COMMENTARY

Pharmacological dosage concepts: How useful are they for educators and speech-language pathologists?

ALAN G. KAMHI

University of North Carolina-Greensboro, USA

Abstract

The first part of this response to Baker (2012) examines studies that have attempted to determine the optimum treatment intensity of reading interventions associated with a Response to Intervention (RTI) model of service delivery. In general, the findings indicated that differences in broad measures of intensity (duration and scheduling) did not result in differences in reading outcomes. These non-significant findings and Baker’s excellent discussion of all of the factors that impact treatment outcomes led me to question how useful pharmacological dosage concepts are for educators and speech-language pathologists (SLPs). This commentary concludes by acknowledging that the more information available about the active ingredients of treatment episodes, the better one will be to design effective and efficient interventions to improve speech, language, and literacy.

Keywords: Intervention, treatment, speech-language pathology.

Introduction

Baker’s (2012) article addresses a question about intervention that has begun to receive more attention in the literature: What is the optimal intervention intensity? Warren, Fey, and Yoder (2007) presented a framework and terminology for measuring treatment intensity that has proven useful for researchers interested in studying the efficacy of speech-language and literacy interventions (e.g., Proctor-Williams, 2009; Ukraintetz, 2009). Baker (2012) presents this framework in the first few pages of her article, and then proceeds to discuss all of the factors (e.g., goals, type of client, clinician experience, service-related variables) that interact with treatment intensity to affect treatment outcomes. The five articles in the Topics in Language Disorders (TLD) issue edited by Ukraintetz (2009) all show the difficulty involved in studying the impact of treatment intensity with different language and literacy goals. Even when the teaching episodes and goals are relatively simple (e.g., using recasts to teach irregular past tense), the findings were unimpressive (Proctor-Williams, 2009; Proctor-Williams & Fey, 2007). When the goals targeted are more complex, as is the case with narrative intervention, defining teaching episodes becomes very challenging (cf. Hoffman, 2009).

After reading these articles and Baker’s excellent discussion of all the issues involved in determining the optimal intensity of speech-language pathology (SLP) interventions, I found myself wondering whether the notion of an ideal or optimal dose of treatment is compatible with the flexible, individualized clinical process that characterizes evidence-based practice (EBP). Nelson and Butler (2009) expressed similar concerns in their foreword to the TLD issue on treatment intensity. They “worry that a simplistic metaphor of pre-measured doses delivered by an agent of intervention to a ‘patient’ conjures up a level of pre-planned control that may be unhealthy for the patient” (p. 289). Like me they also thought that too much attention on the process of counting and delivering doses on schedule might detract from the treatment procedures and clinician–client interactions that determine success or failure.

Given my interest in reading, I decided to examine studies that have attempted to determine the optimum treatment intensity of reading interventions associated with a Response to Intervention (RTI) model of service delivery. After reviewing this research, I will consider the more general question of whether pharmacology-based dosage concepts should be applied to all of the different speech, language, and literacy goals that clinicians and educators might target in their interventions.
Treatment intensity and reading intervention

RTI service delivery models are becoming more prevalent in school districts throughout the U.S. RTI models are gradually replacing the discrepancy-based models that have predominated the field of learning and reading disabilities for the last 40 years (Berkeley, Bender, Peaster, & Saunders, 2009). The focus of RTI models is typically on improving reading abilities in young elementary school children. There are three tiers of intervention in most RTI models. Tier 1 provides universal screening and quality classroom reading instruction to all students. Students who do not make adequate progress in Tier 1 are provided supplemental small-group Tier 2 intervention. Students who do not respond to Tier 2 intervention receive more intensive Tier 3 interventions.

Although RTI models are now widely implemented, there is little consensus on the ideal intensity of Tier 2 and Tier 3 interventions (Denton, Cirino, Barth, Romain, Vaughn, Wexler, et al., 2011). A series of recent studies (e.g., Al Otaiba & Torgesen, 2007; Marston, Lau, & Muyskens, 2007; Wanzek & Vaughn, 2007, 2008) have focused on the adequacy of Tier 2 interventions because these interventions must have sufficient intensity to powerfully accelerate development of reading skills and prevent future reading problems for most students. The Tier 2 interventions in these studies vary in the amount of time devoted to the intervention per week and the total number of weeks of intervention provided. For example, Marston et al. (2007) provided intervention over an 8-week period, whereas Wanzek and Vaughn (2007) provided intervention for 20 weeks or more. A review of Tier 2 interventions by the What Works Clearinghouse (Gersten, Compton, Connor, Dimino, Santoro, Linan-Thompson, et al., 2009) found that those that were effective occurred 3–5 times per week for 20–40 minutes. There was not sufficient data to determine how many weeks of intervention should be provided.

Subsequent research has failed to determine the optimal dosage for Tier 2 interventions. In their follow-up study, Wanzek and Vaughn (2008) found that providing 30 minutes of daily intervention in the fall of first grade followed by 60 minutes of daily intervention in the spring did no better in improving children’s reading performance than providing daily intervention for 30 minutes throughout the school year. A study with British students by Hatcher, Hulme, Miles, Carroll, Hatcher, Gibbs, et al. (2006) similarly found that Year 1 students with reading difficulties who received supplemental intervention for two consecutive 10-week periods (33 hours) performed no better than a comparable group who received the same intervention only during the second 10-week period (16.5 hours). In contrast to these studies, Al Otaiba, Schatschneider, and Silverman (2005) did find differences according to the duration of the intervention. Kindergarten children who received intervention 4-times a week did significantly better on measures of word reading and comprehension than children who received intervention 2-times per week and a control group who received small-group book reading twice a week. Children who received intervention 2-times per week performed better than the control group only on the Comprehensive Test of Phonological Processing (Wagner, Torgesen, & Rashotte, 1999).

Only a few studies have investigated whether reading outcomes are influenced by the spacing of treatment—distributed (e.g., 2 days per week over 20 weeks) vs massed (4 days per week for 10 weeks). Seabrook, Brown, and Solity (2005) found that young children showed more improvement in their knowledge of sound–letter correspondences and word reading with three 2-minute daily instructional sessions than children who received one 6-minute daily session. Ukrainetz, Ross, and Harm (2009), however, found that at-risk kindergarten children who received phonemic awareness intervention 3-times per week for 3 months performed comparably to matched children who received the same intervention once a week for 6 months.

A recent study by Denton et al. (2011) attempted to address some of the gaps and inconsistencies in the Tier 2 intervention research by conducting a large scale study with three different intervention schedules. The initial sample contained 680 first-grade students in a large urban and a partly rural district in Texas. Two hundred and nineteen students passed the initial reading screening and were considered typical readers. Two hundred and seventy-three of the remaining 461 students continued to meet at-risk criteria after four waves of progress monitoring, thus qualifying for Tier 2 intervention. These 273 students received one of three intervention schedules: 4 sessions per week for 16 weeks (extended schedule), 4 sessions per week for 8 weeks (concentrated schedule), or 2 session per week for 16 weeks (distributed schedule). The intervention was a modification of the 1998 version of the Read Well program (Sprick, Howard, & Fidanque, 1998). The program provides systematic, explicit instruction in decoding and fluency that is applied to decodable texts. The modifications included instruction in vocabulary and reading comprehension and partially scripted lesson plans for the 14 tutors who provided the intervention.

The authors hypothesized that students who received more extensive intervention would have better outcomes than those on a briefer schedule, and students on a distributed schedule would have better outcomes than those on a concentrated schedule. Neither of these hypotheses was supported by the data. There were no significant between-group differences on any of the reading outcome measures (decoding, spelling, fluency, and comprehension) or in the rates of adequate responses to the intervention. In addition, the Tier 2 interventions failed to appreciably accelerate the development of broad reading proficiency for most students.
In the discussion of the non-significant findings, Denton et al. (2011) recognized that the measures of treatment intensity used in all of the Tier 2 intervention studies may be too broad. They suggested that future studies consider the number of specific teacher–student interactions as Warren et al. (2007) have argued. Future studies should also examine the pacing of lessons to determine program coverage rate and the level of active student engagement in the instructional activities. Denton et al. conclude by re-affirming the need to determine the treatment intensity required for Tier 2 interventions to close the gap with typical readers and eliminate the need for more complex and costly Tier 3 interventions.

I agree with Denton et al. (2011) that future studies should attempt to determine the most effective teacher–student interactions for improving specific components of reading such as phoneme awareness, letter recognition, sound–letter correspondences, word attack skills, sight word vocabulary, and vocabulary knowledge. I would hope that this research will also determine the extent to which each of these components need to be targeted for students to become proficient readers.

Pharmacological dosage concepts: How useful are they for educators and SLPs?

In the abstract, Baker (2012, p. 401) wrote that “in order for SLP services to be both effective and efficient, SLPs need to know how to faithfully administer ideal doses of the active ingredients of interventions, in what forms, how often, and for how long”. Taken literally, this statement implies that until we have information on ideal treatment intensity, it is not possible to provide effective and efficient services. I’m sure Baker did not intend this statement to be taken so literally and would imagine that she would agree that intervention can be effective without knowledge of ideal treatment intensity. Indeed, Baker and others (e.g., Baker & McLeod, 2011a, b; Cirrin & Gillam, 2008; Cirrin, Schooling, Nelson, Diehl, Flynn, Staskowski, et al., 2010) have shown that many speech and language interventions are effective and efficient without knowledge of ideal treatment intensity.

One key question then is whether knowledge of optimal treatment intensity will lead to a large enough improvement in treatment efficacy/efficiency to justify the time, effort, and resources required not only to obtain this knowledge, but also to reach a consensus about how to use this knowledge with individual clients? Another question is whether it is actually possible to determine optimal treatment intensity given all of the factors (i.e., goals, type of client, clinician experience, service related variables) that influence treatment outcomes (Baker, 2012). With all of these variables, it seems reasonable to question whether there is in fact an ideal dosage for particular treatment episodes and interventions. I recognize that a fine-grained analysis of the components of intervention and identifying the active agents of teaching episodes have benefits, but as I noted previously, I am concerned that by focusing attention on the process of counting and delivering doses on schedule, attention may be diverted from the aspects of the intervention that actually lead to improved speech, language, and literacy outcomes. The notion of fixed, ideal treatment dosage also seems inconsistent with the flexible, individualized clinical process that characterizes evidence-based practice (EBP). EBP, as most clinicians know, is a process in which information from a variety of sources (research, client preferences, prior experience) is gathered and integrated to make decisions about individual clients (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996).

The notion of fixed, ideal dosages is also inconsistent with evidence-based medicine, which requires more than simply referring to the Physicians Desk Reference (PDR) for drug dosage information. Unfortunately, many physicians rely solely on the PDR to set dosage levels. The problem with the PDR is that it is a commercially published compilation of manufacturers’ prescribing information. In other words, the PDR is paid for by the various pharmaceutical manufacturers that present medications within its pages (Cohen, 2001). The data used in the PDR are taken from drug data sheets generated by drug manufacturers, so the PDR may omit studies reporting the worst side-effect and adverse effect data. By not reporting the results from independently conducted studies, the PDR violates the basic principles of evidence-based medicine. Dosage information is often taken from phase 1 trial information where clinical drug information is incomplete, resulting in higher PDR-recommended dosages than therapeutically effective dosages (Cohen, 2001). Physicians who practice evidence-based medicine know that determining appropriate medication dosages is a complex task that requires knowledge of medicine and pharmacokinetics, a good rapport with patients, and some skill in calculating dosages (Walton, Dovy, Harvey, & Freemantle, 1999). Because the management of drug dosages is complex and time-consuming, computers are increasingly being used to maintain therapeutic drug dosages (Walton et al., 1999).

Importantly, the purpose of drug trials is not simply to determine the effectiveness of a medication or optimal dosage levels. An equally important purpose of drug dosage studies is to determine the side-effects and safety of new drugs (Warren et al., 2007). As noted above, medications that are effective in phase 1 drug trials may have significant side-effects that do not appear in short-term studies. Many so-called “miracle drugs” (e.g., Vioxx) have been pulled from the shelves because the side-effects proved to be more dangerous than the condition the drug was treating (cf. www.mastersinhealthcare.net/blog/2010/10-prescription-drugs-pulled-from-the-shelves-and-why/).
Although Warren et al. (2007) acknowledge that determining side-effects and safety are an important purpose of medical dosage studies, they fail to point out that side-effects and safety of interventions are rarely a concern for educators or SLPs. The most typical treatment mistake clinicians make is to use an intervention that is less effective than another one. Professional ethics ensure that teachers and clinicians would never intentionally use an ineffective treatment approach and will modify or discontinue the use of a particular intervention if there is no measurable change in the targeted behavior within a reasonable time period.

Warren et al. (2007) also do not mention that it was safety and false labelling issues rather than therapeutic effectiveness that led to the formation of regulatory agencies like the FDA (U.S. Food and Drug Administration) throughout the developed world. The FDA’s modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act which prohibited interstate commerce in adulterated and misbranded food and drugs. It was only later that the FDA began testing drugs for safety as well as therapeutic effectiveness. If our behavioural interventions had the potential to harm students and clients, there would probably be a regulatory agency like the FDA to ensure that only safe and effective interventions were approved for use. Without the driving force of safety issues, it seems unlikely that pharmacological dosage concepts will be adopted in clinical and educational professions.

Conclusion
I appreciate the opportunity to respond to Baker’s excellent article on optimal intervention intensity. In this response, I began by reviewing research that examined the effects of treatment intensity on Tier 2 interventions which are a critical aspect of RTI models of service delivery. The review indicated there was considerable variability in the effectiveness of Tier 2 interventions using broad measures of treatment intensity. I suggested that future studies should focus on determining the most effective teacher–student interactions for improving specific components of reading such as phoneme awareness, letter recognition, sound-letter correspondences, word attack skills, sight word vocabulary, and vocabulary knowledge.

In the second part of my response, I raised concerns about applying the pharmacological dosage concept to clinical and educational professions. I argued that even though there is extensive clinical trial information on drug dosage levels, there is considerable complexity in selecting initial drug doses and maintaining therapeutic dose levels. In fact, the management of drug dosages is so complex and time-consuming that computers are increasingly being used to maintain therapeutic dose levels.

Determining the most effective and efficient treatment intensity for speech-language and reading interventions is no less complex. I think we can all agree that the more information we have about the active ingredients of treatment episodes, the better able we will be to design effective and efficient interventions to improve speech, language, and literacy.

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