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Welcome...

The Johns Hopkins University School of Medicine is pleased to welcome you to this inaugural issue of **eInfections Review**. Over the course of this series, we will be reporting on issues critical to providing the safest and most effective care for patients presenting with infectious or parasitic diseases.

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In This Issue...

Upper Respiratory Tract Infections

Sinusitis, pharyngitis, and acute bronchitis are three of the most common infections encountered in clinical practice. They are also three of the most challenging in terms of management decisions for diagnosis, treatment, and particularly antibiotic usage. How should the decision to treat or test be made? Which agents, if any, should be prescribed? What outcomes can be expected in which populations?

In this issue we report on the current research addressing these upper respiratory infection management concerns.

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■ **ACUTE BRONCHITIS: AN OVERVIEW**

■ **ACUTE BRONCHITIS: AMBULATORY ANTIBIOTIC PRESCRIBING**

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Guest Faculty Disclosures

John G. Bartlett, MD, has disclosed that he has served on the HIV Advisory Board for GlaxoSmithKline, Abbott, Bristol-Myers Squibb, Pfizer and Tibotec. He is also on the Policy Board for Johnson & Johnson.

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Sara E. Cosgrove, MD, MS, has disclosed that as a co-investigator, she has received grants or research support from Merck and served on the Advisory Boards for Ortho-McNeil and Cadence Pharmaceuticals.

Unlabeled / Unapproved Uses

The authors have indicated that there are no references to unlabeled/ unapproved uses of drugs or products in this presentation.

LEARNING OBJECTIVES

At the conclusion of this activity, participants should be able to:

- Integrate into practice the new diagnostic techniques and treatment protocols presented in the program
- Recognize and incorporate into practice the effects of emerging drug resistance
- Identify and incorporate into practice the public health imperative for a comprehensive treatment strategy across a wide spectrum of communicable diseases

Acute sinusitis is one of the most common conditions managed in primary care. Although current guidelines recommend using antibiotics only if a bacterial pathogen is suspected and only after patients have failed supportive measures after 7 to 10 days, acute sinusitis accounts for 21% of all antibiotic prescriptions in adults, indicating that antibiotics are overused in this syndrome^[1]. The studies reviewed herein further support the idea that the majority of cases of acute sinusitis do not require antibiotic therapy. Merenstein et al found no significant difference in improvement rates between amoxicillin vs placebo, as well as no difference in patients' rating of illness severity. While it is possible that if the sample size were greater, the difference between the amoxicillin arm (48%) and the placebo arm (37%) would have been significant, the overall percentage of patients who might gain this benefit would likely remain low.

While the study by Meltzer et al does not show a difference in symptom scores in a similar group of patients with at least 7 days of symptoms who are treated with amoxicillin or placebo, it does demonstrate a significant difference in symptom scores in patients who receive intranasal steroids. A recent Cochrane Review found that intranasal steroids may contribute to earlier improvement and faster resolution of symptoms^[2], although this is the first study to demonstrate the benefit of intranasal steroids as monotherapy for acute sinusitis.

The rationale to treat Group A streptococcal (GAS) pharyngitis with antibiotics has been historically grounded in the prevention of acute rheumatic fever, which has essentially vanished as an affliction of adults in developed countries. At best, antibiotics prescribed for GAS pharyngitis result in a 16 hour shorter duration of symptoms, although they do reduce the incidence of uncommon suppurative complications such as sinusitis or peritonsillar abscess^[3]. Despite these issues, pharyngitis remains one of the most common illnesses prompting office visits for primary care providers and pediatricians. The study by St Sauvin et al on recurrent strep should be of particular interest to the latter: although only a relatively small percentage of children were afflicted with recurrences, the authors argue that on a population basis, this finding actually represents a substantial number of children.

Since viruses cause the majority of adult pharyngitis, both the Infectious Diseases Society of America (IDSA)^[4] and the American College of Physicians—American Society of Internal Medicine (ACP-ASIM)^[5] recommend to neither test nor treat mild pharyngitis as defined by the Centor scoring system of 0 or 1 (one point each for history of fever, lack of cough, enlarged/tender anterior cervical lymphadenopathy and tonsillar exudates). The guidelines do differ for more severe pharyngitis, with IDSA recommending antibiotic therapy only for patients with positive rapid Group A streptococcal testing, while ACP-ASIM suggests empiric therapy for patients with scores of 3 or 4. The report by Linder et al (reviewed herein) found non-adherence to any of these guidelines in 66% of office visits. Another study prospectively examining these different strategies found that the specificity using clinical criteria (modified Centor score of 3 or 4 in adults) was only 43.8% for GAS-related pharyngitis^[6]. Moreover, unnecessary prescriptions were judged to be highest in the group diagnosed empirically (45.7%) compared to those treated based upon the results of rapid testing (24.7%), suggesting that, compared to relying solely on clinical criteria, following the IDSA guideline results in lower antibiotic prescribing.

As supported by both the Wenzel & Fowler New England Journal of Medicine article, and the study by Mainous et al, acute bronchitis is possibly the "king" of all clinical examples of antibiotic abuse in the sense that it is common practice to prescribe when other antibacterial agents are rarely indicated. The major exception is influenza, which can be proven with the rapid influenza test (sensitivity of 70%), and, if caught early, can be treated with oseltamivir or zanamivir within 48 hours of onset of symptoms. The other treatable pathogen is *Bordetella pertussis*, which is relatively uncommon, but should be considered in the patient with a paroxysmal cough that persists for weeks. The major condition to exclude in patients with acute bronchitis is community-acquired pneumonia (CAP): abnormal vital signs or rales are the key indicators that should lead the clinician to order a chest x-ray.

The unifying concept in these three conditions is the fact that most are caused by viral infections that

do not benefit from antibacterial treatment. Diagnostic testing is of little use in the majority of presentations: the notable exceptions are the rapid strep antigen test in patients that have pharyngitis and the rapid influenza test in patients with typical flu symptoms in the presence of an influenza epidemic. Both tests are generally available for use in office practice and both can be used for therapeutic decisions. The widespread use of antibacterial agents for these conditions is to be discouraged, although there are exceptions with all three.

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ACUTE SINUSITIS: THE ROLE OF ANTIBIOTICS

Merenstein D, Whittaker C, Chadwell T, Wegner B, D'Amico F. **Are antibiotics beneficial for patients with sinusitis complaints? A randomized double-blind clinical trial.** *J Fam Pract*. 2005;54:144-151.

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Merenstein et al performed a prospective, randomized, double-blind, placebo controlled trial of amoxicillin 1g orally twice daily for 10 days vs placebo in the treatment of acute sinusitis in adults ≥ 18 years. Patients had to have symptoms for at least seven days, and show at least one cardinal clinical feature of bacterial sinusitis: 1) purulent nasal discharge predominating on one side, 2) local facial pain predominating on one side, 3) purulent nasal discharge on both sides, or 4) pus in the nasal cavity. Patients were excluded if they had received antibiotics in the past month, were penicillin allergic, were immunocompromised, had concomitant pneumonia or streptococcal pharyngitis, or had a history of sinus surgery. Follow-up telephone interviews were conducted on days 3, 7, and 14 to assess for clinical improvement. The primary outcome measures were resolution of symptoms by the end of two weeks, and time to improvement.

One hundred and thirty five patients were randomized to amoxicillin (n = 67) or placebo (n = 68). Patients had a mean of 11 days of symptoms prior to enrollment. About 1/3 of patients had 3-4 cardinal symptoms. At two weeks, there was no significant difference in rates of improvement in the two groups: 32 (48%) in the amoxicillin arm and 25 (37%) in the placebo arm (RR for failure 1.3, 95% CI 0.87-1.94). In addition, there were no differences in patients' ratings of how sick they felt on days 0, 3, 7, and 14 in either arm. However, patients in the amoxicillin arm had a significantly faster time to improvement than those in the placebo arm (p = .04). Among patients who experienced complete recovery (n = 57), the median time to any improvement was 8 days for the amoxicillin arm vs 12 days for the placebo arm (p = .005). There was no correlation between the number of signs and symptoms and days to improvement in either arm of the study.

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This study suggests that the use of antibiotics provides only minimal benefit in the management of most cases of acute sinusitis that have persisted for at least 7 days. However, among patients with complete improvement, there is a subgroup of patients in whom amoxicillin therapy decreased signs and symptoms by 2-3 days relative to placebo. Unfortunately, the number of cardinal symptoms was not helpful in distinguishing which patients would respond. Note that acute sinusitis was not rigorously diagnosed using imaging or sinus puncture and culture as in some previous studies; however, the clinical criteria used in this study reflect those available to primary care practitioners.

ACUTE SINUSITIS: THE ROLE OF INTRANASAL STEROIDS

Meltzer EO, Bachert C, Staudinger H. **Treating acute rhinosinusitis: comparing efficacy and safety of mometasone furoate nasal spray, amoxicillin, and placebo.** *J Allergy Clin Immunol.* 2005;116:1289-95.

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Meltzer et al performed a prospective, randomized, double-blind, placebo controlled trial of mometasone furoate nasal spray (MFNS) 200 mcg once daily vs. twice daily vs amoxicillin 500 mg take three times daily for 10 days vs placebo in the treatment of acute sinusitis in persons ≥ 12 years. Patients had to have symptoms for between 7 and 28 days as well as a major symptom score (MSS) between 5 and 12. MSS was the sum of scores on a 0-3 scale (none to severe) for rhinorrhea, postnasal drip, nasal congestion/stuffiness, sinus headache, facial pain, pressure, and/or tenderness over paranasal sinuses. Patients were excluded if they had signs and symptoms suggestive of fulminant bacterial rhinosinusitis, if they had chronic rhinosinusitis, or if they were allergic to study medications. Patients were monitored by telephone on days 3 to 4 and treatment visits on days 8, 15, and 29. The primary efficacy endpoint was mean MSS over days 2 to 15 of treatment.

Nine hundred eighty-one patients were randomized to MFNS daily ($n = 243$), MFNS twice daily ($n = 235$), amoxicillin ($n = 251$) or placebo ($n = 252$). Two thirds of patients had 6-14 days of symptoms prior to enrollment and one third had 15-28 days of symptoms. The mean MSS at baseline was 8.17 to 8.53 across treatment groups, indicative of mild to moderate disease. The mean MSS over days 2 to 15 of treatment was significantly lower in the MFNS twice daily arm than in the amoxicillin arm ($p = .002$) or placebo arm ($p < .001$). The mean MSS during this same period was significantly lower in the MFNS daily arm than in the placebo arm ($p = .018$) but not the amoxicillin arm ($p = .19$). There were no significant differences in recurrence rates in the treatment groups.

This study suggests that intranasal steroids may provide benefits similar to or better than antibiotics in the management of acute sinusitis without exposing patients to the risk of colonization or infection with resistant organisms, or putting them at risk for recurrence of disease. It is the first study to assess the benefit of intranasal steroids as monotherapy compared to placebo rather than as an adjunct to antibiotic therapy. Higher doses of intranasal steroids (mometasone furoate 200 mcg twice daily) provided greater benefit relative to once daily dosing, as well as to amoxicillin therapy and placebo. In addition, this study again demonstrates that in this population of patients with mild to moderate acute sinusitis, no difference in outcomes was seen in between patients receiving amoxicillin and those receiving placebo.

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ADULT PHARYNGITIS: NONADHERENCE TO CLINICAL GUIDELINES IN PRIMARY CARE PRACTICE

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Linder JA, Chan JC, Bates DW. **Evaluation and treatment of pharyngitis in primary care practice: the difference between guidelines is largely academic.** *Arch Intern Med.* 2006 Jul 10;166(13):1374-9.

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Linder et al examined the practice patterns of primary care physicians in nine Partners HealthCare Clinics in the Boston area for adults with pharyngitis. Over two thousand visits were evaluated, retrospectively, to determine whether physicians followed one of three recommended strategies:

ACP empirical strategy:

- Centor scores of 0, 1, or 2 = no streptococcal testing and no antibiotics prescribed
- Centor 3 or 4 = no streptococcal test performed but antibiotics prescribed

ACP test strategy:

- Centor 0 or 1 = no streptococcal test performed and no antibiotics prescribed
- Centor 2 or 3 = subject to streptococcal testing with positive tests associated with an antibiotic prescription
- Centor 4 criteria = no streptococcal test performed and an antibiotic prescribed

IDSA strategy:

- Centor 0 or 1 = no test and no antibiotic
- Centor 2, 3 or 4 = considered candidates for streptococcal testing with receipt of antibiotics for a positive test

ACTUAL VS. HYPOTHETICALLY PERFECT ADHERENCE TO DIFFERENT GUIDELINE STRATEGIES

STRATEGY	TESTING	POSITIVE TEST	ANTIBIOTIC PRESCRIBING
Actual cohort	1671 (80)	357 (17)	988 (47%)
Strategy			
Test all*	2097 (100)	448 (21)	448 (21%)
ACP empirical	0	NA	370 (18%)
ACP test	799 (38)	253 (12)	323 (15%)
IDSA	869 (41)	281 (13)	281 (13%)
Total sample size 2097 (100%)			

*Hypothetical assessment assuming the Centor criteria were distributed as the actual cohort and the rate of positive streptococcal tests was the same in each stratum.

As the findings above show, antibiotics were prescribed to 47% of patients even though 80% of

patients received rapid streptococcal testing and a positive result was obtained in only 17%. Overall, patients clearly received more testing than warranted by guidelines; further, they also received more antibiotics despite the negative results of the excessive testing. Nonadherence to guidelines was found in 66% of visits, with the most common reasons for nonadherence found to be testing and antibiotic prescriptions given to patients at low risk for streptococcal pharyngitis.

Given the retrospective nature of the study, physicians may not have accurately documented the signs and symptoms of pharyngitis. Moreover, the study was not done with a gold standard test in each patient (streptococcal throat culture).

Regardless, the authors rightly suggest that dickering over which guideline to follow is not important. Rather, for physicians who fail to follow any of the guidelines, there is great potential to reduce inappropriate streptococcal testing and antibiotic prescribing by adoption of one guideline or another.

RECURRENT STREP THROAT

St Sauver JL, Weaver AL, Orvidas LJ, Jacobson RM, Jacobsen SJ. **Population-based prevalence of repeated group A beta-hemolytic streptococcal pharyngitis episodes.** *Mayo Clin Proc.* 2006 Sep;81(9):1172-6.

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Bisno AL, Kaplan EL. **Strep throat over and over: how frequent? How real?** *Mayo Clin Proc.* 2006;81:1153-4.

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The rate of streptococcal infection in children has routinely been found to account for at least 15-30% of acute pharyngitis. Although usually a benign illness, recurrent episodes of GAS (group A β -hemolytic streptococcal) pharyngitis may be especially costly in terms of high treatment costs, lost guardian work productivity, and potential tonsillectomy. This study by St Sauver et al was done to determine population-based prevalence of repeated GAS pharyngitis, as little information exists on actual rates.

The authors used the Olmsted County, Minnesota linked medical record system to determine how commonly recurrent streptococcal pharyngitis afflicts children between the ages of 4-15 years of age. Cases were defined as evidence of a sore throat accompanied by either a positive rapid streptococcal antigen test or positive throat culture for GAS. Repeated GAS cases were defined using the American Academy of Otolaryngology-Head and Neck Surgery 2000 guidelines indicating that children with 3 or more infections of the tonsils/adenoids per year were candidates for tonsillectomy. GAS pharyngitis recurring within one month of a prior bout was judged as inadequate medical therapy rather than a repeated case.

Key findings based upon age-specific rates for all residents 4 to 15 years of age in Rochester, Minnesota (1996-1998) were as follows:



AGE	RECURRENT GAS PHARYNGITIS (%)
4 – 15 yrs	1%
4 – 6 yrs	2%
13 – 15 yrs	0.1%

Although only a relatively small percentage of children were afflicted with recurrences, the authors argue that on a population basis, this finding represents a substantial number of children. They note that future studies on patients with recurrent GAS pharyngitis should focus on yielding the highest benefit via reducing episodes and trimming healthcare and productivity costs.

The accompanying editorial by Alan Bisno of the University of Miami rightly points out that these low rates may represent an overestimation, given the retrospective methodology as well as GAS pharyngeal colonization rates that may be as high as 15% in school-aged children. Separation of streptococcal colonization from actual infection may be difficult although children with cough, hoarseness, conjunctivitis, diarrhea, or coryza are highly suggestive of a viral process and therefore a positive strep test in this setting may merely reflect colonization. Regardless, recent efforts at developing a GAS vaccine, if successful, may prove to be of highest value to this subset of patients and their parents.

ACUTE BRONCHITIS: AN OVERVIEW

Wenzel RP, Fowler AA. **Clinical practice. Acute bronchitis.** *N Engl J Med.* 2006;355:2125-30.

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The authors provide a well-referenced scholarly review in this 2006 “Clinical Practice” feature in the New England Journal of Medicine. Highlights include:

Etiology: The most common causes of viral bronchitis include influenza, parainfluenza, respiratory syncytial virus, coronavirus, adenovirus, and rhinovirus. In some cases atypical bacteria including *Bordetella pertussis*, *Chlamydia pneumoniae* and *Mycoplasma pneumoniae* are involved. The authors note that the number of cases involving *B. pertussis* in patients with persistent cough (lasting weeks or months) is highly variable in different studies.

Natural History: The typical case is a URI that is associated with cough lasting more than five days. Forty percent of patients have significant reduction in forced expiratory volume at one second or bronchial hyperreactivity. The cough usually lasts 10-20 days, with an average of 18 days in one large study of 2,781 patients^[1]. About 50% of patients report purulent sputum, although this does not indicate either pneumonitis or bacterial infection.

Diagnosis: One of the first diagnostic questions concerns the need for a chest x-ray to rule out CAP or other pulmonary process. Prior studies indicate this is generally unnecessary if vital signs are normal and there are no rales on chest exam^[2]. A possible exception is cough in an elderly patient; for example, a study of patients over 75 years of age with CAP showed only 30% had temperatures above 38°C, and only 37% had tachycardia exceeding 100/min^[3]. With regard to microbiology, the recommendation from the American College of Physicians are to avoid sputum cultures for bacterial pathogens since they are often misleading^[4]. Diagnostic tests for other agents should be done, if available, and would detect a treatable agent. This is most common with influenza, which should be suspected in any patient who has a typical febrile illness during an influenza epidemic. In these



cases, a rapid test for influenza virus would be useful, since treatment needs to be given within 48 hours of the onset of symptoms to be useful (these tests show a sensitivity of about 70%).

Antimicrobial Therapy: This is not recommended in the great majority of cases. A Cochrane Review of randomized, controlled trials of antibiotics for acute bronchitis showed a reduction in the duration of cough by an average of 0.6 days, which was statistically significant, but not felt to be recommended because the minor benefit of treatment vs the risk associated with antibiotic exposure in terms of side effects, cost, and resistance^[5]. Oseltamivir or zanamivir have been shown to decrease the duration of symptoms by approximately one day and return to normal activity by 0.5 days if given within 48 hours of the onset of flu symptoms^[6]. It should be noted that the benefit is substantially increased when one of these neuraminidase inhibitors is given very early in the course. As noted, other treatable pathogens include *M pneumoniae* or *C pneumoniae*, but there is little evidence that antibiotic treatment is beneficial in the absence of pneumonia. With regard to pertussis, a macrolide is advocated to prevent transmission, but does not alter the natural history of the infection.

Other Therapies: Several placebo-controlled trials have examined the potential benefit of β 2-agonists and shown minimal benefit, even in patients with airflow obstruction^[7]. A brief (7 days) trial of inhaled or oral corticosteroids may be tried in some patients with "troublesome cough," but there are no clinical trial data to support this recommendation. There is also minimal support for the use of mucolytic or antitussive agents.

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ACUTE BRONCHITIS: AMBULATORY ANTIBIOTIC PRESCRIBING

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Acute bronchitis is one of the most common infections seen in primary care, as well as a condition that is subject to substantial concerns regarding the overuse of antibiotics. Mainous et al sought to determine the relationship between antibiotic prescribing for acute bronchitis with hospitalization for respiratory infections in the US for the period 1996-2003. Their analysis was based on data from the National Ambulatory Medical Care Survey and the National Hospital Ambulatory Medical Care Survey for prescribing practices, and was limited to adults 18-64 years. The results indicated total visits ranged from 5,687,503 in 1996 to 9,892,260 in 2003. The number of patients with the diagnosis of acute bronchitis who received antibiotics ranged from a high of 73% in 1998 to a nadir of 53% in 2001. The figure for 2003 was 65%.

It should be noted that the data provided in this report are consistent with multiple other studies which show that about 50-70% of patients with the diagnosis of acute bronchitis who seek medical care receive an antibiotic despite a consistent recommendation against this practice.

Important observations highlighted in the report include:

- Nearly all cases are due to viral infections.
- The diagnostic evaluation is usually limited to decisions regarding the need for a chest x-ray, the need for microbiology studies, and treatment options. With regard to x-rays, the recommendation is to order them only if there is evidence of other processes, primarily pneumonia as indicated by rales or abnormal vital signs including fever and/or tachypnea. Note that these guidelines do not always apply with elderly patients, since they may have pneumonia that is much less likely to show fever. The most commonly useful test for etiology is the rapid influenza test, which is recommended if therapy is considered, symptoms are typical, and there is influenza in the region.
- Antimicrobial agents are recommended for influenza (using oseltamivir or zanamivir) if symptoms are less than 48 hours in duration; the earlier these agents are prescribed, the better. Occasionally patients with very prolonged cough have pertussis, which should be confirmed and treated with a macrolide. However, the great majority of patients with acute bronchitis who have an untreatable viral infection do not benefit from antibacterial agents.
- The use of antibacterials is commonly viewed as one of the most common abuses of antibiotics, and is potentially harmful due to resistance, cost, and side effects. Surveys have shown that most physicians and most patients equate "acute bronchitis" with the need for antibacterials — this has led Ralph Gonzales et al to avoid that term and instead call it a "chest cold"^[1].

References

1. Gonzales R, Bartlett JG, Besser RE, et al. [Principles of appropriate antibiotic use for treatment of uncomplicated acute bronchitis: background.](#) *Ann Intern Med.* 2001;134:521-9.

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Target Audience — [back to top](#)

This activity has been developed for the Primary Care Physician, Internist, and Infectious Disease Specialist.

Learning Objectives — [back to top](#)

At the conclusion of this activity, participants should be able to:

- Describe the proper use of antibiotic agents in treating upper respiratory infections
- Discuss diagnostic strategies for evaluating the severity of upper respiratory infections
- Evaluate how the data presented may best be integrated into current clinical practice

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- **Paul G. Auwaerter, MD**, has disclosed that he has served as a consultant for Novartis, Pfizer, Ortho-McNeil, Schering-Plough, and Genzyme. He is on the Speaker Bureaus' for Schering-Plough and has also disclosed that he is a Stock Shareholder for Johnson & Johnson.
- **Sara E. Cosgrove, MD, MS**, has disclosed that as a co-investigator, she has received grants or research support from Merck and served on the Advisory Boards for Ortho-McNeil and Cadence Pharmaceuticals.

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