Foodborne Illness Associated with Niacin: Report of an Outbreak Linked to Excessive Niacin in Enriched Cornmeal

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SUPPLEMENTATION of commercially prepared foods with vitamins and minerals has become routine in the United States since the 1940s. Although such additives are classified as "generally regarded as safe" (GRAS) (*1*), mistakes in adding or mixing can result in concentrations that can cause illness. In this report we describe an outbreak of foodborne illness attributed to excessive amounts of a vitamin and mineral additive mix in cornmeal. Symptoms were compatible with niacin toxicity; this is the first outbreak of niacin toxicity reported in association with a commercially prepared additive mix. The outbreak emphasizes the need for care in commercial processing when dealing with additives. It also underscores the relative safety of the additives involved, in that no serious sequelae resulted despite high concentrations of the vitamin and mineral supplements.

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Background and Findings

On December 17, 1980, 18 of 43 residents (42 percent) of a nursing home in northern Illinois became ill 15–30 minutes after eating breakfast. Three residents had facial flushing and tingling; 11 had an erythematous, macular rash on the face and arms; 1 had slight total-body erythroderma; and 3 had a heavy total-body erythroderma. The symptoms lasted from 15 to 105 minutes, with a mean duration of 50 minutes.

Vital signs were not affected. The mean pulse rate was 74 (range 64–80) for 8 persons who were examined while they were symptomatic, and the blood pressure did not change from the usual values for the 2 persons who were checked. In terms of age and sex, there was no significant difference between residents who became ill and those who did not; the mean age of ill residents was 87 years and 88 percent were women. The ill-

ness was not associated with known underlying disease or with routine use of any specific group of medications such as vasodilators, diuretics, antihypertensives, or antihistamines.

All residents who became ill had eaten cornmeal mush for breakfast. The cornmeal had been taken from a large container that had been filled with a new 50-pound shipment purchased from a commercial manufacturer. Residents in the nursing home's two wards were served from the same pot; the staff noted that the mush was an unusual "pea-soup" green. The residents in the west ward—self-care patients better able to select food alternatives to the green mush—had an attack rate of 22 percent (4 of 18). This rate was significantly lower than the rate of 56 percent (14 of 25) for patients on the east ward, who were more debilitated and did not have an opportunity to select their menu ($P = 0.034$, Fisher's exact test, 2-tail).

The cornmeal used in making the mush contained a commercial vitamin and mineral additive mix that included riboflavin, thiamine, niacin, and reduced iron; the vitamin and mineral supplements made up 20 percent of the dry weight of the additive mix. Standard analytic techniques (2) were used to assay samples of the cornmeal for these additives; the methods and assay results are included in the table. Niacin, thiamine, riboflavin, and iron were found to be present in the cornmeal at greater than 100 times the recommended concentrations.

The production code numbers of the cornmeal could not be identified because the sacks in which the cornmeal was shipped had been discarded. Consequently, it was not possible to take further action to determine the source of the processing error. Other samples of cornmeal from the same manufacturer did not have significantly high or low levels of the nutrient supplements. No other outbreaks of illness associated with consumption of cornmeal were reported to the Illinois Department of Public Health, the Centers for Disease Control, or the Food and Drug Administration.

Discussion

The clinical syndrome in this outbreak is compatible with niacin (nicotinic acid) toxicity. Although outbreaks associated with vitamin

Vitamin and mineral content of enriched cornmeal associated with illness among residents of a nursing home in Illinois, December 1980

Supplements	Concentration (mg per lb of dry cornmeal)			
	FDA limits [1]	Declared to have been added	Actual present	Ratio: actual ÷ declared
Thiamine	2–3	1.9	[2] 233	123
Riboflavin	1.2–1.8	1.2	[3] 122	102
Niacin	16–24	14.0	[4] 1,767	126
			[5] 1,780	
Iron	13–26	12.0	[6] 1,328	111
			[7] 1,299	

[1] Includes amounts naturally present in the cornmeal; from Code of Federal Regulations, 21 CFR 137.260.
[2] Mean of 2 results from same specimen; assay from FDA in-house automated procedure.
[3] Reference 2, paragraph 43.039 (assay by chemical method).
[4] Mean of 2 results from same specimen; assay by automated procedure, reference 2, paragraph 43.047.
[5] Reference 2, paragraph 43.150 (assay by microbiological method).
[6] Reference 2, paragraph 2.109 (assay by atomic absorption spectrophotometry).
[7] Reference 2, paragraph 14.011.

and mineral additive mixes have not been reported previously, several outbreaks of illness among people have resulted from ingesting meat containing excessive amounts of niacin added to preserve the red color. Lyman and co-workers reported that 61 percent (88 of 145) of the persons who ate meat containing 0.5–3.7 g of niacin per kg developed cutaneous flushing, a sensation of warmth, itching, and nausea (*3*). Press and Yeager reported that 36 percent (44 of 121) of persons developed flushing of the face, neck, extremities, and trunk, itching, and erythroderma 10–60 minutes after eating meatballs containing up to 2.25 g of niacin per kg (*4*). As in the outbreak at the nursing home, vital signs of the persons who became ill did not change significantly.

It appears unlikely that the excess amounts of the other additives in the nutrient package influenced the clinical syndrome. Oral doses of thiamine far in excess of that received by the nursing home residents have been reported with no discernible ill effects (*5*). Large doses of riboflavin have been used in medicine for a variety of conditions among people, and apart from rare instances of sensitivity riboflavin toxicity has not been reported (*6*). Large doses of iron salts can cause gastroenteritis in people; however, reduced iron is among the least toxic of the various iron preparations. Acute toxicity from iron-fortified foods has never been reported, and reduced iron has been orally administered without noticeable effect to laboratory animals at greater than 100 times the dosage levels in the cornmeal eaten by the nursing home residents (*7*).

It is not clear what error in processing was responsible for the excess vitamin and mineral supplements in the cornmeal. The approximately equal proportions by which the concentrations of niacin, thiamine, riboflavin, and reduced iron were increased suggest that the entire additive mix was involved. Other possible sources of the excess vitamins and minerals would not be expected to contain niacin, thiamine, riboflavin, and iron in the same ratio as was present in the mix. Since the mix normally contained 20 percent active ingredients, a mistake in the manufacturing or mixing of the additive mix itself could not account for the greater than 100-fold increase in the final nutrient concentrations in the cornmeal. Possible processing errors include the addition of excessive amounts of the nutrient mix to the cornmeal, or perhaps more likely, inadequate mixing of the cornmeal after addition of the vitamin and mineral supplements.

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