Transfer of Patients from Acute to Long-Term Care: Influence of Patient Characteristics on Waiting Period

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Abstract
Hawaii’s number of nursing home beds per capita is much lower than the national average, making it difficult to transfer some hospitalized patients to long-term care facilities. We prospectively followed patients wait-listed for nursing home placement in two Honolulu hospitals and found several patient characteristics that impeded transfer. These results could be used to help with long-term care planning.

Introduction
In the U.S. there is growing concern about the ability of the current healthcare system to deal effectively with the growing need for long-term care services for a rapidly growing older population. Previous studies have already documented delays in transferring patients to nursing homes from acute care hospitals. With the predicted increase in the older population over the next 20 to 30 years, this situation may become even more common. Because of the longevity of its population and the costs of land and construction for new nursing homes, finding placement for some long-term care patients is already quite difficult in Hawaii.

In 1994 and 1995, there was an average of 1500 patients in acute care hospital beds in Hawaii who were ready to be discharged to a long-term care facility but were unable to be placed. By the fourth quarter of 1998 that number had risen to almost 2800. The majority of these wait-listed patients were awaiting transfer to a Skilled Nursing Facility (SNF) or Intermediate Care Facility (ICF) and most were elderly. There are several reasons why this situation exists in Hawaii; some of which are unique to this State and others that are a part of the emerging national problem in the provision of long-term care.

As in the rest of the nation, the older population in Hawaii is increasing, and there is no system of universal long-term care insurance. This places a great financial burden on individuals and on government resources. People 65 years and older now represent 12% of the population of Hawaii, a figure similar to that of the rest of the United States. However, while nationally there are an average 53 long-term care (SNF/ICF) beds for every 1000 people aged 65 and older, in Hawaii there are less than half this number. The shortage of long-term care beds creates competition for available vacancies and explains why average nursing home occupancy rates in Hawaii are consistently over 95%, and in some areas over 100%. It also explains why Hawaii has the highest acuity rate in all of the U.S. in its long-term care beds.

This competition for scarce beds means that most long-term care facilities can be somewhat selective when choosing patients for admission to their facility. To provide quality care to their residents, nursing homes attempt to select patients for whom they can safely provide care within current levels of reimbursement. For this reason, some patients will be more difficult to place because they have certain characteristics that make them less attractive to the nursing home.

While the shortage of nursing home beds in Hawaii has been well documented, there is only one other published report of a study done in this state that documented the reasons why patients had greater difficulty finding nursing home care. The conclusions of the previous report focused mainly on the shortage of nursing home beds as well as certain financial and administrative barriers to nursing home placement. The purpose of our study was to identify individual characteristics making certain patients easier or more difficult to place from acute care hospital to a nursing home. Identifying these characteristics may suggest interventions that could help wait-listed patients overcome barriers to finding a nursing home. Another objective was to identify patient characteristics that could be used in planning for future long-term care needs.

Methods
Study Design
This is a prospective cohort study of patients aged 65 or older in acute care hospital beds who were awaiting permanent nursing home placement.

Study Sites
The study was conducted in 2 private nonprofit acute care hospitals located in Honolulu, Hawaii. At the time of the study one facility was licensed for 250 acute medical/surgical beds while the other facility was licensed for 530 acute medical/surgical beds. The larger hospi-
tal also had 30 beds designated for subacute care. Both facilities provide a wide variety of programs and services and are accredited by the Joint Commission on Accreditation of Healthcare Organizations. The institutional review boards of both facilities approved the study prior to data collection.

Survey of Social Workers
The initial phase of this study involved a questionnaire survey of social workers performing discharge planning services for the two acute care hospitals involved in this study. One hospital is the largest in Honolulu, the other has the greatest proportion of Medicare patients. Social workers were asked from their experience to rate possible factors making it difficult to transfer patients to a Skilled Nursing Facility (SNF) or to an Intermediate Care Facility (ICF). They were also asked to rate the factors on a scale of major, moderate, or minor. The questionnaire also asked for suggestions for factors other than those included in the survey. From this survey, a list of the patient factors rated as either “major” or “moderate” barriers to nursing home transfer of wait-listed patients was compiled. This list was subsequently used to gather data for the remainder of the study.

Study Population
Patients evaluated were aged 65 or older, whose status had been lowered from acute, and who were wait-listed for long-term care facility placement (i.e. their condition no longer required acute care hospitalization). Only patients who were to be transferred for permanent nursing home placement at the ICF or SNF level of care were included in the study. Finding placement for patients needing short-term nursing home placement, for example for rehabilitation services, was not a major problem. The nursing homes usually accept these patients more readily because of the higher reimbursement rates for short-term rehabilitation services and because many of these patients did not present a discharge problem for the nursing home when their rehabilitation services were completed.

Data Collection
The lists of appropriate patients were obtained from the records of the social work departments of both hospitals. Information was collected by a medical record review on each subject using a checklist of patient characteristics generated by the survey of the social workers, as described above. The principal domains of the data collected included: 1) medical conditions; 2) psychiatric conditions; 3) behavioral conditions; 4) social and financial factors; and 5) miscellaneous factors. Medical conditions included: ventilator dependency; intravenous antibiotics; diabetes mellitus on insulin; isolation precautions; tracheostomy care; renal failure on hemodialysis; stage II or greater pressure ulcer; MRSA infection or colonization; VRE infection or colonization; urinary/fecal incontinence; irreversible coma; and enteral tube feeding. Psychiatric conditions included: any psychiatric diagnosis requiring psychiatric clearance prior to transfer (PASAAR). Behavioral conditions included: wandering; verbally abusive behavior; physically abusive behavior; socially inappropriate behavior; resistance to care; and memory impairment. Social and financial factors included: no responsible family or guardian; patients living on neighbor islands; no durable power of attorney for health matters; Medicaid recipient or Medic-aid application pending; and ability to pay privately for care. Miscellaneous factors included: “full code” Vs “no code” status; end-of-life care; family preference for a particular nursing home facility; hospital where wait-listed; marital status; ethnic background; age; and nursing home that eventually accepted the patient. Most of the data were available in the patient’s chart. The chart review was supplemented by interviewing the social workers and nursing staff assigned to each patient.

Following the initial chart review, patients were followed prospectively from the day they were placed on the wait-list until the time they either transferred to a long-term care facility, expired while on the wait-list, or were changed to the acute level of care because of a new illness while still on the wait-list. The period of patient enrollment was from July 31, 1996 until January 31, 1997, and included all patients downgraded and expected to require permanent nursing home placement. Data collection was continued for two months after patient enrollment was completed. Patients still waitlisted at the end of the data collection period were censored on the final day of data collection.

Data Analysis
Patient characteristic variables were dichotomized (yes/no) depending on whether or not the patient had the characteristic. Age was initially used as a continuous variable but was subsequently dichotomized to ≥ or < 80. Marital status (married, single, widowed, or divorced) and ethnicity were analyzed by comparing each characteristic to all of the remaining ones in separate analyses. For each dichotomized patient characteristic a comparison was made between the mean number of days spent wait-listed for nursing home placement in those with and without the characteristic using the Wilcoxon Rank Sum test. Two clinically significant cutpoints for number of days waitlisted for nursing home placement were subsequently chosen: > 14 days compared to ≤ 14 days, and > 30 days compared to ≤ 30 days. Separate univariate logistic regression analyses were performed using these two cutpoints as the outcome variables for each patient characteristic. All significant variables were then entered into separate multivariate logistic regression analyses using the same cutpoints for the number of days waitlisted for placement.

Results
There were a total of 176 waitlisted patients who met the entry criteria and were ultimately enrolled in the study (Table 1). The average age was 82.4 (range 65-99, SD ± 8.1) and 57% were women. Sixty-one percent of the patients were of Japanese ancestry. This large percentage was due to the large proportion (about 30%) of Japanese-Americans in the older Hawaii population and because one of the hospitals traditionally serves a Japanese-American population. Of the patients who were transferred, 86% were ultimately placed in a long-term care facility. The remainder either required readmission to the acute hospital or expired while still wait-listed. The patients spent a mean of 15.3 days wait-listed (range 0-163, SD ± 25.1) with a median length of time of 7 days waiting for transfer. The data were highly skewed with 137 (78%) of the patients being placed within 2 weeks of being wait-listed while the remaining patients continued to be wait-listed for various longer lengths of time. The longest length of time an individual was wait-listed prior
to eventually being placed in a nursing home was 57 days. At the end of the study there were 11 patients who remained wait-listed.

Patient characteristics evaluated were dichotomized (yes/no) and the mean days spent wait-listed were compared using the Wilcoxon Rank Sum test. Variables that reached statistical significance are shown in the figure. Patients requiring intravenous antibiotics at the time they were wait-listed (p=0.01), those with a stage II or higher grade pressure ulcer (p=0.02), and those with diabetes mellitus requiring at least once daily insulin injection (p=0.03) were found to spend significantly more time wait-listed. Patients who required isolation precautions in the hospital due to a suspected or documented infection with methicillin-resistant Staph. Aureus (MRSA), Mycobacterium tuberculosis (MTB), or vancomycin resistant enterococcus (VRE) were more likely to remain wait-listed for longer periods (p<0.001). Most of these patients (8 out of 13) were on isolation precautions due to an infection with VRE which was itself significantly associated with being wait-listed longer (p<0.001). VRE thus accounted for the majority of increased wait-listed days for patients on isolation precautions. Of the behavioral problems studied, only resistance to care (p=0.02) was found to be significant. However, when all behavior variables were combined, any patient who had at least one behavioral problem waited significantly longer for a nursing home bed (p=0.03) than those without any such problems.

Patients being evaluated for nursing home placement are required to be screened for psychiatric disorders and developmental disabilities to insure that they receive proper placement and follow-up psychiatric care once they are transferred to a long-term care facility. If the patient is found to have a psychiatric diagnosis or is on psychoactive medication for a psychiatric condition, evaluation by a psychiatrist is required prior to transfer (PASAAR). As shown in the figure, patients awaiting psychiatric clearance were found to wait for a longer period of time before transfer (p=0.01).

When age was evaluated as a continuous variable there was a positive trend showing an increased ease of transfer with increasing age, but this was not statistically significant. Patient age was then dichotomized to ≥80 or <80 years with the patients in the older group numbering 106. The group of patients ≥ age 80 showed significantly less time being wait-listed (p=0.003).

Patients who were able to pay privately for care also found it much easier to secure a bed in a long-term care facility (p<0.001). None of the other variables reached statistical significance although patients without an identified responsible family member or guardian showed a trend towards longer wait-list time (p=0.07). No significant differences were seen between the two participating hospitals or whether the patient required SNF or ICF level of care.

Statistically significant variables were subsequently analyzed using univariate and multivariate logistic regression (tables 2 and 4). Patients who were wait-listed beyond 14 days and those who remained wait-listed for over 30 days were separately analyzed. Most of the same variables that were significant using the Wilcoxon Rank Sum test remained statistically significant in patients wait-listed beyond 14 days except for patients with behavioral problems. Many of the patients wait-listed beyond 14 days continued to have difficulty being transferred beyond 30 days. This is particularly true in patients with a history of VRE infections who were 25 times more likely to remain on the wait-list for over a month. In both the univariate and multivariate models patients ≥ 80 years of age were
Table 2—Univariate Logistic Regression—waitlisted > 14 days

<table>
<thead>
<tr>
<th>Variable</th>
<th>odds ratio</th>
<th>95% CI</th>
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</thead>
<tbody>
<tr>
<td>IV antibiotics</td>
<td>9.2</td>
<td>1.7-48.5</td>
</tr>
<tr>
<td>DM on insulin</td>
<td>5.4</td>
<td>1.6-18.0</td>
</tr>
<tr>
<td>Pressure ulcer</td>
<td>2.4</td>
<td>1.1-5.8</td>
</tr>
<tr>
<td>Isolation precautions</td>
<td>5.4</td>
<td>1.6-17.9</td>
</tr>
<tr>
<td>VRE infection</td>
<td>2.2</td>
<td>1.7-19.6</td>
</tr>
<tr>
<td>Psychiatric evaluation</td>
<td>5.9</td>
<td>1.6-22.2</td>
</tr>
<tr>
<td>Age ≥ 80</td>
<td>0.42</td>
<td>0.21-0.85</td>
</tr>
<tr>
<td>Private pay ICF</td>
<td>0.08</td>
<td>0.01-0.58</td>
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</table>

Table 3—Univariate Logistic Regression—waitlisted > 30 days

<table>
<thead>
<tr>
<th>Variable</th>
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<tbody>
<tr>
<td>IV antibiotics</td>
<td>12.8</td>
<td>2.6-62.1</td>
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<tr>
<td>DM on insulin</td>
<td>4.6</td>
<td>1.3-17.1</td>
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<tr>
<td>Isolation precautions</td>
<td>10.7</td>
<td>3.0-37.7</td>
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<tr>
<td>VRE infection</td>
<td>25.7</td>
<td>4.6-143</td>
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<tr>
<td>Resists care</td>
<td>3.7</td>
<td>1.1-11.7</td>
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<tr>
<td>Age ≥ 80</td>
<td>0.24</td>
<td>0.09-0.66</td>
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Table 4.—Multivariate Logistic Regression Models

<table>
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<tr>
<th>Variable</th>
<th>odds ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>waitlisted &gt; 14 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV antibiotics</td>
<td>16.7</td>
<td>1.3-211</td>
</tr>
<tr>
<td>DM on insulin</td>
<td>4.8</td>
<td>1.2-20.4</td>
</tr>
<tr>
<td>Psychiatric evaluation</td>
<td>5.1</td>
<td>1.2-22.1</td>
</tr>
<tr>
<td>waitlisted &gt; 30 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV antibiotics</td>
<td>14.5</td>
<td>1.5-144</td>
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<tr>
<td>DM on insulin</td>
<td>8.9</td>
<td>1.2-67.2</td>
</tr>
<tr>
<td>Age ≥ 80</td>
<td>0.07</td>
<td>0.01-0.46</td>
</tr>
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much less likely to wait for a nursing home bed while those on IV antibiotics or insulin injections waited significantly longer to be placed.

Discussion

In the U.S., the average risk of nursing home admission for persons over age 65 is approximately 43%, with a lifetime risk of 28% for men and 45% for women. While the risk for nursing home admission is great, only about 1.3 million people in this age group (about 5% of the population) reside in nursing homes at any point in time. With this increase in the number of persons over 65 from 1977 to 1985, the percentage of persons residing in nursing homes has remained steady. Thus, many elders will spend at least some time in a nursing home, but most do not permanently reside there.

Factors that have previously predicted higher nursing home utilization included increased age, poor functional status, and lack of an available caregiver. Age was the most consistent predictor. In 1989, the number of persons aged 65 and older represented 12% of the total U.S. population and life expectancy at birth rose from 46.9 years in 1900 to 71.9 years in 1989. Assuming that this trend continues, the year 2030 will have 65.6 million people in this age group representing 22% of the population. By far, the fastest growing segment of this population is people aged 85 and older, who are projected to total 6.5 million by the year 2020. The implications of this demographic change for nursing home utilization will be profound since 45% of current nursing home residents are persons over 85 years old.

The implications for Hawaii may be even more profound. While the percent population aged 65 and older is currently similar to the rest of the country, the number of available long-term care beds are far fewer. Further, Hawaii has the longest life expectancy of any state, and the rate of increase in the percent population aged 65 and older is two and one-half times the national average. One report has predicted a shortage of 4000 nursing home beds in Hawaii by the year 2010 unless steps are taken now to reduce demand or increase alternatives for long-term care. A previous study conducted by the Healthcare Association of Hawaii noted that the main reason patients were wait-listed was the lack of an available nursing home bed. Other studies have also documented this inverse relationship between the number of nursing home beds in a community and the number of days spent wait-listed prior to transfer. It has also been observed that some patients experience other barriers to placement and may remain wait-listed, even if a bed becomes available.

The current study attempted to characterize this group of patients and the characteristics of those who remain wait-listed longer.

We observed that patients with pressure ulcers, those receiving long-term IV antibiotics, and diabetics receiving insulin injections all waited longer for nursing home placement. All of these conditions require skilled nursing intervention and are costly in staff time, medications and supplies. Diabetics on insulin are often multiply impaired. They require increased nursing time for blood glucose monitoring, careful insulin administration, and nursing observation for adverse events associated with dosing. Intravenous antibiotic administration and diabetics requiring insulin injections also require closer physician monitoring, which may be difficult to obtain in an open-staff, fee-for-service environment, when physicians are not based in the facility. Subsequent to our study, the Medicare Prospective Payment System (PPS) was instituted in which the facility is paid a flat rate for Medicare SNF patients. It is anticipated that cost factors will only further increase the undesirability of these patients, especially if the facility already has an adverse case mix. Facility size may also be a factor. In nursing homes with fewer beds there would be a smaller patient base over which to distribute costs. While facilities may be willing to accept some of these patients, they will likely keep their census of costly and time consuming patients to a manageable level.

The emergence of multi-drug resistant microorganisms is a serious concern for nursing homes as well as for acute hospitals. The cost of the antibiotics used to treat these patients is prohibitive, and the nursing hours required per patient is also greater when numerous administrations of parenteral antibiotics are required. Our study found that patients with VRE were four times more likely to have nursing home placement delayed and were twenty-five times more likely to wait for over a month to be transferred. In addition to cost, an important concern for the nursing home is the infrequent availability of private rooms and the possibility of VRE transmission to other residents. This situation is reminiscent of previous concerns...
about MRSA. There are now so many patients with MRSA that nursing homes are sometimes able to cohort these residents into gender-appropriate multi-bed rooms. In our study population there were five patients with MRSA; yet, we found that this was not a significant factor delaying transfer to the nursing home. Studies in the long-term care setting show that while VRE colonization rates are increasing in nursing homes the risk of infection is low\textsuperscript{21,22} and transmission to other patients can be effectively minimized with proper infection control.\textsuperscript{23} However, most facilities are likely to be concerned about occasional lapses in infection control procedures, and subsequent spread of infection to other frail and vulnerable residents.

The lack of significant impact on placement attributed to cognitive impairment or behavior was surprising. Patients who resisted care or who demonstrated at least one problem behavior remained wait-listed for longer periods of time on univariate analyses; however, these factors were not significant when analyzed with other variables in multivariate models. The behavior variables cited most often in our study population were wandering (n=27) and resisting care (n=19), behaviors that are frequently present in persons with cognitive impairment. Cognitive impairment was given as a problem in 64\% of the patients in this study but was not shown to prolong the time they spent wait-listed. Patients with cognitive impairment and behavior problems also tend to be dependent for at least some of their activities of daily living (ADL’s). These factors are often the reasons that family member decide on placement. In 1996, the Hawaii Long-term Care Task Force reported that when using the level of ADL dependence as a measure of patient acuity, nursing home patients in Hawaii consistently required higher levels of care than in the remainder of the U.S.\textsuperscript{24} Thus, it would appear that nursing homes in Hawaii are accustomed to caring for higher acuity patients with cognitive impairment.

There were only 10 patients requiring psychiatric screening in our study population but they showed a statistically significant time being wait-listed beyond 14 days. Delays in transfer to nursing homes while awaiting psychiatric screening was also noted in the 1990 Healthcare Association of Hawaii report.\textsuperscript{19} The reason for the delay is uncertain, but may include regulations that nursing facilities assure ongoing psychiatric follow-up. It is often difficult to obtain psychiatric care in nursing homes, especially in facilities located at some distance from major medical centers. There may also be a delay in obtaining inpatient psychiatric evaluation in the hospital for the required screening assessment.

Patients in this study who were over 80 years of age were found to remain wait-listed for significantly shorter periods of time. This unanticipated result was consistently found, regardless of how the data analysis was performed. The reason for this finding is uncertain. Given that the mean age of the study population was 82.4 with a median of 83, many of the patients fell into the over 80 age group. Thus it would seem unlikely that an age differential could be demonstrated. It is possible that a variable not included in the study influenced the finding.

Patients able to pay privately for nursing home care were found to be wait-listed for significantly less time. Only 48 patients in our study had the funds to pay privately and all were ICF level of care. The reasons for this finding are understandable since Medicare does not pay for ICF care, and the private-pay rate for ICF is greater than the Medicaid reimbursement. However, although some patients can afford to pay privately for some period of time, without long-term care insurance most patients exhaust their savings and require Medicaid assistance at some point.

There are several limitations to this study that could influence the results. The study group consisted on only 176 patients. While there were a number of variables that were highly significant even in this population, there were others that the social workers reported had a strong negative impact on placement but which did not rise to significance in our study. Most of these negative findings were due to a small number or absence of these characteristics in our study population. Examples of this include patients on hemodialysis (n=3), those with tracheostomies (n=2), ventilator dependent patients (n=0), comatose patients (n=0), and patients without an identified responsible family member or guardian (n=2). By including only patients 65 years of age and older we undoubtedly missed a group of younger individuals who may have even more difficulty being transferred due to the lack of Medicare SNF benefit. The study was conducted in only two hospitals and thus may not reflect the experience of other hospitals in Hawaii. However, the results from both hospitals were quite similar. This is especially interesting since one hospital has a larger proportion of Medicare admissions and its own attached long-term care facility. It appears as though certain patient characteristics make long-term care placement difficult, even in a hospital’s own long-term care facility. This study may not be able to be generalizable to other areas of the country where capitalization costs are much less and, hence, nursing home beds are more plentiful. The current situation in Hawaii might predict conditions that will emerge in areas with a growing population of older people and a stable or declining number of long-term care beds.\textsuperscript{5,19}

The State of Hawaii and the private sector have put forth several initiatives as a way of attempting to deal with the increasing numbers of patients requiring long-term care. Several are currently being undertaken using residential care homes. Higher-level care homes (ARCH I) may now have up to 20\% of their residents at the ICF level of care. There are also special programs, such as the Foster Family Program, wherein care home operators receive special training to be able to care for ICF patients in their care home. The State of Hawaii was also instrumental in helping to establish a PACE program (Program for All-inclusive Care for the Elderly) demonstration project which attempts to keep ICF-level Medicaid eligible older people in their own homes by providing medical care, day care, and other services. In 2002, the PACE program currently operates as an independent entity based at Maluhia Hospital and has approximately 80 clients enrolled.

The major factors causing delays in nursing home placement in Hawaii is the shortage of nursing home beds, the resulting high occupancy rates, the shortage of available family caregivers, and the few nursing home alternatives. In our study, several patient characteristics further delayed transfer from acute-care facilities to nursing homes. Some of these, such as the presence of VRE, pressure ulcers, long-term IV antibiotics, and diabetes mellitus requiring insulin injections, involve costs for increased staff time, expensive medications, and the need for private rooms. When nursing home beds are in short supply, this study illustrates factors that may result in prolonged lengths of stay in acute hospitals. The finding that nursing home placement is more easily obtained for patients who can afford
TRIZA (benzyl paracitrate)

Rx Only

DESCRIPTION: TRIZA* (benzyl paracitrate) 3% Gel and TRIZA (benzyl paracitrate) 3% Cream are topical gel-based, benzyl paracitrate containing preparations for use in the treatment of acne vulgaris. Benzyl paracitrate is an oxidizing agent that possesses antibacterial properties and is classified as a keratolytic. Benzyl paracitrate (C7H7O2) is represented by the following chemical structure:

\[
\text{C}_7\text{H}_7\text{O}_2
\]

TRIZA 3% Gel contains Benzyl paracitrate 3% as the active ingredient in a gel-based formulation consisting of Purified Water USP, C12-15 Alkyl Benzenesulphonate, Glycolal USP, Cetyl Stearic Alcohol, Glycitol, Poloxamer, and Preservatives. TRIZA 3% Cream contains Benzyl paracitrate 3% as the active ingredient in a vehicle consisting of Glyceryl Oleate/White Petroleum USP, C12-15 Alkyl Benzenesulphonate Copolymer, Purified Water USP, Plasturan HPMC, Sodium C14-16 Olefin Sulfonate, Zinc Laurate, Carbomer, Poloxamer Solution, and Preservatives.

CLINICAL PHARMACOLOGY: The mechanism of action of benzyl paracitrate is not totally understood but its potential activity against Propionibacterium acne is thought to be a major mode of action. In addition, patients treated with benzyl paracitrate show a reduction in lesion, and fair isotaxa and mild desquamation (drying and peeling skin) with simultaneous reduction in comedones and acne lesions. Little is known about the percutaneous penetration metabolism and excretion of benzyl paracitrate, although it has been shown that benzyl paracitrate absorbed by the skin is metabolized to benzaldehyde and then excreted as benzoic acid in the urine. There is no evidence of systemic toxicity caused by benzyl paracitrate in humans.

INDICATIONS AND USAGE: TRIZA 3% Gel and TRIZA 3% Cream are indicated for the topical treatment of acne vulgaris.

CONTRAINdications: These preparations are contraindicated in patients with a history of hypersensitivity to any of their components.

WARNINGS: When using this product, avoid unnecessary sun exposure and use a sunscreen.

PRECAUTIONS: General: For external use only. If sneezing irritation develops, discontinue use and institute appropriate therapy. After rectangular burn treatment may be affected with less frequent application. These preparations should not be used or near the eyes or on mucous membranes.

Information for Patients: Avoid contact with eyes, eyelids, and mucous membranes. If accidental contact occurs, rinse with water. Contact with any colored material (including hair and fabric) may result in staining or discoloration. If excessive irritation develops, discontinue use and consult your physician.

Carcinogenesis/Mutagenesis/Impairment of Fertility: Data from several studies employing a strain of mice that are susceptible to developing cancer suggest that benzyl paracitrate acts as a tumor promoter. The clinical significance of these findings is unknown. Benzyl paracitrate has not been found to be mutagenic (Ames Test) and there is no published data indicating it impairs fertility.

Pregnancy: Teratogenic Effects: Pregnancy Category C: Animal reproduction studies have not been conducted with benzyl paracitrate. It is not known whether benzyl paracitrate can cause fetal harm when administered to a pregnant woman or can effect reproduction capacity. Benzyl paracitrate should be used by a pregnant woman only if clearly needed. There are no available data on the effect of benzyl paracitrate on the labor phase, development, and functional maturation of the unborn child.

Nursing Mothers: It is not known whether the drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when benzyl paracitrate is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Allergic contact dermatitis and dryness have been reported with topical benzyl paracitrate preparations.

OVERDOSAGE: If excessive scaling, erythema, or edema occurs, the use of these preparations should be discontinued. To hasten resolution of the adverse effects, cool compresses may be used. After symptoms and signs subside, a reduced dosage schedule may be cautiously tried if the condition is judged to be due to excessive use and not allergy.

DOSEAGE AND ADMINISTRATION: TRIZA 3% Gel: Apply once or twice daily to cover affected areas, or as directed by your dermatologist. Use after washing with a mild detergent, such as one of the TRIZA Cleaners, and water.

TRIZA 3% Cream: Wash affected areas once or twice daily and as directed by your dermatologist. Avoid contact with eyes or mucous membranes. Use skin and liberally apply to areas to be cleansed and massage gently into skin for 10-20 seconds working into a full lather, rinse thoroughly and pat dry. If drying occurs, it may be controlled by rinsing cleanser off sooner or using less often.

HOW SUPPLIED: TRIZA 3% Gel: 1.5 oz (42.5 g) tube, NDC 99330-204-11. TRIZA 3% Cream: 1 oz (28.3 g) tube, NDC 99270-208. Scored at 15: 25 - 29 (77 - 84%), Covered by US Patent 5,649,889, 5,234,334, 5,409,706, and 5,322,996.

Manufactured for: MEDICIS, The Dermatology Company. San Antonio, TX 78240.


Prescribing Information as of January 2001: 20680-01E9

References:


