EMTALA Panel Tackles Shared Call, Disaster Issues

BY NELLIE BRISTOL
Contributing Writer

WASHINGTON — The Centers for Medicare and Medicaid Services should clarify its position on shared on-call services to assure hospitals that the arrangements are allowed under the Emergency Medical Treatment and Active Labor Act, a federal advisory panel has recommended.

"This is a huge issue around the country," said Dr. David Siegel, chair of the EMTALA technical advisory group and senior physician consultant/clinical coordinator for Florida Medical Quality Assurance Inc. (FMQAI). "We're being told that, essentially, under current policy … there's nothing wrong with [shared call], but the perception out there is that you can't do these things."

CMS staff explained to the advisory group that sharing call is allowed, but hospitals are still required to perform screening exams for patients before they are transferred to the on-duty hospital.

"Our policy is that if two hospitals sharing call coverage divide it up month one, month two, that's fine," said Molly Smith of the agency's Center for Medicare Management. "What hospitals do need to be aware of is that if a hospital this month doesn't have that call coverage but a patient does come to that emergency room asking for an examination … they still have an obligation under EMTALA to do the medical screening exam—they cannot just automatically transfer that patient out."

The panel agreed to the recommendation to publicize CMS's stance on shared call and will continue to discuss the issue at future meetings.

While shared call may be permitted by CMS, hospitals should ensure that their arrangements do not violate antitrust laws, cautioned panel member Julie Mathis Nelson, an attorney with Coppersmith Gordon Schermer Owens & Nelson, Phoenix.

Exemptions in Emergencies

The panel also agreed to explore expansion of EMTALA exemptions during emergency situations. Current law allows exemptions only during national emergencies, is limited to a 72-hour period, and applies only to transfer requirements.

The panel is considering allowing exemptions from EMTALA during state, local, and hospital-specific emergencies, as well as lengthening the exemption time period. "As we have learned from Hurricane Katrina and other types of disasters, a hospital's or physician's ability to comply with EMTALA may extend beyond the EMTALA transfer requirements and exceed 72 hours," according to technical advisory group documents.

EMTALA provisions being considered by the panel for waiver eligibility include medical screening examination, requirements defining qualified medical personnel, patient stabilization, documentation, and duty to accept transfers. Exemptions would be decided retrospectively, with some being decided on a case-by-case basis.

Panel member Warren Jones of the University of Mississippi, Jackson, argued that the technical advisory group did not need to address the issue, because efforts are underway at the national and state levels to reconfigure emergency procedures. "I don't think we need to regulate down to that level," he argued. "The one defense against an EMTALA allegation is that you employed good clinical judgment in providing access and making the decision in the best interest of the patient."

The panel will look into details of the exemptions and discuss recommendations at future meetings.

Consulting Personal Physicians

The group also approved recommendations specifically allowing communications between a treating physician and a patient's personal physician during the initial screening examination. EMTALA could be construed to prohibit those communications, panel members said, and the regulations should be clarified.

The EMTALA technical advisory group recommended that, while the contacted physician may give advice and provide information, the treating physician or qualified medical personnel should be responsible for the patient's care. The contact is not required and should not delay treatment.

After contact is made, the treating physician or qualified medical personnel would proceed with the patient's medical screening and stabilizing treatment as indicated, the recommendation says. If there is a difference of opinion between the physicians, the medical judgment of the treating clinician shall prevail, the panel agreed. ■

PlanB® (LEVONORGESTREL) tablets 0.75 mg

Brief Summary (See Package Brochure for Full Prescribing Information)

Rx only

Plan B® is intended to prevent pregnancy after known or suspected contraceptive failure or unprotected intercourse. Emergency contraceptive pills (like all oral contraceptives) do not protect against infection with HIV (the virus that causes AIDS) and other sexually transmitted diseases.

CONTRAINDICATIONS

Progestin-only contraceptive pills (POPs) are used as a routine method of birth control over longer periods of time, and are contraindicated in some conditions. It is not known whether these same conditions apply to the Plan B® regimen consisting of the emergency use of two progestin pills. POPs however, are not recommended for use in the following conditions:

- Known or suspected pregnancy
- Hypersensitivity to any component of the product
- Undiagnosed abnormal genital bleeding

WARNINGS

Plan B® is not recommended for routine use as a contraceptive.

Plan B® is not effective in terminating an existing pregnancy.

Effects on Menses

Menstrual bleeding patterns are often irregular among women using progestin-only oral contraceptives and in clinical studies of levonorgestrel for postcoital and emergency contraceptive use. Some women may experience spotting a few days after taking Plan B®. At the time of expected menses, approximately 75% of women using Plan B® had vaginal bleeding similar to their normal menses, 12-13% bled more than usual, and 12% bled less than usual. The majority of women (87%) had their next menstrual period at the expected time or within 7 days, while 13% had a delay of more than 7 days beyond the anticipated onset of menses. If there is a delay in the onset of menses beyond 1 week, the possibility of pregnancy should be considered.

Ectopic Pregnancy

Ectopic pregnancies account for approximately 2% of reported pregnancies (19.7 per 1,000 reported pregnancies). Up to 10% of pregnancies reported in clinical studies of routine use of progestin-only contraceptives are ectopic. A history of ectopic pregnancy need not be considered a contraindication to use of this emergency contraceptive method. Health providers, however, should be alert to the possibility of an ectopic pregnancy in women who become pregnant or complain of lower abdominal pain after taking Plan B®.

PRECAUTIONS

Pregnancy

Many studies have found no effects on fetal development associated with long-term use of contraceptive doses of oral progestins (POPs). The few studies of infant growth and development that have been conducted with POPs have not demonstrated significant adverse effects.

STD/HIV

Plan B®, like progestin-only contraceptives, does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

Physical Examination and Follow-up

A physical examination is not required prior to prescribing Plan B®. A follow-up physical or pelvic examination, however, is recommended if there is any doubt concerning the general health or pregnancy status of any woman after taking Plan B®.

Carbohydrate Metabolism

The effects of Plan B® on carbohydrate metabolism are unknown. Some users of progestin-only oral contraceptives (POPs) may experience slight deterioration in glucose tolerance, with increases in plasma insulin; however, women with diabetes mellitus who use POPs do not generally experience changes in their insulin requirements. Nonetheless, diabetic women should be monitored while taking Plan B®.

Drug Interactions

Theoretically, the effectiveness of low-dose progestin-only pills is reduced by hepatic enzyme-inducing drugs such as the anticonvulsants phenytoin, carbamazepine, and barbiturates, and the antituberculosis drug rifampin. No significant interaction has been found with broad-spectrum antibiotics. It is not known whether the efficacy of Plan B® would be affected by these or any other medications.

Nursing Mothers

Small amounts of progestin pass into the breast milk in women taking progestin-only pills for long-term contraception resulting in steroid levels in infant plasma of 1-6% of the levels of maternal plasma. However, no adverse effects due to progestin-only pills have been found on breastfeeding performance, either in the quality or quantity of the milk, or on the health, growth or development of the infant.

Pediatric Use

Safety and efficacy of progestin-only pills have been established in women of reproductive age for long-term contraception. Safety and efficacy are expected to be the same for postpubertal adolescents under the age of 16 and for users 16 years and older. Use of Plan B® emergency contraception before menarche is not indicated.

Fertility Following Discontinuation

The limited available data indicate a rapid return of normal ovulation and fertility following discontinuation of progestin-only pills for emergency contraception and long-term contraception.

ADVERSE REACTIONS

The most common adverse events in the clinical trial for women receiving Plan B® included nausea (23%), abdominal pain (18%), fatigue (17%), headache (17%), and menstrual changes. The table below shows those adverse events that occurred in ≥5% of Plan B® users.

Table 3 Adverse Events in ≥5% of Women, by % Frequency

Most Common Adverse Events	Plan B® Levonorgestrel N=977 (%)
Nausea	23.1
Abdominal Pain	17.6
Fatigue	16.9
Headache	16.8
Heavier Menstrual Bleeding	13.8
Lighter Menstrual Bleeding	12.5
Dizziness	11.2
Breast Tenderness	10.7
Other complaints	9.7
Vomiting	5.6
Diarrhea	5.0

Plan B® demonstrated a superior safety profile over the Yuzpe regimen for the following adverse events:

- Nausea: Occurred in 23% of women taking Plan B® (compared to 50% with Yuzpe)
- Vomiting: Occurred in 6% of women taking Plan B® (compared to 19% with Yuzpe)

DRUG ABUSE AND DEPENDENCE

There is no information about dependence associated with the use of Plan B®.

OVERDOSAGE

There are no data on overdosage of Plan B®, although the common adverse event of nausea and its associated vomiting may be anticipated.

Mfg. by Gedeon Richter, Ltd., Budapest, Hungary
for Duramed Pharmaceuticals, Inc.
Subsidiary of Barr Pharmaceuticals, Inc.
Pomona, New York 10970
Phone: 1-800-330-1271
Web site: www.go2planB.com
Revised FEBRUARY 2004
BR- 038 / 21000382503

Plan B® is a registered trademark of Women's Capital Corporation, a subsidiary of Duramed Pharmaceuticals, Inc.

DURAmed® | Duramed Pharmaceuticals, Inc. Subsidiary of Barr Pharmaceuticals, Inc. Pomona, New York 10970

©2005 Duramed Pharmaceuticals, Inc. PLB0546 June 2005 Printed in USA