Survey: Use of Temporary Physicians on the Rise

BY NASEEM S. MILLER

Demand for temporary physicians, known as "locum tenens" positions, is rising, according to a survey of temporary physicians and the hospitals and health groups that use them.

The findings suggest a shift in the reasons for hiring staff on a temporary basis. "Historically, locum tenens doctors have been used to hold a place for ill, vacationing, or otherwise absent doctors pending their return. Today, national doctor shortages have prompted hospitals, medical groups, and others to use temporary doctors to maintain services in lieu of permanent doctors, who may be difficult to find," according to the survey, which was conducted by Staff Care Inc., a company that matches temporary health care providers with medical institutions.

The number of facilities using locum tenens physicians rose from 72% in 2009 to 85% in 2010. Meanwhile, a slightly higher percentage of locum tenens physicians (33%) reported having less than 1 year of experience in 2010, compared with those in 2009 (30%), suggesting that locum tenens is attracting new physicians, according to the survey.

Demand was higher for physicians in certain specialties, especially in behavioral health, which topped the list for the type of temporary physicians requested most by health care groups, at 22%. Primary care physicians were the next most requested (20%), and temporary physicians were used to fill internal medicine slots in 12% of the cases.

The company surveyed 626 locum tenens physicians and 105 groups that use temporary physicians, via e-mail in 2010.

Staff Care estimates that 30,000-40,000 physicians worked on a locum tenens basis in 2010. "This number could grow significantly in the next several years as health reform and other challenges push physicians to seek alternative practice styles," according to the survey.

Among surveyed locum tenens physicians, the top reasons for working on a temporary basis were the ability to have freedom and flexibility and not to have to deal with medical politics. Being away from home and the uncertainty of the assignments were the top two drawbacks.

Groups that hired temporary physicians listed continuity of care and prevention of revenue loss as the top two benefits of bringing in locum tenens providers. Cost and lack of familiarity with the department or practice were the top two drawbacks.

Among the other survey findings were the following:

► In all, 41% of facilities were seeking locum tenens physicians in 2010, up from 40% in 2009. The slight uptick may suggest "that the downturn in physician utilization caused by the recession may be reversing," according to the survey.

► Locum tenens physicians are mostly accepted by patients, colleagues, and administrators.

► Of groups that hired locum tenens physicians, 84% said that bringing them to their facility was "worth the cost," compared with 79% in 2009.

► Some 55% of health care groups reported using one to three locum tenens physicians in a typical month; 37% reported using none, 7% reported using four to six, and 1% reported using seven or more.

► Of surveyed physicians, 80% said they find working on a locum tenens basis to be as satisfying as or more satisfying than conventional practice.

► Overall, 60% of the physicians said they plan to practice on a locum tenens basis for more than 3 years.

► The largest percentage of locum tenens physicians (28%) reported primary care as their specialty.

► In all, 68% of physicians reported having 21 or more years of experience; 16% had 11-20 years; 7% had 6-10 years; 7% had 1-5 years, and 2% had less than 1 year.

► Some 63% of physicians surveyed reported taking on one to three locum tenens assignments per year; 19% reported taking on four to six assignments annually, and 18% took on seven or more. ■

abatacept was associated with a greater proportion of serious infections than the use of a TNF-blocker alone; and the combination therapy, compared to the use of a TNF-blocker alone, has not demonstrated improved clinical benefit in the treatment of RA. Therefore, the combination of TNF-blockers including SIMPONI® and abatacept is not recommended (see Drug Interactions). **Use with Anakinra** Concurrent administration of anakinra (an interleukin-1 antagonist) and another TNF-blocker, was associated with a greater portion of serious infections and neutropenia and no additional benefits compared with the TNF-blocker alone. Therefore, the combination of anakinra with TNF-blockers, including SIMPONI®, is not recommended (see Drug Interactions). **Hematologic Cytopenias** There have been post-marketing reports of pancytopenia, leukopenia, neutropenia, aplastic anemia, and thrombocytopenia in patients receiving TNF-blockers. Although, there were no cases of severe cytopenias seen in the SIMPONI® clinical trials, caution should be exercised when using TNF-blockers, including SIMPONI®, in patients who have significant cytopenias. **Vaccinations** Patients treated with SIMPONI® may receive vaccinations, except for live vaccines. No data are available on the response to live vaccination or the risk of infection, or transmission of infection after the administration of live vaccines to patients receiving SIMPONI®. In the Phase 3 PsA study, after pneumococcal vaccination, a similar proportion of SIMPONI®-treated and placebo-treated patients were able to mount an adequate immune response of at least a 2-fold increase in antibody titers to pneumococcal polysaccharide vaccine. In both SIMPONI®-treated and placebo-treated patients, the proportions of patients with response to pneumococcal vaccine were lower among patients receiving MTX compared with patients not receiving MTX. The data suggest that SIMPONI® does not suppress the humoral immune response to the pneumococcal vaccine. **ADVERSE REACTIONS** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. **Clinical Studies Experience** The safety data described below are based on 5 pooled, randomized, double-blind, controlled Phase 3 trials in patients with RA, PsA, and AS (Studies RA-1, RA-2, RA-3, PsA and AS). These 5 trials included 639 control-treated patients and 1659 SIMPONI®-treated patients including 1089 with RA, 292 with PsA, and 277 with AS. The proportion of patients who discontinued treatment due to adverse reactions in the controlled Phase 3 trials through Week 16 in RA, PsA and AS was 2% for SIMPONI®-treated patients and 3% for placebo-treated patients. The most common adverse reactions leading to discontinuation of SIMPONI® in the controlled Phase 3 trials through Week 16 were sepsis (0.2%), alanine aminotransferase increased (0.2%), and aspartate aminotransferase increased (0.2%). The most serious adverse reactions were: Serious Infections; Malignancies. Upper respiratory tract infection and nasopharyngitis, were the most common adverse reactions reported in the combined Phase 3 RA, PsA and AS trials through Week 16, occurring in 7% and 6% of SIMPONI®-treated patients as compared with 6% and 5% of control-treated patients, respectively. **Infections** In controlled Phase 3 trials through Week 16 in RA, PsA, and AS, infections were observed in 28% of SIMPONI®-treated patients compared to 25% of control-treated patients. **Liver Enzyme Elevations** There have been reports of severe hepatic reactions including acute liver failure in patients receiving TNF-blockers. In controlled Phase 3 trials of SIMPONI® in patients with RA, PsA, and AS through Week 16, ALT elevations ≥5 x ULN occurred in 0.2% of control-treated patients and 0.7% of SIMPONI®-treated patients, and ALT elevations ≥3 x ULN occurred in 2% of control-treated patients and 2% of SIMPONI®-treated patients. Since many of the patients in the Phase 3 trials were also taking medications that cause liver enzyme elevations (e.g., NSAIDs, MTX), the relationship between SIMPONI® and liver enzyme elevation is not clear. **Autoimmune Disorders and Autoantibodies** The use of TNF-blockers has been associated with the formation of autoantibodies and, rarely, with the development of a lupus-like syndrome. In the controlled Phase 3 trials in patients with RA, PsA, and AS through Week 14, there was no association of SIMPONI® treatment and the development of newly positive anti-dsDNA antibodies. **Injection Site Reactions** In controlled Phase 3 trials through Week 16 in RA, PsA and AS, 6% of SIMPONI® treated patients had injection site reactions compared with 2% of control-treated patients. The majority of the injection site reactions were mild and the most frequent manifestation was injection site erythema. In controlled Phase 2 and 3 trials in RA, PsA, and AS, no patients treated with SIMPONI® developed anaphylactic reactions. **Psoriasis: New-Onset and Exacerbations** Cases of new onset psoriasis, including pustular psoriasis and palmoplantar psoriasis, have been reported with the use of TNF-blockers, including SIMPONI. Cases of exacerbation of pre-existing psoriasis have also been reported with the use of TNF-blockers. Many of these patients were taking concomitant immunosuppressants (e.g., MTX, corticosteroids). Some of these patients required hospitalization. Most patients had improvement of their psoriasis following discontinuation of their TNF-blocker. Some patients have had recurrences of the psoriasis when they were re-challenged with a different TNF-blocker. Discontinuation of SIMPONI® should be considered for severe cases and those that do not improve or that worsen despite topical treatments. **Immunogenicity** Antibodies to SIMPONI® were detected in 57 (4%) of SIMPONI®-treated patients across the Phase 3 RA, PsA and AS trials through Week 24. Similar rates were observed in each of the 3 indications. Patients who received SIMPONI® with concomitant MTX had a lower proportion of antibodies to SIMPONI® than patients who received SIMPONI® without MTX (approximately 2% versus 7%, respectively). Of the patients with a positive antibody response to SIMPONI® in the Phase 2 and 3 trials, most were determined to have neutralizing antibodies to golimumab as measured by a cell-based functional assay. The small number of patients positive for antibodies to SIMPONI® limits the ability to draw definitive conclusions regarding the relationship between antibodies to golimumab and clinical efficacy or safety measures. The data above reflect the percentage of patients whose test results were considered positive for antibodies to SIMPONI® in an ELISA assay, and are highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody positivity in an assay may be influenced by several factors including sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to SIMPONI® with the incidence of antibodies to other products may be misleading. **Other Adverse Reactions** The adverse drug reactions that occurred at a rate of at least 1% in the combined SIMPONI® groups during the controlled period of the 5 pooled Phase 3 trials through Week 16 in patients with RA, PsA, and AS are summarized below. Patients may have taken concomitant MTX, sulfasalazine, hydroxychloroquine, low-dose corticosteroids (≤10 mg of prednisone/day or equivalent), and/or NSAIDs during the trials.

The numbers (percentages) of adverse drug reactions for Placebo ± DMARDS-treated patients (n=639) and SIMPONI® ± DMARDS-treated patients (n=1659), respectively, were: *Upper respiratory tract infection:* 37 (6%), 120 (7%); *Nasopharyngitis:* 31 (5%), 91 (6%); *Alanine aminotransferase increased:* 18 (3%), 58 (4%); *Injection site erythema:* 6 (1%), 56 (3%); *Hypertension:* 9 (1%), 48 (3%); *Aspartate aminotransferase increased:* 10 (2%), 44 (3%); *Bronchitis:* 9 (1%), 31 (2%); *Dizziness:* 7 (1%), 32 (2%); *Sinusitis:* 7 (1%), 7 (2%); *Influenza:* 7 (1%), 25 (2%); *Pharyngitis:* 8 (1%), 22 (1%); *Rhinitis:* 4 (< 1%), 20 (1%); *Pyrexia:* 4 (< 1%), 20 (1%); *Oral herpes:* 2 (< 1%), 16 (1%); *Paraesthesia:* 2 (< 1%), 16 (1%). ***Less common clinical trial adverse drug reactions*** Adverse drug reactions that occurred <1% during the SIMPONI clinical trials included the following events listed by system organ class: *Nervous system disorders:* central nervous system demyelinating disorders (such as multiple sclerosis), peripheral demyelinating polyneuropathy; *Vascular disorders:* vasculitis (systemic); *Skin and subcutaneous tissue disorders:* vasculitis (cutaneous) **DRUG INTERACTIONS: Methotrexate**. For the treatment of RA, SIMPONI® should be used with MTX. Since the presence or absence of concomitant MTX did not appear to influence the efficacy or safety of SIMPONI® in the treatment of PsA or AS, SIMPONI® can be used with or without MTX in the treatment of PsA and AS. **Biologic Products for RA, PsA, and/or AS** An increased risk of serious infections has been seen in clinical RA studies of other TNF-blockers used in combination with anakinra or abatacept, with no added benefit; therefore, use of SIMPONI® with abatacept or anakinra is not recommended. A higher rate of serious infections has also been observed in RA patients treated with rituximab who received subsequent treatment with a TNF-blocker. There is insufficient information to provide recommendations regarding the concomitant use of SIMPONI® and other biologic products approved to treat RA, PsA, or AS. **Live Vaccines** Live vaccines should not be given concurrently with SIMPONI®. **Cytochrome P450 Substrates** The formation of CYP450 enzymes may be suppressed by increased levels of cytokines (e.g., TNFα) during chronic inflammation. Therefore, it is expected that for a molecule that antagonizes cytokine activity, such as golimumab, the formation of CYP450 enzymes could be normalized. Upon initiation or discontinuation of SIMPONI® in patients being treated with CYP450 substrates with a narrow therapeutic index, monitoring of the effect (e.g., warfarin) or drug concentration (e.g., cyclosporine or theophylline) is recommended and the individual dose of the drug product may be adjusted as needed. **USE IN SPECIFIC POPULATIONS: Pregnancy** Pregnancy Category B – There are no adequate and well-controlled studies of SIMPONI® in pregnant women. Because animal reproduction and developmental studies are not always predictive of human response, it is not known whether SIMPONI® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. SIMPONI® should be used during pregnancy only if clearly needed. An embryofetal developmental toxicology study was performed in which pregnant cynomolgus monkeys were treated subcutaneously with golimumab during the first trimester with doses up to 50 mg/kg twice weekly (360 times greater than the maximum recommended human dose-MHRD) and has revealed no evidence of harm to maternal animals or fetuses. Umbilical cord blood samples collected at the end of the second trimester showed that fetuses were exposed to golimumab during gestation. In this study, *in utero* exposure to golimumab produced no developmental defects to the fetus. A pre- and post-natal developmental study was performed in which pregnant cynomolgus monkeys were treated with golimumab during the second and third trimesters, and during lactation at doses up to 50 mg/kg twice weekly (860 times and 310 times greater than the maximal steady state human blood levels for maternal animals and neonates, respectively) and has revealed no evidence of harm to maternal animals or neonates. Golimumab was present in the neonatal serum from the time of birth and for up to 6 months postpartum. Exposure to golimumab during gestation and during the postnatal period caused no developmental defects in the infants. **Nursing Mothers** It is not known whether SIMPONI® is excreted in human milk or absorbed systemically after ingestion. Because many drugs and immunoglobulins are excreted in human milk, and because of the potential for adverse reactions in nursing infants from SIMPONI®, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. In the pre- and post-natal development study in cynomolgus monkeys in which golimumab was administered subcutaneously during pregnancy and lactation, golimumab was detected in the breast milk at concentrations that were approximately 400-fold lower than the maternal serum concentrations. **Pediatric Use** Safety and effectiveness of SIMPONI® in patients less than 18 years of age have not been established. **Geriatric Use** In the Phase 3 trials in RA, PsA, and AS, there were no overall differences in SAEs, serious infections, and AEs in SIMPONI®-treated patients ages 65 or older (N=155) compared with younger SIMPONI®-treated patients. Because there is a higher incidence of infections in the geriatric population in general, caution should be used in treating geriatric patients with SIMPONI®. **OVERDOSAGE** In a clinical study, 5 patients received protocol-directed single infusions of 10 mg/kg of intravenous SIMPONI® without serious adverse reactions or other significant reactions. The highest weight patient was 100 kg, and therefore received a single intravenous infusion of 1000 mg of SIMPONI®. There were no SIMPONI® overdoses in the clinical studies. **PATIENT COUNSELING INFORMATION Patient Counseling** Patients should be advised of the potential benefits and risks of SIMPONI®. Physicians should instruct their patients to read the Medication Guide before starting SIMPONI® therapy and to read it each time the prescription is renewed. **Infections** Inform patients that SIMPONI® may lower the ability of their immune system to fight infections. Instruct the patient of the importance of contacting their doctor if they develop any symptoms of infection, including tuberculosis, invasive fungal infections, and hepatitis B reactivation. **Malignancies** Patients should be counseled about the risk of lymphoma and other malignancies while receiving SIMPONI®. **Allergic Reactions** Advise latex-sensitive patients that the needle cover on the prefilled syringe as well as the prefilled syringe in the prefilled SmartJect® autoinjector contains dry natural rubber (a derivative of latex). **Other Medical Conditions** Advise patients to report any signs of new or worsening medical conditions such as congestive heart failure, demyelinating disorders, autoimmune diseases, liver disease, cytopenias, or psoriasis.

References: 1. SEER [database online]. U.S. Population Data—1969-2004. Bethesda, MD; National Cancer Institute. Release date: January 3, 2007. Available at: http://www.seer.cancer.gov/popdata.

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Horsham, PA 19044, US 1-800-457-6399 December 2010 25SM11001