# DERMATOLOGY Evidence-Based Therapeutics Assignment

This assignment is designed to reinforce evidence-based medicine principles in the context of your clinical training, and to improve your ability to critically evaluate and extract important information from papers. It will build on the learning objectives from other courses related to using available evidence to make clinical decisions of all kinds.

## I. Learning objectives:

By evaluating two papers and making a clinical recommendation, you will improve your ability to:

1. Integrate the practice of evidence-based medicine into your daily practice.
2. Apply the evidence you find to clinical decision-making.

## II. Order of the Assignment

(Part 1) **Review the material** below ("Making Therapeutic Decisions: Evidence for Effectiveness or Adverse Effects") about how to write good clinical PICO questions, appraise evidence, and apply evidence.

(Part 2) **Write a clinical question** about dermatology or a related topic. **Send your clinical question** *(avoid questions about canine demodicosis*) **via email to Dr. X by 8:00 a.m. on XXX.**

Late questions will be handled as follows: questions received between 8:01 a.m. on Tuesday and 12:00 p.m. on Tuesday will result in a loss of 5 points on the final assignment grade. Questions received after 12:00 p.m. on Tuesday will result in a zero on the assignment.

(Part 3) You will be emailed pdfs of two papers related to your clinical question by 8:00 a.m. on the first Wednesday of the rotation.

1. **Critically appraise the papers** using the checklist for evaluating evidence at the end of this document to answer your clinical question and make a clinical recommendation
2. **Complete the template below**

(Part 4) **Present your report** to your classmates and faculty. EBVM Rounds will usually take place on the first Friday of the rotation at 8:00; this will be confirmed on the first day of the Dermatology Rotation. Rounds will consist of each student **presenting a clinical question, discussing the evidence from the papers to help answer that question, and making a clinical recommendation.** Rounds will be one hour, so plan your time accordingly.

(Part 5) After rounds, send your completed template electronically to Dr. X by 5:00 p.m. on the first Friday of the rotation. Papers received after 5:00 p.m. on Friday will lose 5 points for each 24 hours late.

## III. Grading Rubric for Completed Template

VERSION 1

| % | Section |
|---|---|
| 15 | Clinical question (as originally posed by the student)<br>An excellent clinical question includes all PICO elements, and they are specific and complete; the question is highly relevant to clinical practice (that is, it takes into consideration mechanisms of action and known usages of drugs) |
| 85 | Assessment of the studies<br>An excellent report includes:<br>1. Accurate description of the study types of both papers (randomized controlled trial, case series, etc.) and appropriate assessment of the quality of each paper, with a BRIEF description of the reason for your assessment (for example, major flaws, applicability of study design and outcomes) [50%]<br>2. Reasonable answer to your clinical question based on your appraisal and synthesis of evidence from the two papers [15%]<br>3. Clinically relevant recommendation you would make to a client related to this clinical question, including an **estimate of treatment effect** using the Fact Box [15%]<br>4. Defensible strength of clinical recommendation (options are only WEAK RECOMMENDATION or STRONG RECOMMENDATION) [5%] |

VERSION 2

| ***Competency criteria*** | | | | | |
|---|---|---|---|---|---|
| ***Use evidence to make clinical decisions (using the template provided): ask specific, complete and clinically relevant PICO question, accurately describe published study types, accurately assess quality of published studies, make clinically relevant recommendation including an estimate of the treatment effect, and provide a defensible strength of recommendation*** | *Complete* | *Mostly complete* | *Somewhat complete* | *Mostly incomplete* | *Not turned in* |

## IV. Making Therapeutic Decisions: Evidence for Effectiveness and Adverse Effects

### PART A: Overview of steps for EBVM

1. Ask relevant, answerable clinical questions regarding diagnosis, treatment or prognosis, keeping in mind PICO: Patient or Problem, Intervention, Comparison, and Outcome.

First, define the patient or patients (P) specifically and completely. Then, define the outcome (O) you're interested in. Focus on making the outcome specific, measurable, and clinically relevant. Then you can add the specific intervention (I) and the comparator (C). Be sure to avoid phrases like "is more effective than" or "is better than"; if you are interested in adverse effects, be specific about which adverse effects are of interest. Finally, be careful to only include one question – asking about effectiveness AND adverse effects in the same clinical question will result in confusion. (In practice, you would ask one question about effectiveness, and another about adverse effects, and then look at the evidence for both to make a final clinical decision.)

2. Locate the best evidence to answer the question.

In practice, you may do some of your own searching using free resources such as PubMed. For high quality searching, you should investigate other options depending on your location to access other literature databases or get assistance with searching proprietary databases, via local libraries, veterinary library in your state, or professional association.

3. Critically appraise the evidence for validity, impact and applicability.

Critical appraisal of the validity and applicability of the available evidence is the crux of evidence-based decision-making. The form below focuses on the likelihood of bias of different types of studies. First, decide what type of evidence it is, then complete the appropriate parts of the form.

4. Integrate the appraisal with clinical expertise and with the patient's unique biology and client's values and circumstances. This means, "Make a decision about using the therapeutic."

Once you have assigned a quality score to each article or piece of evidence, you will make a recommendation related to your clinical question (i.e., what would you recommend to a client), and then rate the strength of that recommendation based on the quality of evidence that you reviewed.

## Common types of evidence (study designs)

Studies are sorted based on the potential for risk of bias (lower is better) and strength of evidence

| Evidence Type | Description | Primary Research or Research Summary | Potential for risk of bias | Ability to assess the risk of bias | Estimate of treatment effect/ effect size* | Precision of the effect |
|---|---|---|---|---|---|---|
| Systematic review with meta-analysis of RCT | Attempts to identify all relevant literature related to a specific condition or treatment with specific inclusion and exclusion criteria using a team of authors; qualitatively reviews and summarizes all results in a clear and repeatable manner; meta-analysis pools and quantifies data from the literature | Summary | Low | High | Yes | High |
| Systematic review without meta-analysis | Attempts to identify all relevant literature with specific inclusion and exclusion criteria using a team of authors; qualitatively reviews and summarizes results in a clear and repeatable manner. | Primary | Low | High | No | - |
| Large randomized controlled trial (RCT) | At least two groups of individuals are included, one with the treatment of interest and one with placebo or comparison treatment; randomization to group is required; >150 per group | Primary | Low | High | Yes | High |
| Small randomized controlled trial (RCT) | Same as large RCT, with <150 per group | Primary | Low | High | Yes | Low |
| Cohort study | Follows a group of individuals over time; comparison is group with different exposure or different treatment | Primary | High | Low | Yes | Variable |
| Case series | Reports on the treatment of individuals with the same condition; no control groups | Primary | High | Low | No | - |
| Case reports | Very small case series (<5 patients) | Primary | High | Low | No | - |
| Narrative review | Description of conditions or treatments; sources of data are not reviewed or graded; no data pooling performed; literature inclusion and exclusion criteria not specified | Summary | High | Low | No | - |
| Opinion | May be oral or written; may be based on one's own clinical experience | N/A | High | Low | No | - |
| Pharmacokinetic studies | Measures drug concentrations in plasma or other tissues | Primary | Cannot assess | Cannot assess | No | - |
| In vitro studies | Performed on cells or tissues outside of animals | Primary | Cannot assess | Cannot assess | No | - |

*This might be a treatment effect, effect size, risk ratio, or other estimate, and it might be included in the report or it might need to be calculated by the reader.

## Template for Appraising and Applying the Evidence for Therapeutics

**Clinical Question:**

**Evidence Source 1:**

**1: Use the table of types and sources of evidence (previous page) to determine the type of evidence, and check the boxes below that apply to the risk of bias and your ability to assess the risk of bias.**

**Evidence Type: _____**

| | | | |
|---|---|---|---|
| Risk of bias | ☐ Low | ☐ High | ☐ Cannot assess |
| Ability to assess risk of bias | ☐ High | ☐ Low | ☐ Cannot assess |

**2: Use the checklist below, based on the type of evidence. Once you completed the checklist, and in light of your responses to Step 1, circle which quality assessment you would give this evidence.**

High Moderate Low Very Low

| | YES | NO |
|---|---|---|
| <u>For all evidence types</u> | | |
| Results were discussed critically | ☐ | ☐ |
| The bibliography is adequate (complete and up to date) | ☐ | ☐ |
| <u>Systematic review (with or without meta-analysis)</u> | | |
| The literature search was exhaustive and reproducible | ☐ | ☐ |
| Trials of high quality (randomized, controlled, blinded, trials) were included | ☐ | ☐ |
| Comparability and publication bias were discussed | ☐ | ☐ |
| <u>Randomized controlled trial (RCT)</u> | | |
| Randomization procedure was described | ☐ | ☐ |
| The trial comprised an adequate number of animals (e.g., a sample size calculation was performed) | ☐ | ☐ |
| The control group was completely described and was appropriate for the study | ☐ | ☐ |
| The trial was blinded (single, double, triple) | ☐ | ☐ |
| <u>RCT, cohort study, or case series</u> | | |
| Data are complete, or missing data were documented | ☐ | ☐ |
| Essential information regarding the animals were given: number, breed, age, sex, housing, inclusion criteria, etc. | ☐ | ☐ |
| Exposures and outcomes were described in detail | ☐ | ☐ |
| Appropriate statistical assessments were used | ☐ | ☐ |
| ***See flow chart on front and back covers of "Statistics for Veterinary and Animal Science" to aid your assessment of the statistics – you know enough to make this judgment!*** | | |
| <u>PK study</u> | | |
| Regimen was comparable to clinical use | ☐ | ☐ |
| Data exist about concentrations required for pharmacological effect | ☐ | ☐ |
| <u>In vitro study</u> | | |
| Cells or system used were similar to in vivo setting | ☐ | ☐ |
| Drugs or concentrations used were comparable to those achievable in vivo | ☐ | ☐ |

**Evidence Source 2:**

**1: Use the table of types and sources of evidence (previous page) to determine the type of evidence, and check the boxes below that apply to the risk of bias and your ability to assess the risk of bias.**

**Evidence Type: _____**

| | | | |
|---|---|---|---|
| Risk of bias | ☐ Low | ☐ High | ☐ Cannot assess |
| Ability to assess risk of bias | ☐ High | ☐ Low | ☐ Cannot assess |

**2: Use the checklist below, based on the type of evidence. Once you completed the checklist, and in light of your responses to Step 1, circle which quality assessment you would give this evidence.**

High Moderate Low Very Low

| | YES | NO |
|---|---|---|
| <u>For all evidence types</u> | | |
| Results were discussed critically | ☐ | ☐ |
| The bibliography is adequate (complete and up to date) | ☐ | ☐ |
| <u>Systematic review (with or without meta-analysis)</u> | | |
| The literature search was exhaustive and reproducible | ☐ | ☐ |
| Trials of high quality (randomized, controlled, blinded, trials) were included | ☐ | ☐ |
| Comparability and publication bias were discussed | ☐ | ☐ |
| <u>Randomized controlled trial (RCT)</u> | | |
| Randomization procedure was described | ☐ | ☐ |
| The trial comprised an adequate number of animals (e.g., a sample size calculation was performed) | ☐ | ☐ |
| The control group was completely described and was appropriate for the study | ☐ | ☐ |
| The trial was blinded (single, double, triple) | ☐ | ☐ |
| <u>RCT, cohort study, or case series</u> | | |
| Data are complete, or missing data were documented | ☐ | ☐ |
| Essential information regarding the animals were given: number, breed, age, sex, housing, inclusion criteria, etc. | ☐ | ☐ |
| Exposures and outcomes were described in detail | ☐ | ☐ |
| Appropriate statistical assessments were used | ☐ | ☐ |
| ***See flow chart on front and back covers of "Statistics for Veterinary and Animal Science" to aid your assessment of the statistics – you know enough to make this judgment!*** | | |
| <u>PK study</u> | | |
| Regimen was comparable to clinical use | ☐ | ☐ |
| Data exist about concentrations required for pharmacological effect | ☐ | ☐ |
| <u>In vitro study</u> | | |
| Cells or system used were similar to in vivo setting | ☐ | ☐ |
| Drugs or concentrations used were comparable to those achievable in vivo | ☐ | ☐ |

**3: Estimate at least one treatment effect (or adverse effect) by completing the Fact Box below (or explain why you couldn't complete it because of study type).**

| | Group 1 | Group 2 |
|---|---|---|
| List one parameter that was evaluated (this is an "outcome" in the studied animals; treatment effects are benefits) | List the treatment given to this group | List the treatment given to this group |
| **Article 1** | | |
| How many animals, or what percentage of animals, experienced the outcome in each group? Alternatively, what is the mean or average for the outcome you're interested in in each group? | | |
| What is the numerical difference between the two groups in the outcome (this is the **treatment effect** or "relative" treatment effect if there is not a placebo controlled group)? | | |
| **Article 2** | | |
| How many animals, or what percentage of animals, experienced the outcome in each group? Alternatively, what is the mean or average for the outcome you're interested in in each group? | | |
| What is the numerical difference between the two groups in the outcome (this is the **treatment effect** or "relative" treatment effect if there is not a placebo controlled group)? | | |

**4. Based on your assessments of both sources and on the estimated treatment effect:**

a. answer your clinical question

b. make your **clinical recommendation,** and make sure to describe how the quality, as well as the applicability, of the papers supported your answer and the strength of your recommendation

c. assess the **strength** of your recommendation based on your assessment of the quality of the evidence (options are **Weak** or **Strong**)