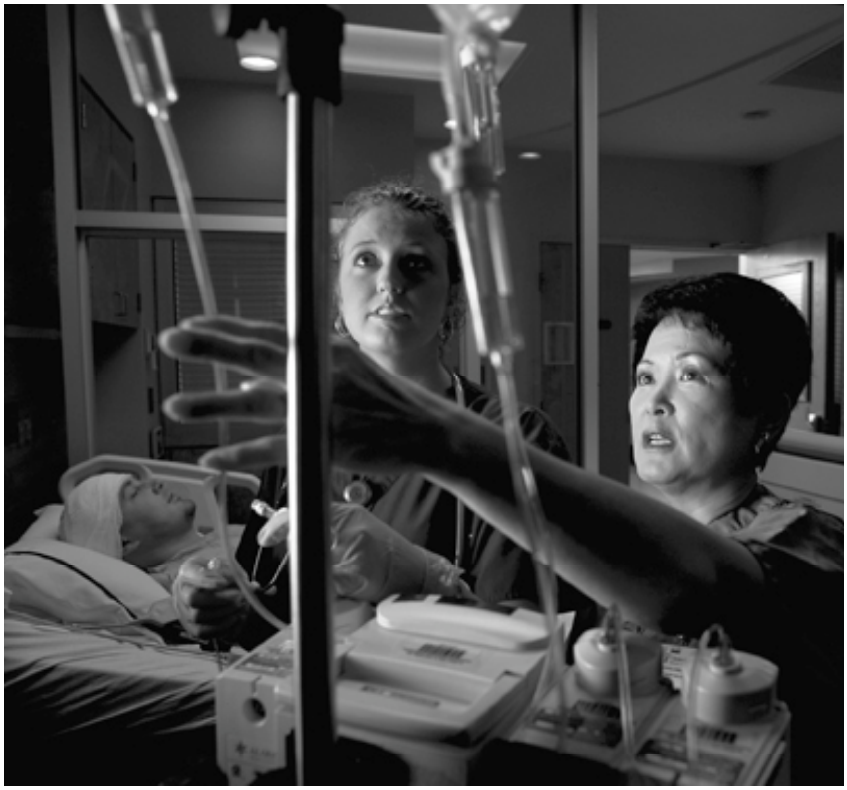
INDIANA

CENTER FOR URBAN POLICY AND THE ENVIRONMENT SEPTEMBER 2005

A Challenge for Indiana

Medical Error Reporting System Could Boost Patient Safety



In 1999, the Institute of Medicine thrust the issue of patient safety into public awareness when it reported that at least 44,000 preventable deaths per year in the United States are due to medical errors. This made medical errors the 8th leading cause of death in the United States, claiming a higher death toll than motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).

In response, at least 22 states have initiated *medical error reporting systems* (MERS) in an effort to improve patient safety (see Table 1, page 2, for a list of those states). And in July 2005, Congress overwhelmingly voted to pass the Patient Safety and Quality Improvement Act of 2005. This bill was designed to encourage states to participate in a national medical error database, and it protects the confidentiality of the individuals who report errors and the organizations involved in the errors.

As Indiana leaders consider innovative strategies to improve healthcare, the state has an opportunity to make its own meaningful contribution to patient safety. In recognition of this, as one of his first initiatives in 2005, Governor Mitch Daniels issued a directive to establish a MERS (see page 6 for a copy of this directive). This directive builds on the many innovative efforts already at work in the state to improve patient safety. A list of these initiatives is included at the end of this issue brief on page 7.

This issue brief outlines the importance of developing a state MERS for improving patient safety. We also discuss important factors that leaders should consider when developing reporting systems.

Over the years, the Center for Urban Policy and the Environment has focused on issues that affect the quality of life in Indiana—issues such as economic development, criminal justice, taxes, urban development, nonprofits, the arts, education, social services, and gaming.

We have now added a critically important new topic to the focus of the Center: **health policy**. We are all keenly aware that health policy dramatically affects the quality of life of our citizens. This issue brief is the Center's first report on a health policy issue. We are pleased to produce this report in conjunction with two community leaders: **Patricia R. Ebright**, of the School of Nursing at Indiana University–Purdue University Indianapolis, and **Kathryn Rapala**, director of risk management and patient safety at Clarian Health Partners.

As always, we welcome your comments about this and other public policy issues.

Table 1: **States that have enacted legislation for a medical error reporting system, as of March 31, 2004**

Colorado	California
Connecticut	Florida
Georgia	Kansas
Massachusetts	Maine
Maryland	Minnesota
New Jersey	New York
Nevada	Ohio
Pennsylvania	Rhode Island
South Carolina	South Dakota
Tennessee	Texas
Utah	Washington

Source: National Academy for State Health Policy, retrieved August 2, 2005, from http://www.nashp.org/_docdisp_page.cfm?LID=2A789909-5310-11D6-BCF000A0CC558925

Patient safety practices, in a nutshell, are techniques for reducing the chance of error and adverse outcomes in patient care. The scope of patient safety ranges from a broad culture of safety to specific procedures such as hand-washing.

Many regulatory influences outside Indiana already impact patient safety through mandates, standards, and reporting requirements (see Table 2). And many individual states are developing their own standards for reporting systems. For example, Minnesota hospitals began reporting medical error events to the Minnesota Hospital Association in July 2003 during a transition period, and started full implementation of their amended state system in December 2004. Minnesota hospitals now report errors and patient safety issues to the Minnesota Department of Health.

Table 2: **Agencies that promote patient safety and quality guidelines, mandates, or requirements for healthcare organizations**

Department of Health and Human Services
Joint Commission on Accreditation of Healthcare Organizations
Institute for Healthcare Improvement
Institute of Medicine
Center for Disease Control and Prevention
Agency for Healthcare Research and Quality
Center for Medicare and Medicaid Services
National Patient Safety Foundation
Leapfrog Group
Healthgrades
Anthem/Wellpoint

Their state requirements are based on the National Quality Forum's recommendations for serious reportable events in healthcare (2002). The Minnesota Department of Health Web site offers information about errors that have been reported in the state and its reporting requirements (see http://www.health.state.mn.us/patientsafety/index.html).

Reporting initiatives, though well-intentioned and important, can create a maze of confusing requirements for healthcare organizations. The actual reporting and measuring is labor intensive, requiring reorganization and additional resources. As Indiana decision-makers develop a MERS, they must remember two critical principles:

1. The system should be based on sound patient safety methodology that does not create a punitive system for providers.
2. The system should be consistent with other voluntary and required reporting systems so that healthcare providers are not burdened with additional requirements.

Who's To Blame?

The traditional approach to healthcare provider performance is to expect perfection with no errors and demand accountability and punishment when errors occur. However, other industries with high-stake outcomes, such as airlines and power plants, have helped us learn to appreciate human limitations in complex and difficult situations. We have recognized that well-intentioned individuals are not the appropriate target for most sustainable safety improvement efforts, and, as a result, the goal of patient safety has shifted from punishment of the individuals involved in the error to reducing risk and limiting the consequences of error (Berwick, 2003).

People who are expected to perform without error in all situations may not be open and honest about reporting the details of an error, but in a non-blame culture, the focus after an error is not on the individual, but rather on everything surrounding the situation that might have contributed to the error. In a hospital, errors typically arise from a combination of multiple system failures. For example, contributions to an error might include a failure to educate all staff on a seldom-used procedure, a practice of stocking medications in the wrong drawer, and staffing allocations based on the number of people per shift rather than on the experience required for the patients currently receiving care.

A non-blame culture helps us better analyze system failures that contribute to errors. Information about failures helps us develop improvements to reduce error risk. A non-blame approach also lets us limit consequences for healthcare providers when an error occurs despite best efforts (Runciman, et. al, 2003).

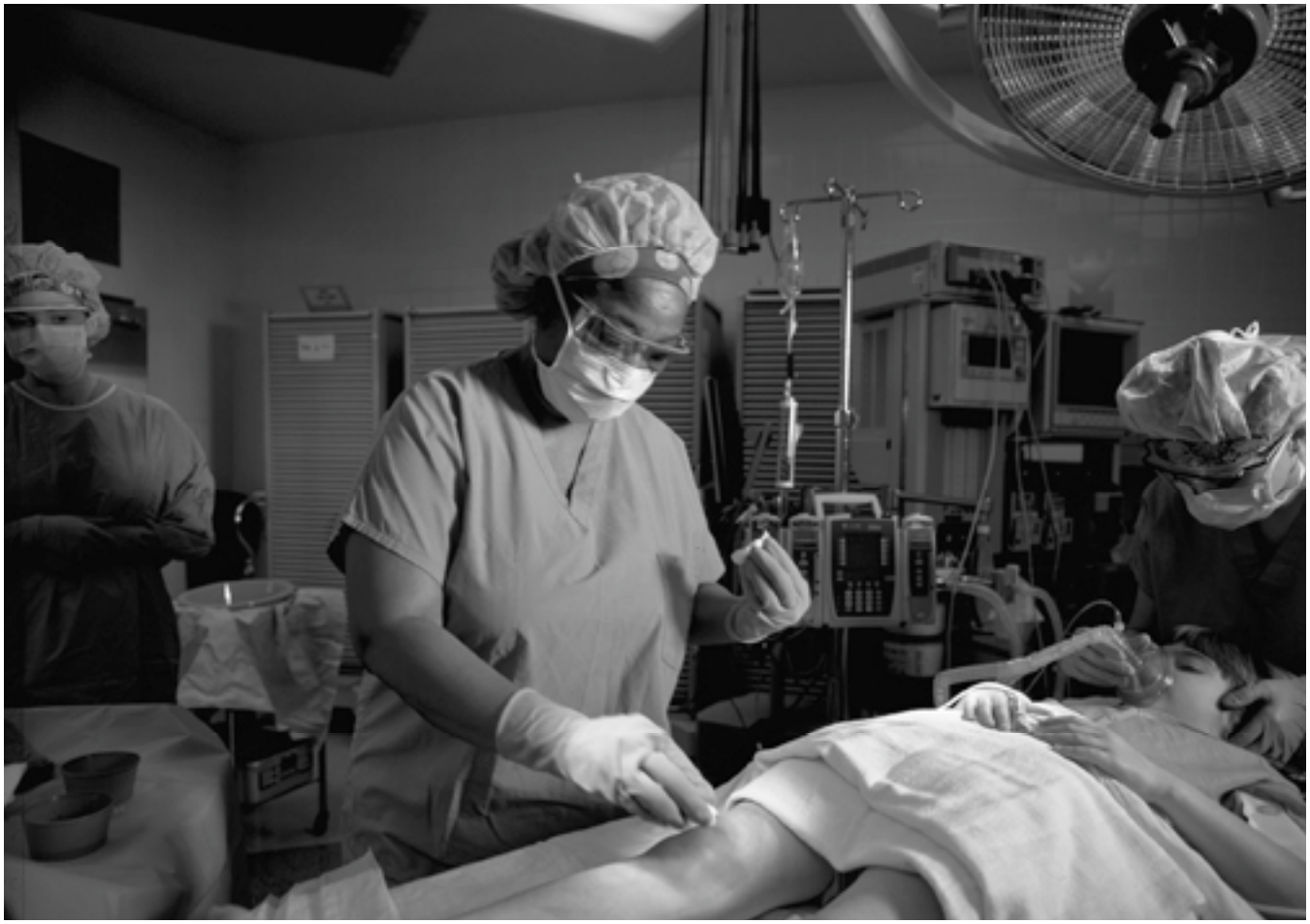
It is also clear that decisions from multiple sources—even from outside hospitals—influence the risk for errors. Vicente (2002) goes beyond understanding the human factor issues that other industries describe as crucial for analyzing error. He includes not only elements of healthcare organizations in patient safety analysis, but also regulators, associations, and the government. He says healthcare is a "complex socio-technical system" consisting of several levels and stakeholders that impact risk management.

State Government Plays a Crucial Role in Reporting

The state makes decisions that influence patient safety beyond standardizing and regulating practices. For example, how the MERS is designed and implemented will influence providers' decisions about whether and how openly to report errors—this, in turn, affects what we can subsequently learn from these reports.

Indiana has an opportunity to develop a MERS that combines the best efforts to decrease risk of medical error while increasing consumers' access to accurate information for healthcare decision-making. A system that balances accuracy, accessibility, evidenced-based outcomes, and legal protection will help us achieve that goal. A system leaning too far to the side of liability and assignment of blame will result in decreased learning about how to make improvements in patient safety and inaccurate data for healthcare decision making. A system leaning too far on the side of no accountability for outcomes will result in inadequate management of poor performance.

The perception of liability may also influence providers' decisions about attempting high-risk procedures. Ultimately, the MERS developed by the Indiana government will influence whether the



risk for healthcare error is reduced and the consequences of error limited for the people of Indiana.

Patient safety advocates have suggested a variety of functions that should be included by policymakers during the design of a state reporting system. Most or all of these functions have been adopted by various states. They include:

- minimum standards for reporting timelines and action steps—including guidelines for identifying who reports, what to report, and how to report;
- collection of data and statistics showing trends;
- analysis of data for thoroughness and appropriateness;
- a mechanism for sharing data across the state;
- appropriate statutory protection of data to protect individual reporters;
- a mechanism for informing the public for the purpose of enhancing healthcare decision making; and
- statewide education programs to disseminate learning from the data.

The specific data reported by hospitals in other states include numbers of the types of errors as defined by the state, causes of the errors, solutions designed and implemented to prevent future events, and evaluations of whether the solutions were effective.

Licensure and Individual Performances Play a Role

A move to a non-blame culture would not relieve healthcare providers from responsible performance of licensure requirements. Licensure requirements for healthcare providers and individuals are baseline elements needed for safe operation. The Indiana Health Professions Bureau helps protect the health and safety of the citizens of our state by offering a Web site where the public can verify whether physicians and nurses have active licenses.

In addition, we must continue to identify, counsel, and remove poor performers from the system. However, poor performance is a separate issue from practices that help us learn how to decrease error risk. Poor performance is usually the result of a larger system failing to address unacceptable behaviors. The failed system could be at a micro-system healthcare unit level, organizational policy level, or at the state regulatory level. While we must address poor performance, we also need to learn from error events, so a separate system for reporting and managing data is essential.

Roadblocks to Improving the Reporting System

Our traditional approach of blaming individual providers for errors has created some stubborn roadblocks to open and honest error reports. When providers discuss their reluctance to report the details of error events, they cite fear of retribution, ethical dilemmas, and economic pressures. Even providers who understand complex system errors and the importance of learning from them hesitate to report problems because they know that the public often does not understand the complexity of the situation, and this lack of understanding may have legal implications for the provider. A system that decreases error risk, rather than a system that increases anxiety among healthcare providers and limits learning, must be created.

While providers may see error reports as an opportunity to learn, the public and other stakeholders often see only the failure intrinsic in an error (Hofler, 2005). If a hospital openly discloses an error that resulted in a patient's death, the public might view that hospital as "more risky." But in fact, hospitals promote a safer environment if they report and review errors that have occured.

For example, in January 2005, the Minnesota Department of Health published a public report that reveals the types and frequency of errors that were reported in specific hospitals in the state, how often they were reported, and if the result was death, serious disability, or neither.

One relatively frequent error type that occurs across the country is operations on the wrong body part, and Minnesota hospitals reported that their surgical teams operated on the wrong body part 13 times during July 2003–October 2004.

Because the medical community has learned that operations on the wrong body part are a problem, surgical teams have taken additional precautions to avoid this error. The Associated Press (June 21, 2004) reported that surgeons and nurses now take "time out" before cutting. The team double-checks that the correct patient is on the table. They then double-check to be sure they are performing the scheduled operation. And if the patient is, for example, scheduled to lose a kidney, the team double-checks whether they need to remove the right or left kidney.

Open disclosure of errors may also result in increased scrutiny from other accreditation or regulatory bodies. For example, based on the Minnesota model, when adverse events are disclosed, the Joint Commission on Accreditation of Healthcare Organizations or the Center for Medicare and Medicaid Services (CMS) may ask the hospital for more information.

The CMS Hospital Quality Initiative goals for voluntary reporting from hospitals include (1) standardization of reporting, and (2) provision for consumer access to data. Reporting is linked to market basket increases in Medicare reimbursement, however, which makes it difficult for hospitals to avoid participating. The voluntary nature of the system is weakened by the tie to economics.

When Congress passed the Patient Safety and Quality Improvement Act of 2005, they included federal legal assurances that reported data generally cannot be used by individuals and legal representatives. Hopefully, this bill will encourage providers to voluntarily report errors. Open and honest reporting offers the best chance for accurate national benchmarking to improve patient safety across the nation.

However, given the Freedom of Information Act (a law passed in 1996 regarding the rights of individuals to request information collected by the federal government), it is possible that these confidentiality assurances may not hold up in court. We were all aware of the media uproar over the Terri Shiavo case—if there is a high profile case of alleged medical malpractice and the public become aware of this provision, it may be difficult for the federal or state government to protect the confidentiality of such information.

Characteristics of a Good Reporting System for Increasing Patient Safety

An effective MERS should try to balance the following factors:

- accurate and full reporting of patient safety data guided by clear standards,
- reconciliation of multiple reporting requirements to prevent financial burdens that could be used for safety and quality improvement efforts,
- centralized databases that enable identification of patient safety trends in errors and that can be used to share evidence-based interventions and outcomes,
- documented efforts of quality of care improvements by multiple healthcare organizations,
- legal protection for those who report (to encourage accurate reporting),
- clear definitions of patient safety and other quality terms used in information accessed by the public, along with
- basic education so that the public understands that increases in the numbers of reported errors do not necessarily suggest that a hospital is unsafe.

A system with these characteristics and safeguards would make data available for improvements and accessible to consumers for informed decision-making.

Importance for Policymakers

More and more states have initiated their own MERS, but state regulations vary, and they are affected by all of the issues outlined in this issue brief.

One benefit to Indiana for having not instilled a MERS thus far is that we have an opportunity to learn from the experience of other states. For example, we can evaluate the benefit to the public, not only in terms of increased patient safety which is hard to measure, but also in terms of public learning about safety and the availability of valid information about healthcare providers and facilities. We can also evaluate the lessons that healthcare organizations have learned from sharing information about adverse events.

A well-designed MERS can help identify the causes of medical errors, causes which are often complex. Once we understand the causes, we can act to prevent these tragic errors. In its role as an important supervisor of patient safety, the state has an obligation to citizens to help ensure good outcomes. A good MERS would work in the best interests of all Hoosiers.

05-10

FOR: **DIRECTIVE TO ESTABLISH MEDICAL ERROR REPORTING AND QUALITY SYSTEM**

TO ALL WHOM THESE PRESENTS MAY COME, GREETINGS.

WHEREAS, Indiana's hospitals are among the most advanced in the country and must continue to lead the way in improving patient care and health outcomes;

WHEREAS, a landmark report by the Institute of Medicine and other evidence demonstrates that medical errors are among the leading causes of death in the United States and impose an enormous economic cost on families and businesses;

WHEREAS, a growing, widely respected body of standards, best practices, and technical support services now exists on which to construct medical error reporting and quality systems (MERS), including the work of the Hospital Quality Initiative of the federal Department of Health and Human Services, the Institute for Healthcare Improvement, and the "Leapfrog Group" of private business and healthcare purchasers;

WHEREAS, hospitals across the country are implementing MERS to improve healthcare and demonstrate to both health professionals and the public that procedures can be implemented to reduce medical errors by identifying and controlling the associated hazards;

WHEREAS, successfully implemented MERSs reduce the frequency of medical errors and can reveal the causes for errors and empower healthcare professionals to design methods to prevent or discover errors before patients are harmed; and

WHEREAS, Indiana hospitals are not currently required to implement a MERS, and the successful implementation of a MERS would likely radically improve Hoosier healthcare and lessen healthcare costs;

NOW, THEREFORE, I, **Mitchell E. Daniels, Jr.**, by virtue of the authority vested in me as Governor of the State of Indiana, do hereby order that:

1. As soon as practicable, the Department of Health (DOH) shall promulgate regulation, and, if necessary, propose legislation, requiring each hospital in this State to implement a MERS.
2. The DOH shall confer with various representatives of the State's hospitals, physicians, nurses, pharmacists, and quality improvement experts and consult best practices guides, including the 10-measure "starter set" of quality reporting indicators that are supported by the federal Hospital Quality Initiative, to develop minimum standards applicable to every MERS in the State.
3. To ensure that each hospital's MERS is effective, the MERS should, at a minimum:
   a. ensure that patients' and healthcare professionals' identities are kept confidential and not discoverable in any court or administrative proceeding;
   b. not be used as the basis for punishing any healthcare professional;
   c. require all healthcare professionals to report medical errors promptly;
   d. require hospitals to report all MERS data to the DOH, which shall make the information available on its website for the public to see which hospitals are the most successful in reducing medical errors;
   e. require DOH to regularly disseminate medical error data and trends analysis to hospital administrators, front-line caregivers, and the public so that hospitals can implement useful error prevention strategies;
   f. require hospitals to provide patients with easy to understand aggregate data and trends analysis so that patients understand their role in helping to prevent errors; and
   g. require hospitals to share successful solutions and improvements with other hospitals.

IN TESTIMONY WHEREOF, I, Mitchell E. Daniels, Jr., have hereunto set my hand and caused to be affixed the Great Seal of the State of Indiana on this 10th day of January, 2005.

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Mitchell E. Daniels, Jr.
Governor of Indiana

ATTEST: Todd Rokita
Secretary of State

Source: Governor Mitch Daniels. Available from the Access Indiana Web site from http://www.in.gov/gov/media/eo/EO_05-10_Medical_Error_Reporting.pdf

Current Indiana initiatives for improving patient safety include:

The work of the Regenstrief Institute—Regenstrief is continuing development of a computerized medical record. It is also working on several other research projects related to patient safety and quality care.

National Health Information Infrastructure—Wishard Hospital and Marion County Department of Health are collaborating on standardized sharing of health information to facilitate transfer of quality and safety data.

The Indianapolis Executive Session on Patient Safety—This working group of local executives is committed to addressing patient safety by focusing on healthcare leader learning about creating safety. Their goal is to make Indianapolis the safest city in America in terms of delivering inpatient medical care.

Centers for Medicare and Medicaid Services (CMS) Patient Safety Learning Pilot—the goal of this pilot is to implement and test a patient safety improvement prototype to reduce harm to patients in the hospital. Participants include two hospitals from each of three state quality improvement organizations (Indiana, Wisconsin and Nevada),

Community Health Network (CHN)Teaming with Institute for Healthcare Improvement (IHI)—CHN participates in IHI's IMPACT program, a program to ensure that patients are as safe in healthcare facilities as they would be in own homes. CHN is one of 58 participating organizations in 28 states. CHN's initiatives include reducing known risks for infection, reducing patient stays in ICUs, and improving patient satisfaction.

Indianapolis Network for Patient Care (INPC)—This Indianapolis-wide clinical informatics network includes the five major hospital systems. The INPC may improve patient safety by offering increased coordination and follow-up of healthcare across the geographic region.

Indiana Health Information Exchange (IHIE)—IHIE is a non-profit company focused on using information technology to develop a model of health-information exchange for the United States. Many healthcare partners in Indiana participate in this collaboration, including healthcare organizations, state and county departments, and the Indiana University School of Medicine.

Source*: Report of the Patient Safety Subcommittee of the Commission on Excellence in Health Care Of the Indiana General Assembly*. The William S. and Christine S. Hall Center for Law and Health, Indiana University of Law–Indianapolis. August, 2004.

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Indiana's Future:
Identifying Choices and Supporting Action to Improve Communities

State of Indiana

This project, funded by an award of general support from Lilly Endowment, Inc., builds on the Center's research to increase understanding of Indiana. The Center's faculty and staff work to identify choices that can be made by households, governments, businesses, and nonprofit organizations to improve our community's quality of life. Our goal is to understand the people, economics, problems, and opportunities in Indiana, and to help decision-makers understand the impacts of policy decisions. The Center also works to mobilize energy to accomplish these goals.

One way the Center works to achieve its goals is through joint efforts with community leaders and faculty members at Indiana University–Purdue University Indianapolis. Center staff members worked with two community leaders to create this report about the need for a well-designed medical error reporting system in Indiana.

The Center for Urban Policy and the Environment is part of the School of Public and Environmental Affairs at Indiana University–Purdue University Indianapolis. An electronic copy of this document and other information about community issues can be accessed via the Center Web site (http://www.urbancenter.iupui.edu/). For more information, visit the Center Web site or contact the Center at 317-261-3000.

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