

# HHS Hopes to Spur Electronic Biosurveillance

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WASHINGTON — Government officials and health information technology leaders plan to spend this year laying the groundwork for a system that would allow for the electronic transfer of ambulatory, emergency department, and laboratory data to public health agencies in less than a day.

Over time, officials would like to implement a real-time nationwide public

health monitoring system. "The system we have is simply not adequate," Mike Leavitt, secretary of the Health and Human Services department (HHS), said at a meeting of the American Health Information Community, which is an advisory committee to HHS.

The United States faces not only the possibility of a bioterrorist attack but also the threat of pandemic, he said.

Mr. Leavitt said he would like to get a "spotty net" of surveillance off the ground

quickly by collecting a few key indicators from as many electronic data sources as possible. Getting just 2-4 basic data points from all available sources would be a "quantum leap forward," he said.

Information from small and medium-sized primary care practices will be key to any electronic biosurveillance system, said Dr. David Kibbe, who represented the American Academy of Family Physicians at the meeting.

"There is widespread agreement that in-

formation technology can substantially improve surveillance both for ongoing public health and for health emergencies," said Dr. Thomas R. Frieden, commissioner of the New York City Department of Health and Mental Hygiene, who presented information on current electronic surveillance programs at the meeting.

Currently, there is a wide range of biosurveillance activities underway at the federal, state, and local levels, and in the private sector, Dr. Frieden said. For example, the Centers for Disease Control and Prevention operates the Public Health Information Network, which provides an architecture for public health information technology. Most recently, the agency es-



Brief Summary (See Package Brochure for Full Prescribing Information)

#### Rx only

Plan B<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> is not recommended for routine use as a contraceptive.**

**Plan B<sup>®</sup> 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<sup>®</sup>. At the time of expected menses, approximately 75% of women using Plan B<sup>®</sup> 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<sup>®</sup>.

#### 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<sup>®</sup>, like progestin-only contraceptives, does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

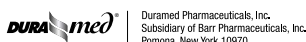
##### Physical Examination and Follow-up

A physical examination is not required prior to prescribing Plan B<sup>®</sup>. 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<sup>®</sup>.

##### Carbohydrate Metabolism

The effects of Plan B<sup>®</sup> 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<sup>®</sup>.

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



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#### 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> users.

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

Most Common Adverse Events	Plan B <sup>®</sup> 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<sup>®</sup> demonstrated a superior safety profile over the Yuzpe regimen for the following adverse events:

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

#### DRUG ABUSE AND DEPENDENCE

There is no information about dependence associated with the use of Plan B<sup>®</sup>.

#### OVERDOSAGE

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

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Information from small and medium-sized primary care practices will be key to any system.

DR. KIBBE

established the BioSense program to support the connection of clinical care to public health and supporting "situational awareness" at the national level.

A number of state and local health departments have begun electronic reporting either from clinical laboratories or clinical information systems.

In New York City, the health department uses electronic reporting data on a daily basis. The system, which has been operating for more than 5 years, collects information from ambulance dispatches, emergency department visits, pharmacy purchases, outpatient visits, and other sources. The system also collects free text, which allows officials to evaluate information they might not have thought about otherwise. Currently, 50 hospitals—representing about 90% of emergency department visits in the city—report daily.

The electronic reporting system has proved helpful in the early detection of pockets of influenza. The electronic syndromic system consistently picks up influenza activity 2-3 weeks before any other system.

New York City is not alone. North Carolina has a statewide, hospital-based clinical data monitoring system. It allows for monitoring of real-time inpatient, outpatient, and emergency department data.

But some major needs must be addressed to reach the goal of a nationwide system, Dr. John Loonsk, of the federal Office of the National Coordinator for Health Information Technology, said at the meeting.

For example, data need to be standardized so they can be compared across reporting organizations, privacy and confidentiality need to be ensured, and improvements need to be made in the current patchwork of state and local health information technology capability, he said.

One area that potentially could be implemented rapidly is the electronic reporting of lab results, Dr. Loonsk said. This has value both to public health and for the routine use of clinicians, he said. ■