



HCSP FACT SHEET

• HCV ADVOCACY •

A Simple Guide to Reading an Abstract

Written by: Alan Franciscus, Editor-in-Chief

Reading – and understanding – an abstract can be very challenging because there are so many pieces of information to put together, like in a puzzle. This fact sheet focuses on tips for reading and understanding an abstract.

General Tip for Reading and Understanding an Abstract:

An abstract is usually divided into seven sections. Start by reading the entire abstract quickly – highlight or note any important facts that are key points, such as the number of participants, overall effectiveness, etc. After a quick review go back and read it slowly and carefully. A natural inclination is to just read the conclusion section, but remember that a conclusion, at times, can be what the author wanted to prove and not necessarily the real facts.

The abstract below is from the Association for the Study of Liver Diseases (AASLD) Conference 2007. This particular abstract is about HCV-796 – a drug that is no longer in clinical development due to severe side effects.

1: Title

A very brief (one or two brief sentences) description of the study – this will give you an idea of what the study authors are trying to test or prove.

Example:

Phase 1 evaluation of antiviral activity of the nonnucleoside polymerase inhibitor, HCV-796, in combination with different pegylated interferons in treatment-naïve patients with chronic HCV.

2: Authors

All the authors will be listed and sometimes the affiliations of the authors will also be listed. Look for reputable authors and medical institutions. The author and affiliation can carry a lot of weight.

Example:

S. Villano; D. Raible; D. Harper; P. Chandra; L. Bazisotto; G. Bichier.

3: Introduction or background

A brief history of what is known about the topic under study and why the study is important.

Example:

Background:

HCV-796 is an inhibitor of hepatitis C virus (HCV) RNA-dependent RNA polymerase that has demonstrated clinical antiviral activity across multiple HCV genotypes when administered as monotherapy or in combination with pegylated interferon alfa-2b (PEG2b). We further evaluated HCV-796 when administered with pegylated interferon alfa-2a (PEG2a).

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**EXECUTIVE DIRECTOR,
EDITOR-IN-CHIEF,
HCSP PUBLICATIONS**
Alan Franciscus

DESIGN
Leslie Hoex,
Blue Kangaroo Design

PRODUCTION
C.D. Mazoff, PhD

CONTACT INFORMATION

Hepatitis C Support Project
PO Box 15144
Sacramento, CA 95813
alanfranciscus@hcvadvocate.org

The information in this fact sheet is designed to help you understand and manage HCV and is not intended as medical advice. All persons with HCV should consult a medical practitioner for diagnosis and treatment of HCV.

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4: Aim

This is one of the most important sections because it spells out the original intent or design of the study. The aim should include definite end points that are carefully planned and executed. Look for prospective studies that are designed in advance with certain clinical outcomes.

Retrospective studies are studies that look back over time at a previous study or population. They are important for compiling information for future studies, but they can also be manipulated and do not carry as much weight in evidence based medicine as prospective studies. As you have probably noticed some abstracts are formatted differently than others. In the example I have listed the 'aim' is included in the background information.

5: Patients/Methods

This section will give you information on patient characteristics, drug dosing and other valuable information.

Important points to ask yourself when reviewing this section:

A: How many patients were enrolled in the study?

Larger studies carry more weight.

B: Outcomes vary widely depending on many factors. What were the patient characteristics?

Were they evenly matched by age, gender, race, genotype, viral load, degree of liver damage, biochemical markers and other important patient information?

C: Was the clinical trial randomized and blinded to prevent bias?

The gold standard of clinical research on humans is the blinded, randomized control trial. In this type of trial, patients are randomly selected. Randomization means that patients are randomly assigned – usually by a computer program – to a particular study group to receive the test drug, a standard of care drug or a placebo.

D: How did the researchers test their hypothesis and what tools did they use?

Are they using sensitive diagnostic tools?

E: Was the study designed to compare one drug against another drug, or against the current standard of care?

Was the dose of medication the same in both groups?

Example:

Methods:

Evaluations were performed within a randomized, double-blind, Phase 1 study in adult patients with chronic HCV infection who were naïve to treatment. In one group, patients were randomized to receive oral HCV-796 or placebo Q12h for 14 days, and all were to receive PEG2b (1.5 mcg/kg) on day-1 (one day before start of HCV-796/placebo) and day 7. In another group, the design was the same except the PEG therapy was PEG2a (180 mcg) on day-1 and day-7. In each group 12-16 patients were to receive the active HCV-796 (500 mg Q12h) with one of the PEG therapies.

6: Results

This section reports on the outcome of the study. It should break the information down by overall results and then by patient characteristics and medication dose. The results should also report the statistical significance, which is an indicator of how well the drug will work under the same circumstances in a different setting. This is usually reported as a p-value. P-value of < 0.05 is considered statistically significant. P=0.05 means that there is a 95% chance the drug will work in a similar patient population and a 5% chance that it will not. If the abstract is testing a new medication, there should also be a brief overview of the side effects. In this example you will note that the authors reported that the side effects of HCV-796 were typical of the side effects reports for Peginterferon therapy. However, we now know that early studies with small patient populations provide limited information and that studies conducted over a longer period of time with large patient populations give us the best information.

Example:

Results:

The mean baseline HCV RNA level was 6.4-6.5 log10 in each group and 71% of patients were infected with HCV genotype 1. For both PEG therapies, combination with HCV-796 reduced plasma HCV RNA levels to a greater extent than either PEG alone. At day 14, the mean reduction in HCV RNA for HCV-796+PEG2b was 3.4 log10 vs. 1.6 log10 for PEG2b alone. The mean reduction for HCV-796+PEG2a was 3.7 log10 vs. 1.1 log10 for PEG2a alone. For both groups, activity differed by HCV genotype. Mean HCV RNA reductions at day 14 for genotype 1 was 2.9 log10 for HCV-796+PEG2b and 3.2 log10 for HCV-796+PEG2a. For genotype non-1 the respective reductions were 4.4 vs. 4.7 log10. Combination of HCV-796

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with either PEG therapy was generally well-tolerated. Common adverse events in all groups were those typically associated with interferons, including headache, chills, and myalgia.

7: Conclusion

Be careful because the conclusion can be greatly manipulated to fit the author’s needs. Refer back to the results and compare the results with the author’s conclusions. The example used is very straightforward and appropriate for the intent of the study. Always be careful, though, reading the conclusion – it is always better to understand the information in an abstract and come to your own interpretation and conclusion.

Example:

Conclusions:

The combination of HCV-796 with either PEG2b or PEG2a provides similar antiviral activity across multiple HCV genotypes over 14 days of therapy. Results support clinical studies of more longterm administration of HCV-796 with either PEG therapy.

The more you practice reading an abstract the more likely you will be able to understand the information presented. It is important to know that the abstract gives you a snapshot of the study. There is much more information that you will need before you can truly understand the study results which will help you independently judge for yourself if the study results are what the authors argue. The best information will come in the form of a peer-reviewed journal from a prestigious medical journal. Be sure to always use your mind critically when trying to interpret scientific data or any other source of information. Question all the information and never be afraid to ask questions.

... a conclusion can be what the author wanted to prove, not necessarily the real facts. Read the entire article.

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For More Information

- **ClinicalTrials.gov**
Understanding clinical trials:
www.clinicaltrials.gov/ct2/info/understand
- **National Institutes of Health (NIH)**
www.nih.gov
- **Patient Inform**
www.patientinform.org/understanding-research/
- **United States National Library of Medicine**
www.nlm.nih.gov
- **PubMed**
www.ncbi.nlm.nih.gov/pubmed/
- **MedlinePlus**
<http://medlineplus.gov/>

Glossary of Terms

The glossary below lists some of the terms most commonly used in clinical trials

BLIND OR DOUBLE-BLIND STUDY

Blinding in a clinical study is a method of conducting clinical trials in which participants do not know who is taking an experimental treatment, a standard (control) treatment, or a placebo. In a blinded study, the volunteers do not know what treatment (if any) they are receiving. In a double-blind study, neither the volunteers nor the researchers administering the treatment know who is receiving what. Blinding is done to reduce bias in drug trials. In the case of medical necessity, a study may be unblinded to reveal who is receiving what treatment.

COHORT

A group of individuals in a study who share a demographic, clinical, or other characteristic.

CONTROL GROUP

A control arm is a comparison group in a clinical trial that is used to verify an experimental result.

A control group is typically given an older standard treatment or a placebo rather than the new experimental treatment under study.

A controlled trial is a clinical trial in which a group receiving an experimental treatment is compared to a control group that is given a standard treatment or a placebo.

DOSE-RANGING TRIAL

A clinical trial in which different doses of a drug are compared to determine which dosage has the best balance of effectiveness and acceptable side effects.

DRUG INTERACTION

A phenomenon that occurs when multiple drugs are taken together or drugs are taken with certain herbs or foods. Drug Interactions may enhance or reduce the action of a drug and may increase its side effects.

EXCLUSION CRITERIA

Exclusion criteria are conditions that disqualify someone from participating in a clinical trial. Contrast with inclusion criteria.

INCLUSION CRITERIA

Inclusion criteria are conditions that a person must meet in order to be eligible for a clinical trial. Contrast with exclusion criteria.

INTENT-TO-TREAT

An analysis of a clinical trial in which all participants who were originally assigned to an arm are analyzed, including those who dropped out due to treatment failure or side effects.

PLACEBO

A placebo drug is an inert, inactive agent (e.g., pill, injection) that has no treatment value, sometimes referred to as a “sugar pill.”

PROTOCOL

A protocol is a written plan for a clinical trial, which typically includes details such as the hypothesis to be tested, who can participate, length of the trial, how the treatment under study will be administered, endpoints, and potential risks and benefits.

RANDOMIZATION

A randomized trial is a clinical trial arranged to produce a chance distribution of participants into different arms (e.g., experimental treatment, standard treatment, or placebo). Randomization is done to minimize bias.

STUDY ARM

A study arm is a group of patients in clinical trials who are assigned to one part or segment of a study – a study “arm.” One arm usually receives a different treatment (for example, a different dose of medication or treatment duration) from another.