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## **Compliance issues for clinical trials conference Jan. 15**

Research and Sponsored Programs has registered the IUPUI campus for the series of live satellite video conferences sponsored by The National Council of University Research Administrators. The second program of this series will be 11:30 a.m. to 3:30 p.m., Tuesday, Jan. 15, in the Lilly Auditorium of University Library.

To register, contact JoAnn Pipkin at [rspinfo@iupui.edu](mailto:rspinfo@iupui.edu).

Clinical trials are highly regulated and monitored activities. At the same time, universities and affiliated medical centers are under tremendous pressure to move quickly in order for sponsors to capitalize on

intellectual property protection, obtain FDA approval and deliver a safe and effective product to the public.

This broadcast will examine major compliance issues affecting clinical trials and the partnership that exists among federal agencies, drug manufacturers, clinical research organizations, academic health centers and private research organizations for maintaining compliance. Viewers will be able to ask questions of the panel.

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## **Applications for NIH loan repayment program due Feb. 28**

The National Institutes of Health has posted two important notices with short application deadlines about newly authorized and funded extramural loan repayment programs.

The notice concerning the NIH Extramural Loan Repayment Program for Clinical Researchers can be read at [grants.nih.gov/grants/guide/notice-files/NOT-OD-02-024.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-024.html). The notice concerning the NIH Extramural Pediatric Research Loan Repayment Program is at [grants.nih.gov/grants/guide/notice-files/NOT-OD-02-025.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-025.html).

Applications for both programs are due by **Thursday, Feb. 28**. Applications submitted by this date will be considered for funding in the fiscal year ending Sept. 30, 2002.

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## **A Moment for Patient Safety and Quality Health Care**

### ***Fourth in a series***

By Herbert E. Cushing, M.D.

## **Appropriate Use of Prophylactic Antibiotics Reduces Surgical Site Infections**

A great deal of evidence is available to document the effectiveness of appropriately administered prophylactic antibiotics in the prevention of surgical site infections. The agent used should be selected for its effectiveness against the most probable contaminants for the particular procedure. It should be administered, usually intravenously, to result in a concentration in serum and tissues by the time the incision is made and should be maintained until a few hours after the incision is closed.

Although nearly 90 percent of surgical patients receive prophylactic antibiotics, studies show that the choice of regimen, timing or duration of administration may be sub-optimal in as many as half the cases. Risks of improper administration include not only infection, with its clinical and economic costs, but also the emergence of resistant pathogens.

Many studies have been undertaken to evaluate various strategies for improving compliance with recommended practices for perioperative antibiotic prophylaxis, including chart audits, dissemination of guidelines, provider education programs and delegating administration of antibiotics to the anesthesia team or nursing staff.

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This is the fourth of 11 practices identified by the Agency for Healthcare Research and Quality's Evidence-based Practice Center at the University

of California at San Francisco-Stanford as "clear opportunities for safety improvement." Through a critical study of recent literature and clinical trials, these practices were found to have the greatest positive impact on patient outcomes, with the least downside risk, including cost, of the 79 practices studied.

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## **Retirement reception for Richard Hamburger, MD**

Richard J. Hamburger, MD, is retiring after more than 30 years of service to IUSM in the Division of Nephrology, Department of Medicine.

A reception in his honor will be from 3 p.m. to 6 p.m., Friday, Jan. 18, in the Presidents Room at University Place Conference Center. All are invited to stop by to wish him well.

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## **Seminars in Medical Ethics and Humanities**

Two January seminars are scheduled by the Medical Humanities Program at IUPUI in conjunction with the Indiana University Center for Bioethics.

Monday, Jan. 14, "The Face/Form Behind the Mask: Medical Cosmetology and Physiognomy in Thirteenth- and Early Fourteenth-century Europe" will be presented by Walton O. Schalick III, MD, PhD, from Washington University departments of pediatrics and history. The presentation will be from 4 p.m. to 5 p.m. in room 301 of the Ruth Lilly Medical Library. Refreshments will be served beginning at 3:30 p.m.

Dr. Schalick's presentation is co-sponsored by the John Shaw Billings History of Medicine Society.

"Mental Health Professionals and the HIV Epidemic Among Persons with Serious Mental Illness" is the topic of the Wednesday, Jan. 23, lecture. That seminar will be from noon to 1 p.m. in conference room B in the Ruth Lilly Learning Center in the Riley Outpatient Center and lunch will be served.

This seminar is open to the public but attendance is limited to 40 persons. Call Judi Campbell at 274-4740 or email a message to [jizukac@iupui.edu](mailto:jizukac@iupui.edu) to reserve a spot.

The presenter at this seminar will be Eric Wright, PhD, from the IUPUI Department of Sociology.

Over the past decade, public health experts have become alarmed about the spread of HIV/AIDS among people with serious mental disorders. Mental health professionals, however, have been slow to respond to this emerging epidemic. This presentation will share preliminary findings from the ongoing "Indiana Mental Health Services and HIV Risk Study," which explores the HIV/AIDS-related attitudes and clinical experiences of mental health professionals at two state psychiatric hospitals and three community mental health centers, and the factors that affect these attitudes.

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## **Joe Mamlin, MD: A word from Kenya -- December 2001**

**(Editor's Note:** The following was sent by Joseph Mamlin, MD, to members of the IU-Moi Program. It was his holiday greeting but it

carries a message that goes beyond the holiday observance. Dr. Mamlin, a emeritus professor of medicine and one of the founders of the program at Moi University in Kenya, is highly regarded by patients, colleagues, staff and friends and we believe people who know him and those who never had the pleasure of meeting him might enjoy his message. It is reprinted in *Scope* with his permission. Dr. Mamlin retired from IUSM faculty in 1999. He and his wife Sarah Ellen moved to Africa in 2000 to devote some of their retirement years to helping the disadvantaged in Kenya.)

I realize my messages from Kenya this year have been far too infrequent. I hope seeing many of you at the October Kenya Gala will provide a measure of forgiveness.

I will begin this "word" with a few personal comments and do the same as I close. I admit I am somewhat lonely during this holiday season. Not that I would be elsewhere, but this is my first Christmas without Sarah Ellen in over 45 years. Thankfully, she feels great and will complete her radiation therapy (for cancer) in time to return to Kenya by mid-January. She has found her own way to "be in Kenya" during these days.

Many of you will recall my relating Daniel's story. He is the fifth-year medical student with AIDS who has found both the mission and the courage to offer to Kenya so much in return for the marvelous help he has received from so many friends at Brown University and IU. Daniel suddenly lost visual acuity in his one remaining eye a few weeks ago. Miraculously, we were able to get a passport and visa in record time. With the loving arms of Brown University guiding his travel to Rhode Island and then on to Sarah Ellen, he is recovering from surgery performed at Wishard for a severe retinal detachment. I encourage anyone within reach of Daniel to visit him and share your concern for him. You may not be able to restore his vision to him, but I can assure you that you and he will feel healed for having spent time together.

I am pleased to report that the IU/Kenya Program is alive and well as we close this year. So many outstanding faculty, house staff and students have shared our home here in Eldoret. I have yet to see any visitors leave without a healthy change in the prism through which they view the world. This magic of exchange works in both directions - as experiencing the U.S similarly changes Kenyan faculty and student lives.

Endowed funds continue to rescue Kenyan students unable to buy food; they provide 50 coveted work-study jobs and merit awards for academic excellence and 12 full scholarships. This particular contribution from IU was singled out by the vice chancellor during his address at the Moi University's December graduation ceremonies --in the presence of President Moi no less! And new gifts keep on coming. Friends from our church, North United Methodist, along with others have added 12 more scholarships this year. To top it all off, Dr. Angeneita Biegel, a long-time supporter of this program, made the marvelous gift of providing excellent stethoscopes to every third-year student. She plans continue this for years to come. Boy! Do I have an easy life--standing up in front of the student body and taking credit for everyone else's gifts.

Of course, there is also the "other" project. There is not much left to say about the HIV pandemic that has not been said. Between 800 and 1,000 young Kenyans are dying every day. These are not simple numbers to me. I walk among them daily. I hold their hands; listen to their lungs and hearts; treat their opportunistic infections and look into those hopeless eyes. This is a physician's worst nightmare.

It would be one thing if there were no therapies. But, that is not the case. For less than \$1,000 per year, I could make any and all of them as well as we are. With access to generic medication the cost is less than half of that. Ninety-five per cent of the patients in Kenya cannot afford \$5 a month--- most can afford far less than that. What shall we do? We either find a way to creatively engage this struggle with our Kenyan brothers

and sisters, or we fold our tents and quietly slip away. One cannot enjoy the excitement of student exchange and scholarships unless one also engages in the challenges presented by the greatest pandemic in recorded history.

Let me mention briefly what IU and its consortium partners are trying to do:

We will assist in bring up an Academic Model of Prevention and Treatment of HIV/AIDS (AMPATH). For the last several months we felt we were on a fast tract toward one of the most daring interventions in sub-Saharan Africa. The Gates Foundation gave every indication of funding the first 5 years of our proposal. Then the bottom fell out when the Gates Foundation decided not to fund treatment. Thankfully, it does appear that they will contribute to the prevention aspects of our proposal. But that means we remain without drugs with which to treat.

With the original Gates proposal, AMPATH would have developed a robust treatment program and that would have allowed us to superimpose upon that foundation outstanding research. Now we must change tactics. We must develop a robust research program that will allow us to bring up treatment. I cannot tell you how sad this leaves me because so many lives will needlessly be lost as we take the years necessary to build substantial treatment interventions on the back of successful research. But, it is **ALL WE CAN DO** at the moment. So, we must set out to do it with boldness and daring.

If we are to be successful with research as the leading component, we will need to quickly create evidence that we are "in the business" of HIV research in Africa. The cornerstone of this effort will be the establishment of pilot HIV treatment settings with an infrastructure that makes this clinical care research-ready. A major step in that direction was (Dr.) Bill Tierney's (IUSM professor of medicine) success in guiding an NIH-funded project that culminated in a computerized medical record system in the nearby Mosoriot rural health center. My

task was to start up two HIV treatment clinics, an urban one at the Moi Teaching and Referral Hospital (MTRH) and a rural-based one at Mosoriot. Both clinics are now up and running. This is a pilot, and every effort must be made to leverage this investment into the infrastructure that will enhance our chances for successful grants. These grants remain our only real hope of eventually responding to sizeable numbers of patients.

Funding from IU and Brown will allow me to treat only 40 patients -- 25 at MTRH and 15 at Mosoriot. Our hospital serves a referral population of over 1.5 million persons with HIV -- but 40 patients is a beginning. When one looks into the eyes of a single patient, that is enough for that moment. We will massage this pilot until its infrastructure hums and the data from this effort enhances every possible proposal. Who knows where this might lead? It is so much better than doing nothing. Special thanks must go to (Dr.) Joe Wheat, (IUSM professor of medicine and director of the AIDS Clinical Trials Unit) a quiet scientist and friend, who continues to push us in the right direction.

Let me conclude with a personal word. There is something horribly wrong with what is happening in Africa. I can get free drugs to stop HIV transmission from a pregnant mother to her baby, but I cannot keep the mother alive -- much less go find and treat the father as well. I admit to weeping for a world that fails to respond. The consequences for Africa pale compared to those for a society that turns its eyes and resources inward. I openly call upon every person of goodwill to sense this outrage and seek creative responses. I see the "least of these, my brethren" everyday -- when my eyes are open and even when they are closed.

God, in this holiday season, give us the wisdom and the courage to find a way to be truly helpful.

Joe

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## Scientific Calendar online

A comprehensive listing on IUSM seminars, lectures and Grand Rounds can be accessed at <http://www.medlib.iupui.edu/calendar/>. To place items on the Scientific Calendar, please forward them to Iona Sewell at [imsewell@iupui.edu](mailto:imsewell@iupui.edu).

To keep the electronic version of Scope as streamlined as possible, only seminars and lectures of general or multi-disciplinary interest will be included.

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## Submissions to Scope

*Scope* wants your news items.

The deadline for submission is 8:30 a.m. on Fridays. *Scope* is published electronically and sent to faculty, staff, students, and residents.

There are four easy ways to submit story ideas or information to *Scope*:

- fax the information to 278-3502
- e-mail the information to [mhardin@iupui.edu](mailto:mhardin@iupui.edu)
- mail the information to Mary Hardin, LO 401, IUPUI
- paste your plain text message into Scope Web form on the IUSM faculty & staff page: <http://medicine.iu.edu/faculty/index.html>

Contributions submitted by e-mail should be forwarded in 12 point, plain text format.

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