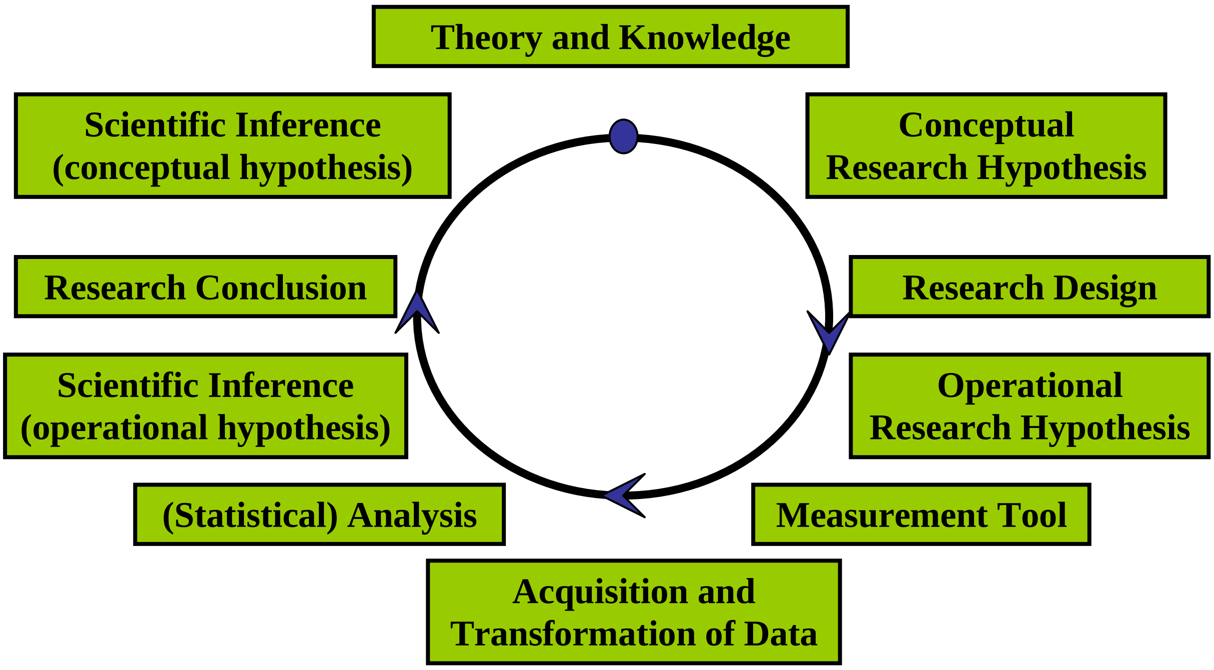
Figure 1 shows that the scientific method works in cycles: some observations might form the basis for a new hypothesis that requires to be tested and the results may or may not alter theories, leading to new hypotheses, for which observational evidence can be established or not. Or – in the opposite direction: a theory leads to certain hypotheses which lead to experimental observations which might support the hypotheses and therefore the theory or not.

A **theory** is a set of statements that try to explain a set of facts, giving them a structure. A theory is used to describe, explain or predict events or behaviours. Examples of well-known theories are the Big Bang theory to explain the beginning of our universe or the General Theory of Relativity formulated by Albert Einstein.

The scientific method is by no means unanimously accepted, but undergoes constant critical evaluation and should not be seen as fixed. Major controversies concerning the scientific method are (1) the question of whether observations are indeed *independent* of the observer or whether the theory specifies what is to be observed and how; (2) the validity of *induction*, that is whether the observation of a limited number of persons can be sufficient to induce general statements that are always true or always false; (3) the problem of *falsification*, that is new empirical evidence that contradicts current theory does not necessarily falsify the theory, but may lead to modifications of it.

Figure 1 provides the core structure of the scientific method which has been expanded in Figure 2 to tailor suit research in the health sciences (adapted from Kleinbaum, D.G. et al 1982).

**Figure 2:** An idealized concept of the **research cycle**




Our knowledge about disease is gradually modified and expanded by means of research studies. Quantitative studies should ideally be conducted following the research cycle of Figure 2. In reality Figure 2 represents a spiral as we hopefully have improved theory and knowledge after each research cycle. Figure 2 depicts one ideal quantitative research cycle.

Theory and knowledge as found in the literature, as well as previous experience lead to the formulation of a new research hypothesis. We differentiate between a conceptual and an operationalized research hypothesis. The conceptual research hypothesis is the initial idea for the research. Issues related to the study design, experience and feasibility including resources and time frame will shape this idea to an operational research hypothesis. This operational research hypothesis is falsifiable and is investigated by means of empirical observations in form of a planned study. Research design and operational hypothesis are closely intertwined. The necessary data will be collected according to a set protocol with standardised measurement tools. The raw data will be collected in a suitable format, summarized appropriately, and analysed by testing the operational hypothesis statistically. The results of the study will lead to research conclusions that allow us to add to or modify existing theory and knowledge.

According to Figure 2 the first step of every research study in the health sciences should be a comprehensive understanding of the existing knowledge and theory about the topic of interest. A **literature review** as well as critical input from fellow researchers are essential - research does not happen in isolation and should be regarded as a combined and concentrated effort to increase knowledge for the benefit of human kind. The second step is to formulate the **operational research hypothesis.** The operational research question is the question that the research will be able to confirm or reject. In quantitative studies, this hypothesis should be a complete and quantitative precise statement about what the study is set up to achieve. **Study design** and the development of the research hypothesis are closely interlinked. That is, you have to choose the right design based on what you want to proof and the research environment permits you to do so. For example, a randomised controlled trial is considered a high quality study design, but may be a wrong or impossible design for your research question.

The remainder of the research cycle is related to developing measurement tools, like questionnaires, conducting the research, entering the collected information into a data base, and analysing the data statistically. Ultimately the vast majority of quantitative studies will use statistical techniques to test (and attempt to falsify) the stated research hypothesis. Finally, research results should be published in order to be accessible for other scientists and to become part of the available knowledge.

Studies in the health sciences can be large and expensive; often involving hundreds of participants. It is therefore crucial to the success of any such study to have a written **study protocol** in which all steps described in Figure 2 are outlined in detail.

Please note that qualitative studies do not follow figures 1 and 2; at least not as strictly as quantitative studies. Qualitative studies do not state a research hypothesis but have research questions which may change during the data collection process. Qualitative studies also go through the notion of a research cycle as depicted in Figure 2 however they may do so repeatedly within one study as analysis runs parallel to data collection and results from one group or participant may alter the research questions and may therefore also change the topics explored with the next participant(s). We say that qualitative studies do not follow the positivistic tradition applied in quantitative research. One of the main differences between qualitative and quantitative research is that quantitative studies aim to generalise their results to a wider population; while qualitative studies do not. Qualitative studies aim to describe experiences and processes of individuals. Both research approaches combined (called mixed methods) often provide a much better overall evidence base than either of them.

## How does one identify a Research Topic?

Research is the vehicle by which a discipline advances; it is a process ongoing in all disciplines and with experience (that is, with time) you will become familiar with the “hot” topics that are currently discussed and investigated in your discipline. Research creates new knowledge, adds new ideas and reviews old practices. Each profession requires its own knowledge base. Research also refutes inadequate practices based solely on “unscientific methods” such as, tradition, authority, personal preferences, untested hypothesis, or common sense.

As a health professional you are required to be aware of the latest developments in your discipline, because your professional work should be based on all the available evidence. This is called **evidence based practice**.

### Definition of "evidence based practice"

"*Evidence-based practice* is an approach to health care wherein health professionals use the best evidence possible, i.e. the most appropriate information available, to make clinical decisions for individual patients. Evidence based practice values, enhances and builds on clinical expertise, knowledge of disease mechanisms, and pathophysiology. It involves complex and conscientious decision-making based not only on the available evidence but also on patient characteristics, situations, and preferences. It recognizes that health care is individualized and ever changing and involves uncertainties and probabilities. Ultimately evidence based practice is the formalization of the care process that the best clinicians have practiced for generations".

Source: McKibbon KA (1998).

Evidence based practice implies that every health professional requires an understanding of the basic principles of research, the ability to read articles critically and possibly providing a contribution to research in their own discipline.

As a starting point you will need a research topic. Research topics may arise from the work environment, the professional literature, or from conference presentations. As a student a topic might be given to you by your supervisor, but this will not be the case for an established researcher. Nowadays health professionals and hence researchers (as these are the same people) work in specific specialised disciplines. For example, you might work as a physiotherapist specialising in improving sleep using pillow research; or your area could be sports injuries. A nurse could specialise in breast cancer or mental health or midwifery, while a medical practitioner might work in family medicine or as a dermatologist or paediatrician. Today disciplines are extremely specialised in sub-disciplines and someone outside the discipline cannot easily judge what a worthwhile research topic in a particular area might be.

For most health professionals research topics arise during their work as they ask themselves and their colleagues work based questions. At some stage you want to find the answers to these questions. If those answers are not available in the literature then you may have a research project. Likewise, the question you want to research may suddenly "click" in your mind while you are listening to a conference presentation or reading a publication. Please note that identifying an interesting and maybe new research topic in your discipline cannot be taught. It requires genuine intellectual input – from you! It includes paying attention to current affairs about your practices or your practice environment.

**Examples of possible research topics – conceptual research hypotheses**

Another word for "research topic" or "having an idea for a research project" is conceptual research hypothesis.

Example 1: Assume you work as a midwife in a specialised neonatal care unit for premature babies. You are interested in the optimal criteria for deciding when a baby should be moved from the incubator to an open cot to ensure optimal physiological functioning and development of the premature infant.

Example 2: Assume you work as a general practitioner based in Alice Springs, Australia, and you provide medical services to many remote Aboriginal communities. You are interested in identifying the causes of the high suicide rates among Indigenous people and exploring appropriate methods of prevention.

Example 3: Assume you work as a nurse in a refugee camp in Tanzania, Africa. You are very interested in the nutritional requirements of the refugees. One topic that is of interest to you relates to stainless steel cooking pots. You would like to find out whether using these pots would help reduce iron-deficiency anaemia in the refugees you are caring for.

When you have decided on your research topic, in particular when you start your *first* ever research project keep the following things in mind:

- ✓ **Choose an area that fascinates you**. Research is usually a lengthy process and is often conducted on top of everything else in your life. For example, as an Honours student you will still have to attend all the other lectures in the curriculum. Many PhD students conduct their research part time, work, and some also have family duties. The topic that you choose must be fascinating – otherwise the workload will feel excessive and it may never happen!
- ✓ **Keep it simple!** It is better to try to answer one question at a time. With research the difficulty is in the detail. For instance, conducting a "simple" survey (e.g. to assess physical activity, quality of life, sun protective behaviours, activities of daily living, etc.) is often underestimated: developing a questionnaire with the right questions, phrased correctly, with not too many questions but at the same time including everything that is necessary – is almost a form of art. It is actually very difficult! Sampling the target group correctly is another issue which is easily underestimated. Also, you may be confused if you try to answer too many questions in one project.
- ✓ **Conduct, if possible, a pilot study**. Please note a pilot study is a small study (usually including about 5 to 20 people, sometimes more) mirroring the larger project. A pilot study is done to identify in advance any problems with the process of the planned large study. Many large studies are initially tested with a smaller version. The pilot study can discover issues with sampling, the questionnaire, the sample size, and with all processes involved. It is a very valuable tool and if well-conducted can be published in its own right.
- ✓ **Keep a written record of all decisions you make**. Research is a lengthy process that will often take years, and afterwards the results need to be written up, as a thesis or publication. Within those documents we need to be able to state exactly what we have done, why and how. This part of a thesis or publication is called the Methods. It is difficult to remember details over years. Hence, keeping a so called **study protocol** is important.

  Please note a study protocol is an evolving text which starts out with the details of the research as planned but includes all amendments made over time.

  A written record also allows you to check your research process. Sometimes, new research ideas may come up during your research and then you may be confused with what are the major objectives of your research. A constant review and a written protocol will help you focus on what you want to achieve.

Coming up with a reasonable research question may be a difficult process and you might go through several stages, such as:

- Having an idea; the conceptual research hypothesis;
- Discussing the idea with colleagues;
- Checking the literature;
- Deciding exactly what aims are to be achieved by the research; and
- Defining the operational research hypothesis.

A research question is *reasonable* if it is related to your profession, has some useful purpose, adds to the body of knowledge in your profession, and is doable. *Doable* implies that it is possible to find an appropriate research design for the question. Doable also implies that there will be instruments at hand or instruments will be developed to measure the necessary characteristics being studied. For example, a questionnaire will be developed to measure quality of life or pedometers will be used to assess physical activity of the participants. Doable as well implies that potential participants and necessary resources will be available. A reasonable question should be based on current theory and knowledge of a profession, it should have significance and it should be feasible. Bear in mind that feasibility is closely linked to the M word - money. This limitation might for example determine the number of people to whom you can send a questionnaire. Ultimately resource availability often dictates design options of a study.

**PICOT and FINER**

PICOT stands for population, intervention, comparison, outcome, and timeframe.
FINER stands for feasible, interesting, novel, ethical, and relevant.

Think PICOT and FINER when you are developing a research topic!

Example:

**P – Population:** For which group do you want to collect information?
e.g. “Obese Australian men aged 60 years or older”

**I – Intervention (or Exposure):** What medical event do you want to study the effect of? e.g. “Dietary intervention”

**C – Comparison:** To whom do you intend to compare?
e.g. “Obese Australian men aged 60 years or older without intervention”

**O – Outcome:** What is the expected effect of the Intervention (or Exposure)?
e.g. “Reduction in body mass index”

**T – Time frame**: What will be the time frame of your study?
e.g. “Participants will be recruited throughout 2011 and then followed-up for one year.”

Please note: A well-developed research question is an important starting point for your literature review.

# The Research Hypothesis

The initial research idea is called the **conceptual research hypothesis.** It usually states in general terms the overall aim and has links to theoretical models and frameworks accepted in the research discipline being studied. Further above we explained that the research hypothesis for a quantitative study should be falsifiable. For a research hypothesis to be falsifiable, a precise quantified statement of the expected outcome (result) is required. The quantified expected result allows the conceptual research hypothesis to be re-stated so that it is falsifiable. When additional specific information about participants and administered intervention(s) – if any - are added, the statement becomes the **operational research hypothesis**.

The operational research hypothesis is closely linked to the chosen study design; the actual wording might differ with the study design even if the content remains the same. The operational research hypothesis for the planned study is then investigated using empirical observations.

Please note that research hypotheses are necessary for all quantitative research projects.

**The operational research hypothesis**

The operational research hypothesis is central to quantitative research. The operational research hypothesis must be plausible and - most importantly - falsifiable. The operational research hypothesis is a clear and precise quantified statement of the question that the research is designed to answer. In order for the hypothesis to be **falsifiable,** the expected result has to be quantified in measureable terms.

An operational research hypothesis is the centre of every well-planned quantitative research project in the health sciences!

Every word in an operational research hypothesis has to be **clearly defined** and relevant parts have to be **quantified** as much as possible.

Therefore, the operational research hypothesis is a complete and precise quantitative statement about (1) the participants, (2) the interventions (if any) being administered, (3) comparison or control group and (4) the expected outcome. Hence, the operational research hypothesis should include statements about the participants (inclusion and exclusion criteria), the therapies, interventions, or drugs that are administered (if any), and the *expected* result of the study. The operational research hypothesis must correspond to the purpose of the study, and all statements must be clear and expressed in measurable terms. Here you can see how developing your question using the PICOT format described previously can help you when it is time to transform your question into an hypothesis.

Please note that in order to write an operational research hypothesis we need to know the approximate outcome we expect, or at least what outcome would be **relevant**. The expected result makes the hypothesis falsifiable; if the specified result is not achieved, the hypothesis is falsified.

## Examples of conceptual and operational research hypotheses

Example 1: Assume that you are working with male soccer players investigating how to improve their endurance performance. Your work and the sports science literature suggest that "nutritional supplements might increase endurance during exercise" (= conceptual research hypothesis).

In order to develop an operational research hypothesis you are required to define "nutritional supplements", your participants, "endurance", and the kind of "exercise". You also need to quantify the "increase" you are expecting when the soccer players take the supplements. The latter is necessary to achieve a falsifiable hypothesis.

Your resulting operational hypothesis could be: "The use of carbohydrate gel (amount not yet defined; I of PICOT) during one season in 2011 (T of PICOT) will increase the run time to exhaustion (O of PICOT) of healthy male soccer players (aged 20 to 28; P of PICOT) by 2 minutes when compared to placebo (C of PICOT)."

Comment: This operational research hypothesis indirectly identifies your research design as an experimental study (the supplements are to be given to some players while others will receive only placebo). 2 minutes is the expected outcome difference between the intervention and control groups. This difference should be of practical or clinical relevance, otherwise there is little point in conducting the research. If the result of the study shows that the supplement led to an increase in 1.5 minutes, then the operational hypothesis is falsified. If an increase of 2 minutes or more is detected then the hypothesis is supported by the study.

Source: based on Patterson, S.D. and Gray, S.C. (2007).

Example 2: Assume you are working in a physiotherapy practice and you are interested in evaluating the effectiveness of an integrated care programme for patients with chronic low back pain (= conceptual research hypothesis).

In order to develop an operational research hypothesis you are required to define "integrated care programme", your participants, and "chronic lower back pain". You also need to decide how you assess "effectiveness" and you need to quantify the "effectiveness" you are expecting from the integrated care programme in comparison to "usual care". The latter will make the hypothesis falsifiable.

Your operational hypothesis could be: "An integrated care programme consisting of a workplace intervention based on participatory ergonomics, involving a supervisor, and a graded activity programme based on cognitive behavioural principles (I of PICOT) is compared to usual care (C of PICOT) for adult patients listed as sick for at least 12 weeks due to lower back pain (P of PICOT) and will after one year of application in 2013 (T in PICOT) have reduced the median duration until sustainable return to work from 200 to 80 days (O of PICOT)."

Comment: The design from Example 2 is again experimental (some participants receive the integrated care programme, others only usual care). The expected difference of the main outcome measure is 200 – 80 = 120 days (4 months). If the difference detected by the study is less than 120 days then the hypothesis is falsified; if it is 120 days or more, it is supported.

Source: Lambeek, L.C. et al (2010).

From the examples above it is obvious that a great deal of personal experience and in depth knowledge of the literature is required before a meaningful operational research hypothesis can be produced. A particularly difficult part of the operational research hypothesis is the quantitative statement of the *expected* outcome of the study (as in Example 1, an expected difference of 2 minutes). The expected outcome and the wording of the operational research hypothesis are closely linked to the study design and to the required **sample size**. Please note that the expected result or difference should be of practical or clinical importance. It is irresponsible and arguably unethical to plan a study to show a result which is irrelevant.

In Example 1, the 2 minutes (together with the associated standard deviation) will define the appropriate sample size which is required to provide the study with sufficient statistical power to detect a 2 minutes difference, if present, as statistically significant. Because of this statistical connection between expected result and sample size, the expected difference is directly linked to the feasibility of the study. Please note that in general the smaller the expected difference the larger the required sample size.

## Research questions for literature reviews

In general one requires an operational research hypothesis for any quantitative project. Your second assignment requires you to write a project proposal; this is when you will be asked to define an operational research hypothesis. Systematic literature reviews also require you to state a very specific, searchable research question. The principles behind the statement of a research question for a literature review (your first assignment) and a research project are very similar; although the research hypothesis for a project will require a falsifiable statement (statement of the expected result) while the literature review does not.
The Cochrane Handbook for Systematic Reviews of Interventions (handbook.cochrane.org) explains in detail all the factors which require consideration when stating a searchable research question for a literature review (Higgins and Green, 2011). Although this handbook is for interventions studies only, many rules can be applied to reviews that include studies with other designs. Part 2, chapter 5 of the handbook outlines important eligibility criteria for studies to be selected, including: types of participants (population), types of interventions (if applicable), types of outcome measures, and the design of the studies. In chapter 5.6 the handbook also discusses advantages and disadvantages of a broad versus a narrow scope of review questions with instructive examples. Following these criteria helps formulating a searchable research question for your literature review.

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