

# Critical Appraisal of Biomedical Literature With a Succinct Journal Club Template: The ROOTs Format

Hospital Pharmacy  
2017, Vol. 52(7) 488–495  
© The Author(s) 2017  
Reprints and permissions:  
sagepub.com/journalsPermissions.nav  
DOI: 10.1177/0018578717721104  
journals.sagepub.com/home/hpx  


Ashley Johnson<sup>1</sup>, Krisy-Ann Thornby<sup>2</sup>, Mary Ferrill<sup>3</sup>

## Abstract

Journal clubs are a valuable tool to assist pharmacists in the evaluation of biomedical literature and to promote adoption of evidence-based practices. The concise ROOTs (*relevance, observe validity, obtain clinically significant results, and translate results to clinical practice*) method was developed to help simplify and provide structure to any journal club process. Although there are a variety of recommended practices on how to conduct journal clubs using a variety of questions and checklists, many are cumbersome and difficult to complete and present in less than 30 minutes. The concise ROOTs journal club format may be beneficial for clinicians to help them develop an efficient and consistent means to appraise evidence in clinical practice. A sample completed ROOTs template, utilizing the 2015 IMPROVE-IT trial, is provided to further assist in utilizing the template.

## Keywords

journal club, literature evaluation

## Introduction

Journal clubs are an accepted means of critically analyzing the literature in a systematic fashion to assist in dissemination of evidenced-based medicine. Within pharmacy, many key stakeholders specifically mention the need for pharmacists to be able to critically analyze the medical literature. The American College of Clinical Pharmacy Drug Information PRN Opinion Paper recommends minimum core concepts for drug information education that include “preparing, presenting, and participating in journal clubs.”<sup>1</sup> The American Society of Health-System Pharmacists residency requirements state in Goal R2.2 that residents must “demonstrate ability to evaluate and investigate practice, review data, and assimilate scientific evidence to improve patient care and/or the medication use system.”<sup>2</sup> Furthermore, the outline for board of pharmacy licensure exams includes the need for journal clubs. For example, the board of pharmacy specialties’ content outline for the ambulatory care pharmacy certification examination includes a statement that pharmacists should have knowledge of “staff development principles and avenues for providing continuing education (e.g., in-service, small group discussion, journal club).”<sup>3</sup> The World Health Organization’s Framework for Action on Interprofessional Education and Collaborative Practice also suggests that ongoing joint in-service training be provided for all members of the health team to strengthen the collaborative team effort to improve health outcomes.<sup>4</sup> Journal clubs serve as an opportunity to educate multidisciplinary health professionals on current

evidenced-based medicine and promote discussion on its impact in patient care. Apart from the references listed above that state the need for journal clubs in pharmacy education and pharmacy practice, there is little information about the logistics of journal clubs in pharmacy, such as how frequently they should occur, who leads them, and who evaluates them. In academic settings, students, residents, and/or fellows are often charged with presenting the journal club. Most journal clubs occur monthly, are 1 hour in length, with lunchtime recommended as the most convenient opportunity. For a shorter version of a journal club, a summary handout, such as the ROOTs (*relevance, observe validity, obtain clinically significant results, and translate results to clinical practice*) template, should be distributed prior to the start of the meeting.<sup>5</sup> Because of this lack of specific information and direction, there is need for some guidance to help standardize the process. The objective of this article is to provide a framework for the presentation and discussion of research results in a streamlined journal club format focusing on the domains R, O, O, and T.

<sup>1</sup>Jonathan M. Wainwright Memorial VA Medical Center, Wainwright Drive Walla Walla, WA, USA

<sup>2</sup>Palm Beach Atlantic University, West Palm Beach, FL, USA

<sup>3</sup>California Health Sciences University, Clovis, CA, USA

## Corresponding Author:

Krisy-Ann Thornby, Associate Professor of Pharmacy Practice, Lloyd L. Gregory School of Pharmacy, Palm Beach Atlantic University, West Palm Beach, FL 33416, USA.  
Email: krisy\_thornby@pba.edu

## Journal Clubs as a Means of Efficient Critical Appraisal

It is not surprising to see why organizations and schools/colleges of pharmacy support the concept of a journal club. When searching the online database PubMed<sup>6</sup> for the year 2016, there were 23, 206 citations indexed that were clinical trials (located by combining 11 trial-type article limits such as clinical study, clinical trial, and comparative study) or meta-analyses (used meta-analysis and systematic reviews as article types) which equates to approximately 63 articles per day. It would be impossible for someone to independently critically analyze that many articles to stay abreast of the changes in medicine. Implementing journal clubs in practice has been shown to instill habits of lifelong learning, promote critical appraisal skills, improve understanding of current health topics, and encourage debate among and across other health care professions.<sup>7</sup>

## Journal Club Best Practices

Even if there is buy-in regarding the need for journal clubs, many health care practitioners need guidance on conducting such a review. Deenadayalan and colleagues published a systematic review of what constitutes an effective journal club. They found that “using established critical appraisal processes and summarizing journal club findings” were key to determining effectiveness.<sup>8</sup> A considerable number of articles have been published showcasing various goals, journal club templates, and best practices for conducting journal clubs in diverse medical disciplines.<sup>9</sup> Although there may be subtleties among each of them, many templates incorporate core questions asked in the Consolidated Standards Of Reporting Trials (CONSORT) checklist.<sup>10</sup> While the CONSORT and other similar reporting guidelines serve as tools for the reader to be aware of research reporting requirements, there is little emphasis on how to analyze, appraise, and distill the information. In the health care literature, there are a few recommendations for evaluating journal clubs, and limited templates to assist the reader.<sup>5,11-19</sup> The Center for Evidence-Based Medicine provides access to a clinical trial appraisal tool termed “CATmaker.”<sup>16,20</sup> A study that surveyed medical residents showed that only 39% found the software to be useful; however, they did find that having a process helped to add structure to the presentations to allow for better dialogue. The type of resources utilized will vary based on the different health care settings. With so many journal club templates to choose from, it may be difficult to ensure consistency with regard to questions asked, details of statistics included, length of assignment, and expectations of timing for discussions. Depending on the practice setting and the number of students, residents, or pharmacists participating, time dedicated to the journal club may be limited. Reviews have shown that the duration of a journal club ranges from 1 to 2 hours,<sup>21,22</sup> with some stating that the entire process should be about 15 minutes<sup>23</sup> per article while others suggest

15 minutes for presentation and 15 minutes for a question-and-answer session.<sup>12</sup> Often a concern for facilitators of journal clubs is the limited emphasis to which presenters communicate the clinical relevance of an article. Literature has shown that a key characteristic of effective journal clubs is critically appraising the article by discussing the article’s strengths and limitations, external validity, and recommendations to current practice.<sup>22,24</sup> Simply reciting detailed facts of the article is not enough to foster critical thinking to apply the results in practice. Deenadayalan and colleagues suggest using structured journal club worksheets which can promote participation and discussion among the audience.<sup>8</sup>

Although CONSORT provides information and a checklist of what should be in clinical trials, it may be cumbersome to use for those desiring to conduct a journal club.<sup>10</sup> Other examples of journal club documentation forms are equally difficult and may be too time-consuming to complete.<sup>19</sup>

## ROOTs Journal Club Format

An acronym was designed to help readers critically evaluate the clinical relevance of research articles using the adage of not losing sight of the forest for the trees. Often, it is easy for readers to get caught in the details of the article (ie, tree) which distracts them from observing the entire clinical picture (ie, forest). After analyzing a research article, the reader should be prepared to articulate the bottom line messages (ie, roots) to the audience by discussing the article’s place in therapy compared with current evidence-based medicine practices. The ROOTs journal club is intended to be an efficient and succinct format which can be delivered in 15 minutes (See online appendix/supplemental material). This template can be used by both the novice and skilled expert. It is designed to help each individual navigate an article without missing key features, and it also helps to provide consistency to the journal club process among its members.

In an effort to not muddle the main take-away messages from original research, this journal club template focuses on 4 major “ROOT” sections to structure the critical appraisal. These ROOT sections, showcased in Figure 1, are *relevance*, *observe* validity, *obtain* clinically significant results, and *translate* results to clinical practice. A discussion of pertinent information to address in each respective section is discussed below, and a summary is provided in Table 1. The ROOTs journal club format is best suited to appraise experimental and observational studies, in superiority, noninferiority, and equivalence models, such as randomized controlled trials, cohort studies, and case-control studies. Analyzing systematic reviews and meta-analyses requires special considerations, and readers are referred elsewhere for guidance on their appraisal.<sup>25,26</sup> The intent of this article is to highlight key elements of study design, statistical analysis, and clinical practice guideline recommendations that should be considered in determining potential application to clinical practice. An in-depth explanation of study design and interpretation of study results are outside the scope of this article. Also,

Relevance															
<ul style="list-style-type: none"> <li>- <b>Study Rationale:</b> High dose statins have been shown to lower LDL and nonfatal CV events. However, other lipid-lowering therapies (e.g., fibrates, niacin) added to statin therapies have not demonstrated a reduction in CV events. Ezetimibe added to statin therapy has been shown to improve lipid lowering yet its effects on clinical outcomes have not been evaluated.</li> <li>- <b>Study Objective:</b> To evaluate the safety and efficacy of ezetimibe/simvastatin compared with simvastatin alone on the composite outcome of CV death, major coronary events, and stroke in ACS patients.</li> <li>- <b>Null hypothesis:</b> There is no difference in the primary occurrence of the composite outcomes between simvastatin-ezetimibe 40/10 mg and simvastatin 40 mg.</li> <li><b>Patients:</b> 18,144 patients with <math>\geq 1</math> high-risk feature previously hospitalized for an ACS event within the past 10 days; LDL 50-125 mg/dL or LDL 50-100 mg/dL if on lipid-lowering therapy</li> <li>- <b>Intervention:</b> Simvastatin 40 mg daily plus ezetimibe 10 mg daily</li> <li>- <b>Comparison:</b> Simvastatin 40 mg daily plus placebo</li> <li>- <b>Outcome(s):</b> <ul style="list-style-type: none"> <li>o Primary: Composite of cardiovascular death, major coronary events (documented unstable angina, requiring admission, all PCI or CABG revascularization within 30 days after randomization), non-fatal stroke</li> <li>o Secondary: Composite of death from any cause, major coronary event, or non-fatal stroke; composite of death from CHD, non-fatal MI, or urgent coronary revascularization (PCI or CABG) 30 days or more after randomization; composite CV death, non-fatal MI, hospitalization for unstable angina, all revascularization (coronary and non-coronary) 30 days or more after randomization, or non-fatal stroke.</li> </ul> </li> <li>- <b>Key Exclusion Criteria:</b> ACS qualifying for CABG, current use of statin more equipotent than simvastatin 40 mg, and Creatinine clearance <math>&lt; 30</math> mL/min or active liver disease</li> <li>- <b>Key Baseline Characteristics:</b> Majority white (~84%) males (~75%) with an average age of 64, BMI of 28 kg/m<sup>2</sup>, 27% diagnosed with diabetes, 61% with hypertension, 20% had previous MI, 70% had PCI for ACS event with an average LDL of 94 mg/dL</li> </ul>															
Observe Validity															
-Study design: Randomized, double-blind, placebo-controlled, parallel-group, modified ITT, multicenter superiority trial.															
Statistical analysis:	PARAMETRIC		NON-PARAMETRIC												
Independent/Dependent #Groups 2	Interval/Ratio (e.g., ht, wt, age, etc)	Ordinal (e.g., scales, rankings)	Nominal (e.g., Gender, Y/N)												
List all study outcomes (include baseline characteristics, outcomes and ADEs)	Baseline characteristics; LDL		Baseline characteristics, primary endpoint, mortality endpoints, other endpoints, and adverse events												
List statistical tests used in study	Descriptive statistics (average) for baseline Analysis of covariance (ANCOVA) for LDL		Chi-square test Fisher's exact Cox Model; Kaplan-Meier												
List ALL possible appropriate tests	ANOVA/ANCOVA, Mann-Whitney, Wilcoxon rank sum, Kruskal Wallis		Cox Model Kaplan-Meier												
Were stats used in study appropriate?	Yes/No/Not applicable	Yes/No/Not applicable	Yes/No/ Not applicable												
<p>-Critique of statistical analysis: An appropriate statistical analysis was performed and the trial is adequately powered as the primary outcome is statistically significant.</p> <p>-NNT and NNH application:</p> <p><b>NNT for primary composite outcome:</b></p> <table border="1" style="display: inline-table; margin-right: 20px;"> <thead> <tr> <th></th> <th>YES</th> <th>NO</th> <th>TOTAL</th> </tr> </thead> <tbody> <tr> <td>Simvastatin plus ezetimibe</td> <td>2572 (32.7%)</td> <td>5293 (67.3%)</td> <td>7865 100%</td> </tr> <tr> <td>Simvastatin plus Placebo</td> <td>2742 (34.7%)</td> <td>5160 (65.3%)</td> <td>7902 100%</td> </tr> </tbody> </table> <div style="border: 1px solid black; padding: 5px; display: inline-block;"> <p><b>RR:</b> 32.7 %/ 34.7% = 0.94      <b>RRR:</b> 1 - 0.94 = 0.06  <b>ARR:</b> 34.7-32.7%=2%    <b>NNT:</b> 1/0.02 = 50 patients need to be treated with <i>combination simvastatin 40 mg plus ezetimibe 10 mg</i> for 7 years to prevent 1 composite endpoint (CV death, major coronary events, and non-fatal stroke)</p> </div>					YES	NO	TOTAL	Simvastatin plus ezetimibe	2572 (32.7%)	5293 (67.3%)	7865 100%	Simvastatin plus Placebo	2742 (34.7%)	5160 (65.3%)	7902 100%
	YES	NO	TOTAL												
Simvastatin plus ezetimibe	2572 (32.7%)	5293 (67.3%)	7865 100%												
Simvastatin plus Placebo	2742 (34.7%)	5160 (65.3%)	7902 100%												
<p><b>NNH:</b> Adverse effects were not statistically significant or clinically different between groups. Therefore, NNH would not be useful in this case, however monitoring of adverse effects are still warranted and described below.</p>															
Obtain Clinically Significant Results															
<p><b>Drop-outs discussion:</b> An intention-to-treat analysis was performed and the number of patients included from the final analysis was similar among the simvastatin plus ezetimibe group and placebo groups (Figure S1).</p> <p><b>Safety: Results of safety outcome (numerical results with p values and CIs):</b></p> <ul style="list-style-type: none"> <li>o Adverse events leading to drug withdrawal were similar among groups (10.6% with combination compared with 10.1% with monotherapy). Elevated transaminases between combination and monotherapy was 2.5% and 2.3% (p=0.43), respectively; rhabdomyolysis or myopathy was 0.3% in both groups (p=0.9); gall-bladder related adverse events between combination and monotherapy was 3.1% and 3.5% (p=0.10), respectively.</li> </ul>															

(continued)

<p><b>Efficacy: Key results of primary outcomes (numerical results with p values and CIs):</b></p> <ul style="list-style-type: none"> <li>○ <b>Primary outcome (CV death, major coronary events, and non-fatal stroke):</b> combination (32.7%) vs. placebo (34.7%) HR 0.936 [95% CI (0.89 – 0.99); p =0.016].</li> <li>○ <b>Secondary outcomes:</b> The composite endpoint was influenced by significant reductions in MI and ischemic stroke (i.e. non-fatal endpoints) but no significant reduction in all-cause death was observed. Death from any cause, major coronary event, or non-fatal stroke – combination (38.7%) vs. monotherapy (40.3%) p=0.03; death from coronary heart disease, nonfatal MI, urgent coronary revascularization ≥30 days – combination (17.5%) vs. monotherapy (18.9%) p=0.02; death from cardiovascular causes, nonfatal MI, hospitalization for unstable angina, all revascularization ≥30 days, nonfatal stroke – combination (34.5%) vs. monotherapy (36.2%) p=0.04.</li> <li>○ <b>Clinical relevance of primary outcome results:</b> While the primary composite outcome was found to be statistically significant possibly due to the large sample size, the absolute risk reduction between groups was modest (2%) in patients deemed high-risk post ACS and the NNT was (50) over a 7 year observation period.</li> </ul> <p><b>Cost:</b></p> <ul style="list-style-type: none"> <li>○ Using GoodRx cash prices for a 30 day supply range from \$91- \$336 for simvastatin/ezetimibe (generic) and \$3- \$27 for simvastatin (generic)</li> </ul> <p><b>Convenience:</b></p> <ul style="list-style-type: none"> <li>○ Both are once daily medications; combination ezetimibe/simvastatin is available as Vytorin (10/40) for ease of pill burden</li> </ul> <p><b>Clinical Guidelines (place in therapy):</b> 2013 ACC/AHA guidelines: “Clinicians treating high-risk patients who are unable to tolerate less-than-recommended intensity of a statin, or who are completely statin intolerant may consider the addition of a nonstatin cholesterol-lowering therapy (GRADE E [expert opinion]).”</p> <p><b>Major trial strengths:</b></p> <ul style="list-style-type: none"> <li>○ Investigated clinical outcomes in a large sample size</li> <li>○ Utilized design features to minimize bias: randomization, double-blinding, and active with placebo control</li> </ul> <p><b>Major potential trial limitations:</b></p> <ul style="list-style-type: none"> <li>○ Lack of other relevant control arms with a high intensity statin regimen commonly used in practice (e.g., atorvastatin 80 mg or rosuvastatin 40 mg)</li> <li>○ Only 15% of patients were &gt;75 years of age which would warrant use of a moderate dose statin</li> <li>○ High rate of discontinuations (42%) for any reason</li> <li>○ No explanation for primary endpoint calculations or explained adjustments such as person-years. The hazard ratio is not reproducible with numbers provided in the study</li> <li>○ No information provided regarding lifestyle modifications</li> </ul>
<p><b>Translate Results into Practice</b></p> <p><b>Authors’ Conclusions:</b> The authors’ concluded that the risk of CV events was reduced in patients receiving combination therapy with simvastatin and ezetimibe, in post-ACS patients with LDL levels within guideline recommendations compared to simvastatin alone.</p> <p><b>Recommendations:</b> Although the results in this trial were shown to be statistically significant, they did not show clinical relevance. These findings do not show any clinically relevant change in morbidity or mortality when ezetimibe is added to a statin in patients previously hospitalized for an ACS event over an observation period of 7 years. Simvastatin 40 mg plus ezetimibe 10 mg daily may be an alternative option for patients who cannot tolerate high intensity statins to decrease risk of recurrent ACS events. A head to head trial comparing simvastatin plus ezetimibe to other preferred statins and commonly prescribed high intensity doses (e.g. atorvastatin and rosuvastatin) might help solidify the clinical picture of combination therapy in patients post-ACS and may be more representative of clinical practice.</p>
<p><b>References:</b></p> <ul style="list-style-type: none"> <li>○ Cannon CP, Blazing MA, Giugliano RP, et al. Ezetimibe Added to Statin Therapy after Acute Coronary Syndromes. N Engl J Med. 2015; 372(25):2387-97. doi: 10.1056/NEJMoa1410489.</li> <li>○ Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults. Circulation. 2014.;129:S1-S45. doi: 10.1161/01.cir.0000437738.63853.7a. Accessed July 10, 2017.</li> <li>○ Ezetimibe [package insert]. Merck Sharp &amp; Dohme Corp. Whitehouse Station, NJ; 2012.</li> <li>○ Simvastatin [package insert]. Merck Sharp &amp; Dohme Corp. Whitehouse Station, NJ; 2015.</li> <li>○ GoodRx pricing. <a href="http://www.goodrx.com/">http://www.goodrx.com/</a>. Accessed on July 10, 2017.</li> </ul>

**Figure 1.** Sample ROOTs (*relevance, observe validity, obtain clinically significant results, and translate results into practice*) journal club.

readers using this format should note that a comprehensive efficacy and safety review of a medication’s place in therapy should not be based on a single research article.

### Relevance

Given the abundance of published research, it is critical that the article selected for a journal club is relevant so as to best

utilize limited resources. Readers can readily determine the relevancy of a particular piece of literature by considering 2 questions. First, is the article relevant to a clinical issue or patient population that the reader is serving? And second, will this information, if true, require the reader to change their current practice? If the answer to both of these questions is yes, then further examination is likely warranted. Within this section, the reader should succinctly discuss the

**Table 1.** Explanation of ROOTs Subheadings and Time Estimate for Delivery.

Subheadings	Explanation	Time
Relevance		3 minutes
Study rationale	Foundational for determining whether the article potentially adds to the existing body of literature	
Study objective	Everything must connect to the objective to ensure the results and conclusions answer the objective	
Null hypothesis	Need to determine what the <i>P</i> values are reflecting	
Patients	For extrapolation to your institution's specific patient population	
Intervention	Include dose and duration to determine whether appropriate to your institution and patients	
Comparison	Ensure the standard, dose, and duration are an appropriate comparison	
Outcome(s)-primary	Ensure that the outcome is the standard used, ideally a patient-oriented outcome, and that it will answer the study objective	
Outcome(s)-secondary	Ensure they are appropriate to support the primary objective and to remind participants that these are only hypothesis generating	
Key exclusion criteria	List only those that might limit or question extrapolation	
Key baseline characteristics	This is for the group to have a clear picture of who was studied	
Observe validity		4 minutes
Study design	To ensure that the design will be able to limit study bias	
Statistical analysis	This section is often overlooked but can limit reliability of the results if inappropriate statistics are used. Statistical tests are based on 3 main factors: study design, data types, and number of groups compared in the study. This section can be shortened as the group feels more comfortable with statistical analysis	
Number needed to treat and number needed to harm	Help to provide absolute risks for the primary efficacy and safety outcomes and are less likely to distort the results	
Obtain clinically significant results		5 minutes
Dropouts	Only list those that could affect the results or are not expected	
Safety	Provide only those side effects that are clinically relevant, statistically significant, or unexpected	
Efficacy	Provide summative statements of numerical results, or highlight trends and deviations from trends, rather than presenting all the results	
Cost	Conform to your institution's reimbursement method. Make sure to consider monitoring or other ancillary costs	
Convenience	List anything that might favor one treatment over another	
Clinical practice guidelines (CPGs)	Briefly state current CPG(s) recommendation(s) and whether this study adds or subtracts from them	
Major trial strengths	What helps to support the findings	
Major potential trial limitations	What major limitations cause questioning of the results	
Translate results into practice		3 minutes
Author's conclusions	Briefly state their conclusion	
Recommendations	State your specific recommendation and whether it differs from the authors or CPGs, use information from above to support your recommendation. Be sure to include statistical versus clinical significance if they do not align.	
References	Key articles to use for future reference. Applicable CPGs need to be included	

study rationale, specifically focusing on what the selected article potentially adds to the existing body of literature, as well as the study objective and null hypothesis. A concise reporting of the patients included in the study derived from inclusion criteria; the intervention and comparison investigated which may be a therapeutic agent, risk factor, or test with a corresponding description of dosing regimens and titrations as applicable; and primary and secondary outcomes should be listed. Next, it is noteworthy to critically examine what patients were excluded from the study as the results of

the trial would not be applicable to these patient populations. Last, provide a global description of patients enrolled in the study based on key baseline characteristics to assist in extrapolating the results.

### Observe Validity

In this section, readers take a closer look at the validity of the study design elements and statistical analysis in the study along with calculating estimates of risk (eg, absolute,

relative risk) as applicable. In terms of study design, readers should take into consideration elements included to reduce the potential risk of bias such as randomization, blinding, use of an appropriate control (including dose and interval), intention-to-treat or per protocol analysis, sample size, and accounting for potential confounders and number of study centers. The study design elements used in a trial should be analyzed in an effort to confidently determine whether any differences detected are due to the intervention alone and not bias. As seen in Figure 1, a table enables the reader to denote the study design and number of groups and classify the type of data for baseline characteristics, outcomes, and adverse drug events to assist with determining the appropriate use of statistical tests. With this information, readers can rule in or out the possibility of a type I error. Power should also be reviewed if no statistically significant difference was observed in the primary outcome. It is recommended to calculate risk estimates, particularly the absolute risk reduction which is the actual difference in event rates between treatments. Relative risk estimates such as relative risk and relative risk reduction are often reported in studies as the results may appear better. Thus, calculating both provides greater insight to the study's results and clinical importance. The absolute risk reduction will also lead to calculating number needed-to-treat if a statistically significant difference was observed between an intervention and control for a nominal outcome in a superiority trial.

### *Obtain Clinically Significant Results*

In the ROOTs journal club format, this section is typically the lengthiest due to a detailed analysis of study results, factors that may impact the clinical application of the study findings, and major potential limitations of the trial. To begin, readers should clearly state the results of key safety and efficacy outcome measures with the numerical results and accompanying *P* values and confidence intervals. Restating this information in a clear, concise manner allows the reader to showcase the magnitude of treatment effect which carries considerable weight in determining the clinical relevance of the findings. However, try to provide summative statements of numerical results, or highlight trends and deviations from trends, rather than presenting all the results. A comparison of the treatment effect demonstrated by the standard of care is integral to investigating the value, if any, of the intervention under exploration. Likewise, the potential clinical significance of an intervention is influenced by considerations of cost, convenience, and clinical practice guideline recommendations. Cost and convenience might not factor into the interpretation of the study but might be of benefit when translating results to clinical practice. By researching and providing information on these factors, readers provide needed information to appropriately interpret the potential value of the intervention. It should be noted that often a critical assessment of a study requires the reader to

consult numerous resources such as clinical practice guidelines, prescribing information, other published literature, and related commentaries. In the pursuit of providing succinct and thorough decision-making information, readers should be cautious to furnish a well-rounded perspective. Although clinical practice recommendations can be extensive, the presenter should tailor the information to focus on the specific clinical issue in the patient population under investigation with the respective grading of evidence supporting the recommendation. In doing so, readers may be alerted to deficiencies in the study design or potential inconsistencies in the recommended care of patients. Examples of potential study limitations that may hinder clinical relevance of study findings could include inadequate study duration, use of surrogate outcome measures or inappropriate primary outcomes, failure to investigate adherence, comparison with suboptimally dosed control or not the standard of care, lack of assessment of ancillary medications which may alter the efficacy of the intervention, and inclusion or exclusion of a restricted patient population that is not representative of the majority of patients. Interpreting the limitations of a trial and how to translate their implications and then apply to clinical practice is often the biggest "limitation" of a good journal club. An example might help to place the importance of limitations into perspective. A clinical trial published in 2006 and an extension of that same trial in 2007 was the sole study used for aripiprazole to receive Food and Drug Administration (FDA) approval for adjunctive treatment in bipolar disorder.<sup>27,28</sup> In 2011, this trial, and the use of aripiprazole in bipolar disorder, was called into question. Tsai and colleagues determined

four issues that limit the interpretation of that trial as supporting the use of aripiprazole for bipolar maintenance: (1) insufficient duration to demonstrate maintenance efficacy; (2) limited generalizability due to its enriched sample; (3) possible conflation of iatrogenic adverse effects of abrupt medication discontinuation with beneficial effects of treatment; and (4) a low overall completion rate.<sup>29</sup>

A journal club would have revealed these flaws and institutions might have questioned the validity of the results much sooner. The importance of this step in the process cannot be overstated, as interpreting the limitations is often the "missing link" in journal clubs, as limitations are often easy to identify, but translating what they mean for the overall conclusion is important, because some critical flaws, as seen in the aripiprazole example, may make it more difficult to find benefit with a drug, but it is shown in the study to be beneficial anyway. And as with this example, sometimes it may be prudent to further examine the evidence in clinical practice guidelines or evidence used to support recommendations from an authoritative body such as the FDA rather than assume that the drug is safe and effective because it was approved.

## Translating Results into Clinical Practice

Last, this section serves to address the study authors' conclusions and provide specific recommendations based on the analyzed study in concert with clinical guideline recommendations. A summary of the authors' conclusions of the trial and any explanation behind the proposed mechanism of the observed effect of the intervention(s) should be covered. Based on the thorough exploration of the relevance of the study, validity of the study design, and statistical and clinical significance of the results, readers formulate a concrete clinical recommendation specifying what intervention including dosing and duration should be utilized in what specific patient population. This recommendation should include major interactions with medications; alternative therapies, or food; common potential adverse drug events; and monitoring parameters. Special attention should be given to assess the need to change any protocols or clinical pathways based on the findings. An example of the ROOTs journal club format using the IMPROVE-IT trial<sup>30</sup> examining the addition of ezetimibe to statin treatment in patients post acute coronary syndrome is provided in Figure 1. This article was selected to showcase the ROOTs journal club technique due to its potential clinical impact that warrants exploration by those presenting medical evidence to a group of colleagues.

## Conclusion

In an effort to communicate consistent and succinct information from clinical research articles, the ROOTs acronym was created as a method for systematically critiquing journal articles in a journal club format. A sample template and example of a journal club utilizing the template (see Figure 1) is provided to illustrate the concepts reviewed in this article. Readers using this journal club format may be better able to streamline the key elements of the article's study design and validity while articulating the bottom line messages when applying the results to clinical practice.

## Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

## Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

## Supplementary Material

The supplements/online appendix for the article are available online.

## References

- Bernknopf AC, Karpinski JP, McKeever AL, et al. Drug information: From education to practice. *Pharmacotherapy*. 2009;29:331-346.
- American Society of Health-System Pharmacy. Required competency areas, goals, and objectives for postgraduate year one (PGY1) pharmacy residencies. <https://www.ashp.org/-/media/assets/professional-development/residencies/docs/pgy1-accreditation-standard-2016.ashx?la=en&hash=82D0575273AD83E720B114D62B7926FD35792AFD>. Accessed July 10, 2017.
- Board of pharmacy specialties. Content outline for the ambulatory care pharmacy certification examination. [http://www.bpsweb.org/wp-content/uploads/2015/11/content\\_ambulatory.pdf](http://www.bpsweb.org/wp-content/uploads/2015/11/content_ambulatory.pdf). Accessed July 10, 2017.
- World Health Organization (WHO). Framework for action on interprofessional education & collaborative practice. Geneva, Switzerland: World Health Organization. [http://whqlibdoc.who.int/hq/2010/WHO\\_HRH\\_HPN\\_10.3\\_eng.pdf](http://whqlibdoc.who.int/hq/2010/WHO_HRH_HPN_10.3_eng.pdf). Accessed July 10, 2017.
- Hatfield CL. Basics of journal club. In: Aparasu RR and Bentley JP, eds. *Principles of Research Design and Drug Literature Evaluation*. 1st ed. Burlington, MA: Jones & Bartlett Learning; 2015:336-346.
- PubMed.gov. US National Library of Medicine National Institutes of Health. <https://www.ncbi.nlm.nih.gov/pubmed>. Accessed July 10, 2017.
- Esisi M. Journal clubs. <http://careers.bmj.com/careers/advice/view-article.html?id=2631>. Accessed July 10, 2017.
- Deenadayalan Y, Grimmer-Somers K, Prior M, Kumar S. How to run an effective journal club: a systematic review. *J Eval Clin Pract*. 2008;14:898-911.
- Fowler L, Gottschlich MM, Kagan RJ. Burn center journal club promotes clinical research, continuing education, and evidence-based practice. *J Burn Care Res*. 2013;34(2):e92-e98. doi: 10.1097/BCR.0b013e3182839b03.
- Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340:1-28.
- Riegelman RK. *Studying a Study and Testing a Test: Reading Evidence-based Health Research*. 6th ed. Baltimore, MD: Lippincott, Williams & Wilkins; 2012.
- Dawson B, Trapp RG. *Basic & Clinical Biostatistics*. 4th ed. New York, NY: Lange Medical Books/McGraw-Hill; 2004.
- Goodfellow LM. Can a journal club bridge the gap between research and practice? *Nurs Educ*. 2004;29(3):107-110.
- Forsen JW, Hartman JM, Neely G. Tutorials in clinical research, part VIII: creating a journal club. *Laryngoscope*. 2003;113(3):475-483.
- Blommel ML, Abate MA. A rubric to assess critical literature evaluation skills. *Am J Pharm Educ*. 2007;71(4): Article 63.
- Center for Evidence-based Medicine. CATmaker software. [http://cebmb.warne.ox.ac.uk/cebmb/education\\_catmaker.htm](http://cebmb.warne.ox.ac.uk/cebmb/education_catmaker.htm). Accessed July 10, 2017.
- Al Achkar M. Redesigning journal club in residency. *Adv Med Educ Pract*. 2016;7:317-320. doi: 10.2147/AMEP.S107807.
- Morrison JM, Sullivan F, Murray E, Jolly B. Evidence-based education: development of an instrument to critically appraise reports of educational interventions. *Med Educ*. 1999;33(12):890-893.
- Dirschl DR, Tornetta P III, Bhandari M. Designing, conducting, and evaluating journal clubs in orthopaedic surgery. *Clin Orthop Relat Res*. 2003;413:146-157.

20. Hartzell JD, Veerappan GR, Posley K, Shumway NM, Durning SL. Resident run journal club: a model based on the adult learning theory. *Med Teach*. 2009;31:e156-e161.
21. Greene WB. The role of journal clubs in orthopaedic surgery residency programs. *Clin Orthop Relat Res*. 2000;(373):304-310.
22. Moberg-Wolff EA, Kosasih JB. Journal clubs. Prevalence, format, and efficacy in PM&R. *Am J Phys Med Rehabil*. 1995;74(3):224-229.
23. Stapleton JJ. The successful journal club. *Clin Podiatr Med Surg*. 2007;24(1):51-55.
24. Judd S, Antaki F. Approach to presenting a journal club. *Gastroenterology*. 2014;146:1591-1593.
25. Ried K. Interpreting and understanding meta-analysis graphs: a practical guide. *Aust Fam Physician*. 2006;35(8):635-638.
26. Khoshdel A, Attia J, Carney SL. Basic concepts in meta-analysis: a primer for clinicians. *J Clin Pract*. 2006;60(1):1287-1294.
27. Keck PE Jr, Calabrese JR, McQuade RD, et al. A randomized, double-blind, placebo-controlled 26-week trial of aripiprazole in recently manic patients with bipolar I disorder. *J Clin Psychiatry*. 2006;67(4): 626-637.
28. Keck PE Jr, Calabrese JR, McIntyre RS, et al. Aripiprazole monotherapy for maintenance therapy in bipolar I disorder: a 100-week, double-blind study versus placebo. *J Clin Psychiatry*. 2007;68(10):1480-1491.
29. Tsai AC, Rosenlicht NZ, Jureidini JN, et al. Aripiprazole in the maintenance treatment of bipolar disorder: a critical review of the evidence and its dissemination into the scientific literature. *PLoS Med*. 2011;8(5):e1000434.
30. Cannon CP, Blazing MA, Giugliano RP, et al. Ezetimibe added to statin therapy after acute coronary syndromes. IMPROVE-IT Trial. *N Eng J Med*. 2015;372(25):2387-2397.