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Pediculicide Performance, Profit, and the Public Health

A glance at the full-page advertising in the public health, education, or nursing journals published in 1985 makes it clear how fiercely competitive the pediculicide market is today. Unfortunately, promotional literature generated by pharmaceutical companies vying for a share of that market has been the primary resource for many health professionals dealing with head lice on the front lines—to the detriment of establishing consistent protocols for diagnosis, treatment, and prevention. Assured by the manufacturers that pediculicides constitute fully effective treatment and by the medical literature that head lice do not transmit disease, physicians have deemed pediculosis of low importance both as a topic of research and in clinical practice.[1] At the same time, anxious to eliminate a distasteful infestation, patients are desperate to believe in any promised cure-all. As a result, we have all been fair game for misleading pharmaceutical information. We have proceeded on the basis of too little consideration for safety and too much faith in efficacy claims. Faced with a highly communicable condition affecting the public health, we have based control policies and procedures on marketing gambits and wishful thinking.

See also p 267.

The National Pediculosis Association, Newton, Mass, sponsored the pediculicide comparison study by Meinking et al[2] published in this issue of the ARCHIVES, because we view an accurate perception of product performance as the foundation of any pediculosis management strategy. Based, for the first time, on independently obtained data and conducted with field-collected head lice rather than pubic lice or laboratory-reared body lice, this study is the first step in reevaluating treatment decisions at the individual and public health levels.

This study sheds new light on many of the traditionally held wisdoms regarding the performance of the widely used pediculicides. Although the investigators conclude that all six remedies tested (Kwell Shampoo, RID, R&C Shampoo, A-200 Pyrinate Liquid, A-200 Pyrinate Shampoo, and Prioderm Lotion) are *effective*, they have used the term in its broadest sense; in fact, the results obtained reflect a wide range of efficacy levels. Moreover, as the investigators themselves point out, the results should be considered the maximum achievable with these products. Under controlled laboratory conditions, results are not subject to application error generated during home use by haste, anxiety, or user inability to follow package directions. (Application error and product abuse due to frustration concerning treatment failure are the hallmarks of our parent hotline calls.) Other methodology decisions also produced results superior to those that might be achieved at home. For example, in the study, lice remained "in contact with the product until death." Of the six products tested, only Prioderm Lotion was able to knock down and kill crawling lice in a time span equal to or short of its actual recommended application time. Knock-down times of the synergized pyrethrins exceeded their application times by a (mean) range of 0.5 to 12.5 minutes, while Kwell Shampoo, often considered a standard of comparison within the industry, exceeded its application time by a mean of 186.2 minutes.

The likelihood of adult lice dying as a result of exposure to products for their actual, *safe* application times is thereby questioned. At the very least, while manufacturers' package claims of "on contact" kill may mean to physicians eventual certain louse death, such claims are entirely misleading to patients.

The ovicidal ability of Kwell Shampoo is also questionable considering that Meinking et al[2] tested this feature by immersing louse eggs in products for ten minutes—2½ times the safe application period for Kwell Shampoo. Nevertheless, Kwell Shampoo's exhibited hatch rate of viable nymphs (30%) was still higher than that of any of the other products. Except for Prioderm Lotion, all of the products tested left more than one fifth of the eggs viable after treatment. It appears that although the investigators conclude that these are effective pediculicides, what is actually demonstrated is that the products fall far short of expectations. As we begin to reexamine the efficacy claims of the pediculicide manufacturers, we may find that many of the myths and controversies surrounding head-lice treatment will fall like a house of cards.

Many of these controversies have placed physicians, educators, school nurses, and parents in adversarial positions. We address those currently raising questions in many of our communities.

KWELL SHAMPOO AS THE TREATMENT OF CHOICE

Although its popularity has been waning recently, Kwell continues to enjoy the greatest name recognition among physicians and consumers by virtue of its longevity on the market and the fact that it has been subject to more investigation than other newer products. (The *Physicians' Desk Reference* does not yet reflect the change, however, the Food and Drug Administration has recommended that only the shampoo form of Kwell be used as a pediculicide; Kwell Cream and Kwell Lotion are indicated in the treatment of scabies only.) During the three years that the National Pediculosis Association has been involved in testifying about this product before the Dermatology Advisory Committee of the Food and Drug Administration, we have encountered many physicians who appreciated the potential risks associated with lindane exposure but who felt that the benefits outweighed the risks.[3] Meinking et al[2] now suggest not only that Kwell Shampoo fails to outperform the other products but that its performance is considerably worse. If we agree that lindane is more toxic to mammals than either pyrethrins or malathion,[4] there remains no justification for using Kwell Shampoo as a pediculicide. This is particularly true when treating pregnant women, women who are nursing, or infants. We believe that when the lower efficacy of Kwell Shampoo is recognized, arguments over lindane safety and resistance will be moot.

Based on the performance of Prioderm Lotion in the study by Meinking et al[2] and on information from our toxicology advisors who agree as to the safety of malathion as formulated in this product, we today would be obligated to point to Prioderm Lotion as an attractive treatment choice, despite its cosmetic liabilities. Ironically, Prioderm Lotion has been unable to gain sufficient market share, physician acceptance, and profitability and therefore has been removed from the market by its manufacturer.

NIT REMOVAL AS AN ESSENTIAL COMPONENT OF TREATMENT

In schools throughout the country, the dispute over whether to remove eggs rages on, with school nurses often forced to advocate for nit removal in the face of physician resistance.[5] This resistance is, again, based on belief in product performance and in the ability of the second and even third[6] treatments to serve as "mop-up" operations. With nit removal absent from school policy, nurses find themselves readmitting children to class who will have nymphs hatching during the week between treatments. Given the mounting evidence that available pediculicides are less than 80% ovicidal,[7] we must conclude that the child with nits *still has lice* that can be transmitted to others. There are so many advantages to removing nits that it is difficult to comprehend continued resistance to it. In a June 1984 letter to the *New England Journal of Medicine*, we listed the following benefits of nit removal: (1) It prevents self-reinfestation and transmission to others during the seven days prior to the second treatment. (2) It decreases or eliminates the eventual need for a second treatment, thereby limiting exposure of young children (and possibly their pregnant or nursing mothers) to pesticides. (3) It eliminates diagnostic confusion and serves to document treatment for school nurses. (4) It equalizes the efficacy of pediculicides, permitting the use of less-toxic products. (5) The enforcement of no-nit policies encourages parents to inspect their children often—the best form of prevention and control.[8]

HEAD LICE AND DISEASE

Just as inappropriate models have served as the basis for belief in pediculicide efficacy, so have they been used to justify the notion that head lice cannot transmit disease. Meinking et al[2] tell us that prior in vitro pediculicide testing involved the use of colonized body lice or pubic lice because of the difficulties involved in keeping head lice alive in the laboratory. It is noteworthy that scientists have considered head and body lice anatomically *alike* for purposes of researching biology, behavior, and treatment, even noting that the two subspecies occasionally interbreed. Yet, the belief persists that head and body lice are *different* for purposes of disease transmission. Is it rational to suppose you can have it both ways?

Not everyone thinks so. In his biography of typhus, Zinsser[9] categorically states that both head and body lice transmitted the disease. Maunder,[10] in a presentation to the Royal Institution of Great Britain, stated that head, body, and crab lice were able to spread relapsing fever equally well. Sholdt et al[11] suggested that "the principal difference between head and body lice is habitat" and that in the laboratory, "causal organisms for typhus and relapsing fever have been shown to be reproduced in both the head and body louse." Murray and Torrey,[12] in a 1975 study, demonstrated that head lice collected from Boston schoolchildren were highly susceptible to virulent *Rickettsia prowazekii* and therefore "appeared to be potential transmitters of *R prowazekii* under optimal epidemiological circumstances." He further suggested that *the greater prevalence of head lice over body lice today* would position them to be the "sole transmitters of typhus, if they do transmit it." He demonstrated that the feces of infected head lice were heavily contaminated with *R prowazekii*, conferring on these lice the potential to transmit disease.[12]

We now need to weigh the impact of this information in light of today's most urgent health problem—the acquired immunodeficiency syndrome (AIDS) epidemic. Now that the Centers for Disease Control guidelines allow young people with AIDS into our public schools, the statistical and biologic facts about head lice compel us to examine their juxtaposition to AIDS in the classroom. With head lice more prevalent than all other communicable childhood diseases combined[13] and surveys indicating that at least 3

million US households were affected in 1984, there is no doubt that head lice are a problem in our schools. Given the highly mutable and unpredictable nature of the human T-cell lymphotropic virus type III, what kind of risk are we taking when we bring together in the same setting the blood-borne disease and the highly communicable blood-feeding parasite? Is it good science to rule out head lice as a risk factor based on surveying AIDS-afflicted homosexuals with pubic lice? (Pubic lice have been considered to be of little importance as disease vectors; however, pubic lice also merit more conclusive study than they have received in the past.) And how much more worrisome does the theoretical AIDS risk become if the products available for eradicating the lice offer no real guarantees of success?

A recent survey indicated that nearly 50% of those infested with head lice in 1984 turned to a physician for help. This surely places the medical profession in a good position to alter the course of this public health problem, but a shift in attitude and approach will have to take place first. We cannot change the fact that pediculosis has been ignored long enough to become endemic in communities throughout the nation. We *can* change our minds about this disease to address it properly. This will mean two things: First, we must base treatment decisions on data generated by *independent* investigations using *appropriate* models for study. Competition among pharmaceutical companies is not inherently negative; physician and consumer demand can take advantage of it to bring about safer, more effective pediculicides. Second, we must acknowledge that treatment cannot be undertaken as if each case existed in a vacuum. The communicability of pediculosis ensures that others will suffer—or benefit—by choices we make.

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