Clinical Epidemiology Workshop — Introduction

We all read papers in medical journals, to keep ourselves up to date with medical advances and acquire new information or knowledge in medicine, so that we can provide the best possible care for our patients. Amidst the hundreds of new medical journal papers published every week, we have to make choices, which are primarily influenced by our fields of practice or interests. The reported results of a paper may look very interesting and important, but before we contemplate applying new knowledge in our medical practice, we would also like to ensure that the information is correct (valid) and can be trusted. Identifying the good from the bad or ugly requires the ability of critical appraisal. This series will introduce the skills necessary for the judicious reading of medical journal papers. Understanding how such a paper might be critically read could also help potential authors improve their own research studies and how to write it up.

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Workshop 1 — Dissection of a medical journal paper

We want to read good medical research reports that provide valid results that can be trusted, ie free from systematic errors and taking into consideration the influence of chance. A convenient and logical starting point in acquiring the skills for critical appraisal would be an understanding of the structure and contents of a usual medical journal paper.

Most medical journals require the main text of original articles or research papers to have four sections — **Introduction** (with a separate heading or just the first paragraph(s)), **Methods**, **Results** and **Discussion** (or Comments/Interpretations). Usually they also have an abstract, acknowledgement(s), and references.

The **Introduction** — the Introduction is to provide answers to why the study was done and what the author(s) wanted to find out. Unlike a research thesis or dissertation, most medical journals do not require a detailed literature review here. Instead, a succinct summary of the literature is expected, highlighting the current state of knowledge related to the theme of the article, as well as the gap(s) in knowledge identified. This should then be followed by the objectives of the current study (often without a separate heading), and why it is important to carry out the current study, preferably related to the gap(s) in knowledge identified. Objectives can also be expressed in term of research question(s) to answer or hypothesis(es) to test. Authors are expected to utilise this first paragraph(s) to convince the editors and reviewers that the paper is worth considering for publication, and by the same token persuade readers that the paper is worth spending time to read, and not 'just another study'.

The **Methods** — this is the most important part of a paper read to assess its quality. They are expected to cover the study design adopted, the study population and/or sample, how data were collected and analysed. Most international journals now require that enough details be given so that the study can be replicated, if necessary, to examine the consistency of results across different settings.

The study design used should be appropriate for answering the research question(s) or achieving the research objective(s). Medical research should provide evidence to support the practice of medicine, and the most common daily activities of doctors are diagnosis and treatment of diseases. Other common activities may include counselling/advising patients on disease prognosis and prevention, assessing health care needs and other public health and/or health management activities. Major study designs that are most appropriate for generating evidence in different areas of clinical activities are summarised in the Table. Future articles in this series will discuss in more detail the critical appraisal of papers related to the different areas of clinical or public health activities. (More details on the various study designs will be covered in subsequent articles in this series.)

The study subjects or participants should be clearly described with reference to their source (hospital, clinic, volunteers from the community, etc) and selection, as well as in terms of inclusion and exclusion criteria. This can allow readers to judge whether the study subjects are similar enough to their own patients when considering application of results. A brief description of the nature and scale of the hospitals/clinics included would benefit readers outside Hong Kong. If sampling from an eligible pool

TABLE. Major study designs most appropriate for generating evidence in different areas of clinical activity

	Intervention study*	Cohort study	Case-referent study†	Cross-sectional study	Case series
Diagnosis test		+		++	
Therapy	++	+			
Prognosis		++			
Harm/causation	+	++	++		
Screening	++	+	+		
Needs assessment				++	+
Descriptive characteristics				++	++

* Including randomised controlled trial (RCT)

† 'Case-referent study' is preferred over the more commonly used 'case-control study', as the nature of the control (no disease) group in this type of study has been mixed up with the control (no intervention) group in a RCT

of subjects is performed, the details should also be provided (eg random or systematic sampling), so as to allow readers to assess whether the results can be generalised to the whole study population. In intervention studies (eg treatment, screening), how individual subjects or groups of subjects are allocated to the different groups/arms should be clearly described. One should also expect to find details of the randomisation (or random allocation) process.

Data necessary to answer the research question should be collected, including the factor(s) under study, the outcome(s) of interest and others. The study factor may be an exposure, an intervention, a risk factor or a prognostic factor or a combination of these. The health outcome may include disease occurrence, recurrence, survival, or a change in a physiological, biochemical, pathological or self-rating parameter. Both the study factor(s) and outcome(s) should be clearly defined and categorised if appropriate. Most medical studies examine the relationship(s) between study factor(s) and outcome(s), but such relationships can be disturbed (confounded) by unbalanced distribution of other factors (potential confounders). These could affect the outcome(s) in the groups being compared, except perhaps in well-conducted randomised controlled trials. Furthermore, the relationship between a study factor and an outcome may vary across different subgroups of study subjects, eg gender and age (effect modification or interaction). So information on these other factors should also be collected, including demographic data, co-treatments, co-morbidities and other known risk factors or prognostic factors, which may then be utilised in the subsequent data analysis. The ways information on various factors and outcomes is collected should be clearly described, including the tools/instruments used (whether standardised or validated), the persons collecting such data or administering the treatments, and whether blinding was feasible and implemented.

How data are organised and analysed should be clearly spelled out. It is now common that multivariable analyses or statistical models are utilised in data analysis. The outcome (dependent) variable should be clearly identified and defined, the variables used in such multivariable analyses or models should be listed and the criteria for selection of such variables should be clearly spelt out. For independent variables with more than two categories, the baseline or reference categories should be clearly described. The regression strategy should be clearly stated (forced enter, stepwise, etc). Stratified or subgroup analysis is best defined and determined a priori.

The **Results** — this is the part that would usually attract most interest, especially if new and interesting findings are presented. Expected contents include background characteristics of study subjects (sometimes described separately in the comparison groups), the response/participation rates and/or loss to follow-up are all important. The frequency(ies) of occurrence of outcomes and results showing the association(s) between study factor(s) and outcome(s), unadjusted and/or adjusted, as well as some stratified analyses if performed are equally important. Tables and figures are often used to present or summarise results that are too complex or cumbersome to describe in words alone. Duplications of results presented in the text and tables/figures should be avoided.

The **Discussion** — the first paragraph is usually used to summarise and/or highlight important and/or new findings from the study, as well as to confirm that the research question(s) has/have been answered. This can be followed by a discussion of results of the current study in the context of information already available from the medical literature. Familiarisation with the literature (through a thorough review) on the topic is expected for a useful discussion. Major discrepancies between results of the current study and those from the literature need to be discussed critically, making reference to study qualities. The implications of the current study findings on medical practice or public health policy should then be discussed. The authors need to convince readers that the results of their study are valid and can be trusted by emphasising its strengths and addressing potential limitations. A conclusion (not another summary of results) is usually given in the last paragraph of the Discussion or under a separate heading (as required by some journals).