Diabetes Medication Costs

A Comparison Between the United States and Mexico

The following is a summary of a research project undertaken by Joshua Messer, MD in 2004 when he was a medical student at the University of Connecticut. The project was designed and implemented with feedback from MCN's diabetes program staff. For a copy of the complete paper, contact Dr. Messer [messerj@sfmr.com] or Carmel Drewes [carmel@migrantclinician.org].

any migrants return to Mexico, or the U.S./ Mexico border area, for some portion of the year. In order to assist U.S. clinicians helping these migrants manage type 2 diabetes, the researchers compared the availability and cost of the most commonly prescribed oral hypoglycemic medications for treatment of type 2 diabetes in the U.S. and Mexico. By familiarizing themselves with the medications

Diabetes outreach worker with a migrant patient



widely available at low cost in Mexico, U.S. clinicians will be able to prescribe a treatment plan that their patient will likely be able to follow when she or he returns to Mexico or the border region.

The list of medications to be studied was determined using MCN's database of prescriptions written for migrant workers with type 2 diabetes enrolled in the Track II program which provides referral and tracking for mobile diabetic patients (Table 1). The researchers contacted pharmacies in three cities located in two states in Mexico and in two cities in two states in the United States, in addition to querying online pharmacies from both countries. Availability of each of the study medications was determined by the percentage of pharmacies surveyed that carried the medication. Mean prices in each country were compared for significant differences using independent samples t tests.

The Migrant Health News Source

The researchers had complete data for fourteen pharmacies in the U.S. and thirtyseven Mexican pharmacies (Table 2). Significant differences were found in the availability of the nine studied medications between the two countries, with limited availability in Mexico (Table 3). The most widely available oral hypoglycemic was Glyburide 5 mg tablets, followed by the combination medication with Glyburide 5 mg and Metformin 500 mg. The least available medications were the convenience dosing formulations of Glipizide ER, Glyburide

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Table 1: Most Commonly Prescribed Diabetes Medications in Track II Database

Medication	# of prescriptions in Track II database
Metformin (Glucophage)	373
Glipizide ext. release (Glucotrol XL)	188
Glyburide (Glynase, Diabeta, etc.)	119
Glyburide/Metformin (Glucovance)	69
Rosiglitazone (Avandia)	67
Pioglitazone (Actos)	59
Glipizide (Glucotrol)	57
Metformin ext. release (Glucophage XR)	30
Glyburide micronized (Micronase)	3

Table 2: Locations of Pharmacies Studied

Pharmacy Location	Chain	Local	Hospital	Government
Mexico				
Ciudad Juarez	15	12	4	1
Ensenada		1		
Col. Vicente Guerrero	1	2		
USA				
El Paso, TX	4	4	1	
Hartford, CT	3			

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micronized, and Metformin ER. Significant differences were discovered in the retail prices between the two countries for seven of the twelve medications (Table 4). With only one exception (Glipizide 10 mg), all medication prices were at least \$10 lower in Mexico, and in some cases as much as 600% lower (Glyburide/Metformin).

Based on these outcomes, the researchers make the following suggestions:

- Migrant Health Centers across the U.S. should utilize the list of most commonly available diabetes medications as a reference for prescribers who are treating patients with diabetes from Mexico or a border region (Quick Guide 1).
- Clinicians who are treating patients from Mexico, or who are likely to go to Mexico to obtain their medications, should avoid prescribing the newer extended release formulations of sulfonylureas and Metformin.
- Clinicians should take into account the cost of medications in Mexico when making their decisions about prescriptions for patients who will be purchasing (or have the option to purchase, in the case of border regions) their medications in Mexico (Quick Guide 2).

New MCN Resource!

MCN Announces the New MCN Clinical Systems Tool Box for clinical systems materials, your online connection to resources for best clinical practices in migrant and community health centers. MCN has been collecting forms, policies, and protocols from health centers across the United States in an effort to make them available to others working to provide quality health care to the underserved. We have reviewed hundreds of documents and selected these examples for you to use and adapt to your own clinic needs. We have catelogued material in the following major categories:

- Clinical Policies and Procedures
- Clinical Guidelines
- Quality Management
- Human Resources
- Medical Records
- **Patient Education Materials**
- HIPAA
- Clinic Brochures
- Language and Translation
- Practice Management

Go to http://www.migrantclinician.org/ clearinghouse to find out more.

Table 3: Availability of Medications (as percent of pharmacies studied)

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		USA Percent (n)	MEXICO Percent (n)
Glipizide	5 mg	100 (14)	62.2 (23)
•	10 mg	100 (14)	43.2 (16)
Glipizide ER	5 mg	85.7 (12)	0
·	10 mg	85.7 (12)	0
Glyburide	2.5 mg	100 (14)	0
	5 mg	100 (14)	86.5 (32)
	10 mg	21.4 (3)	0
Glyburide micronized	1.5 mg	71.4 (10)	0
•	6 mg	92.9 (13)	0
Glyburide/Metformin	1.25/250 mg	100 (14)	5.4 (2)
	2.5/500 mg	Not evaluated	64.9 (24)
	5/500 mg	100 (14)	78.4 (29)
Metformin	500 mg	100 (14)	75.7 (28)
	1000 mg	92.9 (13)	16.2 (6)
Metformin ER	500 mg	100 (14)	10.8 (4)
Pioglitazone	15 mg	100 (14)	56.8 (21)
	45 mg	100 (14)	32.4 (12)
Rosiglitazone	4 mg	100 (14)	67.6 (25)
	8 mg	100 (14)	51.4 (19)

Table 4: **Mean prices in Mexico and the United States** with Percent Difference, in order from largest to smallest percent difference in price.

	MEXICO		USA						
Medication	N	Mean price	Std dev	N	Mean price	Std dev	Mean Diff.	% Diff.	P
Glyb/Metformin 1.25/250 mg	2	\$3.85	±0.00	14	\$27.19	±5.13	\$23.34	606%	<.001
Metformin XR 500 mg	4	\$5.08	±0.48	14	\$23.73	±5.40	\$18.65	367%	<.001
Glyburide 5 mg	32	\$6.62	±3.33	11	\$24.24	±10.83	\$17.62	266%	<.001
Glyb/Metformin 5/500 mg	29	\$30.73	±16.36	14	\$103.97	±24.78	\$73.24	238%	<.001
Metformin 1000 mg	6	\$16.17	±6.84	13	\$52.34	±15.05	\$36.17	224%	<.001
Metformin 500 mg	28	\$10.36	±6.81	14	\$28.79	±10.88	\$18.43	178%	<.001
Glipizide 5 mg	23	\$7.23	±4.56	14	\$12.61	±4.23	\$5.38	74 %	0.001
Pioglitazone (Actos) 15 mg	21	\$81.98	±14.00	14	\$112.42	±27.28	\$30.44	37%	<.001
Rosiglitazone (Avandia) 8 mg	19	\$139.80	±28.61	14	\$173.74	±28.19	\$33.94	24%	0.002
Pioglitazone (Actos) 45 mg	12	\$161.00	±26.72	14	\$194.83	±34.44	\$33.83	21%	0.011
Rosiglitazone (Avandia) 4 mg	25	\$83.85	±14.62	14	\$96.62	±15.25	\$12.77	15%	0.014
Glipizide 10 mg	16	\$38.36	±16.64	14	\$38.67	±19.09	\$0.31	0.8%	0.962

Quick Guide 1: Availability of Medications in Mexico						
Widely Available (60% - 100% of pharmacies studied)		Somewhat Availal (40%-59% of pharm			Minimally or Not at All Available (0 – 39% of pharmacies studied)	
Glyburide 5 mg	86.5%	Pioglitazone 15 mg	56.8 %	Glipizide ER 5 mg	0%	
Glyburide/Metformin 5/500 mg	78.4%	Rosiglitazone 8 mg	51.4%	Glipizide ER 10 mg	0%	
Metformin 500 mg	75.7%	Glipizide 10 mg	43.2%	Glyburide 2.5 mg	0%	
Rosiglitazone 4 mg	67.6%			Glyburide 10 mg	0%	
Glyburide/Metformin 2.5/500 mg	64.9%			Glyburide micronized 1.5 mg	0%	
Glipizide 5 mg	62.2%			Glyburide micronized 6 mg	0%	
				Glyburide/Metformin 1.25/250 mg	5.4%	
				Metformin ER 500 mg	10.8%	
				Metformin 1000 mg	16.2%	
				Pioglitazone 45 mg	32.4%	

Quick Guide 2: Monthly Costs of Medications					
	Mean Cost in Mexico	Mean Cost in U.S.			
Glyb/Metformin 1.25/250 mg	\$3.85	\$27.19			
Metformin XR 500 mg	\$5.08	\$23.73			
Glyburide 5 mg	\$6.62	\$24.24			
Glipizide 5 mg	\$7.23	\$12.61			
Metformin 500 mg	\$10.36	\$28.79			
Metformin 1000 mg	\$16.17	\$52.34			
Glyb/Metformin 5/500 mg	\$30.73	\$103.97			
Glipizide 10 mg	\$38.36	\$38.67			
Pioglitazone (Actos) 15 mg	\$81.98	\$112.42			
Rosiglitazone (Avandia) 4 mg	\$83.85	\$96.62			
Rosiglitazone (Avandia) 8 mg	\$139.80	\$173.74			
Pioglitazone (Actos) 45 mg	\$161.00	\$194.83			

Do you wonder when your diabetes patient's last A1c was? Want to make sure that your patient's next clinician knows she was prescribed Glucophage? Worried that your patient might not go to another clinic after he leaves yours? Enroll them in Track II - we will transfer medical records and provide care coordination. No one's health should be compromised because she or he is mobile. Call 512-327-2017.

Scholarships Available for the Western Migrant Stream Forum With a Focus on Environmental/Occupational Health

here are numerous barriers to recognizing and treating environmental and occupational health (EOH) problems in the primary care setting. Some of the underlying reasons are the limited EOH training front line providers receive as well as institutional challenges that prevent clinicians from adequately addressing EOH problems. For migrant farmworkers and other vulnerable populations working in hazardous occupations, an occupational injury or exposure is often the reason for first point of contact with the health care system, underscoring the need to begin addressing EOH concerns at the primary care level.

MCN's program, Saving Lives by Changing Practice, is part of a five-year cooperative agreement with the US Environmental Protection Agency, Office of Pesticide Programs, to address pesticides and other EOH issues in practice setting. Through this program MCN will work to link primary care clinicians in Migrant and Community Health Centers with occupational

and environmental specialists and clinics by:

- Developing occupational/environmental medicine clinics in Migrant Health Centers.
- Facilitating clinical consults between the primary care clinician and the occupational medicine clinician.
- · Developing referral mechanisms for complicated pesticide cases.
- Training primary care providers in occupational/environmental medicine.

MCN will also recruit and work with six to eight Migrant and Community Health Centers to develop a flexible center-based model to integrate EOH in the primary care setting. This will involve working to incorporate key practice skills outlined in National **Environmental Education Training** Foundation's, National Pesticide Practice Skills Guidelines for Medical and Nursing Practice (2003).

MCN is offering five \$500 scholarships to the Western Migrant Stream Forum for clinicians interested in Environmental and

Occupational Health Issues. If you would like to attend this conference and become part of a national effort to address EOH in a primary care setting please send the following information either by e-mail or mail to Amy Liebman at aliebman@migrantclinician.org or PO Box 164285, Austin, TX 78716: Name, Title, Organization, Type of Clinician — (Clinicians include case managers, dentists, dental hygienists, health educators, nurse midwives, nurse practitioners, nurses, outreach workers, physician assistants, physicians, program managers, promotoras, and social workers.), Contact Information, Brief description of your work with migrant and seasonal farmworkers and why you are interested in EOH (no more than 300 words

Scholarship recipients will be expected to attend the clinical session on integrating environmental and occupational health into the primary care setting. For more information on the Western Stream Forum, visit http://www.nwrpca.org/.

A Holistic Approach to Addressing Diabetes and **Continuity of Care for Migrant Farmworkers**

A Case Study in Southeast Missouri

Information and Casework provided by staff of Southeast Missouri Health Network (SEMO): Maria Flores, Case Manager; Sandy Sharp, Director; and Debra Wheeler, LPN, Site Manager

Content compiled by Sarah Henly-Shepard, MCN Diabetes Project Coordinator

Southeast Missouri Health Network is a Community Health Center with seven sites in the southeast region of Missouri. Their clinic in Kennett, in the "bootheel" of Missouri (the area bordered on two sides by Arkansas and on one side by Tennessee), has specialized programs serving the migrants in the area. SEMO staff from the Kennett clinic has been involved with MCN's Alianza Initiative uniting clinics to improve their services for migrants with diabetes – for the past two years.

lberto* is a 48 year old undocumented migrant farmworker from Las Lagrimas, a small town southwest of Mexico City. He migrated from Florida to Missouri last fall to work in the fields. Between farm labor in fruits and vegetables, he sometimes works temporarily in a metal recycling plant.

Like many migrant farmworkers, Alberto

faces barriers to accessing health care: he is a monolingual Spanish speaker, lacks transportation, and has financial limitations. He lives far from the migrant clinic in a rural, isolated area, and works long and strenuous hours most days of the week.

The SEMO staff has helped Alberto work through several different health issues. When Alberto was first seen by SEMO health center staff, he complained of dull chest pain and fatigue. He reported a heart murmur that had been diagnosed at age 20 and diabetes and hypertension that had been diagnosed at age 37. During a visit the following spring, staff was concerned about Alberto's blood glucose reading of 392, with an A1c of 10.7%. That summer, while working at the recycling plant, Alberto was injured on the job, breaking the fingers on his right hand when it was trapped in the equipment.

The health center team responded in a comprehensive and far-reaching manner to address Alberto's immediate and chronic

health needs, finding solutions to his various barriers to better healthcare.

Alberto was referred to a cardiologist in Arkansas, however he did not have a way to get to the appointment. At the time the health center did not have transportation services, so the SEMO case manager took time off from work to personally transport Alberto to Arkansas for the appointment. In addition to transporting Alberto and translating during his appointment, the case manager negotiated reduced fees and payment arrangements with the cardiologist and a hospital for an endoscopy and heart cathorization. Alberto is now considering heart surgery, however he did not qualify for Emergency Medicaid or Medicaid assistance. In addition, since there are few hospitals in Missouri, finding one that could do the surgery would mean long distance travel and a large financial commitment.

To address his diabetes, Alberto had two continued on page 6

^{*} Patient name has been changed.

Un Hogar de Salud

Community Health Partnership of Illinois and the Voucher Model of Care for Migrants

"When vouchers come to town, private providers become partners in our health systems and we gain entrée into the wider community of support for migrants" - Susan Bauer, Executive Director, Community Health Partnership of Illinois

or over twenty years a key mechanism of providing care to isolated populations of migrant and seasonal farmworkers has been through voucher programs. These programs generally function in areas where the patient population is too low to warrant a full-scale health care clinic, but where there are significant pockets of people with very limited access to care. At its most basic, voucher programs are defined as programs that use referrals and "vouchers" as the principal means of assuring the provision of primary health care. The vouchers are issued by the voucher program and used to pay for health care services from private providers.

Currently there are twenty-one voucher programs that receive 330g funding from the Health Resources and Services Administration (HRSA). These voucher programs make up the preponderance of migrant-only health centers.

HISTORY

The migrant voucher model has its roots in Minnesota, Illinois and Colorado. This article focuses on the Illinois program.

In the 1970s and early 1980s the migrant population of Illinois was more traditionally migrant with many internal U.S. migrant families coming from South Texas to work in canneries and the fields.

To meet the needs of this population, the Illinois Migrant Council (IMC), funded largely through the Department of Labor, provided a number of services including job training, English as Second Language (ESL) classes and other support services. In addition, the IMC used vouchers to help migrants pay for special needs such as gas or a motel for the night.

The area near Rochelle, IL would regularly see an influx of about 7,000 migrant families coming to work in the canneries between April and October. These families would then leave for the winter. The IMC established a freestanding health clinic to serve this population. The clinic was fully staffed during the busy migrant months and then maintained a skeleton staff during the winter. Susan Bauer and some of the other current Community Health Partnership of Illinois (CHP) staff members started their careers in migrant health working for the Rochelle clinic.

Beginning in 1982 the canneries near Rochelle began to close and the migrant population dropped drastically. Without a significant patient population, the clinic was forced to suspend most services and eventually close its



CHP outreach workers

doors. They kept one nurse on staff to help transition any remaining patients to other health

During the transition, IMC staff began to hear through the grapevine of smaller pockets of more dispersed migrants in the former clinic service area. There was no provider seeing these patients and yet their numbers were not sufficient to justify reestablishing a clinic site.

Faced with the challenge of providing care for these remaining migrants, the IMC staff realized that they could transfer the voucher concept to health care and in that way continue to assure access to care for migrants in the area.

The one nurse who remained from the health center staff championed this concept and began by finding regional service "epicenters". She would then talk to local physicians and pharmacists to recruit them into providing services to migrants, which would be paid for through vouchers.

Over the next few years the first nurse moved out of the area and was replaced by Mary Jule Kulka as clinical director who, together with other key staff, was responsible for greatly expanding the program scope and available services.

VOUCHER MODELS

In 1994, the Health Resources and Services Administration (HRSA) came out with an official Voucher Program Guidance. In this document, HRSA laid out three models of voucher programs:

1. Services Coordinator Model

This is the most basic systems model and used when the patient population is very small. In this model there is typically no onsite medical personnel. Clients are referred by the service coordinator to local private sources of care.

2. Nurse Staffed Model

In this model services are coordinated by licensed nurses who also provide nursing care and case management services. Typically there is a small medical clinic associated with the program where patients can be seen for things such as cholesterol screening, blood pressure and glucose monitoring, chronic care management, other episodic care and general assessment of health. In addition care is often provided off-site by health educators, promotores, or case managers who go to work sites, homes or other locations where they know they will be able to find migrants. As in all the other voucher models, a critical component is referral to private community providers for a variety of conditions which are paid for through the use of vouchers.

3. Midlevel Provider Staffed Model

This model is very similar to the Nurse Staffed Model. However, on-site services are expanded to include triage and treatment on site as directed by established treatment protocols approved by the supervising physician and permitted by state law.

BENEFITS OF THE VOUCHER MODEL

In many ways the voucher programs are held up as a model for public-private partnerships in healthcare. As Susan Bauer says, voucher programs "make the private provider community part of the continuum of care."

Community Health Partnership of Illinois fosters this private-public partnership by contracting with private providers to see patients in their

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offices at a negotiated rate. According to Susan Bauer, the private providers often report great satisfaction working with this population, and CHP does not have to rely on the uncertain participation of volunteer providers.

The need to bring the community together and find sources of care for farmworkers also encourages a great deal of creativity on the part of voucher program staff as they network with public and private services throughout the community.

Another significant benefit of voucher program is summed up in one of the two tenets of CHP's mission: "to enable the farm worker community to prevent and manage health problems and effectively utilize the health care system." This component of the model is a cornerstone of the voucher concept. Susan Bauer says that when the Rochelle clinic first closed, they realized that their patient population had no idea how to navigate the wider health care system. The staff came to see it as a kind of "superdependence" on the clinic.

From that point onward, CHP made it a part of its mission to help patients tap into their own resourcefulness and learn to negotiate the health care system. The ultimate goal is to have patients become truly "bi-systemic" with the ability to find resources and advocate effectively for their own care.

CHALLENGES OF THE VOUCHER MODEL

The American Heritage Dictionary gives the following definitions for community:

- A group of people living in the same locality and under the same government.
- A group of people having common interests.
- A group viewed as forming a distinct segment of society, or
- Sharing, participation, and fellowship. Far from an intellectual exercise, these definitions of community have tremendous impact on the provision of care for a mobile population such as farmworkers. Many funders, while recognizing the importance of distinct subgroups, choose to see community in largely geographic terms. This viewpoint can be particularly challenging for programs serving farmworkers since geographic boundaries place limitations on access to care for a population that moves freely.

The voucher programs were designed to accommodate the mobility of the migrant farmworker population by providing access to care in a variety of locations rather than a single, centralized clinic site. The challenge for voucher programs is to convince funders that they still see a community, even though the community does not live in a specific census tract.

Another challenge brought on by the fact that voucher programs do not operate within the current heath care model is that it is often difficult to secure reimbursement from

Medicaid/Medicare for the services provided through the voucher program.

For instance, Community Health Partnership of Illinois is not reimbursed FQHC Medicaid rates for any services provided using portable equipment. Ironically, if the equipment were on a mobile van, it would be reimbursable. Likewise, CHP does not receive FQHC reimbursement for services that are not provided in their own clinic, such as the vouchered physician visits.

Voucher programs are able to make up for some of these financial challenges by relying on softer grant funding for specific projects, but this does create a more tenuous financial position. The financial challenge is compounded by the fact that voucher programs tend to work with patients who are not Medicaid and Medicare eligible due to their immigration, employment or residency status.

In addition to the funding issues, voucher models have run into challenges recently as much of the health care community is turning to a more physician-centered model of care. This is evidenced by the fact that the current Uniform Data System (UDS) figures coming from HRSA no longer count nursing encounters in the ratio of medical encounters per user. For programs that rely on the nursing voucher model, this means that a great majority of their patient encounters are no longer calculated in this important UDS indicator.

Other challenges for voucher programs include tracking and follow up for patients since patients may be lost after visiting a private provider. Additionally, it can be challenging to find providers that are culturally sensitive, interested in serving the underserved, and have hours compatible with migrant work schedules.

COMMUNITY HEALTH PARTNERSHIP OF ILLINOIS TODAY

Since CHP was founded, there have been a number of changes in the demographics of the population being served. Where there used to be many families, the program now sees a preponderance of unaccompanied men. Many of

these men are coming directly from Mexico rather than from South Texas. There is also significantly less migrant housing available in Illinois and most migrants are now living communally in smaller living arrangements.

CHP is fully committed to serving the migrant population and has grown and flourished in the years since it was first founded in 1991. CHP operates a nursing voucher model and currently provides care to 7,600 migrant and seasonal farmworkers throughout the state of Illinois. There are more than 80 private providers throughout Illinois contracted by CHP to provide medical, dental, diagnostic or pharmacy services on an hourly basis.

CHP operates five nurse-managed health clinics that serve migrant and seasonal farmworkers and their families. These clinics place a great deal of emphasis on outreach, health promotion, and case management.

CHP offers all medical and dental services according to a sliding fee scale. However, the vast majority of patients qualify to pay a modest, voluntary co-pay for doctor visits, diagnostic services and prescription medicines.

In addition to the private providers and the 5 nurse-staffed clinics, CHP has developed a large network of promotores de salud. The promotores visit migrant labor camps, farms and nurseries to enroll workers and families in programs, provide health education and advocacy, and even conduct research and administer surveys on-site.

CHP has augmented its base funding with a number of grants to provide auxiliary services. Additionally, the program participates in a number of national and regional initiatives to expand available services, including the Health Disparities Diabetes Collaborative.

The voucher model of care does not always fit into conventional ideas about the provision of quality health care. However, evidence from CHP and other voucher programs around the country show that this model of care can be very effective, particularly for rural, homeless, and isolated populations.

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visits with a dietician and learned about meal preparation using the Mexican American Meal Planning Diet. He was concurrently prescribed medications to control his blood glucose and was given a glucometer, allowing him to self-monitor and take control of his health.

For Alberto's work-related injury, the clinic staff assisted with follow-up on medical appointments and provided case management. The SEMO staff is also currently assisting his son, who was in a cotton ginning accident and has suffered major trauma, already having undergone multiple surgeries.

The SEMO staff's employment of this extensive and thorough approach to treating the whole individual's health, while overcoming challenges, makes for an effective care coordination model. Through monitoring medications, nutrition, health education, and extensive case management, Alberto's blood sugar levels and general health have stabilized and improved. After only a few months of treatment, Alberto's blood sugar level decreased from the initial reading of 392 to 119. Alberto also lowered his A1c level from 14.0% in the fall of 2004 to 8.8% in the summer of 2005.

Health Department Issues a Report on Farmworker Birth Defect Cases in Immokalee, Florida

Shelley Davis, JD

arlitos is one of three Immokalee babies who were born with massive birth defects to farmworker parents who harvest tomatoes in Florida. Carlos Candelario, or Carlitos, was born in December 2004 without arms or legs. A few months later Jesus Navarrete, whose parents live about 100 feet away from the Candelario family, was born with Pierre Robin syndrome (cleft lip and small jaw). Two days later, Maria Meza gave birth to another baby missing a nose, an ear and with no signs of visible reproductive organs. This baby died a few days later. When all three babies were conceived in 2004, the mothers lived within 200 feet of one another at the same Florida migrant labor camp. All of them are Mexicans who worked for Ag-Mart, picking tomatoes in the same field, where more than 20 different types pesticides were used.

The Collier County Department of Health (CCDH) conducted a review of babies born in Immokalee between December 2004 and February 2005, to determine if they had birth defects due to exposure to agricultural pesticides. CCDH released its investigative report in October 2005.

Of the five babies with birth defects born in that time frame, two had no possible exposure to agricultural chemicals and were eliminated from further study. In analyzing the possible environmental exposures to the three remaining babies, CCDH focused its assessment on the critical period of gestation, between 19 and 60 days after conception, when limbs and body structures are developing. During this critical timeframe, according to CCDH, two of the three mothers were exposed to agricultural pesticides that have been associated with birth defects in animal studies. Even though both these mothers were exposed to possibly teratogenic pesticides and many of these exposures occurred before it was safe to reenter pesticide treated fields (i.e., before the required restricted entry interval had expired), CCDH concluded that it was unlikely that these effects were due to pesticide exposure. In reaching this conclusion, CCDH noted that generally health professionals are able to identify a cause of only about 35% of birth defect cases (25% due to genetic causes and 10% from environmental causes). It was unlikely that the effects were due to an environmental cause, in CCDH's view, because the three cases involved different birth defects, one

of the mothers allegedly had no exposures during the critical time period and while the birth defects rates in Collier County and Immokalee were higher than that of the state as a whole (28% and 33% higher respectively), this could be due to the small numbers of cases in those jurisdictions.

The Florida Department of Agriculture and Consumer Services found that Ag-Mart had committed 88 violations of preharvest intervals and restricted entry intervals during the time period at issue and fined the company \$111,000. Similar violations were found in North Carolina, and that state agency also issued a substantial

CCDH's report is based on a cursory investigation and a more comprehensive study should be undertaken to identify the likely causes of these severe birth defect cases. The flaws in the CCDH study include the following:

- To identify a trend in the incidence of birth defects, CCDH should have looked at a broader time frame. Finding a trend in a three-month time window was extremely unlikely from the outset.
- A fuller investigation should have compared birth defect cases in Immokalee and other agricultural areas to the number of cases in urban areas in the state.
- By looking at a narrow three-month timeframe, CCDH ignored the birth of a fourth farmworker baby born in Immokalee with a cleft palate in the summer of 2005.
- CCDH accepted Ag-Mart's records of employment and pesticide application without question even though one of the farmworker moms disputes the dates of her employment with the company. This controversy is not even mentioned, nor are any reasons given for ignoring the mother's account. If the mother's account had been credited, she would have had exposure to the possibly teratogenic pesticides during the critical period of gestation.
- Two of the three birth defects cases are
- The mothers' exposures to pesticides while working at Ag-Mart in North Carolina is not even mentioned or investigated.
- An acute exposure to one of the farmworker dad's is dismissed because no incident report was filed. Given that pesticide incidents are widely underreported, this was an inappropriate conclusion.

- Given that at least two of the mothers were exposed to potentially teratogenic pesticides during a critical time of gestation – and that these exposures occurred before the expiration of the restricted entry interval – an analysis should have been conducted of the likely doses of exposure (i.e. dose). There is no discussion of the extent of exposure.
- Paternal exposures and the possibility of take home exposures to the moms was ignored.
- The poor pesticide safety record of this company was not mentioned. Only the farmworker parents were interviewed. Other Aq-Mart workers should have been interviewed concerning the extent of pesticide safety violations on that

As a result of these cases, Aq-Mart eliminated the use of five potentially teratogenic pesticides beginning in October 2005. The company continues to use methyl bromide. In addition, Publix supermarket chain has stopped carrying Aq-Mart's tomatoes.

The Florida Department of Health has failed to undertake a comprehensive investigation of birth defect trends in Florida or to enlist the assistance of the Centers for Disease Control and Prevention in comprehensively investigating these severe birth defects cases.

For clinicians these cases underscore both the need to report suspected pesticide-related cases and the problematic, haphazard reporting system. In Florida, the Department of Agriculture receives reports of pesticide-related medical conditions. In 2003 the department received four reports and in 2004 the number of reports doubled to eight. This pales in comparison to California in 2003, which investigated 1,232 cases of "pesticide illness" and confirmed 802 cases. Of those, 405 occurred in agricultural settings. Unlike Florida, California has a separate Department of Pesticide Regulation that is independent of its agriculture department. Nonetheless, in the case of these birth defects, had these cases been reported by clinicians in Florida, the acute exposure to one of the farmworker dad's could not have been so easily dismissed because an incident report would have been filed. It is only when such reports are filed that clinicians can help influence a more protective policy.



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calendar

American Public Health Association NEW DATES, LOCATION, AND **PROGRAM INFORMATION**

133rd Annual Meeting December 10-14, 2005 Philadelphia, Pennsylvania www.apha.org/meetings/

15th Annual Western Migrant Stream Forum

January 27-29, 2006 Portland, Oregon (206) 783-3004 www.nwrpca.org/conf/forum.php

Cancer, Culture & Literacy: Solutions for Addressing Health Disparities through Community Partnerships

5th Biennial Conference. May 18-20, 2006 Sheraton Sand Key Resort Clearwater Beach, Florida E-mail: Chrystyna Pospolyta, M.P.H., Project Coordinator www.moffitt.usf.edu/about moffitt/ calendar/events/200605.asp

2006 National Farmworkers **Health Conference**

May 20-24, 2006 San Antonio, Texas National Association of Community Health Centers www.nachc.com

National Rural Health Association's 2006 Annual Conference

May 15-19, 2006. Reno, Nevada www.nrharural.org/conferences/sub/ AnnConf.html

The National Institute for Farm Safety, 2006 Annual Conference

Blue Harbor Resort in Sheboygan, WI June 25 - 30, 2006 National Farm Medicine Center, (800) 662-6900, or visit www.marshfieldclinic.org/nfmc/ and click on "Education and Training."

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