

Medical Errors Viewed Through Different Lenses

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QUEBEC CITY — Clinicians, staff, and patients report medical errors in distinctly different ways, Robert L. Phillips Jr., M.D., said at the annual meeting of the North American Primary Care Research Group.

Patients tend to file fewer reports, while clinicians and staff are far more likely to report errors of process rather than errors of knowledge and skill.

Such variances are important to consider as error reporting becomes mandatory. The Patient Safety and Quality Improvement Act of 2005 (S. 544), signed into law this summer, establishes a voluntary system to report errors and near misses.

Dr. Phillips presented a study in which 10 family medicine clinics were asked to routinely report errors over a 10-week period. Additionally, on 5 intensive days, they were asked to report every error. Errors could be of omission or commission.

The reports were anonymous and could be filed by mail, phone, or the Internet. Reporting took about 3-5 minutes. Of the eligible reporting population, 401 (86%) clinicians and staff signed consent forms.

A total of 726 events were reported, of which 717 had at least one error. There were a total of 935 errors.

Just over half of the reports came from staff (384), a little over one-third from physicians (278), and relatively few from residents (46) and nurse practitioners and

physician assistants (18). The majority of reports came over the Internet (546), while 180 were mailed.

Although most of the reports were filed on routine versus intensive-reporting days (440 vs. 265), there was a disproportionate amount filed on the 5 intensive-reporting days.

"Routine reporting does not approximate volume," said Dr. Phillips, director of the Robert Graham Center: Policy Studies in Family Medicine and Primary Care, Washington. "There has to be some other mechanism than routine reporting if you want to get at [errors], especially the common, less harmful mistakes."

The top errors were chart completeness and availability (176), medication (127), appointments (111), filing (84), laboratory work (82), and communication with patients (65).

Analysis revealed that 96% of the errors reported were process errors, suggesting that clinicians and staff either recognize more process errors or are reluctant to report errors of knowledge and skill, he said.

Clinicians were significantly more likely to report errors concerning medications, diagnostic imaging, and laboratory investigations, whereas staff members were more likely to report errors related to patient communication and appointments.

One of the more striking findings was that patients filed only 126 reports, of which 18 were actual errors. Of these, 6 were related to waiting too long, 2 were mistaken identity, and 10 cited a variety of issues, including credit card theft and even clinician-induced fear. Most patient reports were sent by mail.

While such insights are important, it's not clear if the overall lack of patient reporting is due to patients not seeing errors or if another tool is needed to collect the data, he said.

The audience suggested that patients may report less often because acknowledging an error might make them feel more at risk.

The analysis revealed that 706 reports indicated errors that caused health consequences or harm. There were no deaths, but nearly a quarter of the patients involved experienced some health consequence.

Reports from both staff and clinicians suggest that patients with complex health issues are vulnerable to more serious harm.

Of the reports that had multiple errors, 4 reports had four errors, 33 had three errors, and 183 had two. In 93 of these cases, a cascade of errors occurred as a result of an initial error, which usually involved an incomplete or unavailable chart.

The Robert Graham Center is a division of the American Academy of Family Physicians.

METROGEL®

(metronidazole gel), 1%

BRIEF SUMMARY

For topical use only. Not for oral, ophthalmic or intravaginal use.

INDICATIONS AND USAGE

METROGEL® (metronidazole gel), 1% is indicated for the topical treatment of inflammatory lesions of rosacea.

CONTRAINDICATIONS

METROGEL® (metronidazole gel), 1% is contraindicated in those patients with a history of hypersensitivity to metronidazole or to any other ingredient in this formulation.

PRECAUTIONS

General: Topical metronidazole has been reported to cause tearing of the eyes. Therefore, contact with the eyes should be avoided. If a reaction suggesting local skin irritation occurs, patients should be directed to use the medication less often or discontinue use. Metronidazole is a nitroimidazole and should be used with care in patients with evidence of, or history of, blood dyscrasia.

Information for Patients: Patients using METROGEL® (metronidazole gel), 1% should receive the following information and instructions:

1. This medication is to be used as directed.
2. It is for external use only.
3. Avoid contact with the eyes.
4. Cleanse affected area(s) before applying METROGEL® (metronidazole gel), 1%.
5. This medication should not be used for any other condition than that for which it is prescribed.
6. Patients should report any adverse reaction to their physicians.

Drug Interaction: Oral metronidazole has been reported to potentiate the anticoagulant effect of coumarin and warfarin, resulting in a prolongation of prothrombin time. Drug interactions should be kept in mind when METROGEL® (metronidazole gel), 1% is prescribed for patients who are receiving anticoagulant treatment, although they are less likely to occur with topical metronidazole administration because of low absorption.

Carcinogenesis, Mutagenesis and Impairment of Fertility: Metronidazole has shown evidence of carcinogenic activity in a number of studies involving chronic, oral administration in mice and rats, but not in studies involving hamsters.

In several long-term studies in mice, oral doses of approximately 225 mg/m²/day or greater (approximately 37 times the human topical dose on a mg/m² basis) were associated with an increase in pulmonary tumors and lymphomas. Several long-term oral studies in the rat have shown statistically significant increases in mammary and hepatic tumors at doses >885 mg/m²/day (144 times the human dose).

Metronidazole has shown evidence of mutagenic activity in several *in vitro* bacterial assay systems. In addition, a dose-related increase in the frequency of micronuclei was observed in mice after intraperitoneal injections. An increase in chromosomal aberrations in peripheral blood lymphocytes was reported in patients with Crohn's disease who were treated with 200 to 1200 mg/day of metronidazole for 1 to 24 months. However, in another study, no increase in chromosomal aberrations in circulating lymphocytes was observed in patients with Crohn's disease treated with the drug for 8 months.

In one published study, using albino hairless mice, intraperitoneal administration of metronidazole at a dose of 45 mg/m²/day (approximately 7 times the human topical dose on a mg/m² basis) was associated with an increase in ultraviolet radiation-induced skin carcinogenesis. Neither dermal carcinogenicity nor photocarcinogenicity studies have been performed with METROGEL® (metronidazole gel), 1% or any marketed metronidazole formulations.

Pregnancy: Teratogenic Effects: Pregnancy Category B. There are no adequate and well-controlled studies with the use of METROGEL® (metronidazole gel), 1% in pregnant women.

Metronidazole crosses the placental barrier and enters the fetal circulation rapidly. No fetotoxicity was observed after oral administration of metronidazole in rats or mice at 200 and 20 times, respectively, the expected clinical dose. However, oral metronidazole has shown carcinogenic activity in rodents. Because animal reproduction studies are not always predictive of human response, METROGEL® (metronidazole gel), 1% should be used during pregnancy only if clearly needed.

Nursing Mothers: After oral administration, metronidazole is secreted in breast milk in concentrations similar to those found in the plasma. Even though blood levels taken after topical metronidazole application are significantly lower than those achieved after oral metronidazole, 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 and the risk to the infant.

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

Geriatric Use: While specific clinical trials in the geriatric population have not been conducted, sixty-six patients aged 65 years and older treated with METROGEL® (metronidazole gel), 1% over ten weeks showed comparable safety and efficacy as compared to the general study population.

ADVERSE REACTIONS

In a controlled clinical trial, 557 patients used METROGEL® (metronidazole gel), 1% and 189 patients used the gel vehicle once daily. The following table summarizes adverse reactions that occur at a rate of ≥1% in the clinical trials:

System Organ Class/Preferred Term	Metronidazole Gel, 1% N= 557	Gel Vehicle N=189
Patients with at least one AE	186 (33.4)	51 (27.0)
Infections and infestations	76 (13.6)	28 (14.8)
Bronchitis	6 (1.1)	3 (1.6)
Influenza	8 (1.4)	1 (0.5)
Nasopharyngitis	17 (3.1)	8 (4.2)
Sinusitis	8 (1.4)	3 (1.6)
Upper respiratory tract infection	14 (2.5)	4 (2.1)
Urinary tract infection	6 (1.1)	1 (0.5)
Vaginal mycosis	1 (0.2)	2 (1.1)
Musculoskeletal and connective tissue disorders	19 (3.4)	5 (2.6)
Back pain	3 (0.5)	2 (1.1)
Neoplasms	4 (0.7)	2 (1.1)
Basal cell carcinoma	1 (0.2)	2 (1.1)
Nervous system disorders	18 (3.2)	3 (1.6)
Headache	12 (2.2)	1 (0.5)
Respiratory, thoracic and mediastinal disorders	22 (3.9)	5 (2.6)
Nasal congestion	6 (1.1)	3 (1.6)
Skin and subcutaneous tissue disorders	36 (6.5)	12 (6.3)
Contact dermatitis	7 (1.3)	1 (0.5)
Dry skin	6 (1.1)	3 (1.6)
Vascular disorders	8 (1.4)	1 (0.5)
Hypertension	6 (1.1)	1 (0.5)

Rx Only

The following table summarizes the highest scores of local cutaneous signs and symptoms of irritation that were worse than baseline:

Sign/Symptom	Metronidazole Gel, 1% N= 544	Gel Vehicle N=184
Dryness	138 (25.4)	63 (34.2)
Mild	93 (17.1)	41 (22.3)
Moderate	42 (7.7)	20 (10.9)
Severe	3 (0.6)	2 (1.1)
Scaling	134 (24.6)	60 (32.6)
Mild	88 (16.2)	32 (17.4)
Moderate	43 (7.9)	27 (14.7)
Severe	3 (0.6)	1 (0.5)
Pruritus	86 (15.8)	35 (19.0)
Mild	53 (9.7)	21 (11.4)
Moderate	27 (5.0)	13 (7.1)
Severe	6 (1.1)	1 (0.5)
Stinging/burning	56 (10.3)	28 (15.2)
Mild	39 (7.2)	18 (9.8)
Moderate	7 (1.3)	9 (4.9)
Severe	10 (1.8)	1 (0.5)

The following additional adverse experiences have been reported with the topical use of metronidazole: skin irritation, transient redness, metallic taste, tingling or numbness of extremities, and nausea.

OVERDOSAGE: There are no reported human experiences with overdosage of METROGEL® (metronidazole gel), 1%. Topically applied metronidazole can be absorbed in sufficient amount to produce systemic effects.

DOSE AND ADMINISTRATION: Areas to be treated should be cleansed before application of METROGEL® (metronidazole gel), 1%. Apply and rub in a thin film of METROGEL® (metronidazole gel), 1% once daily to entire affected area(s). Patients may use cosmetics after application of METROGEL® (metronidazole gel), 1%.

HOW SUPPLIED: METROGEL® (metronidazole gel), 1% is available in a 45-gram tube.

45 gram tube – NDC 0299-3820-45

Keep out of the reach of children.

Storage Conditions: Store at controlled room temperature: 20° to 25°C (68° to 77°F), excursions permitted between 59° and 86°F (15°-30°C).

Prescribing Information as of June 2005.

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US Patent No. 6,881,726

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