

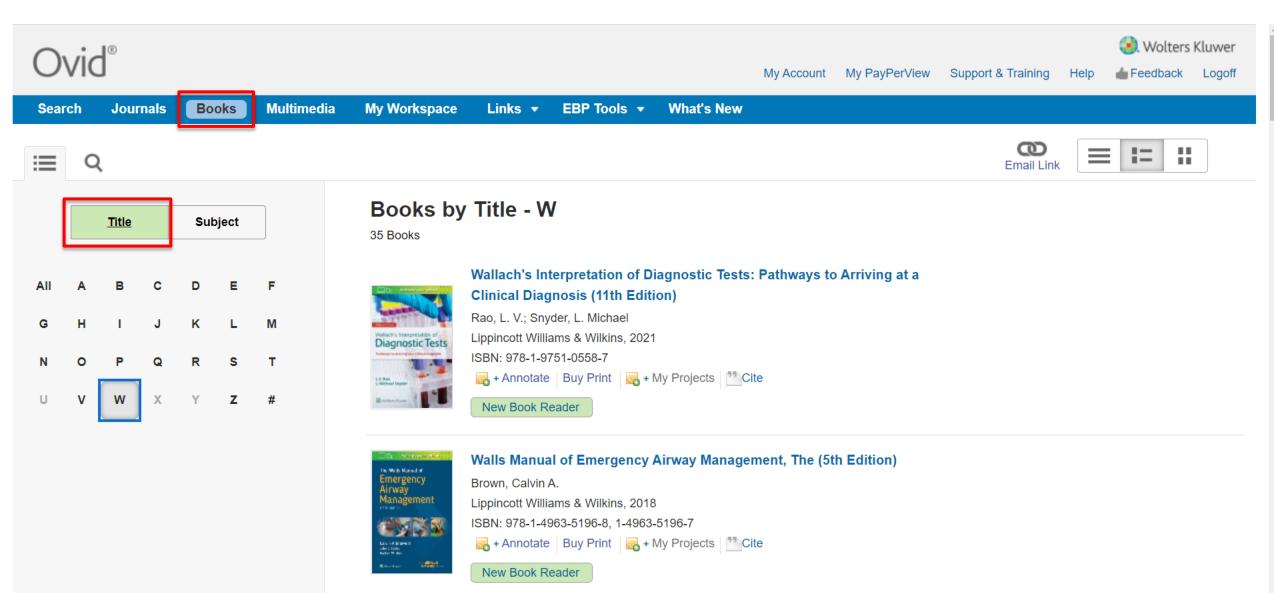
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- 重點說明使用統計篩選和下載報表功能
- 講解counter統計標準的定義,及前台操作所對應的統計數據變化 說明
- Sushi金鑰之取得、使用方式,以及透過sushi協定下載之統計報表 json格式解說
- Q&A

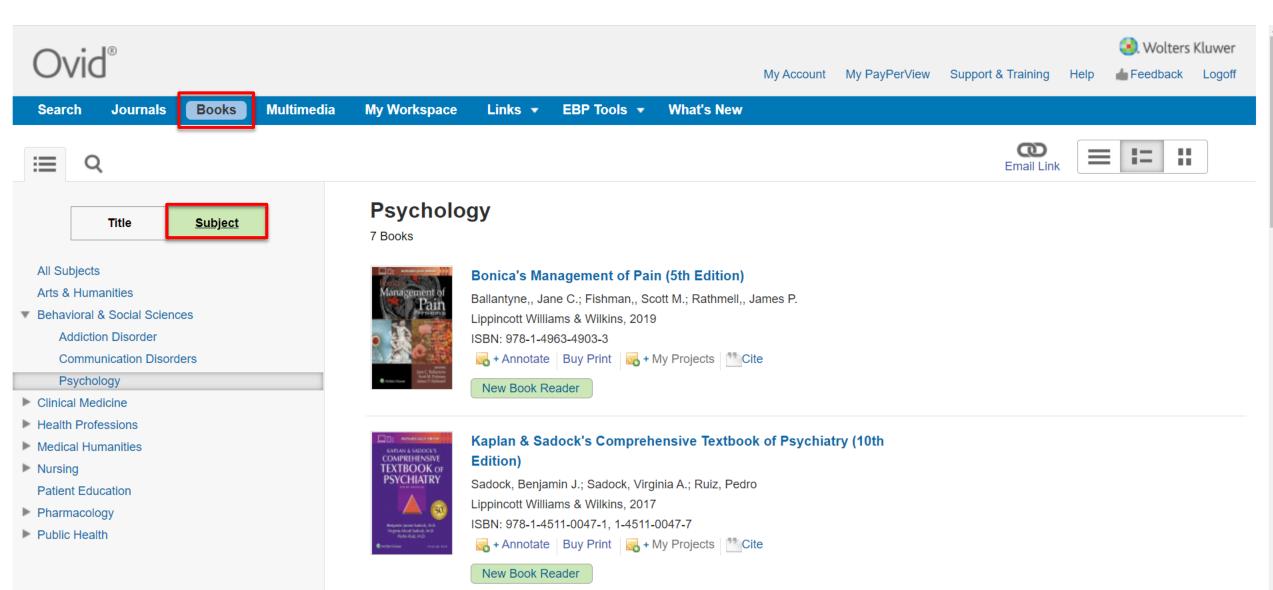




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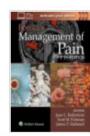
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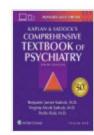
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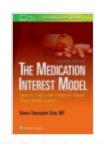
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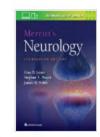
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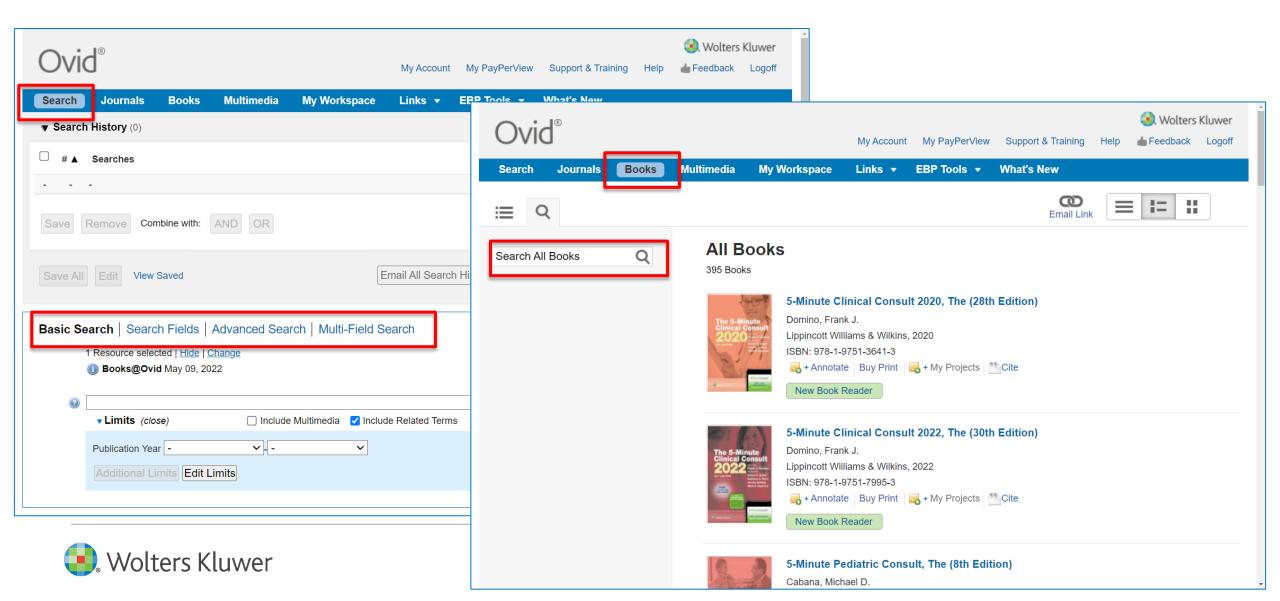


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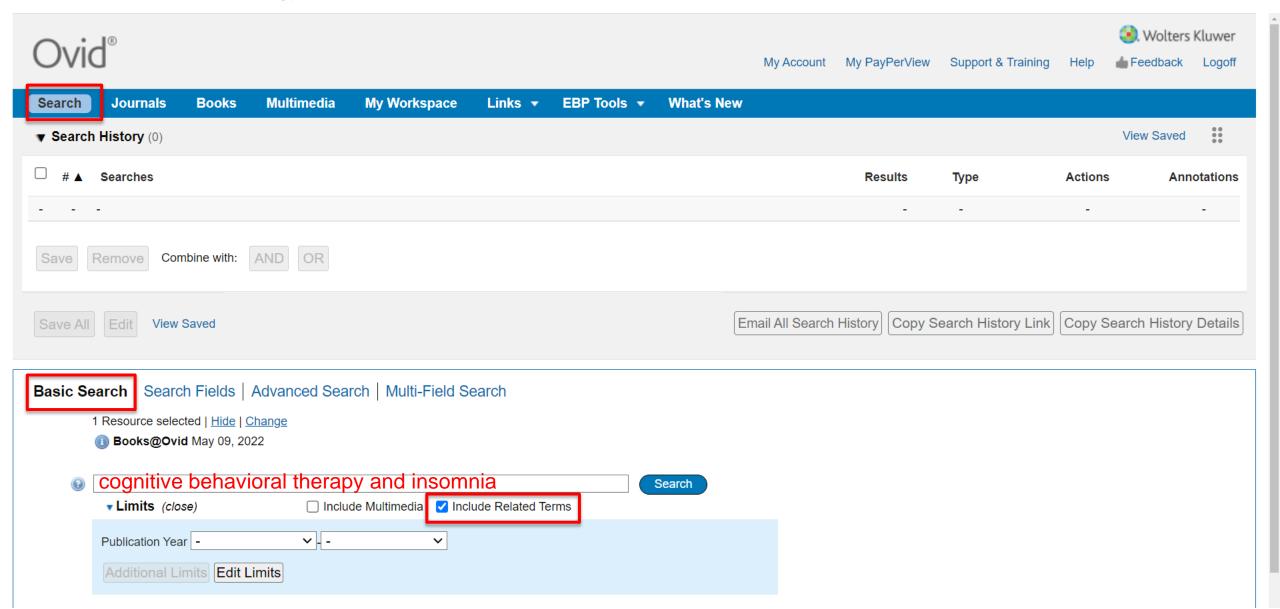




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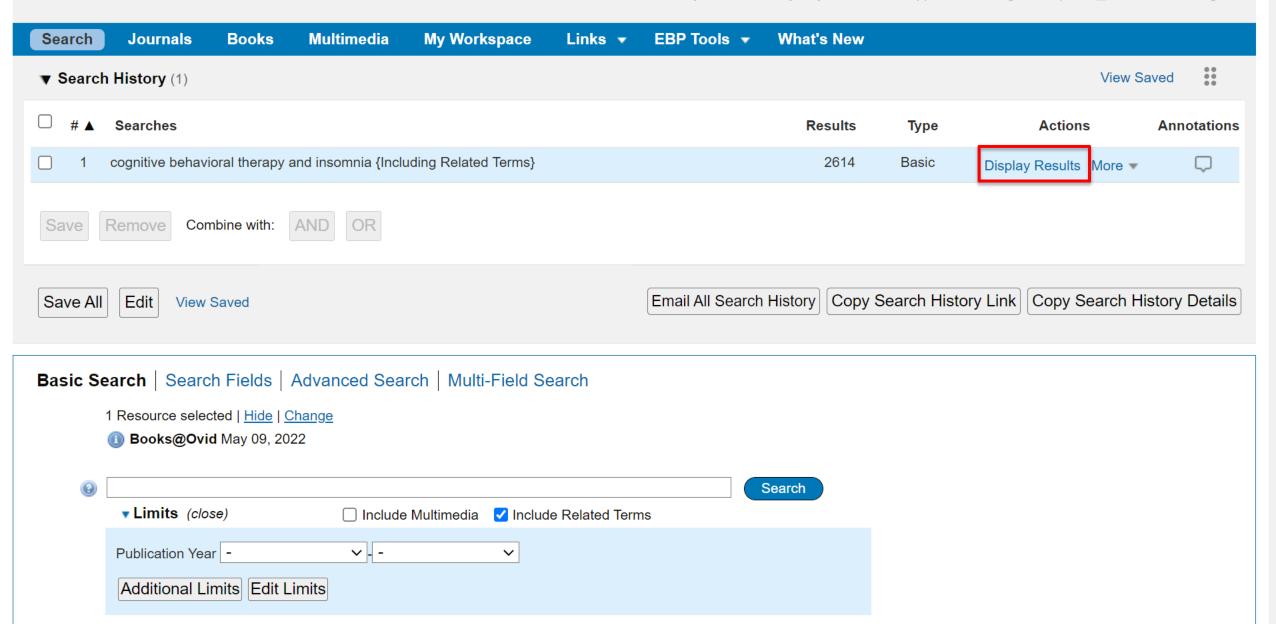
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Prescription medicines are rigorously tested in clinical trials; therefore, they hold an advantage over the virtually untested OTCs. To attain FDA approval as a hypnotic, a medication must be safe and effective. Most hypnotic medications are approved for short-, not long-term, use. Exceptions include zolpidem-modified release, eszopiclone, and ramelteon; all of which are approved for long-term therapy. When properly used, hypnotics can provide immediate and adequate relief from sleeplessness. Insomnia, however, usually returns upon discontinuation of dosing.

Nonpharmacological Treatment with Cognitive-Behavioral Therapy for Insomnia (CBTi)

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Studies repeatedly show significant, sustained improvement in sleep symptoms with CBTi. Improvements include reduced wakefulness duration, decreased number of awakenings, and shorter latency to sleep onset. Short-term benefits are similar to that of medication but CBTi tends to have lasting benefits, even 36 months after treatment. With cessation of the medication **insomnia** frequently returns and is sometimes accompanied by rebound **insomnia**. CBTi has not been shown to produce any adverse effects. There are no established "best practice" guidelines for length or quantity of sessions. CBTi, however, is not without limitations. Most data do not compare the efficacy of the individual components (described below) of CBTi. However, sleep hygiene education alone does not appear to improve sleep. Intuitively, the multi-component approach addresses







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23: Sleep Disorders

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The effects of CBTi take longer to emerge than effects of medications. Individuals are often desperate when they finally seek treatment of their insomnia. This makes it difficult to convince them to try a therapy that may require several weeks before it provides relief. Also, patients must be active participants in this type of therapy. Many individuals not only want a "quick fix" but they also want to undergo a procedure or have something administered rather than be involved in the therapeutic process. For optimal CBTi, patients must commit to multiple sessions and also be open to the idea that modifying thoughts and behaviors about sleep can improve the symptoms of insomnia. The "quick fix" model is common in primary care; by contrast, psychiatrists are accustomed to delayed response from their experience with antidepressants and other psychotropic medicines. Consequently, psychiatrists may be more comfortable recommending CBTi than other practitioners.

Although firmly focused on cognitive and behavioral issues, it helps to extend CBTi just slightly into the psychodynamic sphere. For some patients with longstanding difficulty sleeping, being an insomniac becomes an important part of their identity. There may be primary or secondary gain to such identification. It is the negative emotional response (i.e., anger at the inability to control one's sleep, feeling like a failure because they can't sleep) to insomnia that contributes to its chronicity. In general, these individuals tend to internalize rather than express emotion, feel a heightened need for control, experience interpersonal difficulties, and have significant discontent with past events. For this subset of people, if the emotional response is not addressed, there is more likely to be a limited response to CBTi or a relapse of insomnia over time. The clinician who is attuned (i.e., to patient's tendency to view something as a failure rather than a challenge), will be better able to intercept barriers to treatment. "As chronic insomnia is an extremely psychologically painful condition, a high level of motivation and willingness to explore oneself, at least with a specific focus, is often present."

Universal Sleep Hygiene

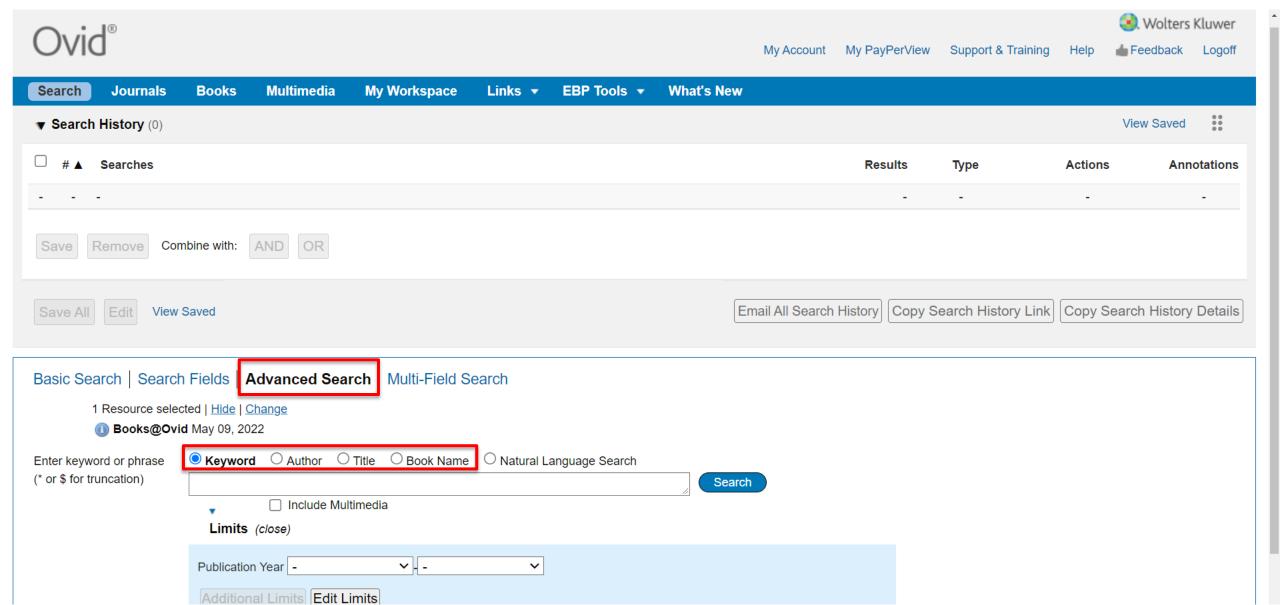
The focus of universal sleep hygiene is on modifiable environmental and lifestyle components that may interfere with sleep as well as behaviors that may improve sleep. Especially because some of these behaviors are difficult to change, only one or two items that are collaboratively chosen by the patient and clinician should be addressed at a time. This will give the patient the best chance at a successful intervention. Sleep enhancing directives are enumerated in Table 23–2. Often a few simple alterations in (*Print pagebreak 2089*) a patient's habits or sleep environment can be effective. The clinician, however, needs to spend time reviewing both the patient's routine and its irregularity. In some respects, the essence of insomnia is its variability. The day-to-day changes in behavior and the changing severity of sleeplessness can obscure the factors responsible for the problem. A carefully explained program of sleep hygiene, with follow-in represents a fairly inexpensive but effective intervention. Furthermore, improving sleep.

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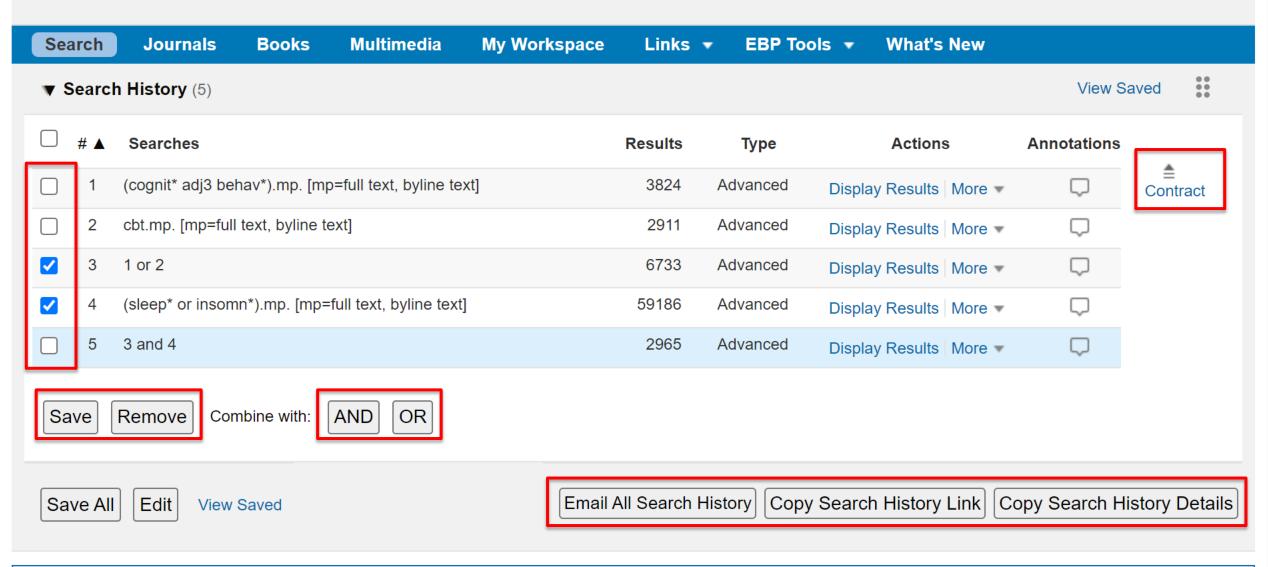
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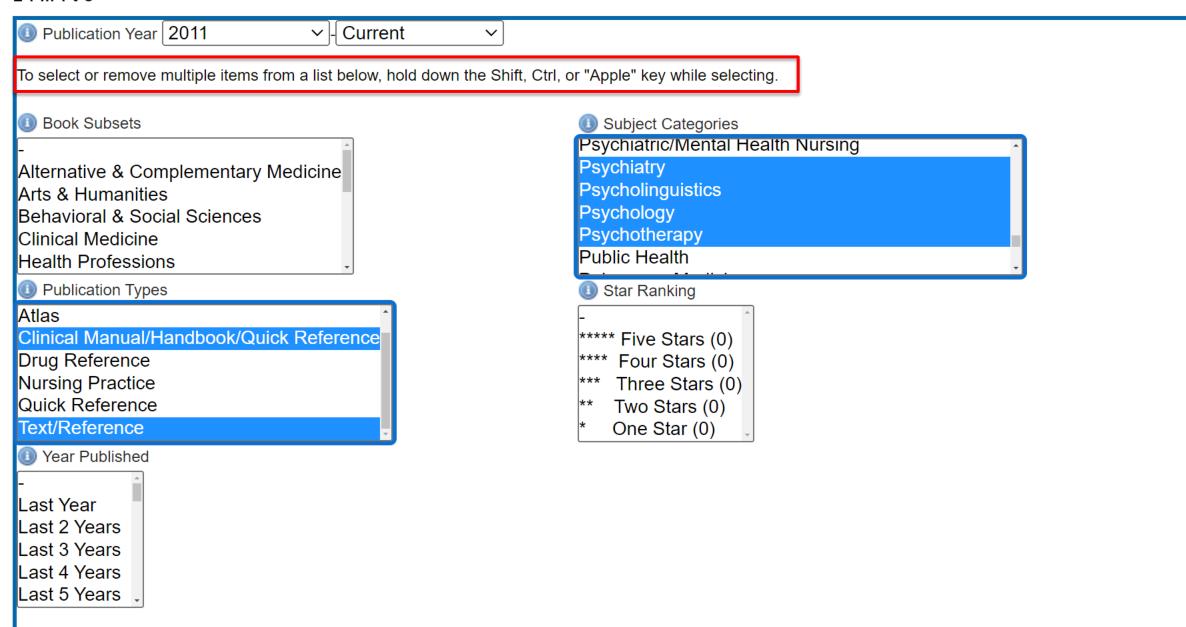
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regarding whether this is dose dependent and how much of this

related myoclonus implicate higher doses, although it has been

reported to occur in patients receiving low doses of opioids,

implicated include methadone 120 and ...

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effect is from parent drug versus metabolites. Most reports of opioid-

particularly hydromorphone. 118, 119 Other opioids that have been

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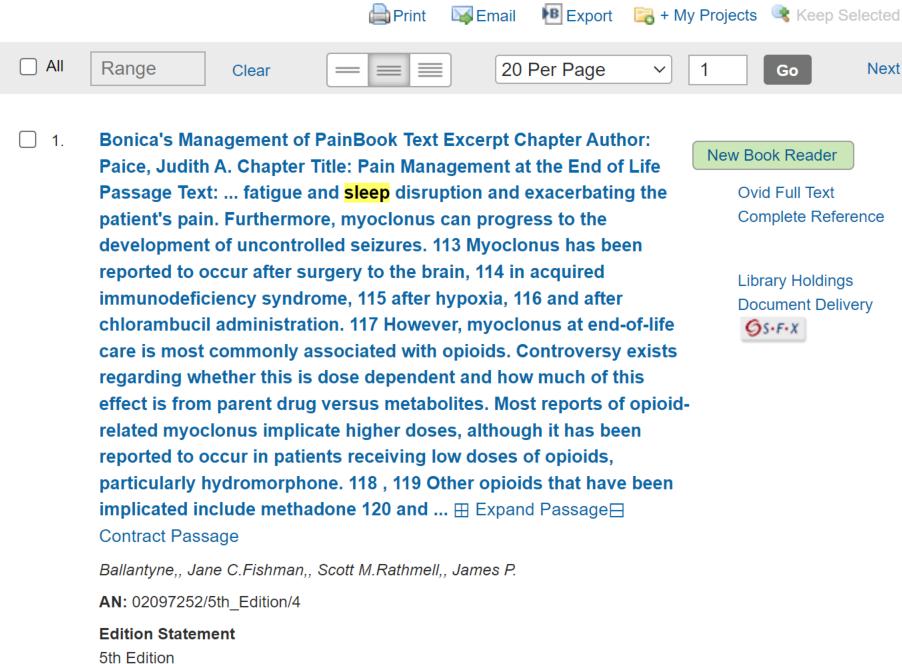
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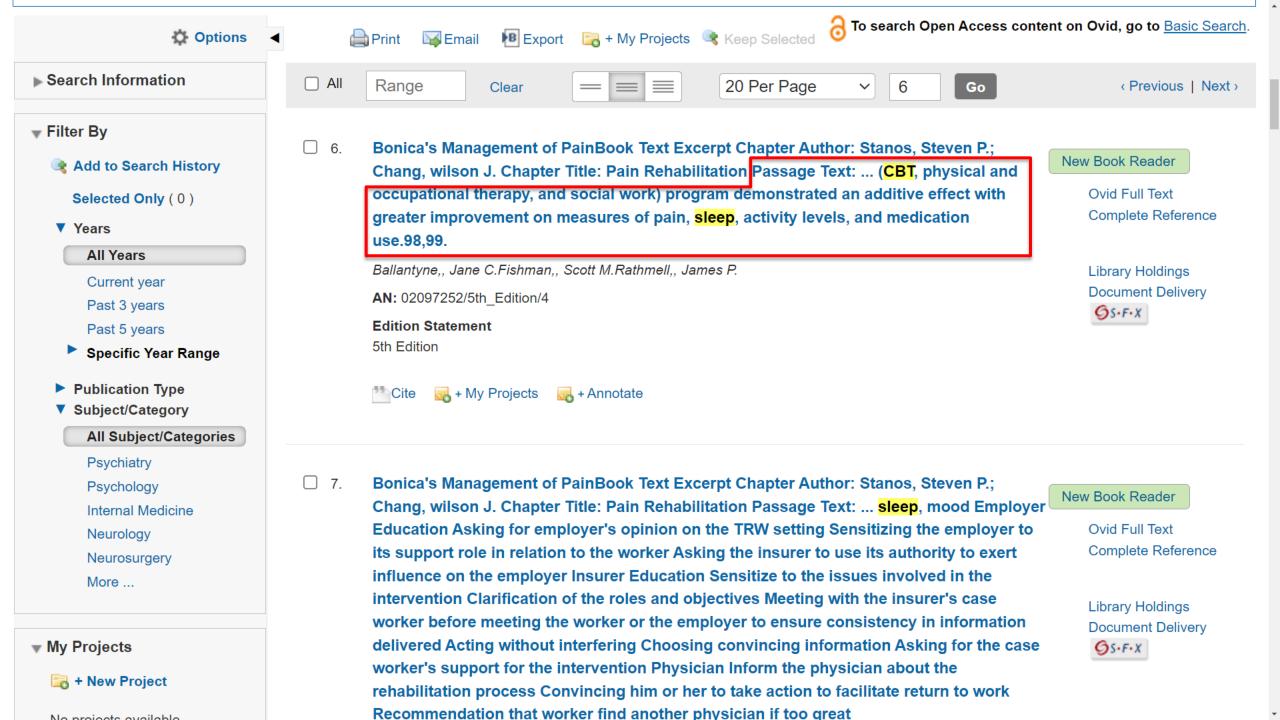
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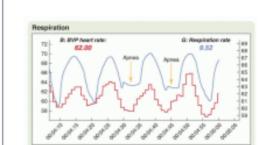
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Conclusion

Combining group CBT and relaxation therapy with an individually based multidisciplinary treatment CBT, physical and occupational therapy, and social work) program demonstrated an additive effect with greater improvement on measures of pain, sleep, activity levels, and medication use. 98,99

Chronic pain frequently accompanied by underlying psychiatric/psychological disorders often benefit from mindfulness meditation. 100 It is characterized by paying attention to the present moment with openness, curiosity, and acceptance. 101 The premise behind mindfulness meditation to target the high prevalence and refractory nature of chronic pain in conjunction with negative consequences of maladaptive behavior, which improved self-referential processing, leads to increased interest in treatment plan including adjunct to therapy and alternative interventions. 100, 102 The goal is to refocus the mind on the present, thereby increasing awareness of one's external surroundings and inner sensations, allowing the individual to step back and reframe experiences. Clinical applications of mindfulness meditation include substance use, stress reduction, tobacco, fixation, and chronic pain.



Representation of transient apnea. X-axis is time. Y-axis is blood volume pulse heart rate. Notice two successive periods of transient apnea indicated by *yellow arrows*. (Source: Adapted from Chapter 16 Respiration Assessment. Shaffer F. HRV Biofeedback Tutor 2018. biosourcesoftware.com.)

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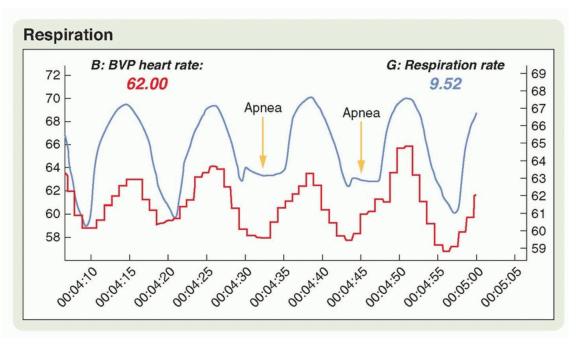
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Chapter 90: Pain Rehabilitation

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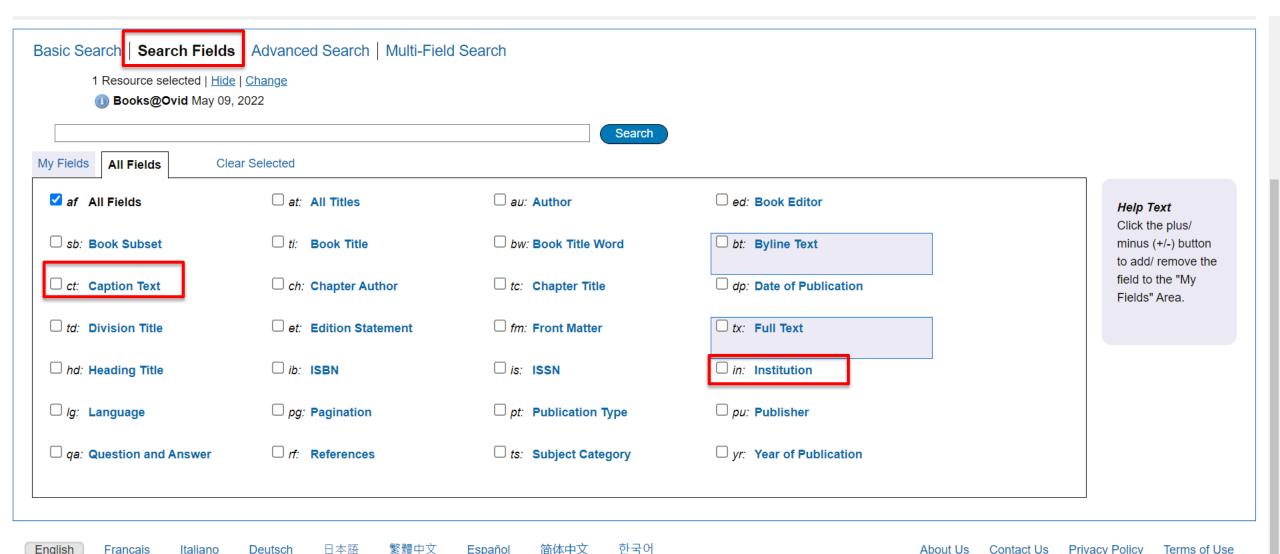
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RELAXATION TRAINING

Furthermore, incorporating relaxation techniques (i.e., deep breathing, progressive muscle relaxation) with therapeutic stretching can help the patient progress in the exercise program and improve activity tolerance. Biofeedback is a treatment that has been shown to be quite effective in the management of pain, 103 The treatment serves to help a patient become more aware of their physiologic responses to pain or other stressors. In general, relaxation

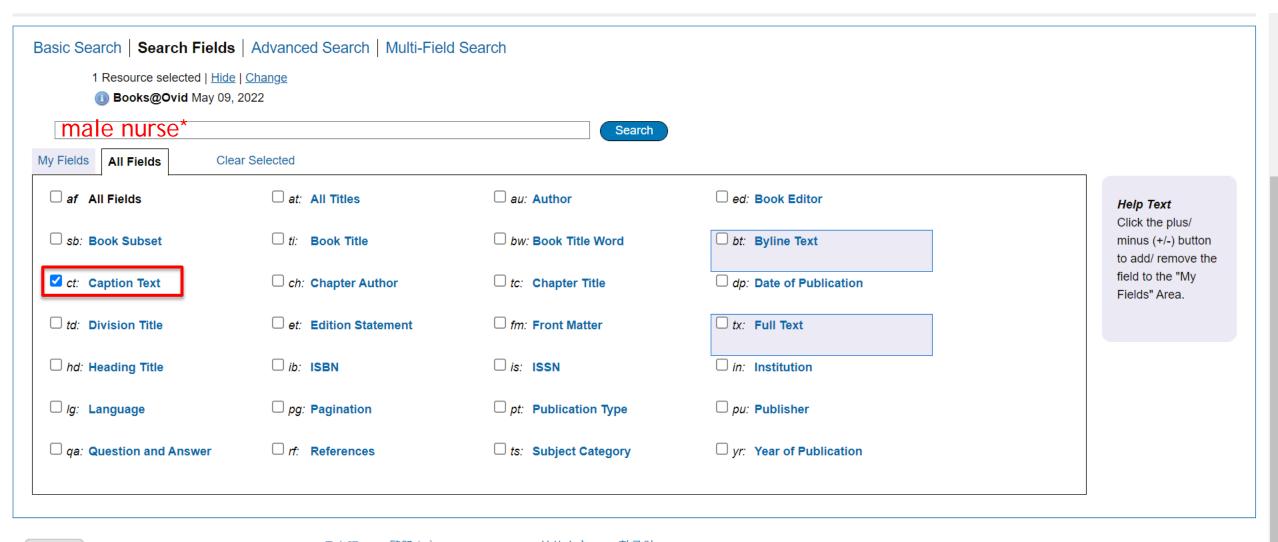
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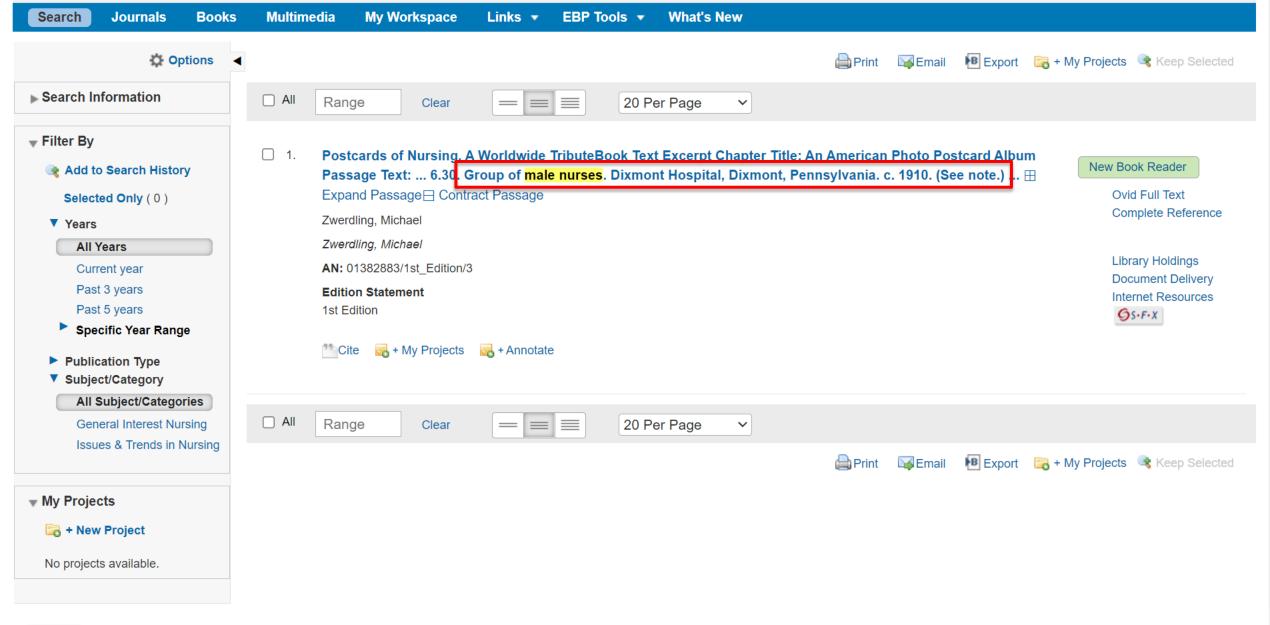
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Figure 6.31. Sonyea, New York.

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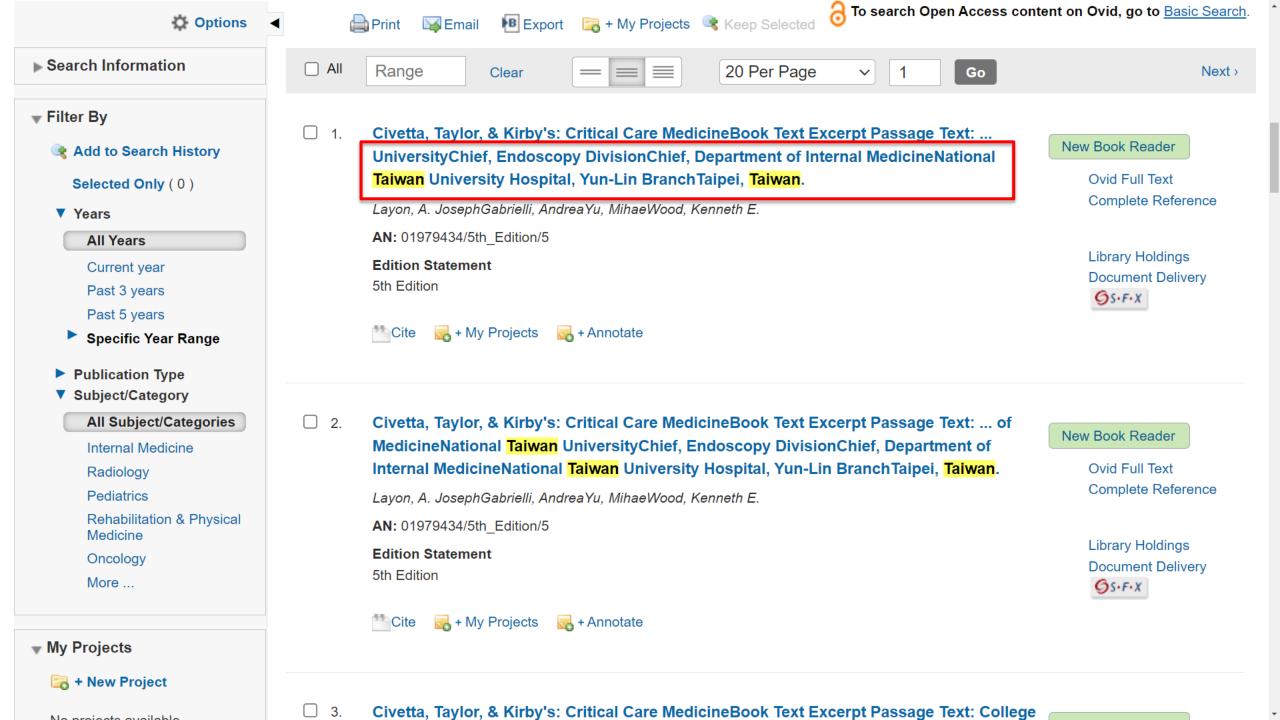
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National Taiwan University Hospital, Yun-Lin Branch

Taipei, Taiwan

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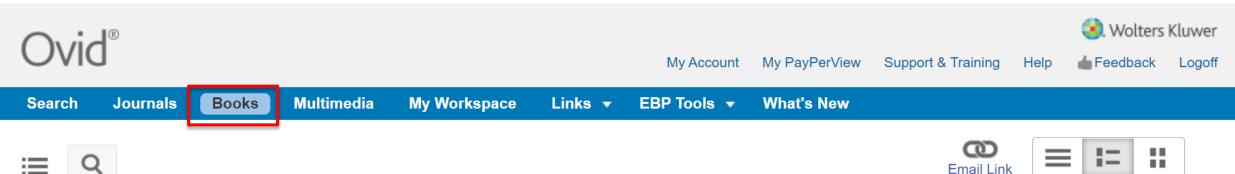
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Nonpharmacological

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Cognitive-

Behavioral

Therapy for

Insomnia (CBTi)

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[+] Narcolepsy

[+] Sleep-Related Breathing Disorders

[+] Circadian Rhythm

Prescription medicines are rigorously tested in clinical trials; therefore, they hold an advantage over the virtually untested OTCs. To attain FDA approval as a hypnotic, a medication must be safe and effective. Most hypnotic medications are approved for short-, not long-term, use. Exceptions include zolpidem-modified release, eszopiclone, and ramelteon; all of which are approved for long-term therapy. When properly used, hypnotics can provide immediate and adequate relief from sleeplessness. Insomnia, however, usually returns upon discontinuation of dosing.

Nonpharmacological Treatment with Cognitive-Behavioral Therapy for Insomnia (CBTi)

This treatment modality combines behavioral and cognitive techniques to overcome dysfunctional sleep behaviors and misperceptions, distorted, disruptive thoughts about sleep. The therapist begins with a careful clinical interview to assess the insomnia's etiology, chronicity, severity, associations, and comorbid conditions. A treatment plan is then designed using cognitive and behavioral techniques deemed relevant and appropriate. These may include: universal sleep hygiene, stimulus control therapy, sleep restriction therapy, relaxation therapies and biofeedback, cognitive therapy, and occasionally, paradoxical intention.

Studies repeatedly show significant, sustained improvement in sleep symptoms with CBTi. Improvements include reduced wakefulness duration, decreased number of awakenings, and shorter latency to sleep onset. Short-term benefits are similar to that of medication but CBTi tends to have lasting benefits, even 36 months after treatment. With cessation of the medication insomnia frequently returns and is sometimes accompanied by rebound insomnia. CBTi has not been shown to produce any adverse effects. There are no established "best practice" guidelines for length or quantity of sessions. CBTi, however, is not without limitations. Most data do not compare the efficacy of the individual components (described below) of CBTi. However, sleep hygiene education alone does not appear to improve sleep. Intuitively, the multi-component approach addresses

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Disorder

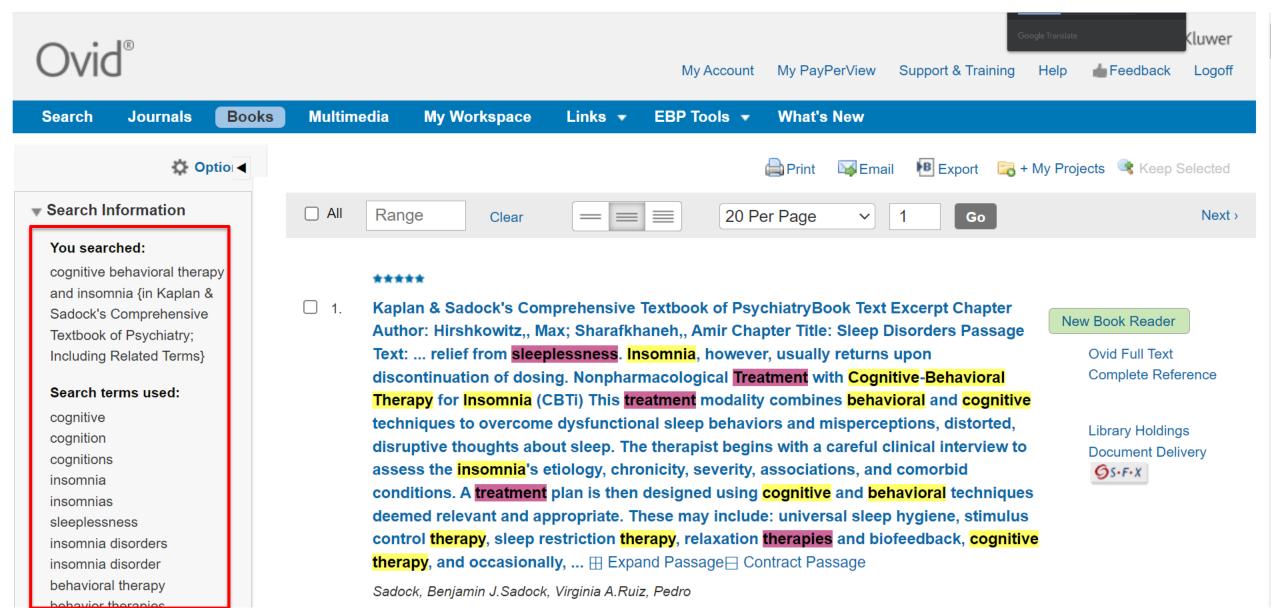
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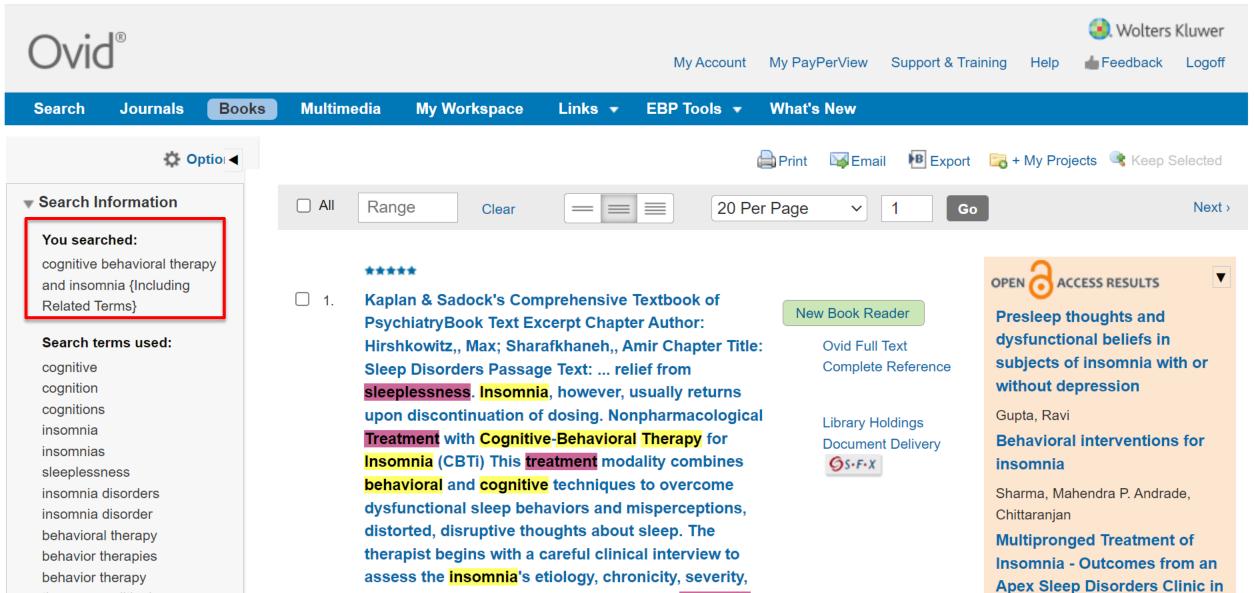
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Studies repeatedly show significant, sustained improvement in sleep symptoms with CRT. Improvements include reduced wakefulness duration

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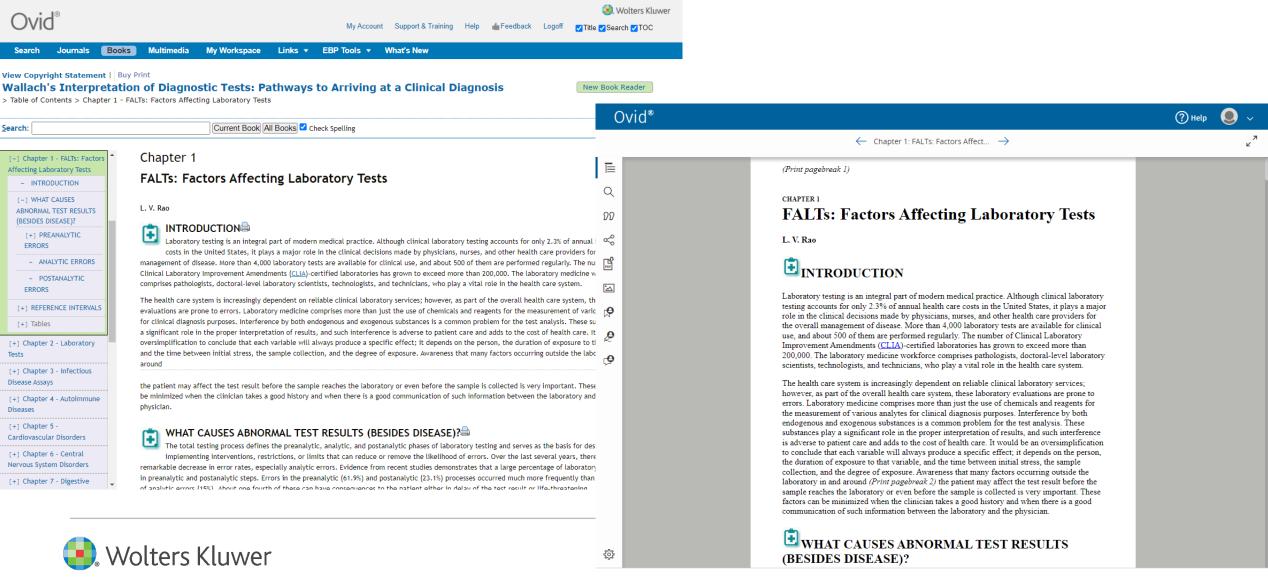
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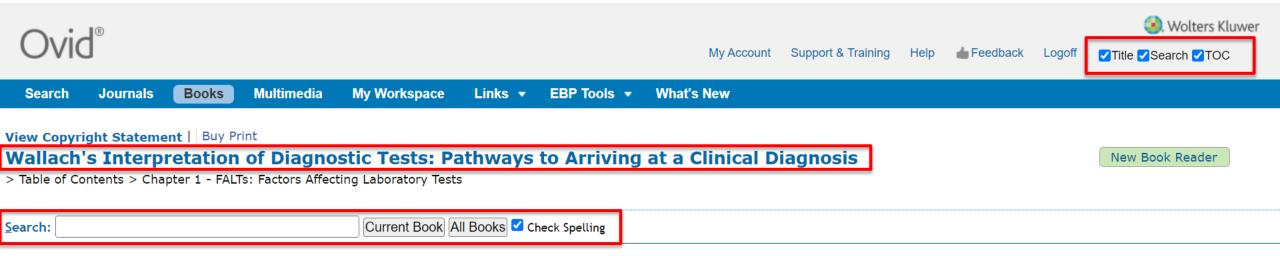
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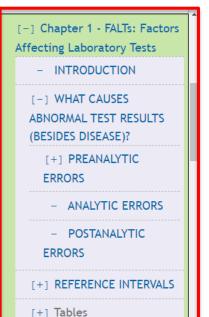
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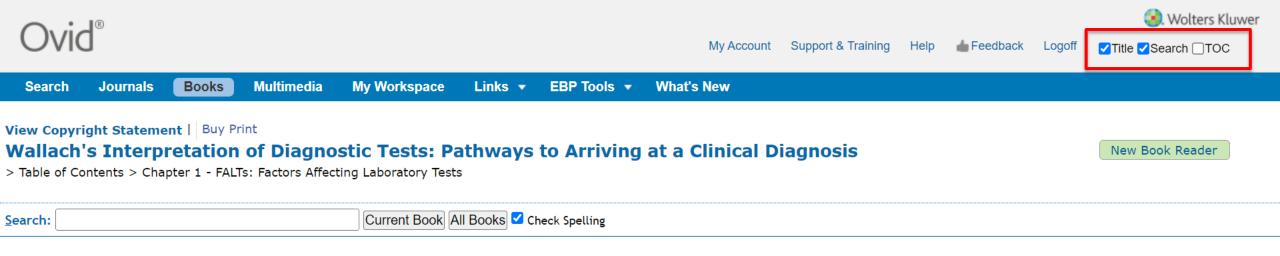
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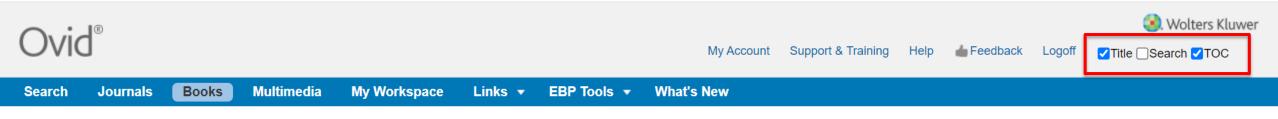
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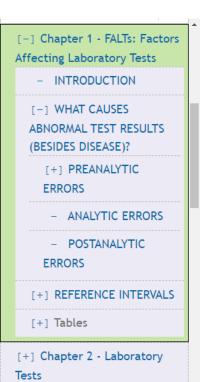
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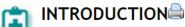
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FALTs: Factors Affecting Laboratory Tests

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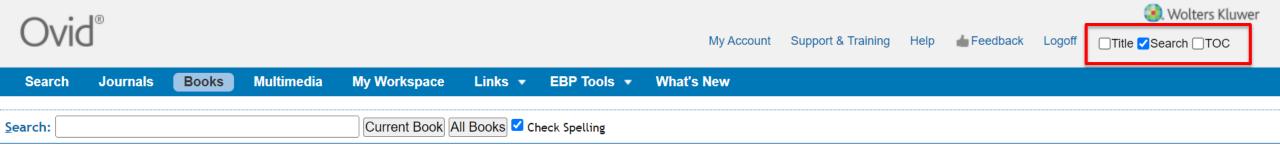


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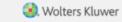
WHAT CAUSES ABNORMAL TEST RESULTS (BESIDES DISEASE)?

doctoral-level laboratory scientists, technologists, and technicians, who play a vital role in the health care system.

The total testing process defines the preanalytic, analytic, and postanalytic phases of laboratory testing and serves as the basis for designing and implementing interventions, restrictions, or limits that can reduce or remove the likelihood of errors. Over the last several years, there has been a remarkable decrease in error rates, especially analytic errors. Evidence from recent studies demonstrates that a large percentage of laboratory errors occur in preanalytic and postanalytic steps. Errors in the preanalytic (61.9%) and postanalytic (23.1%) processes occurred much more frequently than occurrences of analytic errors

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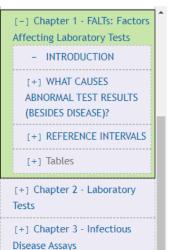
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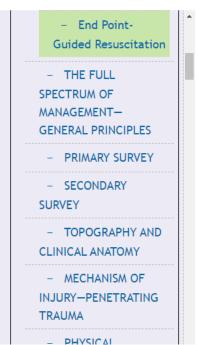
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End Point-Guided Resuscitation

Optimal resuscitation is imperative in the management of any patient in the acute care setting. It is a dynamic process that requires a continued assessment process to ensure that the targeted end points of resuscitation are achieved. Urine output, lactate levels, base deficit, gastric intramucosal pH, and direct determination of oxygen delivery and consumption are all

proposed markers for or end points of resuscitation, although the optimal end points of resuscitation in trauma patients continues to be debated. Irrespective of the end point chosen, the overarching goal in the resuscitation of patients is correction of inadequate organ perfusion and tissue oxygenation. Inability to achieve adequate organ perfusion and tissue oxygenation can result in anaerobic metabolism with the development of acidosis and an associated oxygen debt. Scalea et al. reported that inadequate tissue perfusion can exist even when some of the conventional end points (e.g., blood pressure, heart rate, and urine output) of resuscitation are normal.

THE FULL SPECTRUM OF MANAGEMENT—GENERAL PRINCIPLES

As underscored above, the core principle of acute care surgery is expeditious and effective medical/surgical management, with early diagnosis an essential element. Many of the general principles of trauma management are applicable in the nontrauma setting. However, each specific disease entity has its own unique diagnostic/management paradigm that is covered throughout the textbook. Depending on the regional geography, the disease (nontrauma) entities that are most commonly encountered by the acute care surgeon are outlined in Table 1.2.

The severity of the disease and the stage of presentation, along with the status of the patient (e.g., hemodynamic stability), will often dictate the specific course of management

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End Point-Guided Resuscitation

Optimal resuscitation is imperative in the management of any patient in the acute care setting. It is a dynamic process that requires a continued assessment process to ensure that the targeted end points of resuscitation are achieved. Urine output, lactate levels, base deficit, gastric intramucosal pH, and direct determination of oxygen delivery and consumption are all

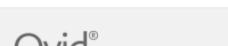
proposed markers for or end points of resuscitation, although the optimal end points of resuscitation in trauma patients continues to be debated. Irrespective of the end point chosen, the overarching goal in the resuscitation of patients is correction of inadequate organ perfusion and tissue oxygenation. Inability to achieve adequate organ perfusion and tissue oxygenation can result in anaerobic metabolism with the development of acidosis and an associated oxygen debt. Scalea et al. reported that inadequate tissue perfusion can exist even when some of the conventional end points (e.g., blood pressure, heart rate, and urine output) of resuscitation are normal.

THE FULL SPECTRUM OF MANAGEMENT—GENERAL PRINCIPLES

As underscored above, the core principle of acute care surgery is expeditious and effective medical/surgical management, with early diagnosis an essential element. Many of the general principles of trauma management are applicable in the nontrauma setting. However, each specific disease entity has its own unique diagnostic/management paradigm that is covered throughout the textbook. Depending on the regional geography, the disease (nontrauma) entities that are most commonly encountered by the acute care surgeon are outlined in Table 1.2.

The severity of the disease and the stage of presentation, along with the status of the patient (e.g., hemodynamic stability), will often dictate the specific course of management

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> Table of Contents > Section 1 - Fundamental Principles > Chapter 1 - Acute Care Surgery: General Principles > Tables > TABLE 1.2 COMMONLY ENCOUNTERED DISEASE ENTITIES

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Appendicitis Intestinal obstruction Diverticulitis and deep (cartilage) tissue abscesses Necrotizing soft tissue infection Biliary diseases

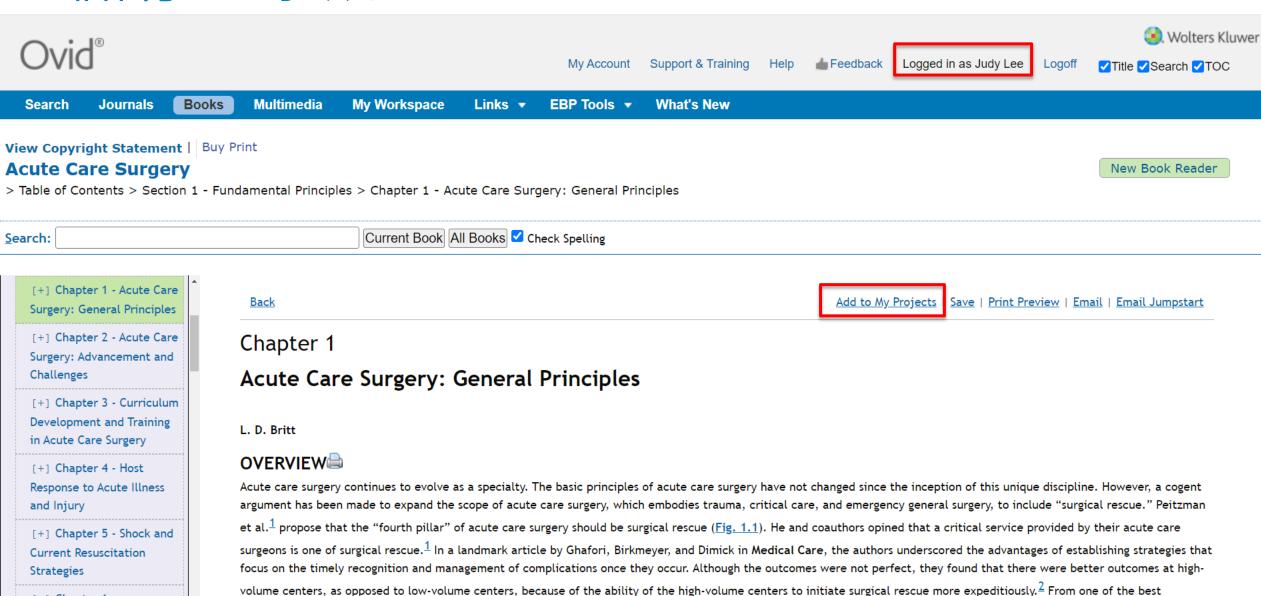
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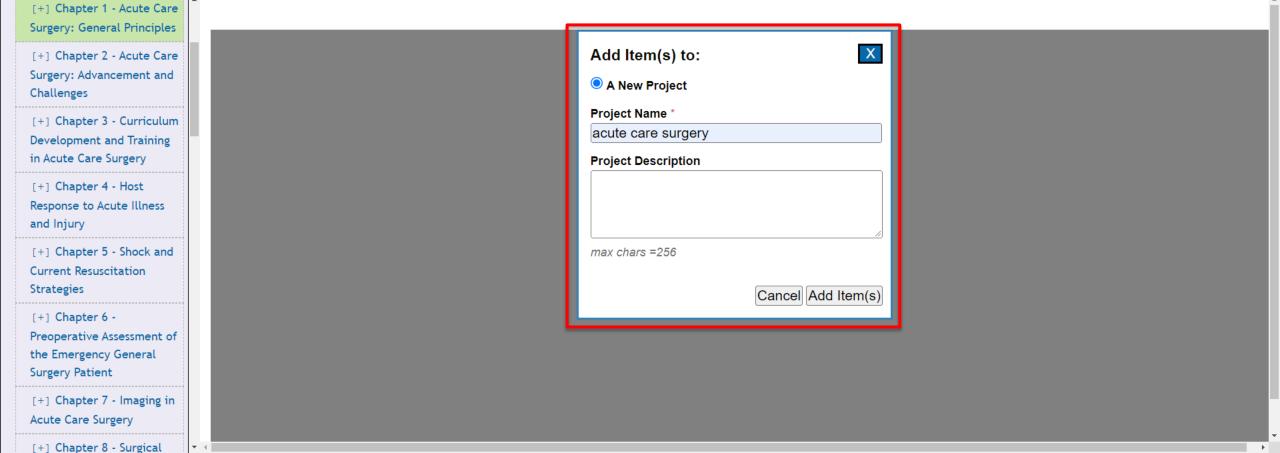
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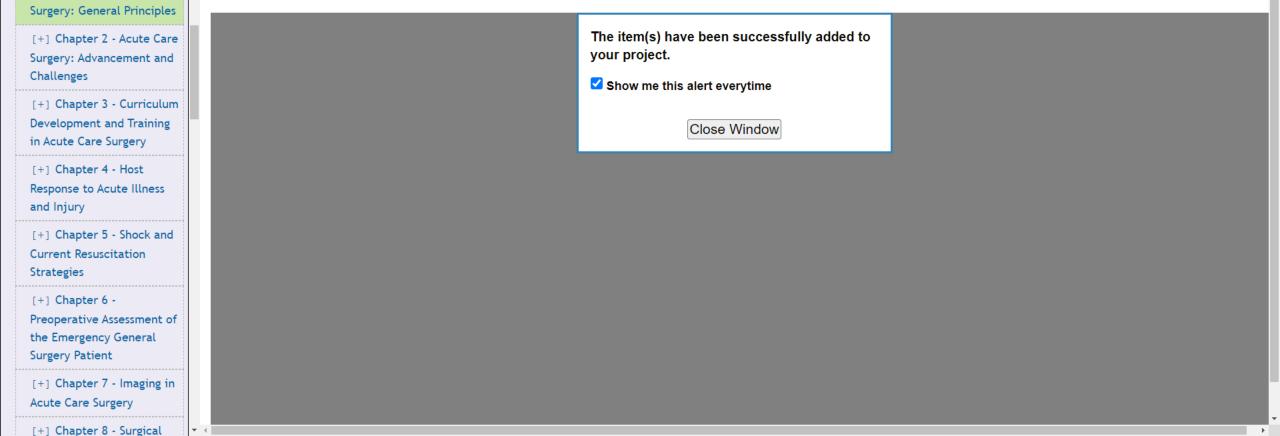
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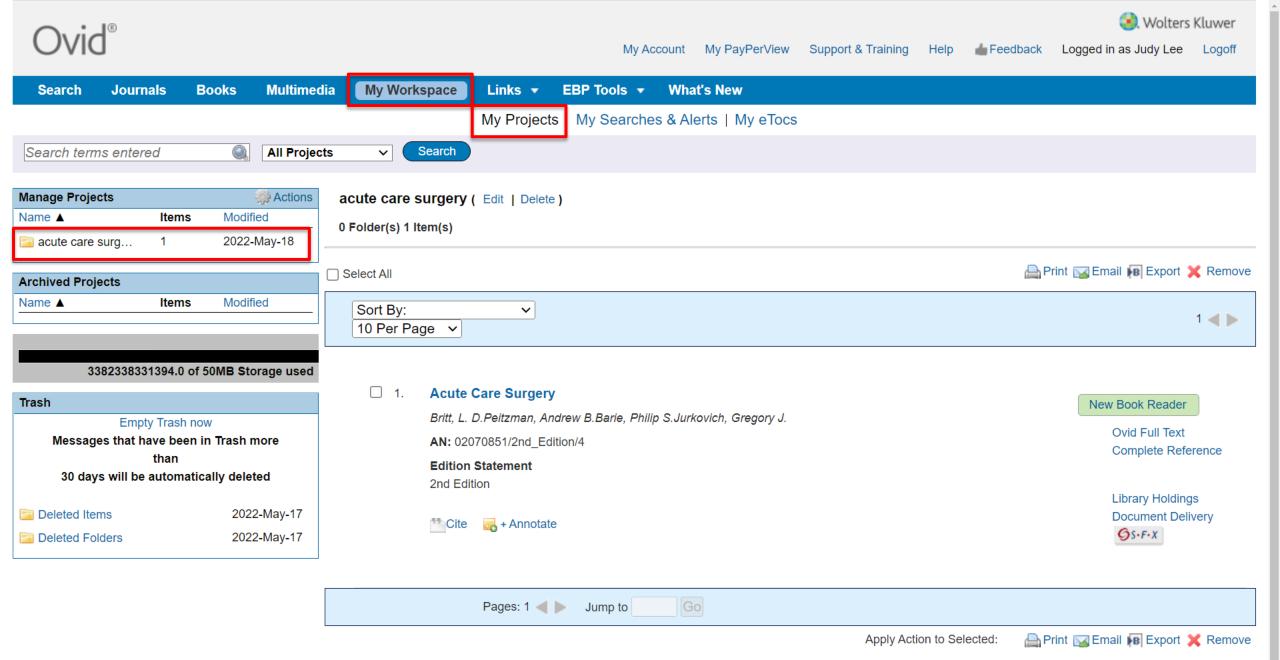
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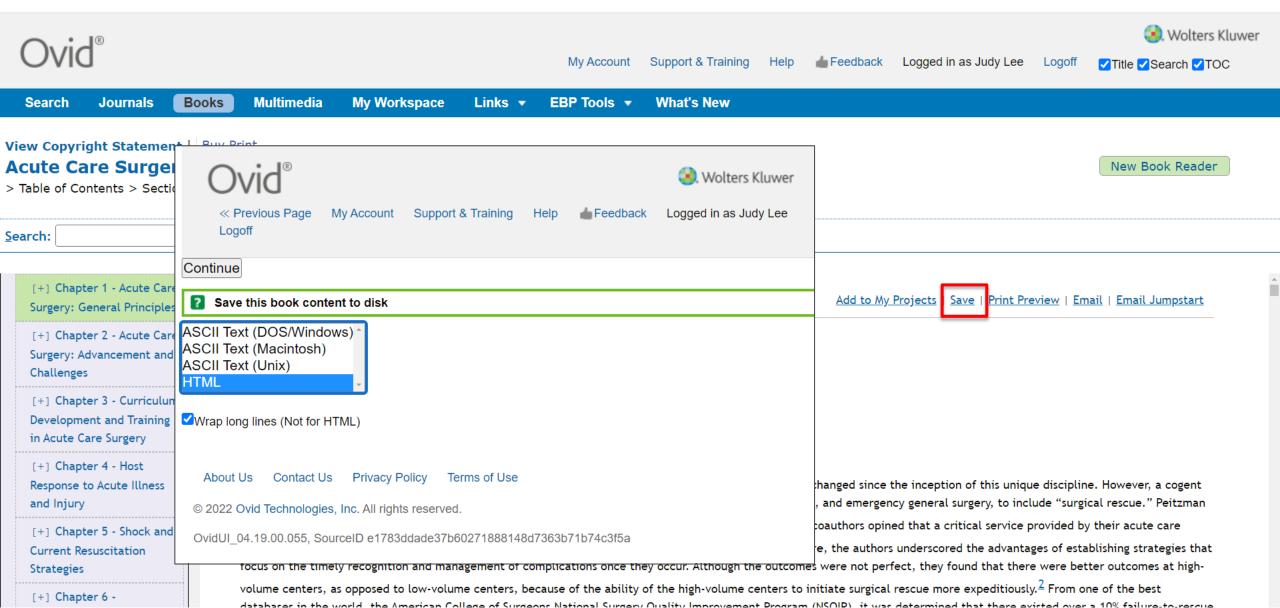
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Chapter 1

Acute Care Surgery: General Principles

L. D. Britt

OVERVIEW

Acute care surgery continues to evolve as a specialty. The basic principles of acute care surgery have not changed since the inception of this unique discipline. However, a cogent argument has been made to expand the scope of acute care surgery, which embodies trauma, critical care, and emergency general surgery, to include "surgical rescue." Peitzman et al. 1 propose that the "fourth pillar" of acute care surgery should be surgical rescue. (Fig. 1.1). He and coauthors opined that a critical service provided by their acute care surgeons is one of surgical rescue. 1 In a landmark article by Ghafori, Birkmeyer, and Dimick in Medical Care, the authors underscored the advantages of establishing strategies that focus on the timely recognition and management of complications once they occur. Although the outcomes were not perfect, they found that there were better outcomes at high-volume centers, as opposed to low-volume centers, because of the ability of the high-volume centers to initiate surgical rescue more expeditiously. From one of the best databases in the world, the American College of Surgeons National Surgery Quality Improvement Program (NSQIP), it was determined that there existed over a 10% failure-to-rescue rate in the surgical population. Twenty percent of patients with the greatest risk for developing postoperative complications account for approximately 90% of failure to rescue. With complications of medical or surgical care being one of the most frequent hospital-based diagnoses (exceeding even cholecystitis, intestinal obstruction, and appendicitis), acute care surgery, undoubtedly, offers the specialty expertise needed to provide the hospital surgical rescue required to optimally address these complications. Early intervention by a high-performance surgical team provides the best opportunity to reduce failure-to-rescue rates. That high-performance surgery service. In fact, the often quoted statements from Dr. William Steward Halsted that "... every important hospital should have on its resident sta

FIGURE 1.1 The four pillars of acute care surgery.

ACUTE CARE SURGERY-CORE PRINCIPLES

The overarching axiom in acute care surgery is expedient assessment and early intervention. Prioritization of management—in an attempt to quickly address disease and injury that can rapidly result in severe morbidity—has always been the cornerstone of all aspects of medicine. Such an approach, however, does not undermine or devalue the merits of comprehensive assessments. Emergency operative intervention, precluding a comprehensive assessment and preoperative clearance, is indicated in many circumstances. In such cases, the comprehensive evaluation is completed after stabilization of the patient. While the importance of preoperative clearance cannot be overemphasized, it often cannot (and should not) be implemented in the acute care setting for a risk-benefit analysis of delaying surgical intervention would be unfavorable and detrimental to the health status of the patient. However, when appropriate, a systematic approach to preoperative clearance should be done.

P.2

The general principles of acute care surgery, in the nontrauma setting, must be applicable in the following states of pathogenesis: (1) inflammation, (2) perforation, (3) obstruction, (4) bleeding, (5) ischemia, (6) necrosis, (7) hypoxia, and (8) infection.

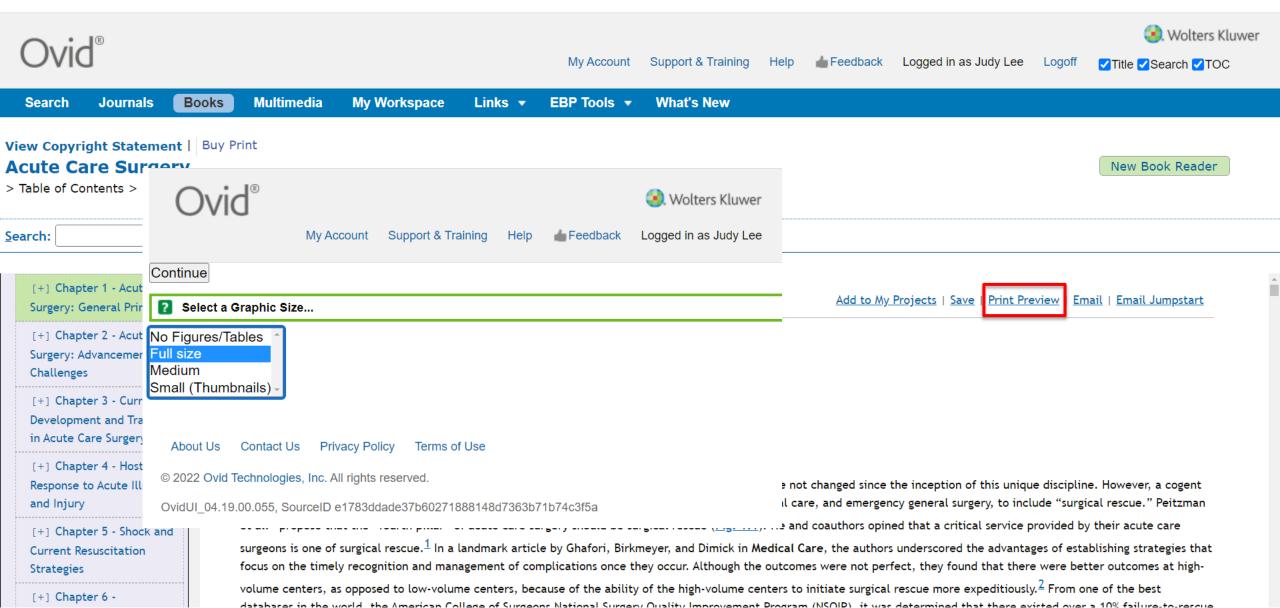
CORE MANAGEMENT PRINCIPLES (THE 4 ES)

The "4 Es" of the core management principles are the following:

- · Expeditious initial assessment
- · End point-guided resuscitation

TABLE 1.1 DIFFERENT FORMS OF PATHOGENESIS IN ACUTE CARE SURGERY		
• INFLAMMATION	• PERFORATION	• OBSTRUCTION
Appendicitis, diverticulitis, cholecystitis, cholangitis, pancreatitis, gastritis, gastric and duodenal ulcer disease	Hollow visceral rupture	Airway
	Esophageal Gastric	Aspiration Foreign body
	Duodenal	Esophagus

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Chapter 1

Acute Care Surgery: General Princ

L. D. Britt

OVERVIEW

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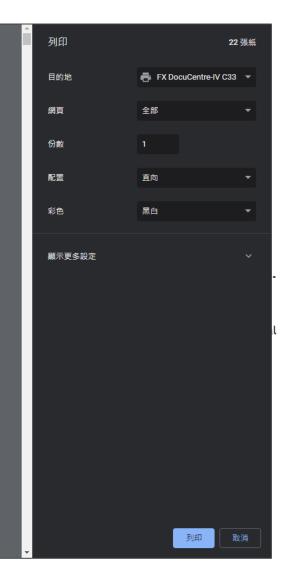
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Acute Care Surgery: General Principles

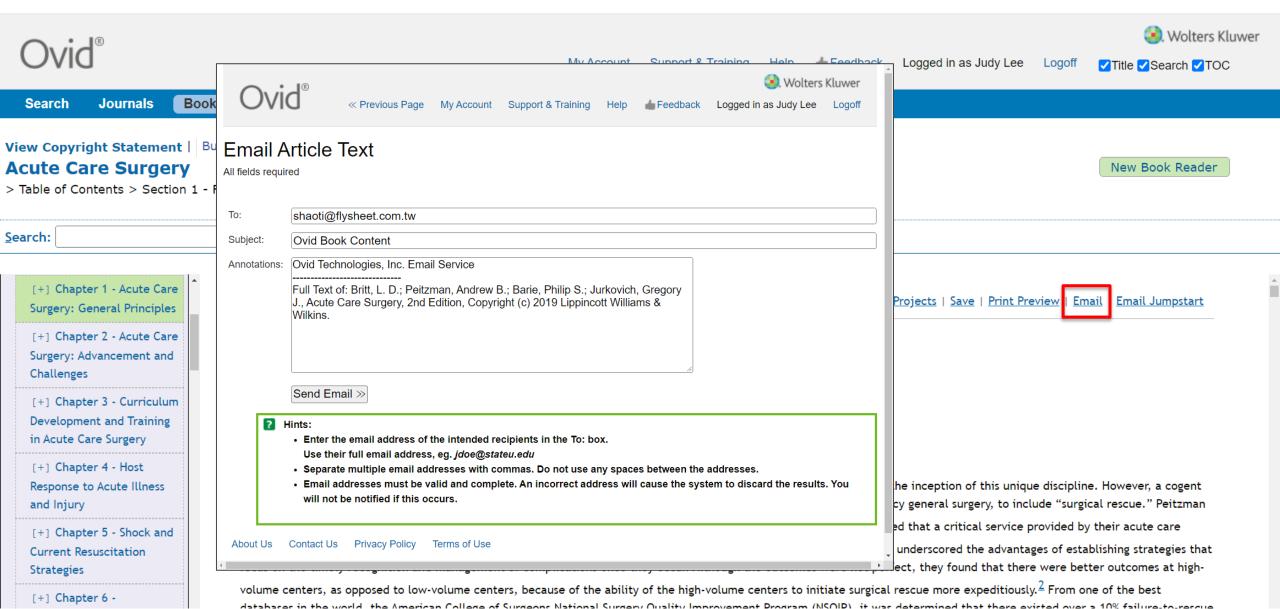
L. D. Britt

OVERVIEW

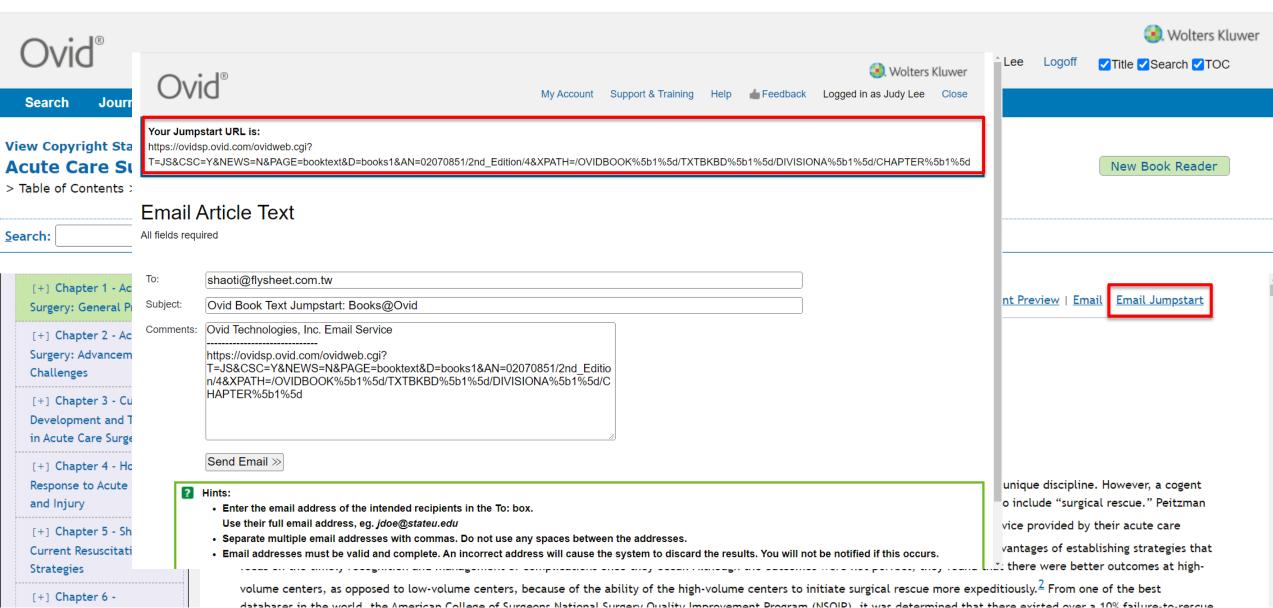
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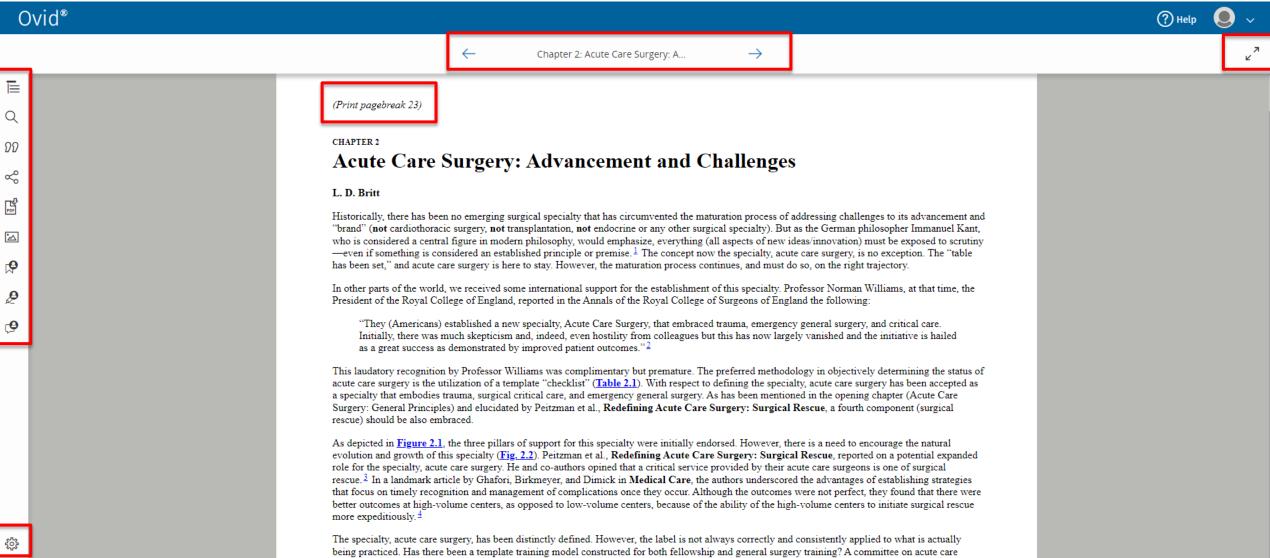
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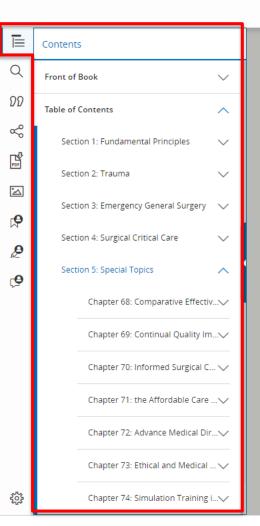




Chapter 68: Comparative Effectiv...







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CHAPTER 68

Comparative Effectiveness Research in Acute Care Surgery

Melissa Ann Hornor Clifford V. Ko

All surgeons strive to deliver care based on the best evidence, making it imperative for surgeons to understand the evidence that drives their decisionmaking around indications for surgery, surgical technique, and expected outcomes. Comparative effectiveness research (CER) has emerged as an ideal research method for testing whether surgical interventions work in the real world. CER seeks to investigate the effectiveness of an intervention in specific patient populations, or what may be considered "best practice" for an individual patient, while traditional clinical research, such as a randomized controlled trial (RCT), often investigates the efficacy of an intervention in a tightly controlled environment. While RCTs have the ability to produce the highest level of evidence, investigators may run into serious issues in terms of feasibility, generalizability, patient selection, and time elapsed prior to integration into clinical practice. CER has helped move surgical research forward by adapting traditional clinical research study designs so that they work in real-world situations.

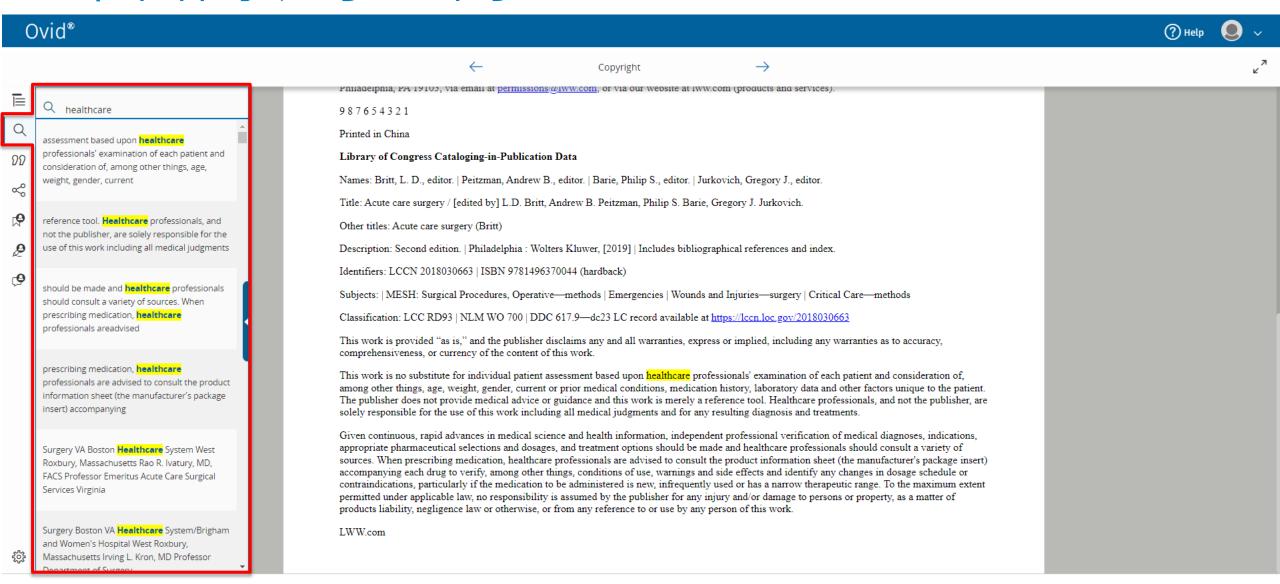
In brief, CER measures the effectiveness of a clinical intervention by comparing active treatments within populations that are representative of usual practice in an evidence-based manner, providing patients, providers, and policymakers with the data required to make informed choices. In point of fact, the Institute of Medicine defines CER as the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. 2

The US health care system is often found to produce inferior health outcomes despite having the highest per capita spending on health care in the world. As such, CER has been identified on the federal level as an effective tool to address the gaps in quality and efficiency in the US health care system. 3.4 The American Reinvestment and Recovery Act of 2008 allocated \$1.1 billion in grant awards to go toward supporting this research, 2 and the Patient Protection and Affordable Care Act of 2010 created the Patient-Centered Outcomes Research Institute (PCORI), an organization that sets national priorities for CER topics with an estimated \$500 million annual budget. PCORI emphasizes the critical importance of maintaining a patient-centered perspective when conducting CER, with a mission to produce highintegrity research that is guided by patients, caregivers, and the broader health care community. 6 CER has become a high priority for surgical researchers, as evidenced by the increase in CER publications in acute care surgery in the last decade (Fig. 68.1).

Comparative effectiveness research is viewed as an extremely worthwhile endeavor within acute care surgery and throughout the medical community. At this juncture, it is essential to understand the advantages, disadvantages, and consequences of increasing the use of CER within acute care surgery. This chapter provides the reader with a comprehensive understanding of CER by first touching on study designs within CER, how to grade and rank each study design, and finally, how to approach creating your own CER study within acute care surgery. The chapter ends with a small handful of recently published clinical studies (randomized controlled and observational trials) in acute care surgery that are meant to provide an example of the types of studies that have been found to be beneficial for clinical surgical care.

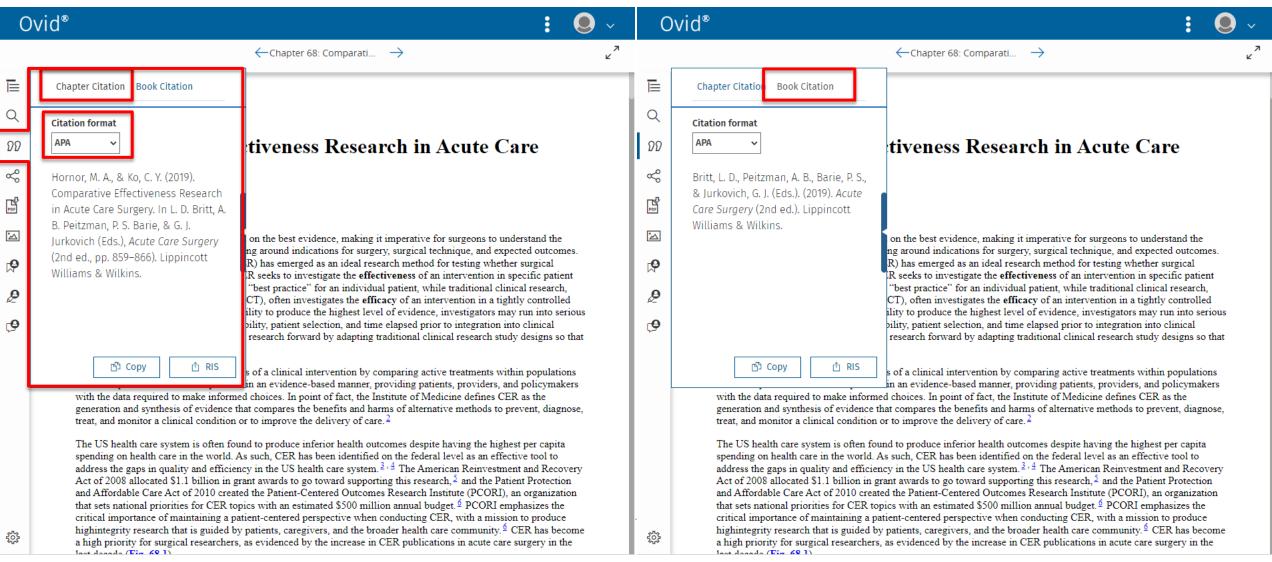
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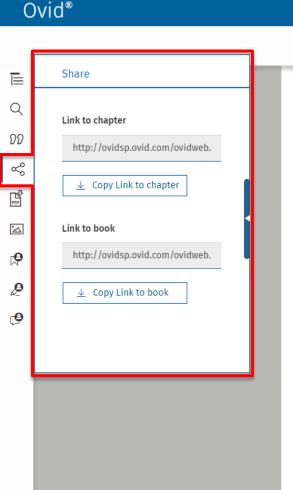


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Melissa Ann Hornor Clifford Y. Ko

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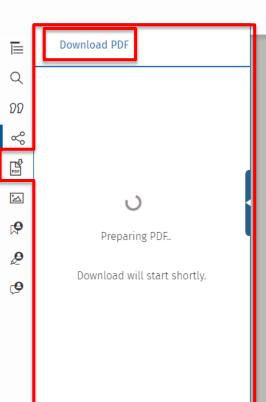
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RANDOMIZED CONTROLLED TRIALS

Randomized controlled trials are designed to provide the best possible clinical evidence on the efficacy of a treatment or intervention-put simply, this is achieved by testing the treatment or intervention in a very tightly controlled environment. This is executed through randomized selection of the sample populations and blinding of both the researchers and the patient to the intervention. According to the National Institutes of Health, an experimental treatment is likely best tested through a clinical trial in four phases (Table 68.1). Phase I tests the experimental treatment in a small test group (20-80 people) to evaluate safety and monitor for side effects; phase II tests the new treatment on a slightly larger group (100-300 people) to determine the efficacy of the treatment; phase III tests the treatment in a larger sample (1,000-3,000 people) to confirm efficacy, monitor for side effects, and compare the experimental treatment to existing treatments; and phase IV is the final phase where the experimental treatment's risks. benefits, and optimal use are refined.

There are many obstacles to the successful completion of randomized trials of surgical interventions, some of which are magnified when researching interventions relevant to acute care surgery. Emergency surgery requires urgent lifesaving treatment of sometimes rare conditions, which makes recruitment, consent, and randomization quite difficult. In surgery, it frequently can be difficult for

recently published clinical studies (randomized controlled and observational trials) in acute care surgery that are meant to provide an example of the types of studies that have been found to be beneficial for clinical surgical care.

Section 5: Special Topics

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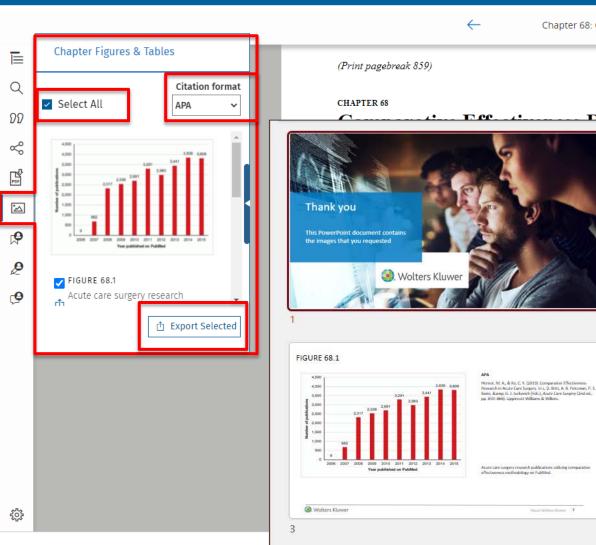
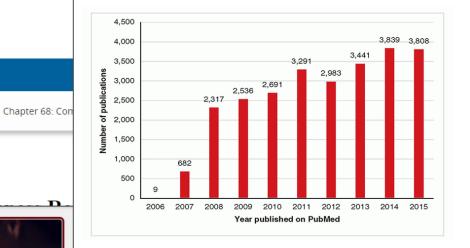


FIGURE 68.1



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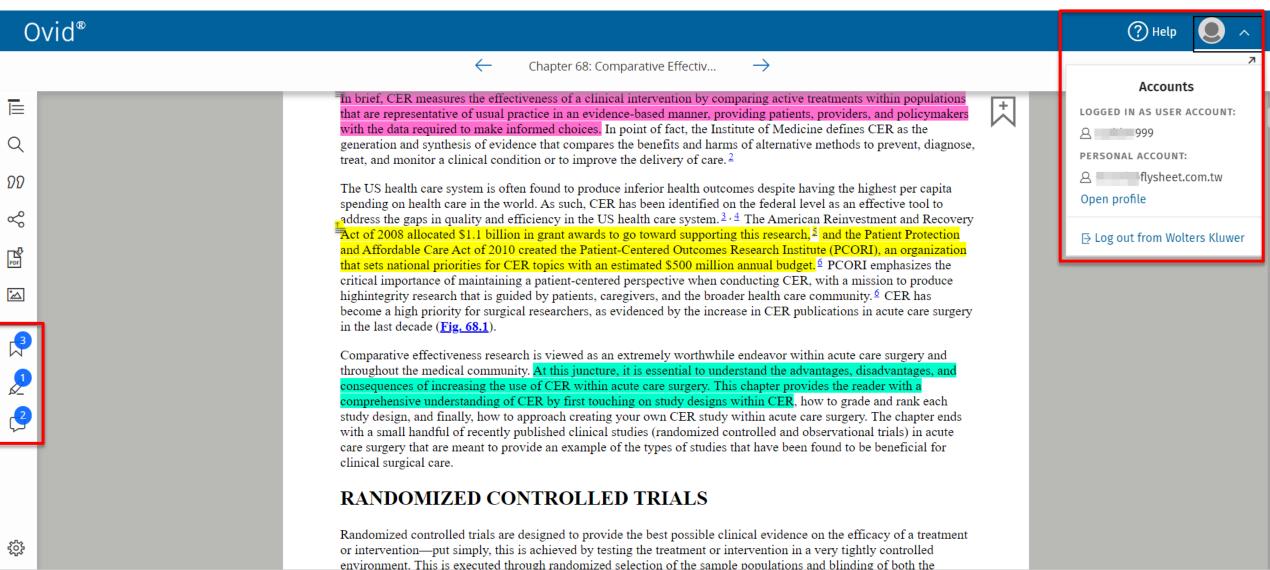
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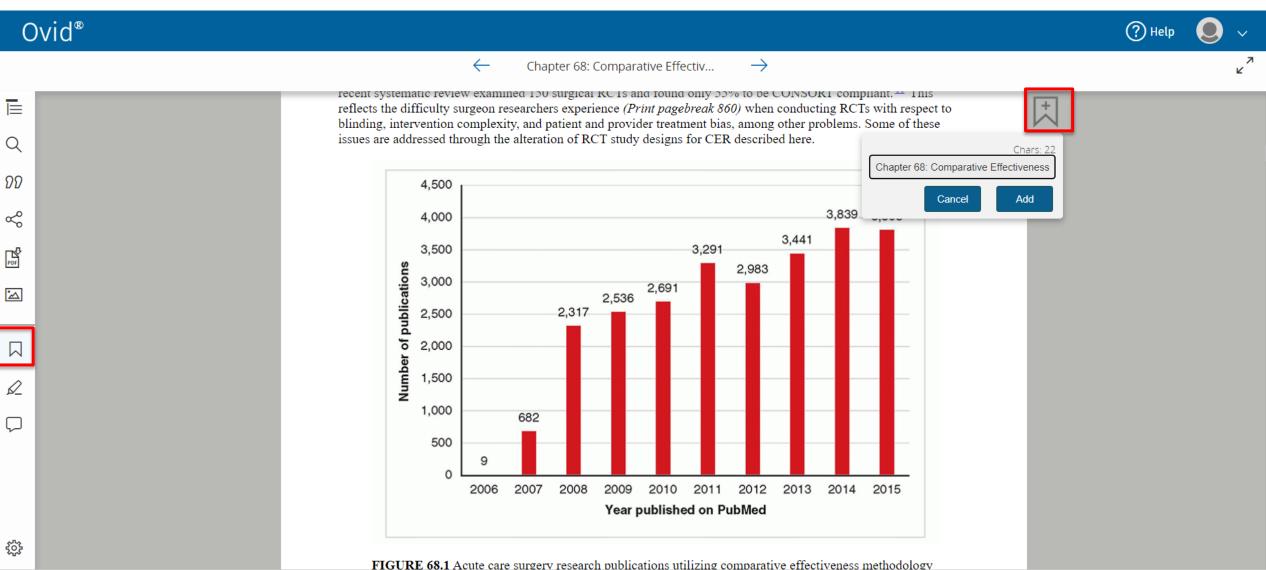
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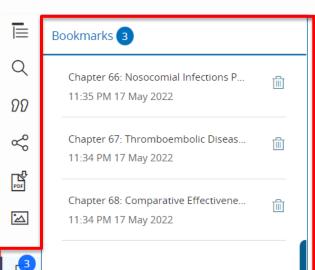








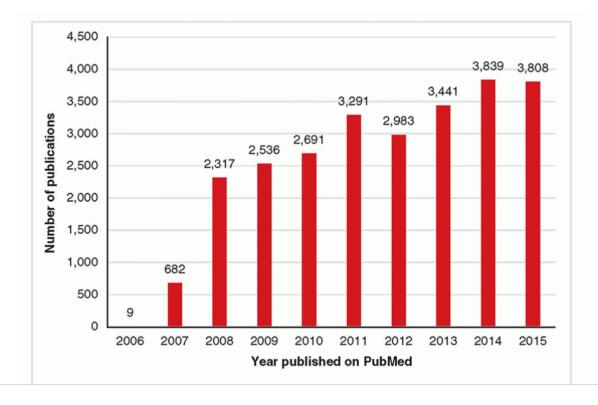
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researcher, the postintervention care provider, and the study patient to the intervention—especially when comparing surgical vs medical treatments. ⁷ · ⁸ In point of fact, CER methodologies can assess outcomes between highly preference-sensitive treatment decisions and can provide important data on effectiveness.



There are several factors to keep in mind when evaluating the quality of a RCT. The CONSORT (Consolidated Standards of Reporting Trials) statement is an evidence-based, minimum set of recommendations for researchers to report when conducting RCTs. This statement emphasizes the reporting of randomization and assignment to treatment groups, masking (blinding) of subjects, timing until follow-up, and data analysis methodology. Occurringly, a recent systematic review examined 150 surgical RCTs and found only 55% to be CONSORT compliant. This reflects the difficulty surgeon researchers experience (*Print pagebreak 860*) when conducting RCTs with respect to blinding, intervention complexity, and patient and provider treatment bias, among other problems. Some of these issues are addressed through the alteration of RCT study designs for CER described here.

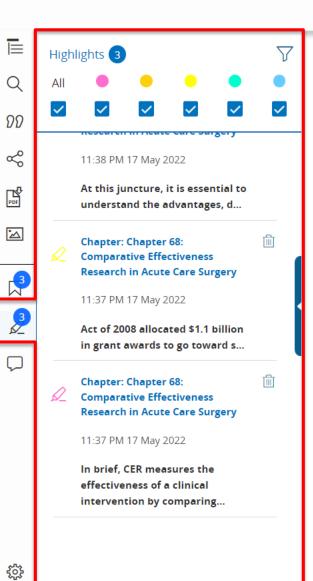


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environment. While RCTs have the ability to produce the highest level of evidence, investigators may run into serious issues in terms of feasibility, generalizability, patient selection, and time elapsed prior to integration into clinical practice. CER has helped move surgical research forward by adapting traditional clinical research study designs so that they work in real-world situations.

In brief, CER measures the effectiveness of a clinical intervention by comparing active treatments within populations that are representative of usual practice in an evidence-based manner, providing patients, providers, and policymakers with the data required to make informed choices. In point of fact, the Institute of Medicine defines CER as the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. ²

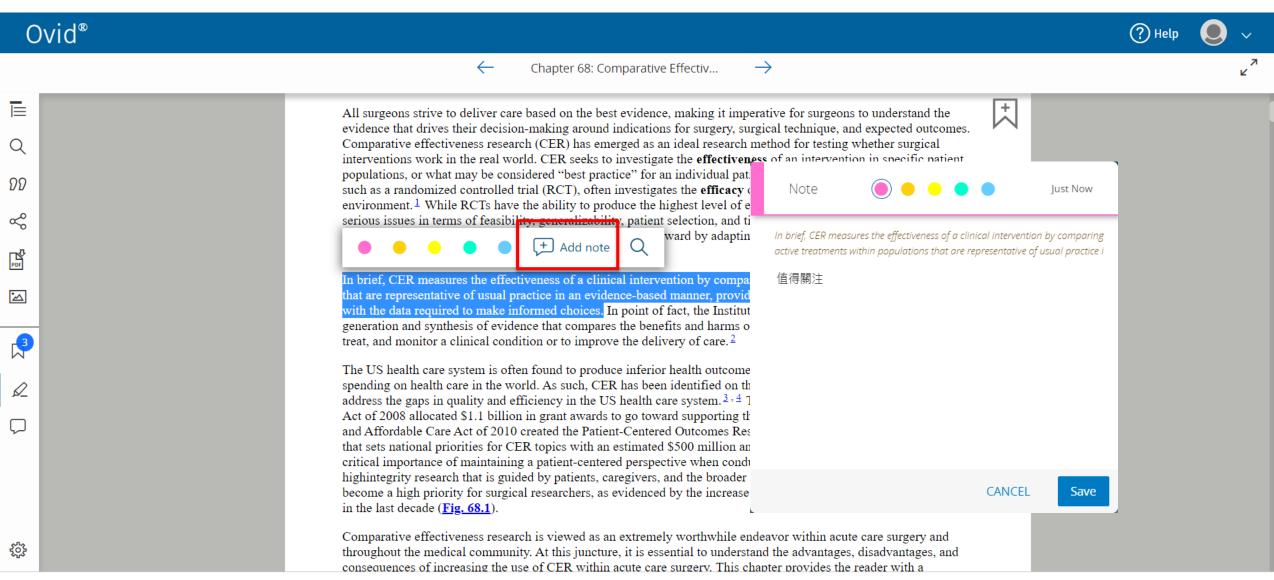
The US health care system is often found to produce inferior health outcomes despite having the highest per capita spending on health care in the world. As such, CER has been identified on the federal level as an effective tool to address the gaps in quality and efficiency in the US health care system. ³ · ⁴ The American Reinvestment and Recovery Act of 2008 allocated \$1.1 billion in grant awards to go toward supporting this research, ⁵ and the Patient Protection and Affordable Care Act of 2010 created the Patient-Centered Outcomes Research Institute (PCORI), an organization that sets national priorities for CER topics with an estimated \$500 million annual budget. ⁶ PCORI emphasizes the critical importance of maintaining a patient-centered perspective when conducting CER, with a mission to produce highintegrity research that is guided by patients, caregivers, and the broader health care community. ⁶ CER has become a high priority for surgical researchers, as evidenced by the increase in CER publications in acute care surgery in the last decade (Fig. 68.1).

Comparative effectiveness research is viewed as an extremely worthwhile endeavor within acute care surgery and throughout the medical community. At this juncture, it is essential to understand the advantages, disadvantages, and consequences of increasing the use of CER within acute care surgery. This chapter provides the reader with a comprehensive understanding of CER by first touching on study designs within CER, how to grade and rank each study design, and finally, how to approach creating your own CER study within acute care surgery. The chapter ends with a small handful of recently published clinical studies (randomized controlled and observational trials) in acute care surgery that are meant to provide an example of the types of studies that have been found to be beneficial for clinical surgical care.

RANDOMIZED CONTROLLED TRIALS

Randomized controlled trials are designed to provide the best possible clinical evidence on the efficacy of a treatment or intervention—put simply, this is achieved by testing the treatment or intervention in a very tightly controlled environment. This is executed through randomized selection of the sample populations and blinding of both the

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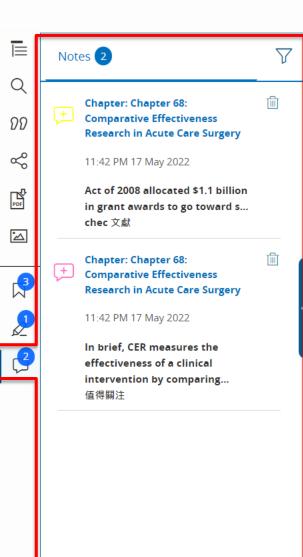






Clifford Y. Ko





All surgeons strive to deliver care based on the best evidence, making it imperative for surgeons to understand the evidence that drives their decision-making around indications for surgery, surgical technique, and expected outcomes. Comparative effectiveness research (CER) has emerged as an ideal research method for testing whether surgical interventions work in the real world. CER seeks to investigate the **effectiveness** of an intervention in specific patient populations, or what may be considered "best practice" for an individual patient, while traditional clinical research, such as a randomized controlled trial (RCT), often investigates the **efficacy** of an intervention in a tightly controlled environment. While RCTs have the ability to produce the highest level of evidence, investigators may run into serious issues in terms of feasibility, generalizability, patient selection, and time elapsed prior to integration into clinical practice. CER has helped move surgical research forward by adapting traditional clinical research study designs so that they work in real-world situations.

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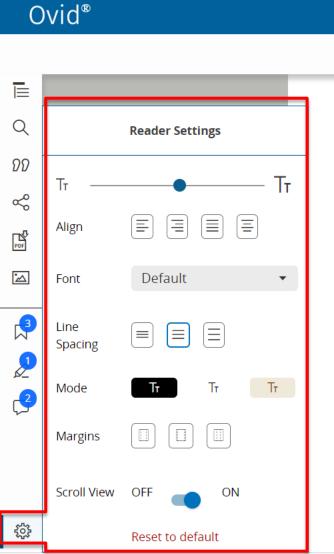
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Chapter 1: Acute Care Surgery: G...

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CHAPTER 1

Acute Care Surgery: General Principles

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L. D. Britt

OVERVIEW

Acute care surgery continues to evolve as a specialty. The basic principles of acute care surgery have not changed since the inception of this unique discipline. However, a cogent argument has been made to expand the scope of acute care surgery, which embodies trauma, critical care, and emergency general surgery, to include "surgical rescue." Peitzman et al. propose that the "fourth pillar" of acute care surgery should be surgical rescue (Fig. 1.1). He and coauthors opined that a critical service provided by their acute care surgeons is one of surgical rescue. In a landmark article by Ghafori, Birkmeyer, and Dimick in Medical Care, the authors underscored the advantages of establishing strategies that focus on the timely recognition and management of complications once they occur. Although the outcomes were not perfect, they found that there were better outcomes at high-volume centers, as opposed to lowvolume centers, because of the ability of the high-volume centers to initiate surgical rescue more expeditiously. From one of the best databases in the world, the American College of Surgeons National Surgery Quality Improvement Program (NSOIP), it was determined that there existed over a 10% failure-to-rescue rate in the surgical population. Twenty percent of natients with the greatest risk for developing postoperative complications account for approximately



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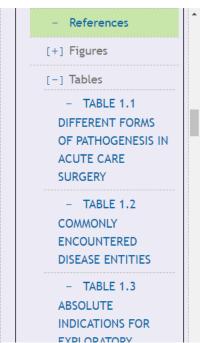
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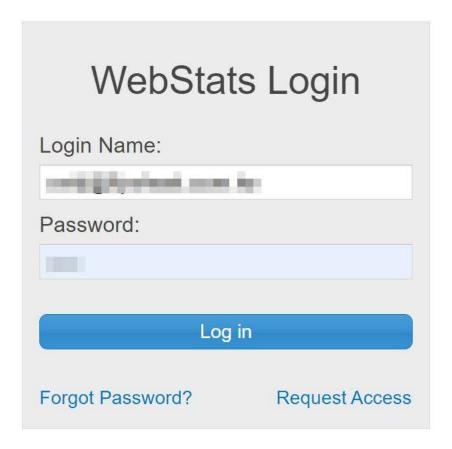
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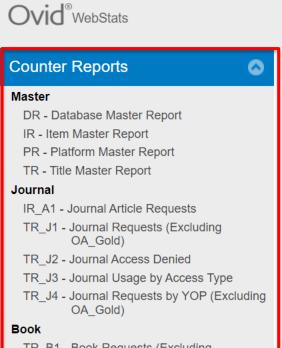
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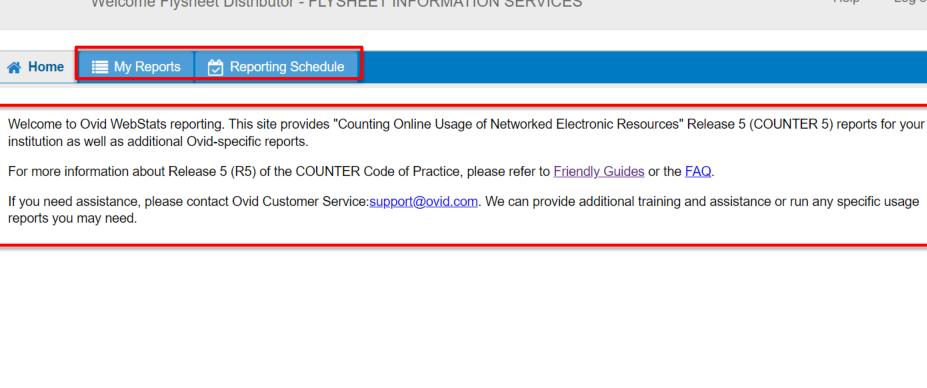
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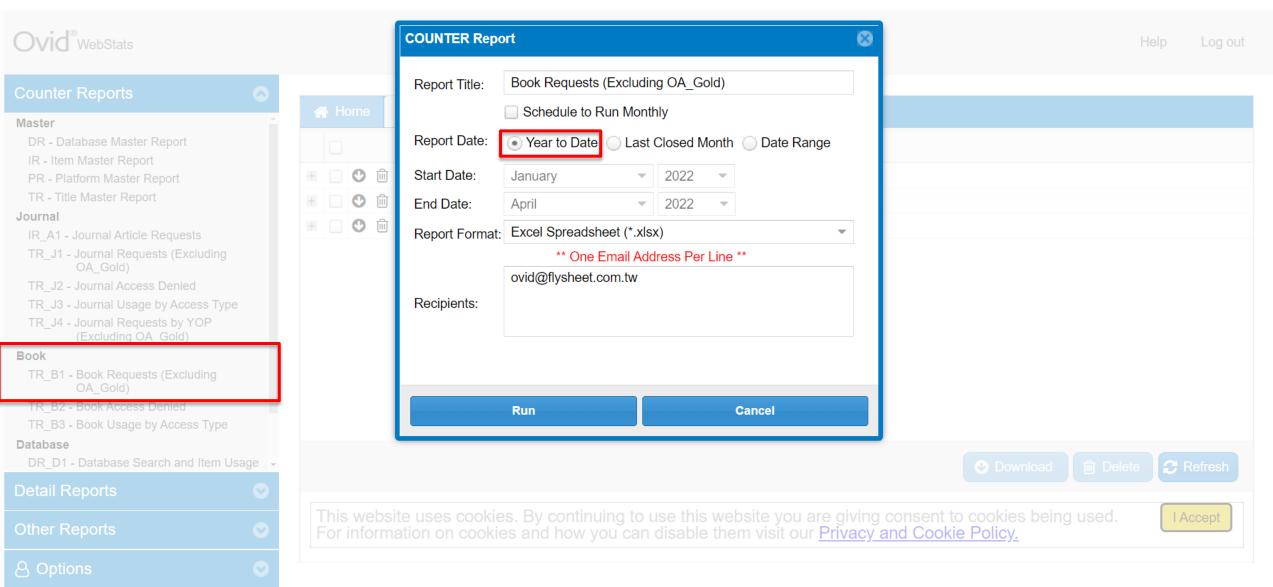


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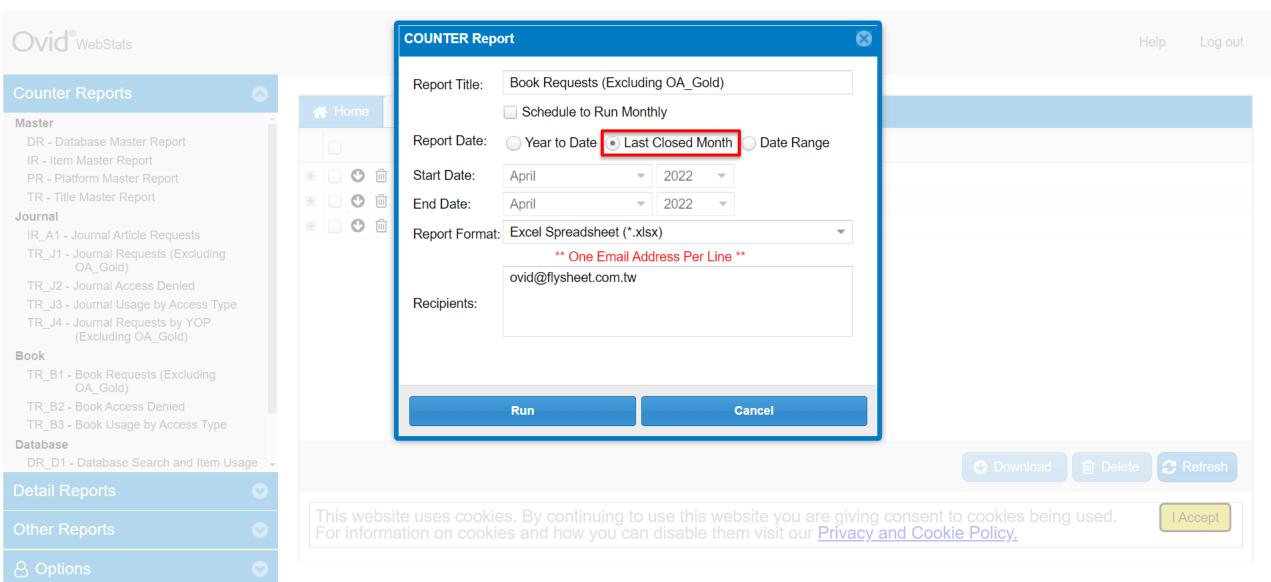
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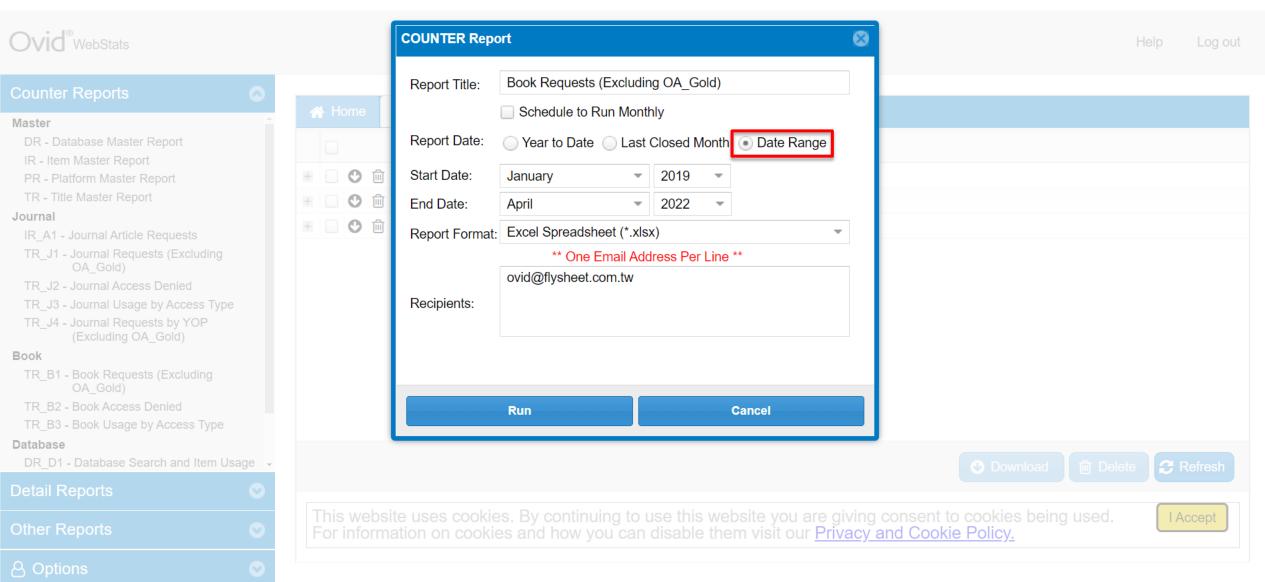
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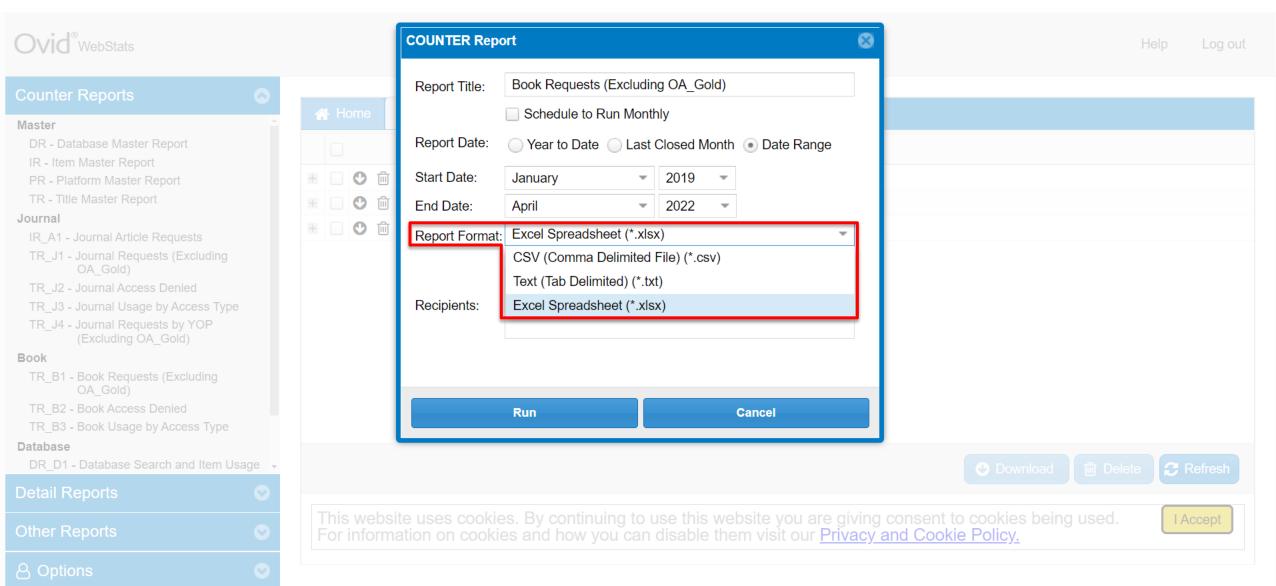
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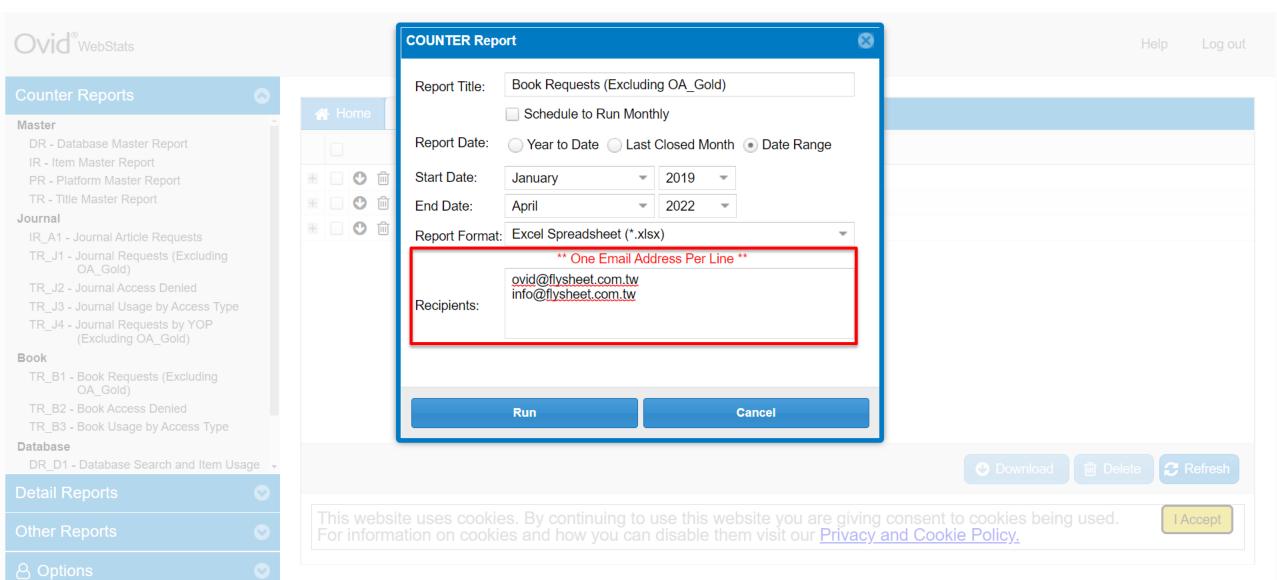
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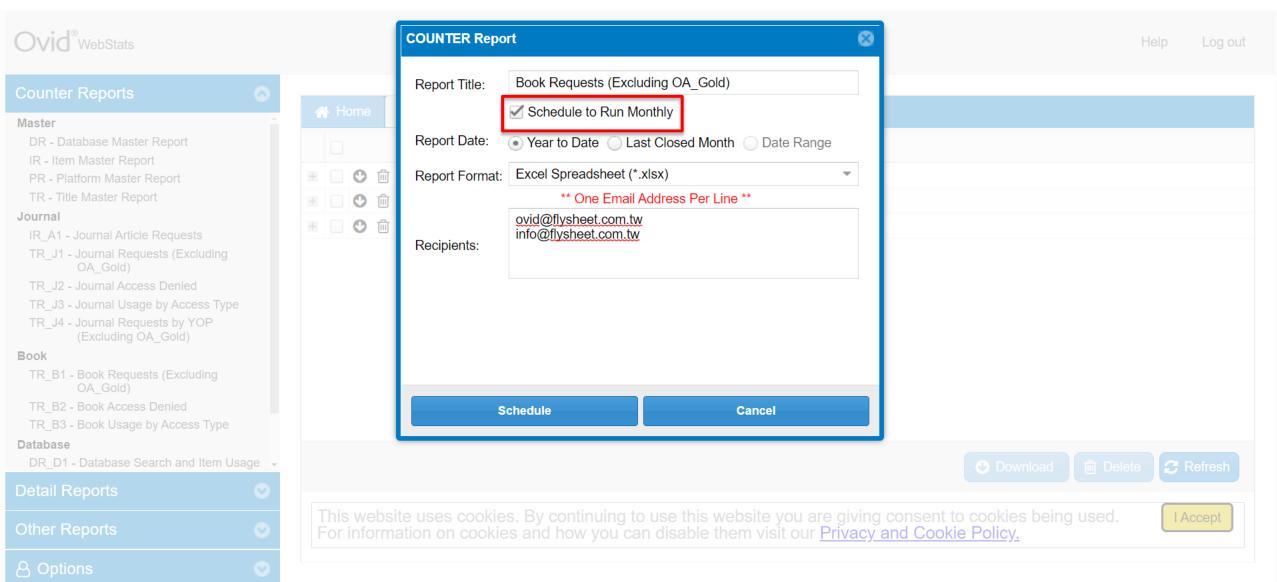


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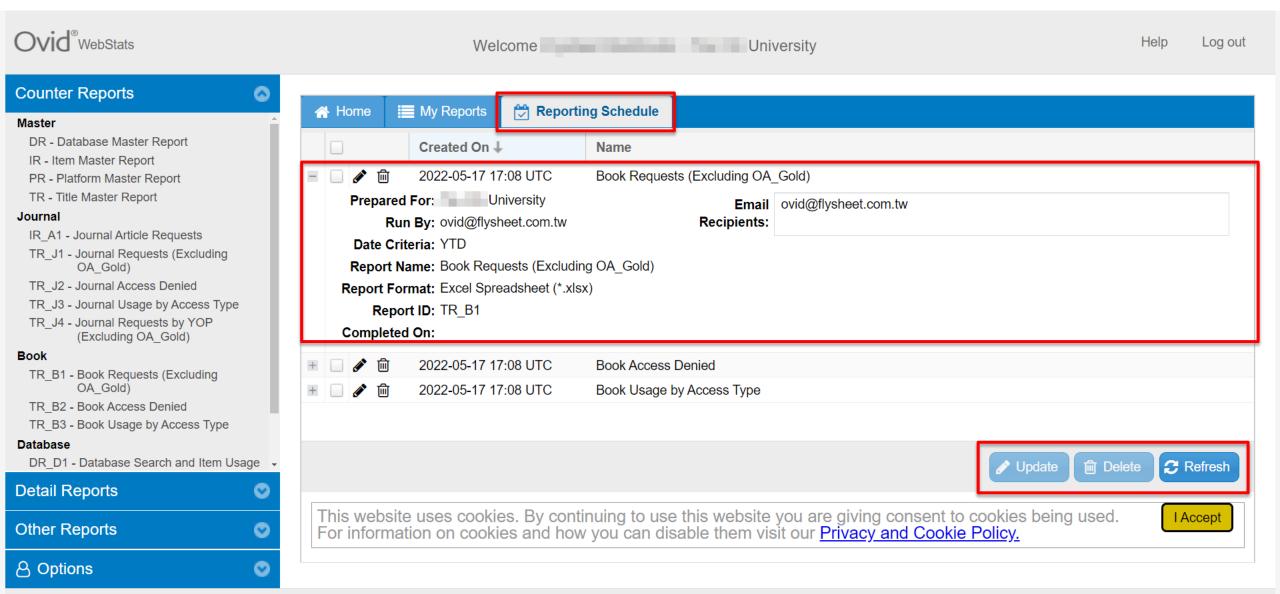


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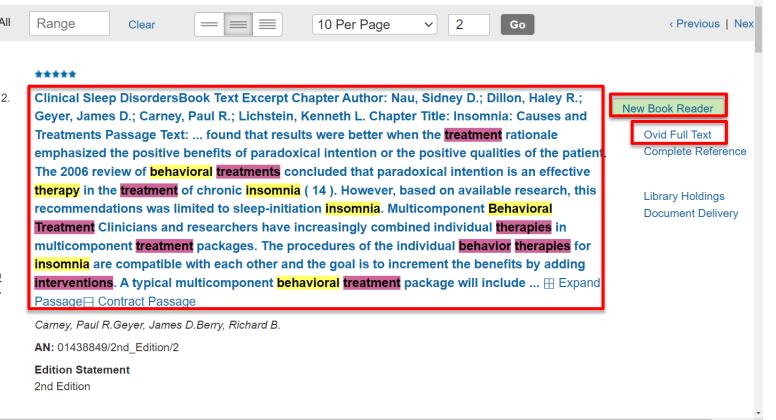
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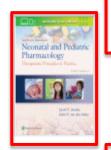
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Chapter 1

Clinical Trials Involving Children: History, Rationale, Regulatory Framework, and Technical Considerations

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INTRODUCTION





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