Real-Life Quality Measurement Projects

Measure, change, measure again. Repeat. That's the basic procedure for measuring outcomes. But anyone who has spent some time measuring statistics knows that there's more to it than that.

Chapter in Brief:

- *Although physicians at North Mississippi Medical Center believed they were providing quality care for their patients with diabetes, quality-of-care data from their electronic health record system showed otherwise. The changes they made as a result have raised the standard of care at the practice.*
- *Although pay-for-performance had not yet come to her region and she was still using a paper record, Erica Swegler, MD, decided to pursue NCQA recognition for her diabetes care.*
- *Four Seasons Pediatrics in Clifton Park, N.Y., took advantage of the Bridges to Excellence program to buy an EHR system. As a result, the practice has qualified for additional incentives and has seen measurable quality gains.*
- *Geisinger Health System in Danville, Pa., is participating in Medicare's Physician Group Practice Demonstration Project, a four-year experiment in pay-for-performance.*

Physicians nationwide have participated in quality improvement initiatives—in practices large and small, with or without electronic records, both primary care and specialties. The case studies in this chapter will examine some quality improvement projects and what it's like to participate in them.

CSL Biotherapies

THIMEROSAL-FREE FLU VACCINE.

The Word Is Out. Pass It On.

Help protect your patients and your community from flu…all season long.

- **Thimerosal-free and latex-free*** (CPT®† code 90656)
- **Convenient,** single-use, prefilled syringe delivery
- **Reliable availability** throughout the flu season
- **From a trusted influenza vaccine manufacturer** with 40 years' experience

Important Safety Information

Afluria® is indicated for active immunization of persons 18 years of age and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine. The indication is based on the immune response elicited by Afluria®; no controlled clinical studies have demonstrated a decrease in influenza disease after vaccination with Afluria®.

Afluria® should not be administered to individuals with hypersensitivity to eggs or chicken protein or other components of Afluria®, or to anyone who has had a life-threatening reaction to previous influenza vaccination.

The most common injection-site adverse reactions were tenderness, pain, redness, and swelling. The most common systemic adverse reactions were headache, malaise, and muscle aches.

Vaccination with Afluria® may not protect all individuals. Immunocompromised persons may have a diminished immune response. If Guillain-Barré syndrome has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give Afluria® should be based on careful consideration of the potential benefits and risks.

Please see brief summary of full prescribing information on adjacent page.

*Afluria® is also available in a latex-free, multidose vial formulation containing thimerosal as a preservative (CPT® code 90658).

†CPT is a registered trademark of the American Medical Association.

For a list of authorized distributors, call **1-888-4FLU-OFF** (1-888-435-8633).
To learn more about Afluria®, visit **www.afluria.com.**

1020 First Avenue, PO Box 60446, King of Prussia, PA 19406-0901
www.cslbiotherapies-us.com Printed in USA 9F010A 07/2008

afluria® influenza virus vaccine

CSL Biotherapies

BRIEF SUMMARY OF PRESCRIBING INFORMATION

AFLURIA®
Influenza Virus Vaccine Suspension for Intramuscular Injection

Before prescribing, please consult full prescribing information, a brief summary of which follows. Some text and references refer to full prescribing information.

4 CONTRAINDICATIONS

AFLURIA® is contraindicated in individuals with known hypersensitivity to eggs or chicken protein, neomycin, or polymyxin, or in anyone who has had a life-threatening reaction to previous influenza vaccination.

5 WARNINGS AND PRECAUTIONS

5.1 Guillain-Barré Syndrome (GBS)

If GBS has occurred within 6 weeks of previous influenza vaccination, the decision to give AFLURIA® should be based on careful consideration of the potential benefits and risks.

5.2 Altered Immunocompetence

If AFLURIA® is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be diminished.

5.3 Preventing and Managing Allergic Reactions

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

5.4 Limitations of Vaccine Effectiveness

Vaccination with AFLURIA® may not protect all individuals.

6 ADVERSE REACTIONS

6.1 Overall Adverse Reactions

Serious allergic reactions, including anaphylactic shock, have been observed during postmarketing surveillance in individuals receiving AFLURIA®.

The most common local (injection-site) adverse reactions observed in clinical studies with AFLURIA® were tenderness, pain, redness, and swelling. The most common systemic adverse reactions observed were headache, malaise, and muscle aches.

6.2 Safety Experience from Clinical Studies

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a vaccine cannot be directly compared to rates in the clinical studies of another vaccine and may not reflect the rates observed in clinical practice.

Clinical safety data for AFLURIA® have been obtained in two clinical studies (*see Clinical Studies [14]*).

A US study (Study 1) included 1,357 subjects for safety analysis, ages 18 to less than 65 years, randomized to receive AFLURIA®, Influenza Virus Vaccine Suspension for Intramuscular Injection, (1,089 subjects) or placebo (268 subjects) (*see Clinical Studies [14] for study demographics*). There were no deaths or serious adverse events reported in this study.

A UK study (Study 2) included 275 subjects, ages 65 years and older, randomized to receive preservative-free AFLURIA® (206 subjects) or a European-licensed trivalent inactivated influenza vaccine as an active control (69 subjects) (*see Clinical Studies [14]*). There were no deaths or serious adverse events reported in this study.

The safety assessment was identical for the two studies. Local (injection-site) and systemic adverse events were solicited by completion of a symptom diary card for 5 days post-vaccination (Table 1). Unsolicited local and systemic adverse events were collected for 21 days post-vaccination (Table 2). These unsolicited adverse events were reported either spontaneously or when subjects were questioned about any changes in their health post-vaccination. All adverse events are presented regardless of any treatment causality assigned by study investigators.

Table 1: Proportion of Subjects With Solicited Local or Systemic Adverse Events* Within 5 days After Administration of AFLURIA® or Placebo, Irrespective of Causality†

	Study 1 Subjects ≥ 18 to < 65 Years		Study 2 Subjects ≥ 65 Years
Solicited Adverse event	AFLURIA®‡ n=1089	Placebo § n=268	AFLURIA® n=206
Local			
Tenderness‖	60%	18%	34%
Pain¶	40%	9%	9%
Redness	16%	8%	23%
Swelling	9%	1%	11%
Bruising	5%	1%	4%
Systemic			
Headache	26%	26%	15%
Malaise	20%	19%	10%
Muscle aches	13%	9%	14%
Nausea	6%	9%	3%
Chills/ Shivering	3%	2%	7%
Fever ≥ 37.7 °C (99.86 °F)	1%	1%	1%
Vomiting	1%	1%	0%

* In Study 1, 87% of solicited local and systemic adverse events were mild, 12% were moderate, and 1% were severe. In Study 2, 76.5% were mild, 20.5% were moderate, and 3% were severe. In both studies, most solicited local and systemic adverse events lasted no longer than 2 days.

† Values rounded to the nearest whole percent.

‡ Includes subjects who received either the single-dose (preservative-free) or multi-dose formulation of AFLURIA®.

§ Thimerosal-containing placebo.

‖ Tenderness defined as pain on touching.

¶ Pain defined as spontaneously painful without touch.

Table 2: Adverse Events* Reported Spontaneously by ≥ 1% of Subjects Within 21 Days After Administration of AFLURIA® or Placebo, Irrespective of Causality†

	Study 1 Subjects ≥ 18 to < 65 years		Study 2 Subjects ≥ 65 years
Adverse Event	AFLURIA® ‡ n=1089	Placebo § n=268	AFLURIA® n=206
Headache	8%	6%	8%
Nasal Congestion	1%	1%	7%
Cough	1%	0.4%	5%
Rhinorrhea	1%	1%	5%
Pharyngolaryngeal Pain	3%	1%	5%
Reactogenicity Event	3%	3%	0%
Diarrhea	2%	3%	1%
Back Pain	2%	0.4%	2%
Upper Respiratory Tract Infection	2%	1%	0.5%
Viral Infection	0.4%	1%	0%
Lower Respiratory Tract Infection	0%	0%	1%
Myalgia	1%	1%	1%
Muscle Spasms	0.4%	1%	0%

* In Study 1, 63% of unsolicited adverse events were mild, 35% were moderate, and 2% were severe. In Study 2, 47% were mild, 51% were moderate, and 3% were severe. In both studies, most unsolicited adverse events lasted no longer than 5 days.

† Values greater than 0.5% rounded to the nearest whole percent.

‡ Includes subjects who received either the single-dose (preservative-free) or multi-dose formulation of AFLURIA®.

§ Thimerosal-containing placebo.

6.3 Postmarketing Experience

Because postmarketing reporting of adverse reactions is voluntary and from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. The adverse reactions described have been included in this section because they: 1) represent reactions that are known to occur following immunizations generally or influenza immunizations specifically; 2) are potentially serious; or 3) have been reported frequently. The following adverse reactions also include those identified during postapproval use of AFLURIA®, Influenza Virus Vaccine Suspension for Intramuscular Injection, outside the US since 1985.

Blood and lymphatic system disorders

Transient thrombocytopenia

Immune system disorders

Allergic reactions including anaphylactic shock and serum sickness

Nervous system disorders

Neuralgia, paresthesia, and convulsions; encephalopathy, neuritis or neuropathy, transverse myelitis, and GBS

Vascular disorders

Vasculitis with transient renal involvement

Skin and subcutaneous tissue disorders

Pruritus, urticaria, and rash

General disorders and administration site conditions

Influenza-like illness (e.g., pyrexia, chills, headache, malaise, myalgia), injection-site inflammation (e.g., pain, erythema, swelling, warmth), and induration

6.4 Other Adverse Reactions Associated With Influenza Vaccination

Anaphylaxis has been reported after administration of AFLURIA®. Although AFLURIA®, Influenza Virus Vaccine Suspension for Intramuscular Injection, contains only a limited quantity of egg protein, this protein can induce immediate hypersensitivity reactions among persons who have severe egg allergy. Allergic reactions include hives, angioedema, allergic asthma, and systemic anaphylaxis (*see Contraindications [4]*).

The 1976 swine influenza vaccine was associated with an increased frequency of GBS. Evidence for a causal relation of GBS with subsequent vaccines prepared from other influenza viruses is unclear. If influenza vaccine does pose a risk, it is probably slightly more than one additional case per 1 million persons vaccinated.

Neurological disorders temporally associated with influenza vaccination, such as encephalopathy, optic neuritis/neuropathy, partial facial paralysis, and brachial plexus neuropathy, have been reported.

Microscopic polyangiitis (vasculitis) has been reported temporally associated with influenza vaccination.

7 DRUG INTERACTIONS

7.1 Concurrent Use With Other Vaccines

There are no data to assess the concomitant administration of AFLURIA® with other vaccines. If AFLURIA® is to be given at the same time as another injectable vaccine(s), the vaccine(s) should be administered at different injection sites.

AFLURIA® should not be mixed with any other vaccine in the same syringe or vial.

7.2 Concurrent Use With Immunosuppressive Therapies

The immunological response to AFLURIA® may be diminished in individuals receiving corticosteroid or immunosuppressive therapies.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C: Animal reproduction studies have not been conducted with AFLURIA®. It is also not known whether AFLURIA® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. AFLURIA® should be given to a pregnant woman only if clearly needed.

8.3 Nursing Mothers

AFLURIA® has not been evaluated in nursing mothers. It is not known whether AFLURIA® is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when AFLURIA® is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

8.5 Geriatric Use

In four clinical studies, 343 subjects ages 65 years and older received AFLURIA®. Hemagglutination-inhibiting (HI) antibody responses in geriatric subjects were lower after administration of AFLURIA® in comparison to younger adult subjects (*see Clinical Studies [14]*). Adverse event rates were generally similar in frequency to those reported in subjects ages 18 to less than 65 years, although some differences were observed (*see Adverse Reactions [6.2]*).

Manufactured by:
CSL Limited
Parkville, Victoria, 3052, Australia
US License No. 1764

Distributed by:
CSL Biotherapies Inc.
King of Prussia, PA 19406 USA

Based on June 2008 revision.

Managing Diabetes

When it comes to top-flight healthcare, Mississippi may not be the first state that springs to mind; but North Mississippi Medical Center won a coveted Malcolm Baldrige National Quality Award in 2006. The center has 7 full-time physicians and 20 residents, takes care of 8,300 patients, and conducts about 30,000 office visits a year at nearly 40 practice sites.

North Mississippi's Family Medicine Residency Center—which serves as headquarters for the Medical Center's residency program as well as a practice site—began looking at its quality issues back in the 1990s. Chief quality officer Michael O'Dell, MD, directs the hospital's family practice residency program and sees patients at the Family Medicine Residency Center. Dr. O'Dell's site acts as a kind of lab for testing new ideas and procedures for the whole system. The first major challenge it chose after installation of an EHR was diabetes care.

The numbers showed that the practice's physicians weren't doing needed interventions as often as they should. "We had room to improve in almost every parameter," Dr. O'Dell says.

Merely looking at the data gave the physicians the impetus to make improvements. For example, they put signs in exam rooms instructing diabetic patients to remove their shoes and socks so that the physicians could do a foot exam. The combination of signs and barefoot patients helped physicians remember to do the exams.

Dr. O'Dell realized that some things aren't so easily measured. What constitutes a thorough foot exam, and how do you put that information in an electronic format in a way that makes it easy to search and analyze? The answer was to create a form with all the exam's discrete elements, such as pulse, warmth, and results of a visual check. Once all the blanks were filled in, the physician would transmit the exam as complete.

One undeniable result of the project was that the number of patient visits went up. People hadn't been coming every three months as recommended, so the system tracked repeat visits and identified patients who needed to be pestered. Dr. O'Dell says many were grateful to have been reminded, and they thought it showed how caring and warm the center was.

Dr. O'Dell hopes to minimize practice variation as well, but

he knows he'll never eliminate it. Dr. O'Dell says," The patient in front of you is unique and has to be dealt with uniquely. It doesn't mean you can't standardize and reduce variation—it just means you can't reduce all of it."

Not in It for the Money

Erica Swegler, MD, doesn't have anything tangible to gain from getting NCQA recognition for diabetes care. Because pay-for-performance hasn't arrived in the Dallas-Fort Worth market, hardly any payers are offering extra money for better care.

She could even argue that she has something to lose: in the time it takes her to give one diabetic patient the care and counseling he needs, another physician could be seeing three patients with less complicated problems.

And the recognition costs aren't nothing: $450 per doctor for a three-year seal of approval, plus $80 for the software tool needed to collect patient data and analyze it to see whether the practice qualifies for the recognition (and if not, what it has to change in order to qualify). In addition, there's someone's clerical time to put the data into the software tool.

Nonetheless, Dr. Swegler sought the recognition out of a sense of obligation to her patients and her profession, and out of personal pride. "All the studies indicate that higher-quality care costs the system less, so for the patient, the population, and the health system, it's the right thing to do," says Dr. Swegler, who used to head the Texas chapter of the American Academy of Family Physicians.

One result of working toward the diabetes recognition is that Dr. Swegler has acquired equipment to perform dilated-eye exams in her office instead of trusting that her patients will have them done elsewhere when she writes them a referral. Her office doesn't get compensated for the exams by all payers, but she no longer has to worry about blanks where the eye exam results should be.

Dr. Swegler says she expects the NCQA recognition programs to become more popular because the American Board of Family Medicine has begun to require quality-improvement activities as part of board certification, and the NCQA recognitions fulfill that requirement. "It's a huge carrot," she says.

Bridges to Excellence

Four Seasons Pediatrics, a three-physician practice in the Albany, N.Y., area, had been receiving repeated letters from Bridges to Excellence (BTE), outlining the program and letting them know how many of their patients would figure into any rewards that were available.

"After the third letter, they called us to have lunch," says Harry Miller, MD. "That's what made us say, 'OK, let's see what this is about.'"

BTE's Physician Office Link program encouraged the adoption of EHRs with incentive payments from employers. Dr. Miller and his wife and practice partner Kimberly Elmer, MD, ran some numbers. They would get a one-time incentive payment of $50 for each of the 220 patients in their practice who were insured by one of the participating companies, which included large area employers like General Electric and Verizon. That payment would cover a basic level of BTE certification (for effective use of registries to track care of chronically ill patients and for having systems in place for follow-up and patient education). If the practice went for advanced certification (an EHR system that provided decision support, the ability to order prescriptions and tests, and the ability to generate patient reminders), it would also get $50 per patient for another two years, which would add up to more than $30,000, or enough to cover the initial costs of hardware, software, upgrades, and maintenance.

But that wasn't all. Several insurers in the area, though not officially part of BTE, were adopting the program's criteria as a basis for incentive payments. "Just getting accredited by BTE allowed us to qualify for $90,000 in incentives in the first couple of years," Dr. Miller says.

The EHR system and the resulting improvements in information accessibility have started to have tangible impacts on the quality of patient care, Dr. Miller says. For example, the practice can report its immunization information to New York State electronically. As a result of setting up that data feed, the physicians saw that nurses were making little mistakes in filling out immunization forms. "They have to enter a lot of data, and there are lots of opportunities to get something a little bit off," Dr.

Miller says. "Probably one out of ten things was incorrect. When we were putting everything on paper, we had no idea that was happening." The practice began running monthly reports to show where the errors were occurring, and the error rate has dropped to 1 in 100.

After Four Seasons began a program to give optimal care to asthma patients (the right medications at the right time, making sure the patient's environment is as free of triggers as possible, and getting patients in for regular assessments), one large insurer saw a 38-percent increase in inhaled-steroid treatment among its Four Seasons patients. "Initially their cost per patient went up as they used more meds, but ER visits and urgent visits dropped, which more than overtook the increase," Dr. Miller says.

Bringing Pay-for-Performance in House

Fairview Health Services, with more than 300 physicians, is the second largest physician group in Minnesota. It has 50 primary care clinics and 37 specialty clinics. In 1999, the practice started installing an EHR system. As a result, it became feasible to undertake an organized internal effort to measure overall quality of care—and eventually to adopt an in-house pay-for-performance program.

Before the start of the project, the practice's physicians assumed they were delivering consistently high-quality care, says Barry Bershow, MD, Fairview's medical director of quality and informatics. But when they started measuring their quality of care, they realized there was room for improvement.

"When physicians know they aren't up to the standards of their peers, they can really move," says Dr. Bershow. "We were scoring low-average on diabetes in 2004, and now we're at the top" in state-wide measures.

The first projects focused on conditions like diabetes and coronary artery disease that can be substantially affected by the office physician's actions. Fairview sent one of its report writers to its EHR vendor, Epic Systems in Madison, Wis., to learn how to pull the right data elements out of the system to assess the care for those conditions. The practice also retrained its physicians and other staff members to enter the data in consistent ways so that the reports would be as clean as possible.

Once baseline reports were generated, Dr. Bershow was able to demonstrate that some physicians were doing better than others on delivering the right care and that there were unexplained variations. "Initially I got some push-back, and some questions about whether the data was 'dirty,' but we could lay auditable data in front of them; and eventually we got very full buy-in," he says.

To reinforce these positive changes, Fairview began its own in-house pay-for-performance program to reward physicians who performed well on the selected quality measures. Only a fraction of the costs were covered by outside incentive payments from health plans—the practice paid the rest out of its own pocket. For the average primary care physician, the quality differential can amount to 10 percent of salary—a significant raise.

Right now no one is actually losing money for not performing as well, but the economics of the situation say that can't last. "Long-term, we'll probably have to penalize those with worse quality, but that gets to be a problem when even our 'worst performers' are above the state average," Dr. Bershow says. To help solve that potential problem, the practice is in "aggressive" talks with payers to restructure reimbursement so that its physicians are rewarded for doing the right things.

Ramping Up Quality With an EHR

Riverbend Medical, a 60-physician multispecialty group with four sites around Springfield, Mass., has long had a culture of trying to address quality issues, but it was a hit-or-miss approach before the practice moved from paper charts to an EHR.

The practice's paper-based quality efforts often paid off, says internist Joseph Kelly, MD, who serves as associate medical director. But the Riverbend physicians and administrators knew they could do even better.

"The thing that spurred us to a quantum leap was that we were getting some improvement but not what we were capable of," Dr. Kelly says. "We needed a better system and a better set of tools. We looked at our strategic plan to see where we had penciled in an EHR, and decided that, given what we thought we needed to do with quality, maybe we should move that timeline up."

That was in 2003. The first site went live in October 2005. Riverbend planned for a 50-percent cut in each physician's pro-

ductivity during the training period and gradually ramped them back up to 100 percent. After the system was fully implemented in 2007, the proportion of physicians' time spent on non-reimbursable activities dropped.

As for quality measurement, the system has allowed Riverbend to put together its own databases rather than depending on claims data. "We can look at the data in real time, which is the most useful and actionable and meaningful data for active physicians," Dr. Kelly says.

The EHR has also proven to be an invaluable check on erroneous claims data. For example, without the EHR, Dr. Kelly would never have discovered that Blue Cross had made a mistake in how it loaded the data, resulting in what looked like woefully bad rates for hemoglobin A1c testing for diabetics. The Blue Cross data showed that Riverbend was doing the recommended test only 46 percent of the time, but the EHR put its results at 88 percent. "There's no way we would have been able to pull 600 paper charts and log each lab result to check this data," he says.

Medicare Physician Group Practice Demonstration Project

Geisinger Health System is one of 10 large group practices participating in Medicare's Physician Group Practice Demonstration Project, a four-year experiment in pay-for-performance that gives the top groups in the project a share in the savings generated by better care of chronically ill patients. Each of the participating practices has 200 physicians or more, which creates economies of scale; but Frederick Bloom, MD, Geisinger's medical director of performance improvement, says even the smallest practice can start to redesign its processes to get similar results.

With 200 physicians in 40 sites, Geisinger provides care to 2.5 million people throughout a 40-county area in central Pennsylvania. It has had an EHR system since 2001 across all its sites, and has an extensive database of clinical information that can be analyzed to identify ways to improve care.

Since it provides both inpatient and outpatient care, and acts as a payer for about 30 percent of its service population, Geisinger is in a better position than most organizations to gauge

the big picture of quality improvement. "The initial things we're doing—seeing patients more frequently and prescribing more meds and ordering more tests—potentially increase the cost of care up front slightly, but those things are nowhere near as expensive as hospitalization," Dr. Bloom says. Geisinger's own health plan offers physicians bonuses for quality gains.

It took almost a year just to get the data in good enough shape so that the practice could with certainty identify those in its patient population who had the conditions being studied. "Even though we had a rich database, getting that kind of information out of it hadn't been a priority in the past," Dr. Bloom says.

With information in hand, Geisinger could begin to redesign its practices to improve its scores on the areas being measured. One successful strategy was to spread the responsibility out over a team so that nurses can concentrate on routine care, leaving the physicians to concentrate on difficult medical decisions, such as when to change a therapy or start a patient on a new medication. Nurses now have standing orders to give needed vaccines so that they don't have to chase down the physician each time.

First the process measures improved: patients were more consistently getting the tests and interventions they needed. Now Geisinger is seeing intermediate outcome improvements: better blood sugar control, healthier blood pressures, lower cholesterol. Within a few years, Dr. Bloom expects and hopes to see measurable improvement in the things that really count: fewer amputations, less blindness, healthier kidneys.

"It's not the tools you can create that make it work," says Dr. Bloom. "It's defining the responsibilities and the operational flow that really makes the difference. Systems of care and process redesign are so important for chronic disease and for prevention," he says.