## **Desert Shield/Storm Medical Issues Review** and Ad Hoc Working Group

A brief description of the Committee formed to look at the medical problems that could come up in support of Desert Shield/Storm, particularly in anticipation of the use of chemical and biological warfare agents and environmental Problems related to SWA and the desert environment.

Following the Iraqi invasion of Kuwait and the Presidents decision to send in US Forces, the Army Medical Department shifted its focus to supporting this mission. What evolved over the next seven months was a Herculean effort that resulted in the deployment of almost 25,000 medical personnel, including over 1,400 physicians and 44 hospitals. The logistical result was nothing short of remarkable. Much of the credit should go to the efforts of many people over the preceding years who worked on developing deployment scenarios and were successful in the development and purchase of DEPMEDS.

In many ways the system worked as it should and policy and doctrine were utilized. However, due to the enemy's capabilities and location, this deployment was anything but routine. Early in the scenario, due to intelligence information, concerns revolving around the potential use of biologic and chemical agents quickly surfaced. A Bio-Chem Working Group was established at the Office of The Surgeon General to address issues related to prevention, diagnosis and treatment of these agents. As we worked through some of the issues, it became apparent that there were many other medical problems which needed attention and could not be handled in the usual way. Colonel Edmund Tramont, MD, suggested that we establish a Problem, Development and Assessment (PDA) Committee to look at the medical problems that would come up in support of Desert Shield and attempt to develop methods to expedite solutions to the issues. The Desert Shield/Storm Medical Issues Review and Ad Hoc Working Group was thus established.

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The author was appointed to chair the majority of the meetings. The membership of the committee was never formally structured but evolved from the members of the Bio-Chem Working Group. This seemed a logical step since at least in the beginning, there was considerable overlap with this committee. The working group was made up of predominately Army Medical Department personnel but had significant representation from both the Air Force and Navy. It included members of the Joint Staff, Armed Forces Medical Intelligence Center (AFMIC), Army and Navy Research and Development Command, Medical Logistics, Medical Operations, as well as clinicians and consultants. Representation was not always the same at each meeting but was fairly consistent. Experts on given subjects were invited as needed.

Concomitant with the establishment of the committee, it was felt that there was no readily available source of information on medical problems in the theater of operations.

This prompted us to develop a pamphlet entitled "Diagnosis and Treatment of Diseases of Tactical Importance to US CENTCOM Forces 1990." As the months went on and more knowledge was obtained, a second edition was published in early 1991. This pamphlet was written by Colonel Charles Oster, MD, Chief of Infectious Disease Service at Walter Reed Army Medical Center and several of his staff. The section on Biological Threat Agents was written by Lt Col Kelly McKee, MD, from the Medical Division, US Army Medical Institute of Infectious Diseases (USAMRIID), Ft. Detrick, Maryland. This was printed at the Department of Defense Printing Office in the Pentagon on a priority basis. Ultimately, 3,000 to 4,000 copies were distributed worldwide. The size of the pamphlet allowed it to be carried in the BDU pocket. Topics to be covered and approaches to therapy were discussed at length during the meetings of the Working Group on Medical Issues. An especially thorny problem was the section on potential biologic agents. Much of this was considered classified data and initially there was considerable criticism for discussing this issue in an open forum. Nonetheless, with support of the Surgeon General we persevered and the pamphlet was published.

A partial listing of Medical issues discussed is as follows:

- Treatment of Sandfly Fever.
- Antibiotic Therapy for Anthrax Exposure.
- Use of Ribavirin for Sandfly Fever and Congo-Crimean Fever.
- Use of Investigational New Drugs (IND).
- Use of Monoclonal Antibody for Gram Negative Sepsis.
- Availability and Purchase of Immune Serum Globulin.
- The Potential Use of Hepatitis A Vaccine.
- The Purchase and Use of Cholera/ETEC Vaccine.
- Consideration of the New Oral Typhoid Vaccine.
- Development of a Shigella Vaccine.
- Treatment of Leishmaniasis Cutaneous and Visceral.
- Use of Antibiotic Prophylaxis for Treatment of Wounds.
- Heat Related Issues.
- Use of Sun Glasses.
- Use of Antibiotics for Treatment of Diarrheal Diseases.
- Use of Insulin for Treatment of Diabetics in Theater.

• Treatment of Asthmatics in Theater Especially the Use and Stability of Epinephrine.

• Drug Interactions such as the Interaction of Pyridostigmine with other Prophylactic Drugs.

• Use of Carbohydrate/Electrolyte Beverages as Fluid Replacement.

• Purchase and Use of Non-FDA Licensed Chloroquine.

• Use of Granulocyte Stimulating Factor for the Potential Bone Marrow Suppression Associated with Chemical Agents such as Mustard Gas.

Disposal of Bodies Potentially Con-

taminated with Biologic or Chemical Agents.

As the Working Group discussed medical issues, recommendations were made. Since this was a multidisciplinary group, appropriate staffing was done at the time eliminating the need for protracted discussion at multiple levels. When it was determined that a drug or procedure was clearly needed and not currently in the inventory, a recommendation was made to the Director, Professional Services. It then went to The Surgeon General for approval. Once this was achieved, the Medical Research and Development Command was instructed, by virtue of its contracting capabilities, in conjunction with Medical Logistics, to purchase what was needed. Since the Army had been designated as the **Executive Agent for medical supplies** in support of Desert Shield/Storm, the purchased items were then made available to all of the Services. Obviously, significant input was obtained from all the Services before significant funds were utilized.

This committee brought many of us to the frontiers of medicine. We discussed and recommended the use of Investigational New Drugs (IND) that had not been approved by the Federal Drug Administration (FDA) for general use and not for use without informed consent. This frequently caused us to step into the murky area of recommending the use of drugs that the literature clearly indicated were of benefit but had not cleared the many

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hurdles that the FDA demands to ensure effectiveness and public safety. Some of the diseases that we could have faced were sufficiently rare to preclude the usual trials to satisfy efficacy and safety. Nonetheless, to not make available the best that we had to the troops seemed objectionable. The policy for the use of ciproflaxacin for the prophylaxis and treatment of pulmonary anthrax and the use of monoclonal antibody for prophylaxis and treatment of gram negative sepsis are two examples. The assistance of the Armed Forces Epidemiology Board was utilized on numerous occasions. They were extremely helpful in reviewing recommendations and making suggestions as appropriate.

The Medical Research and Development Command and the Assistant Secretary of Defense for Health Affairs approached the FDA for waivers and the use of INDs as necessary. This, at times, delayed the purchase and fielding of certain drugs but was unavoidable. Generally, the FDA was very cooperative in assisting in an unusual situation. Two of the stumbling blocks were the issues of perceived experimentation and informed consent. We always operated under the dictum that we were not conducting experiments on the troops. Recommendations were only made on drugs that had, in the experts' opinion, reached enough progress to no longer be considered experimental. That still meant they were considered INDs and, therefore, we were obligated to obtain informed consent. Needless to say, this is extremely difficult to do in a potential combat situation. In all cases, we attempted to develop a structure that would allow informed consent if possible and the collection of data as to efficacy and side effects. How successful we would have been if the scenario had been different is conjecture. Whenever we made a decision to use IND or there was the suggestion of experimentation, the plan was presented to the Human Subject Research and Review Board for their input and concurrence.

Clear benefit to the troops had to be shown before approval was obtained from this board. The suggestion by some supposedly well intentioned individuals that we were experimenting on the troops without their approval, especially in regard to vaccine utilization was very bothersome to us as we could not have agonized over this more, and clearly, we were not.

Drugs that were purchased in limited quantities were a problem in regard to distribution and location. Generally, they were located at the MEDSOM and would be pushed forward upon request. Guidelines for the use of drugs that would not normally be available were sent with the drugs. The Medical Research and Development Command (R&D) packaged the drugs and monitored the delivery and retrieval. They are also storing the INDs that were unused. Hopefully, ongoing protocols can benefit from these purchases.

This working group had wideranging impact on the medical care rendered to our troops during Desert Shield/Storm. It's efficacy and efficiency cannot be overemphasized. A lesson learned is that there needs to be a mechanism that encompasses all the disciplines of military medicine and that meets regularly. Frequently, we have many groups and organizations working in isolation on problems. There seems to be no central clearing house to monitor and recommend approaches to issues. It has been suggested that this working group be institutionalized and given a mission similar to what it did during the recent conflict. It should meet no less then every two months and review new and ongoing initiatives related to clinical and research fields. Recommendations for emphasis on research and the allocation of resources would be appropriate.

The membership of the committee should be more structured. The chairman of the committee should be the chief consultant to The Surgeon Gen-

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eral of the Army. It should have representatives of all three services and cover the spectrum of medicine. At the very least, there should be representatives from the research arena as well as the clinical areas. Logistics should be present to be able to review the issues and make appropriate suggestions. Clinically, the Consultants in Internal Medicine and Preventive Medicine could be permanent members and other consultants invited on a need basis. Recommendations of this committee should be forwarded to The Surgeons General for their concurrence. The appropriate allocation of funds and research emphasis would then be achieved.

During Desert Shield/Storm, the Medical Issues Review and Ad Hoc Working Group was formed to allow the expeditious discussion and review of therapies not readily available. Many issues were discussed and recommendations made. The working group had a great impact on the use of drugs and the establishment of mechanisms to utilize new modalities of therapy. As a lesson learned, this mechanism should be retained for the future and incorporated into the normal activities.