

# IPJ

The Official Journal of FIP



**The rise of interdisciplinary approaches:**

How scientists are working together for international development

**How to get together:**

A collaborative help network

**The light at the end of the tunnel?**

A hopeful beginning for a malaria vaccine

## Integrated Science Collaborative Practice

When we work together, the whole result  
is far beyond the sum of its parts



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# Dear Reader

FIP has always embraced the notion that often the most robust advancements of pharmacy science and practice are a result of individuals from many interests and many corners of the world connecting and sharing knowledge on a common, open platform. In essence, this philosophy was the basis of the Federation and continues as a common thread throughout all FIP projects, and especially our annual Congress: integration and collaboration move us forward. And as such, the theme of our Issue.

Over recent years this dogma has slowly grown beyond the boundaries of each healthcare discipline to acknowledge the fact that when we apply the concept of internal collaboration to external stakeholders, the potential for positive change is vast. This realisation was key in the creation of the World Health Professions Alliance. With FIP as a founding partner, the Alliance was created in 1999 and brings together global organisations of pharmacy, medicine, nursing and dentistry. Its purpose is to deliver better care through the utilisation of each profession to their best, unique ability to deliver quality, cost-effective healthcare. This is a perfect example of capturing the potential of collaboration and, as you will read, will be demonstrated in the Second World Health Professions Conference on Regulation in February of 2010.

This issue is dedicated to highlighting specific examples of how the collaboration of healthcare workers is gaining unique and sometimes unexpected strides in making healthcare more efficient and effective for all involved, most notably, of course, the patients. As this issue shows, these examples are widespread across many countries and many areas of practice, from the treatment of paediatric oncology

patients in Canada to a pioneering student bringing a glimpse of pharmacy practice to an understaffed clinic in Africa. All offer the same message: working together heeds better results.

For FIP, however, the concept of collaboration is pushed one step further when we consider the pharmaceutical sciences. In this regard, we are constantly asking ourselves how to shorten the gap between science and practice; that is, how do we better integrate science into practice? After some discussions regarding this issue one area emerged as a fitting example of parallel advancement in both science and practice: vaccines. As the world seems to be facing an increasing amount of global and easily spreadable viruses, scientists are being pressured to create vaccines that will ease future fears of global pandemics, as seen in relation to the H1N1 scare. As can be read in this issue, complementary to these advancements, community pharmacists are taking on greater roles in the administration and education of vaccines to patients; a perfect example of integrating pharmaceutical sciences in increasing the role of the pharmacist in patient care.

And speaking of the Pharmaceutical Sciences, as you can see this issue is special in both content and form. We invite you to FLIP through and discover the Pharmaceutical Sciences 2020 report, which outlines FIP's role in steering the future of pharmaceutical sciences.

Welcome to the first issue of IPJ in 2009 – we hope that the whole is so much more than the sum of its parts.

**Myriah Lesko** Editor

**Lowell Anderson** Co-Editor

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# The rise of interdisciplinary approaches:

## How scientists are working together for international development

Guy Collender

International development encompasses efforts to address a wide range of severe problems in poor countries, including hunger, neglected diseases, illiteracy and corruption. It is an inherently interdisciplinary subject because it faces complex challenges which transcend disciplinary boundaries as they concern both the natural and social sciences. Tackling hunger, for example, not only involves practising better agricultural techniques to improve crop yields, but also an understanding of the economics of food, including pricing and market access. Improving access to medicines for the poor also requires a fusion of disciplines and systems, including medicine development, regulation, distribution and education. Yet for too long researchers have tended to work in their disciplinary silos, rather than uncovering synergies by collaborating with colleagues using different disciplines to investigate similar issues.

This development research environment has recently started changing thanks to the growing recognition of the benefits of an interdisciplinary approach. A flurry of new interdisciplinary institutions and networks for international development have been created in the UK in the past few years to encourage researchers to work together in more integrated and collaborative ways. These organisations have experienced promising beginnings and are continually gaining momentum. Such pioneering initiatives include the London International Development Centre (LIDC), the UK Collaborative on Development Sciences (UKCDS), the Edinburgh International Development Centre (EIDC) and the Glasgow Centre for International Development (GCID).

These novel approaches to improve the theory and practice of development are much needed today, particularly because poverty reduction may become more difficult. The world faces the biggest economic downturn since World War II and predicted global growth for 2009 is just 0.5 percent<sup>1</sup>. In addition, climate change poses an alarming risk equivalent to losing up to 20 per cent of global GDP if a wide range of impacts are considered<sup>2</sup>. Poorer countries will suffer most from both of these trends. World Bank figures from 2008 show 1.4 billion people live in extreme poverty – a significant upwards revision from earlier estimates<sup>3</sup>. There are also stark and growing inequalities in the distribution of resources and opportunities, and Ban Ki-moon, Secretary General of the UN, has warned that ‘we are not on track’ to reach the Millennium Development Goals (MDGs)<sup>4</sup>.

LIDC was conceived to address these problems by facilitating original interdisciplinary research and training. It was established in 2007 with a £3.7 million grant from the Higher Education Funding Council for England ►





(HEFCE). The collaborative project brings together social and natural scientists from across six University of London Colleges in Bloomsbury:

- Birkbeck
- Institute of Education (IoE)
- London School of Hygiene and Tropical Medicine (LSHTM)
- School of Oriental and African Studies (SOAS)
- Royal Veterinary College (RVC)
- The School of Pharmacy (SoP)

This partnership brings together outstanding expertise across sectors critical to development, including education, health, agriculture and business, and across a range of key disciplines, including biology, chemistry, clinical and veterinary medicine, statistics, information technology, economics, law, political science, sociology, anthropology and history. LIDC now has more than 700 members (438 staff and 267 postgraduate students from the Colleges), and has facilitated workshops and conferences on topics ranging from anthropology to zoonotic diseases (diseases transmitted between animals and humans).

LIDC's vision is a world made more equitable and secure, through a reduction in poverty and more sustainable use of resources. Its mission is to empower tomorrow's development professionals and programmes with more effective tools and better skills, knowledge and understanding to achieve this. LIDC's strategy includes:

- Innovative and integrative research on development issues that builds on an inter-sectoral and interdisciplinary approach
- New, high quality teaching programmes for tomorrow's development professionals
- Support to national and international policymakers through linking research, policy and practice
- Capacity building in low- and middle-income countries that addresses the needs of higher education, civil society and governments

LIDC is presently focusing on three interdisciplinary thematic programmes with its Colleges and partners:

- Emerging and Zoonotic Diseases
- Access to Medicines for the Poor
- Agri-health

Before LIDC was created there were no formal research collaborations in international development between any of the six Bloomsbury Colleges, and only one teaching link. Since then, LIDC has served as a catalyst, bringing together groups of researchers at workshops to explore interests across sectors and disciplines. Researchers are encouraged to continue their discussions and share resources through online workspaces on the shared Bloomsbury Learning Environment (BLE). To date 11 interdisciplinary workshops have been held (another 11 are planned) and there is a growing portfolio of activities and funded projects. For example, LIDC's thematic programme on Agri-health brings together researchers from LSHTM, RVC, SoP, SOAS, and IoE to explore ways of integrating research approaches and methodologies across the health and agriculture sectors. In addition, LIDC is developing a thematic programme on Access to Medicines for the Poor, by integrating skills across LSHTM, SoP, Birkbeck, SOAS and the George Institute for International Health. This will include a workshop exploring why patients don't adhere to drug regimens, from psychological, anthropological, economic, and health systems' perspectives. A third interdisciplinary theme is on Emerging and Zoonotic Diseases, where LIDC is bringing together medical and veterinary approaches to infectious diseases which affect both humans and animals.

As well as the above themes, a partnership between IoE's Development Education Research Centre (DERC) and LIDC has recently also secured funding for the Students as Global Citizens project. The £288,000 grant from the UK's Department for International Development (DFID) aims to assess and identify how students engage with

development in their daily lives and improve the development education they receive from their courses. Undergraduates at SoP, RVC and University College London (UCL) will be involved in the study.

*“LIDC is bringing together medical and veterinary approaches to infectious diseases which affect both humans and animals”*

LIDC's focus on students and training extends overseas too. It is concentrating its efforts, through its Distance Learning for Development (DL4D) initiative, on enhancing distance learning as a tool for development and for reaching students in the developing world. LIDC's constituent Colleges have a particular strength in this area as they run a total of 29 development-related distance degree programmes, mostly through the University of London's External System. A Project Officer working for LIDC is assessing how the Colleges can cooperate most effectively with regards to distance learning and is managing the creation of a web portal to assist international development professionals with finding distance learning courses already available at the Colleges.

LIDC's location in the heart of London adds to its strengths and makes it an ideal platform for dialogue about development issues for academic, policymaking and NGO communities. Its activities include interdisciplinary public conferences to highlight the synergies between the social and natural sciences, and resources from these discussions are posted on LIDC's website so they can be accessed by a global audience. Events focusing on the MDGs and Water Governance have both shown the potential synergies between different disciplines, the inadequacy of so-called technical fixes, and the importance of understanding power and politics when promoting international development.

Professor Jeff Waage, Director of LIDC, said: “Universities have an important and specific role in improving the international development effort. They provide a platform for the study and understanding of international development problems, including the factors underlying success and failure, and for research into solutions to these problems, from drugs for neglected diseases to strategies for economic growth. The Bloomsbury Colleges have strong individual reputations in international development, and LIDC brings their strengths together, building new research and training collaborations between Colleges and with partner institutions in support of international development. What makes LIDC distinctive amongst international development centres is the breadth and depth of its scholarship relevant to international development, and

its capacity to integrate research and education across the natural, biomedical and social sciences.”

More than 400 miles from London at the Glasgow Centre for International Development (GCID), part of the University of Glasgow, a similar emphasis has been placed on combining disciplines to address development. GCID was also established in 2007 and it promotes development and cross-faculty interdisciplinary research at the university and overseas. Its research focuses on:

- Human and Animal Health
- Environmental Management and Infrastructure
- Education, Lifelong Learning and Global Citizenship
- Economic Development

GCID's achievements include developing major interdisciplinary and multi-institutional research proposals totalling more than £9 million, and establishing partnerships with Makerere University (Uganda), University of Dodoma (Tanzania), and University of Veterinary and Animal Sciences (Pakistan). Professor Peter Holmes, Senior Adviser to GCID and former Vice-Principal for Research at the University of Glasgow, added: “GCID is committed to the view that interdisciplinary research has a much greater potential to provide answers to some of the pressing contemporary concerns in international development and poverty alleviation in low-income countries than through more traditional ways of working within disciplinary silos. There is a growing awareness that many significant and innovative developments depend on an interdisciplinary approach. Within international development it is very clear that scientific answers frequently fail to have the desired impact if socio-economic and cultural factors are not taken fully into account.”

*“Universities have an important and specific role in improving the international development effort”*

The Scottish capital is also home to a discipline-bridging initiative called the Edinburgh International Development Centre (EIDC). Established in 2008 with money from the University of Edinburgh's Internationalisation Fund, EIDC aims to build effective partnerships nationally and internationally, foster education in support of development, and promote multidisciplinary or translational research. EIDC's achievements include facilitating the development of new courses which begin this autumn: a blended learning course (part distance and part taught) in non-communicable diseases and a taught MSc on Africa and International Development. In addition, it has created a steering group, chaired by the university's Vice-Principal, with representatives from across the university (including its three Colleges).

Professor Paul van Gardingen, Executive Director of EIDC, said: “Singular disciplinary studies have spectacularly ►





failed. When we focus on one issue we see part of the problem, not the solution. Solutions require a combination of hard science and soft science. There is more and more interest from researchers in interdisciplinary research but the institutions which are supporting them – universities, research councils and funders – are probably lagging behind. It is about taking institutions and individuals out of their comfort zone.” Professor van Gardingen also had a specific message for pharmacists. He said: “We really need the people working on drug discovery to work with the private sector for a viable financial solution, distribution systems etc.”

*“It is about taking institutions and individuals out of their comfort zone”*

However, interdisciplinary developments have not only been confined to the university sector. Development theory, policy and practice is constructed by many stakeholders outside academia, including government, research councils, NGOs and the private sector. Organisations representing some of these interests have responded to the challenges facing development by adopting interdisciplinary approaches. For example, the UK Collaborative on Development Sciences (UKCDS) brings together key UK funders and stakeholders providing support for the development sciences research base. It was established in 2006 following recommendations of the Development Sciences Working Group led by Sir David King, then the UK Government's Chief Scientific Adviser. UKCDS is forging an overview of the UK development sciences research base to create an understanding of its international standing, capacity, skill base, resources and

impact. Its work also includes creating a common vision for the future of development science research, adding value to existing programmes through coordination, and identifying the challenges and opportunities in current and future research funding. UKCDS' interests include climate change and it has recently facilitated a nine-month pilot project in Bangladesh with stakeholders to formulate future research questions.

Professor Sir Gordon Conway, Chairman of the UKCDS Steering Board, said: “The future wellbeing of mankind requires effective cooperation between three very big players: government, private foundations and research councils. Science must have a voice in policymaking both here in the UK and in developing countries and UKCDS aims to provide a coordinated response to current and future policy needs.”

Likewise, Science for Humanity, which was established last year, aims to bring together different sectors and disciplines to address development issues. It is a not-for-profit network of individuals and organisations seeking to use their knowledge and experience to help create solutions to some of the world's most urgent social problems. It links ‘seekers’ looking for innovative solutions to common problems in the developing world with ‘solvers’ ready to provide scientific solutions. As part of the initiative funded by the National Endowment for Science, Technology and the Arts (NESTA) and The Sloane Robinson Foundation, scientists are currently collaborating on projects to produce a low-cost shelter for use in emergency relief, provide an innovative low-cost communications infrastructure solution for rural areas, and improve soil fertility for coffee production on the deforestation-affected eastern slopes of the Andes.



The idea for Science for Humanity was conceived by Baroness Susan Greenfield while researching her book *Tomorrow's People: How 21st Century Technology is Changing the Way We Think and Feel*. It is based on the conviction that while our society is making incredible progress in the fields of science and technology, much more of this knowledge could be translated into genuine innovation that could make a difference to the lives and livelihoods of billions of people all over the world. Science for Humanity currently has at least 350 members, and it has embraced social networking and the internet to publicise its work globally via its website, Facebook, LinkedIn and Twitter.

Assessing the validity of the broadly positive outlook from the interdisciplinary initiatives also requires gathering perspectives from development professionals observing this recent trend. The role of interdisciplinary research and the growing acceptance of its importance have been noted by David Dickson, Director of SciDev.Net (Science and Development Network) – a not-for-profit organisation dedicated to providing reliable and authoritative information about science and technology for the developing world. He said: “Addressing a problem in a practical way involves not only providing a technical solution to the problem, but also developing the procedures and infrastructure needed to put that solution into effect. This requires a range of skills and knowledge which no single discipline can provide. For example, the basic explanation of global warming requires a relatively limited range of scientific disciplines, primarily climate specialists and mathematical model builders. But devising strategies either to mitigate the effects of climate change, or to allow communities to adapt to its inputs, requires input from a wide range of disciplines. My impression is that the mood in the UK is definitely shifting towards encouraging interdisciplinary research.”

However, the obstacles to interdisciplinary research must not be downplayed. At present, incentives and the prospects for career progression, particularly in academia, favour specialising in a single discipline. Dickson added: “Funding and reward structures are built around knowledge development rather than problem solving, and knowledge development remains predominantly single-disciplinary, although that is changing.” Professor van Gardingen has also echoed these thoughts. He said: “The reward system is not adequate to promote and fund interdisciplinary and multidisciplinary ways.”

The cumulative impact of recent interdisciplinary initiatives is generating unprecedented interest for cross-cutting research, yet funding constraints and challenges persist. Existing enthusiasm and collaboration now need to be harnessed to create well-rounded solutions to achieve the potential of interdisciplinary work to address problems in the developing world. ■

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## Resources

- *London International Development Centre*  
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- *Glasgow Centre for International Development*  
[www.gla.ac.uk/gcid](http://www.gla.ac.uk/gcid)
- *Edinburgh International Development Centre*  
[www.eidc.ed.ac.uk/index.html](http://www.eidc.ed.ac.uk/index.html)
- *UK Collaborative on Development Sciences*  
[www.ukcds.org.uk](http://www.ukcds.org.uk)
- *Science for Humanity*  
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- *SciDev.Net*  
[www.scidev.net](http://www.scidev.net)

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# Collaborative care of pediatric oncology patients

## Focus on the Pharmacy Team clinical trials

Tejinder Bains

**When I tell friends and family that I am a hospital pharmacist, the most common response I get is, “I did not know that pharmacists work in hospitals.” Patients in hospitals often do not interact with the pharmacist, who is often perceived as the professional “behind the scenes.” Pharmacy has progressed far beyond the “counting and pouring” of its origins. Today, pharmacists’ specialized knowledge of drugs is being used to help patients and the health care system as a whole achieve more efficient and safe drug therapy. The Children’s Hospital of Eastern Ontario’s (CHEO) oncology pharmacy team has an inpatient, outpatient and pre-printed order pharmacist as well as two pharmacy technicians. They are involved in collaborative practice with the oncology team and the patients/parents to provide pre-admission, admission, inpatient and outpatient care. This collaborative practice will be highlighted through the description of the three pharmacists’ roles, case scenarios and team letters.**

### Practice Site

CHEO is a tertiary care pediatric facility with a catchment population of 1.5 million residents. The oncology team is a multidisciplinary team comprised of pediatric hematologists/oncologists, oncology fellows and residents, disease specific case managers, clinical research associates, nurses, pharmacists, pharmacy technicians, social workers, nutritionists and psychologists. The oncology service sees 60-80 new patient diagnoses per year.

The oncology ward is an 18-bed unit that has 70-100 admissions per month while the outpatient clinic has approximately 3,500 patient visits per year. Clinic patient visits include oncology, bone marrow transplant, neuro-oncology and aftercare clinics. The oncology pharmacy satellite is located within the oncology clinic.

The model of collaborative practice within the oncology team is one that optimizes the scope of practice of pharmacists and provides fully integrated patient care. The oncology team is aware and trusting of the knowledge and skills of the pharmacists and collaborate with them daily to improve patient care. For patient safety, this collaborative practice has a built in validation process for chemotherapy ordering.

### Pre-printed Order pharmacist

To minimize communication system errors in the process of medication administration, the Institute for Safe Medication Practices (ISMP) recommends standardizing communication by the use of pre-printed orders (cite). The inherent risk of using pre-printed orders is the potential for propagation of error due to their widespread distribution. Therefore, ISMP emphasizes the importance of an institutional process to create, review and use pre-printed order forms.

Before patients receive chemotherapy, the pharmacist reviews all new and revised Children's Oncology Group (COG) chemotherapy protocols and digests them into complex pre-printed orders, while adhering to a standardized template. The multidisciplinary order includes: blood work, criteria for administration, monitoring parameters for nursing, hydration,

dosing and administration rates, and detailed supportive care. Presently, CHEO has a thorough process where two pharmacists, two physicians and one nurse independently review each pre-printed order. As there are currently over 1,000 chemotherapy pre-printed orders, this is no small task. Upon final approval by the principal investigator, the order sets are used by the oncology service to order, dispense and administer protocol specific chemotherapy. The development of standardized pre-printed chemotherapy orders not only minimizes errors for high alert cytotoxic medications but also maximizes efficiency in the chemotherapy ordering process.

### Admission

The Canadian Patient Safety Institute (CPSI), the Joint Commission Resources (JCR) and ISMP have recommended the adoption of medication reconciliation programs in

order to optimize patient safety and to facilitate continuity of care. Pharmacists have the optimal knowledge and skills required to perform patient medication histories.

The outpatient pharmacist meets with the patient/parent as part of the admission process prior to their visit with the oncologist. On admission from the clinic, the pharmacist reviews and documents the patient's current regimen of prescription medications, over-the-counter drugs and alternative therapies. This allows the pharmacist to assess therapy for drug-related problems or compliance issues. The pharmacist then writes the most current medications on the admission order sheet. These orders are then reviewed by the oncologist following patient assessment and signed for admission to the oncology ward. ▶

*Oncology Pharmacist Geneviève Goulet and Oncology Technician Marc Bellefeuille in outpatient team rounds*





Upon unscheduled admission from the emergency department, the inpatient pharmacist reconciles the patient's medications with the patient or parent within 24 to 72 hours of admission. Discrepancies between the medication history and medications ordered are corrected by the oncology pharmacist upon discussion with the oncologist.

Upon transfer of an oncology patient to another hospital (i.e., bone marrow transplant or surgery), the pharmacist prepares a transfer note summarizing the patient's medications, drug-related problems as well as their current medication calendar for the pharmacist who will be caring for them at the new center.

### **Inpatient pharmacist**

The inpatient pharmacist is responsible for the pharmaceutical care of oncology patients admitted to CHEO. She actively participates in the daily multidisciplinary rounds. Drug related questions, both from health care professionals and patients/parents are directed to the pharmacist. Most chemotherapy orders are written by the pharmacist and then reviewed for signature by the oncologist. Throughout every phase of therapy, the patients and their family receive chemotherapy and supportive care medication information and education from the pharmacist. During the course of this dialogue, other issues, such as dietary needs, financial concerns or treatment planning, may arise. To provide collaborative care, the pharmacist involves the dietician, social worker or the case manager to help manage these issues.

The pharmacist reviews the patient's medications upon discharge, prepares their discharge prescriptions, and provides a medication calendar.

She will fax prescriptions as well as liaise with the patient's retail pharmacy, ensuring availability of unusual medications and promoting seamless care. The medication calendar consists of a summary of the patient's home medications and includes information such as dosage, indication, administration time, detailed administration instructions and precautions.

Medication reconciliation upon admission, discharge or transfer to another health facility has not only reduced order omissions and clarifications requiring retrospective intervention by the oncology pharmacist, but also improved the continuity of care for the patient.

### **Outpatient clinic pharmacist**

The responsibility for the pharmaceutical care of patients seen in the oncology clinic belongs to the outpatient pharmacist. The pharmacist maintains the traditional roles of reviewing all chemotherapy orders for accuracy, appropriateness of the medication, correct dosage and frequency, interactions and compatibilities, supervising the chemotherapy manufacturing by the technician, final verification and dispensing of chemotherapy for both outpatients and inpatients. This "dispensing role" has expanded over the years to include writing chemotherapy orders and the corresponding outpatient prescriptions for patients.

In order to complete this function, the pharmacist accesses protocols for any potential modifications, reviews previous laboratory results, reviews problems with previous courses of therapy and keeps track of changes in treatment plans. Having these chemotherapy orders prior to the patient visit helps the nurses plan blood work,

diagnostic tests and prioritize patient care for each day. The oncologist confirms that the patient is eligible for chemotherapy and validates medication dosing using the current height and weight. With this expanded pharmacist role, the oncologist can focus on the patient rather than their medications.

The outpatient pharmacist answers requests for drug information from health care providers and patients/parents. She reviews new medications with the patients/families as well as prepares medication calendars for the clinic patients.

### **Teaching**

In addition to their clinical responsibilities, the pharmacists are involved in teaching for medical students, residents, fellows and nurses on chemotherapy and supportive care related topics. They are preceptors for pharmacy undergraduate students, doctorate in pharmacy candidates (PharmD) and pharmacy residents. Involvement in teaching activities such as journal clubs or education days with the multidisciplinary team further enhances the understanding of the pharmacists' role.

One of the oncology pharmacists at CHEO has the unique responsibility of being a member of the hospital's research ethics board. She is responsible for reviewing all new and current oncology research protocols. This collaboration with the research ethics team and clinical research associates improves the pharmacists' knowledge of oncology protocols, which directly enhances their ability to provide patient care.

### **Challenges**

It is challenging working so closely with our young pediatric oncol-



ogy patients. In providing optimal patient care, there is increased patient/family interaction with the pharmacist. This however also leaves the pharmacists faced with personal attachment issues. Although success rates for childhood cancers continue to improve, there is the added stress of devastating diagnoses and the deaths of young children.

Documentation of activities that are performed with patients/parents is necessary so that it can be shared with other health care professionals. This continues to be a challenge for the oncology pharmacist team due to time constraints.

### **Successes/Outcomes**

The oncology pharmacy team has achieved many hospital-specific successes. To expand their collaborative practice, the oncology pharmacists have developed and instituted a medical directive to write continuous care prescriptions for oncology patients. The oncology pharmacists can now write outpatient prescriptions for a list of continuous care medications for oncology patients under this directive.

### **Rewards**

Working within the oncology team is very rewarding for the pharmacists. They feel truly more like a member of the oncology team than the pharmacy team. The pharmacists interact daily with members of the oncology team in order to provide optimal care for the pediatric oncology patient. The most rewarding collaboration is with the patient and their family who know the pharmacists by name. It is an honour and privilege to have a relationship with a child and their family during their journey with any chronic illness but especially cancer.

The oncology pharmacy service is an advanced practice setting where the three pharmacists are fully integrated into a collaborative health care team. Patients managed by the oncology service at CHEO are involved with a pharmacist from diagnosis to end of therapy. Quoting the pediatric oncologists at CHEO, "there is no better example of collaborative pharmacy practice than what exists in the oncology practice at CHEO." ►

### **Case Scenario #1**

A 14-year old girl with medulloblastoma is beginning her chemotherapy protocol. Much of her therapy is taken by mouth at home. The pharmacist provides information and teaching on the chemotherapy and supportive care medications. She then provides a medication calendar, working with the family to determine the day of the week when the medications will be started. One of her medications is Procarbazine, with many potential food interactions. The dietician is contacted to review the dietary restrictions of Procarbazine and general nutritional issues with the patient and her family. The pharmacist works with the social worker and the community outreach nurse to ensure financial coverage of the costly chemotherapy. The pharmacist liaises with the community pharmacist to ensure availability of these uncommon medications.

### **Case Scenario #2**

A young patient has experienced a relapse of acute promyelocytic leukemia (APL). His treatment plan involves the use of Arsenic trioxide and oral Tretinoin. Arsenic trioxide is not on the market in Canada and Health Canada approval must be obtained under the special access program in order to bring the drug to our hospital. The oncologist provides literature and a treatment plan and then meets with the parents to review the plan. The pharmacist completes the special access request form, providing clinical information and literature to support the request. This is reviewed and signed by the oncologist. The pharmacist contacts the pharmacy buyer and computer super-user to deal with the purchasing and computer issues. The pharmacist liaises and provides information for the nurse educators who will be supporting the nursing staff as they administer a new agent. She prepares a parenteral drug monograph that can be used by medical, nursing and pharmacy staff. With the help of the pharmacy buyer, she keeps the team informed of the estimated day of arrival of the drug so that they can plan for the start of treatment. Meanwhile, the nurse case manager coordinates the necessary tests and scans required before treatment can begin and is in regular contact with the family in order to keep them updated. The case manager also is a liaison between inpatient and clinic nursing staff. The social worker and community outreach nurses are providing support for the family as they deal with the news of the relapse.



*The author, Tejinder Bains (Pediatric Oncology Pharmacist/Oncology Pharmacy Team Leader) with a young patient*

#### **Excerpts from a letter written by CHEO's oncology social workers (2006)**

In our experience as Social Workers, many patients and family members are increasingly entertaining alternative therapies, in conjunction with their chemotherapy treatment protocol. Often, there can be a tendency for patients and their families to be reluctant to disclose this information, for fear of reprimand from the medical team. Patients and family members are often very pleased to hear that members of the Oncology Pharmacy Team will sit down and offer their expertise and advisement. Our experience as Social Workers is that the pharmacists are able to discuss these sensitive treatment issues in a non-judgmental way, and at the same time, impart critical recommendations.

As Social Workers, we are very thankful for the resourcefulness of the Oncology Pharmacist Team when addressing drug coverage through health plans and especially when advocating for coverage that is not approved by health plans. The cost of drugs is a major area of distress for parents/guardians of patients. Since it is not unusual for one parent leave his/her employment in order to be at the patient's bedside, families of pediatric oncology patients experience severe compromise to their income. Our Pharmacy Team's effort to advocate for cost coverage instills confidence in parents/guardians.

### Excerpts from a letter written by the mother of a leukemia patient (2006)

From the outset, the oncology pharmacists have provided my husband and I with timely, coherent and comprehensive information about the many medications with which our daughter has been treated. They explain the purpose and effects of these medications, including potential side effects, and give us clear instructions on how and when to administer them. The drug calendars we take home with us are a bonus; stressed parents often find it hard to hear and remember details, and we rely on those calendars to keep us on track. They answer questions patiently, and are always creative in suggesting alternatives if our daughter has difficulty taking any of the medications – transferring them to smaller gel-caps, mixing them with applesauce, and replacing liquids with capsules, to name just a few suggestions that we have tried with success.

We often spend long days at the hospital and it has been very helpful to have the pharmacists call or fax prescriptions to our local pharmacy so they are ready for pick-up when we get home. Our community pharmacist has commented on how helpful the oncology pharmacists have been when he has questions about our daughter's medications.

The oncology pharmacists are an integral part our daughter's health care team, helping us through the difficult process of cancer treatment with sensitivity, kindness and competence.

### Excerpts from a letter written by the CHEO oncologists (2006)

From initial diagnosis, when we meet with the child and parent, the pharmacists assist in the education of their medical treatment and make certain that the information is understood. We rely heavily on the oncology pharmacists' knowledge to aid in our clinical decision-making throughout the child's entire treatment.

The pharmacists are the team member everyone turns to when there is the slightest change, discrepancy or hiccup in the child's treatment medication protocol. They absolutely provide the backbone to each child's pharmacology treatment.

We can readily say that without our oncology pharmacy team, patient care would come to a standstill and serious errors would result. We are totally indebted to the oncology pharmacists for making our workplace run so efficiently and safely. There is not better example of physician/pharmacist collaboration than what exists in the oncology practice at CHEO. ■

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# The 2nd World Health Professions Conference on Regulation

18-19 February, 2010

A report from FIP Headquarters

**The World Health Professions Alliance (WHPA) came into being in 1999, when the global organisations representing the world's pharmacists, nurses and physicians joined forces to create a unique alliance to address global health issues. In 2005, they were joined by the World Dental Federation, further adding to the diversity and strength of a group whose Members have had a clear and relevant focus: to deliver health care to individuals, families and communities regardless of their colour, creed, gender, religion or political affiliation.**

Through its component partners, the World Health Professions Alliance represents a collective of more than 23 million health care professionals worldwide. Its overall mission is to facilitate collaboration between key health professionals and major international stakeholders such as governments, policy makers and the World Health Organization. In light of constant changes and shifting demands of global healthcare, it has become imperative that healthcare providers understand their own and each other's role in the health environment, and work together to provide comprehensive, inter-disciplinary care to those in need.

Through ongoing interaction and collaboration between the Alliance's pharmacists, doctors, nurses and dentists the WHPA is devoted to identifying collective challenges facing each sector of healthcare and examining how a multidisciplinary approach can be applied to achieve solutions. As such, in May of 2008 the WHPA hosted the first World Health Professions Conference on Regulation in Geneva, Switzerland focused on the theme The Role and Future of Health Professions Regulation.

This first of its kind event was met with great success in the eyes of both WHPA organisers (who also included for this event the World Confederation of Physical Therapists) and participants, illustrated by an attendance of more than 500 participants that far exceeded expectations. In addition, the meeting was also presented live via

the Internet to health professionals in 12 other countries, allowing for interaction with those who were unable to attend the meeting in person. Experts in the field of Healthcare Regulation presented on such topics as legislative and policy frameworks, regulatory governance and performance and Current and future scenarios in licensure, registration, revalidation, credentialing and accreditation. The conference was highlighted by a keynote address on "Addressing health needs – the role of professionals." All involved left the conference motivated to move forward in a collaborative approach to healthcare regulation reform. (For a full review of the First WHPCR please visit the website at <http://www.whpa.org/reg/index.htm>)

After the success of the first it was only fitting that plans were soon in place to hold the second World Health Professions Conference on Regulation which is set to convene once again in Geneva, Switzerland on 18 and 19 February 2010. This time the theme will focus on Shaping the future of health professionals' regulation and has great potential to surpass the first in attendance, making this a premiere event for learning, knowledge exchange and multidisciplinary professional growth on an international platform. Recognising that public protection is the primary objective of health professional regulation, the aim of the second WHPCR will be to shape the future of health professional regulation within the context of global health systems' redesign and evolving roles.



This Conference is therefore of interest to all individuals who work within the realm of healthcare regulation, such as:

- CEOs, registrars, board members and policy advisors of health professional regulatory bodies;
- Senior government officials and legal advisors with responsibility for health professions' regulatory legislation;
- CEOs, presidents and policy advisors of professional organisations;
- Academic leaders in healthcare;
- Future leaders in healthcare;
- Leaders from within patients' groups.

The Conference programme will provide a unique opportunity to hear as well as contribute to discussions on current issues being faced by health professionals around the world. Speakers have been selected based on their expertise within selected topics as well as their reputation for engaging audiences.

The programme will focus on three main objectives:

1. Explore a desired future for health professional regulation;
2. Examine the regulatory and professional issues related to the international migration of health professionals;
3. Critically evaluate the relationship between health professional education, regulation and standards of practice.

Regulation is a consequence of the social contract established between professions and society representatives (i.e. government). While the scope and practice of many healthcare professions change and will change throughout the world, so is and will be the regulation model.

Regulation encompasses many aspects of the healthcare professionals' life, from their education to their activities and their entry in the profession. Each of the chosen themes will explore these aspects of regulation and how each profession may best contribute to the constructive evolution of health professions regulation worldwide.

The first theme will explore current trends in regulation in relation to past successes and challenges, potential future models of global policy and drivers for change. Such drivers also include shifts in the social contract and the accountability of each profession and the way they are integrated and translated into regulation. Fraud management and disciplinary action will also be discussed as consequences of increased expectations of safety in the dimension of evolving social responsibility.

The migration of healthcare workers is a current and relevant issue for all health professions. The second theme of the conference will highlight the impact of

migration within a regulatory context, examining how current migratory mobility has the potential to impact local health and both regional and foreign regulations. Moreover, a focus will be made on the recognition of qualifications and the possibility to harmonize regional and/or national standards for qualification.

The third topic will deal with the interaction between healthcare professions and the activities of their respective regulators. Within this general theme the conference will focus on the fact that although regulation is generally based on each respective profession, interdisciplinary healthcare practice is increasingly encouraged and promoted by the government, as such practice is the meeting point of the scope and core competencies of each profession. Questions will be raised as to the role of regulators within such a context and how to ensure efficient, effective and safe quality care.

The format of the conference has been designed to allow representation from within each profession. Through plenary sessions participants will learn of regulatory processes from all disciplines of healthcare, with the goal of offering general philosophies that can be applied to profession-specific situations.

Workshops will also be organised to enable interactivity and debate surrounding the main theme. These workshops will welcome colleagues from within their own disciplines to meet and discuss what has previously taken place, with the aim of recognising applicable information that can be used to build future regulation policy.

In addition, all Conference delegates will be invited to participate in the first ever, global survey designed to capture information about the regulation of health professionals. Data obtained from this survey will be presented early in the Conference as well as be available for discussion during the professional group sessions.

As with the first WHPCR, this second conference will be attended by delegates from around the world; individuals who have a vested interest in the future of health professions regulation and who hold an active and influential role in spearheading effective change. Both the conference and social programmes will provide wonderful opportunities for networking, establishing contacts and the sharing of ideas. In essence, the second World Health Professions Conference on regulation offers an invaluable venue for interdisciplinary development of health professions regulation worldwide – don't miss it! ■

# Collaborative Development of a Health System-Focused Cardiology Elective

## Bringing a Practice Site into the Classroom

Marcia L. Brackbill, Stephen D. Phipps

**The majority of cardiovascular therapeutics content in the Shenandoah University Bernard J. Dunn School of Pharmacy's curriculum is incorporated into a four-credit cardiovascular module, with the primary emphases being pharmacology, pathophysiology and therapeutics. Due to the large number of cardiovascular-related disease states and medications, students are minimally exposed to non-medication related aspects of cardiology. Furthermore, there are few opportunities to learn about interdisciplinary cardiovascular services for cardiovascular patients. Although infrequent, interdisciplinary courses and clinical practice experiences are successful and well accepted by students.<sup>1-3</sup>**

The current course was created to provide a forum for students to expand on content from the cardiovascular module, to explore non-medication related aspects of cardiology, and to expose students to various elements of a heart and vascular center. The course faculty envisioned a course where students would interact with and learn from specialists from various cardiovascular disciplines. This course would complement previous curricular content and help prepare students for their P-4 (experiential) year.

This paper describes the implementation and evaluation of a cardiology elective developed to provide students a broader perspective of the services and resources of a heart and vascular center. Novel aspects of the course include health-system related assignments, on-site visits, and interdisciplinary teaching by various cardiovascular-focused professionals. The course objectives were to: (1) encourage student interaction with non-pharmacist health care professionals and to learn about their roles, (2) integrate and apply knowledge of cardiovascular medications within the context of various cardiology topics and specialties, (3) increase self-confidence and proficiency when evaluating primary literature in making therapeutic decisions, and, (4) enhance oral and written communication skills.

### Heart and vascular center

One of the faculty members coordinating this course maintains a clinical pharmacy practice at a Heart and Vascular Center (HVC), which is part of a 411-bed not-for-profit regional referral hospital. The HVC includes 18 cardiologists, four cardiovascular and thoracic surgeons, four interventional radiologists, and offers comprehensive cardiovascular patient care services including diagnostic testing, non-invasive and invasive procedures, cardiothoracic and vascular surgery, cardiac rehabilitation, and numerous screening and educational programs.

### Course methods

This course was initially offered during the 2008 fall semester to third-year (P-3) pharmacy students who had successfully completed the cardiovascular module during their P-2 year. Enrollment was limited to 15 students in order to encourage group discussion and allow the possibility of two on-site learning experiences at the HVC.

During the semester, the course met once weekly for 1.5 hours and included 11 lectures, two on-site learning experiences, one electrocardiogram (ECG) laboratory, and student presentations. Table 1 describes the lecture topics and the descriptions of the professional specialty of the guest lecturers. Lecturers were encouraged to use interactive discussion formats along with the incorporation of patient cases.

Table 1. Cardiology Elective Lecture Descriptions

Lecture topic	Lecturer
Structure and Outcomes Related to a Heart and Vascular Center	Nurse Administrator
Community Cardiopulmonary Resuscitation	Nurse
Dietary Considerations for Cardiovascular Patients	Registered Dietitian
Surgical Interventions for Cardiovascular Disease	Surgeon
Cardiac Rehabilitation	Physical Therapist
Heart Failure Management	Nurse
Cardiovascular Case Management	Nurse
Cardiac Imaging	Nurse
Antiarrhythmic Agents; Electrocardiogram Basics	Pharmacist

### On-Site Learning Experiences & ECG Laboratory Session

Students were required to travel to the HVC for two on-site learning experiences. The first visit was to the cardiac rehabilitation unit and involved a tour and attendance at a cardiac rehabilitation presentation. During this visit, students interacted with patients, nurses, a physical therapist and a respiratory therapist. The second on-site experience was a visit to the HVC's Heart Disease Screening Program, a regularly offered community program. On this visit, the program coordinator provided students an overview of the program and students then participated as community member attendees. Each student was evaluated for blood pressure, blood glucose, and cholesterol. In addition to receiving individualized counseling regarding their cardiovascular screening, students received literature related to prevention of heart disease.

An ECG laboratory session was conducted in the School of Pharmacy's exercise facility in order to provide students an opportunity to practice patient assessment skills (obtaining pulse; blood pressure) and to observe how ECG testing is performed. Students were invited to participate in an exercise activity ►

to observe how exercise affects heart rate and blood pressure. Additionally, the instructors answered student questions while discussing the principles of conducting an ECG evaluation. After several ECGs were performed, students were given copies of ECGs as the basis of a homework assignment wherein they were required to evaluate the ECGs for QT intervals and QTc values.

### Self-Review of Cardiovascular Medications

Students were responsible for cardiovascular drug information learned during their P-2 year. Questions about cardiovascular drug classes were present on every quiz, and included brand and generic names, mechanism of action, indications, contraindications, monitoring parameters, and adverse effects. The purpose of assessing students on prior content was twofold. First, it prompted students to review drug information they had learned previously. Second, assessments on cardiovascular agents would enable students to increase their competency level in discussing these medications with other health-care professionals. One class period early in the semester was dedicated to reviewing cardiovascular medications; this review was conducted in a game format. All cardiovascular drug classes were represented in the review. The results of the “competition” were not incorporated into students’ course grades.

### Pharmacy and Therapeutics (P&T) Committee Presentation and Drug Monographs

The class was divided into two groups and each group was assigned one new cardiovascular medication to research in order to create a drug monograph and to provide a presentation detailing the medication in a P&T committee format. At the conclusion of the presentation, group members could be called upon to answer questions related to their drug. Students were also instructed to create a drug

monograph in a format consistent with those that are developed at the hospital.

Each student group presented their drug for P&T committee consideration using their monograph as complementary information. After the presentation, group members were queried about the appropriateness of the drug for formulary inclusion. Prior to the presentation, students were encouraged to do a comparative analysis with currently available agents and to summarize their findings by making a recommendation either for or against formulary inclusion. Grading criteria for the project components included spelling, grammar, readability, continuity between sections, content (appropriateness, accuracy, completeness, and clarity), responses to questions, referencing, conclusions, and recommendations.

### Grade Determination

Final grade determination was as follows: five quizzes (50 percent), three homework assignments (30 percent), and the drug monograph and presentation (20 percent). Quiz material was derived from cardiovascular drug information and from speaker content.

### Course assessment and discussion

A 15-item course evaluation, addressing all components of the course, was completed by students at the end of the semester. Evaluation questions were formatted on a 5-point Likert scale (5= “strongly agree”, 4= “agree”, 3= “neutral”, 2= “disagree”, and 1= “strongly disagree”). The mean score for all 15 items was 4.5, indicating a very favorable assessment of all aspects of the course. Of note, all students who participated in the course either “agreed” or “strongly agreed” that the elective met course objectives, that the course was fun and practical and that they would take the course again. The two highest areas of agreement were that the class provided

valuable interdisciplinary perspectives of health care, and that course content helped students to review and apply previous cardiovascular content. Additionally, the cardiovascular “review competition” was well received by the students, indicating that the review was fun and valuable.

The monograph and presentation assignment was well received by the students and perceived as a very “high value” assignment. Two oft-cited student comments were that they were able to learn about new medications that they “will be expected to know” when they enter their advanced practice experiences and that the development of a drug monograph was a worthwhile assignment because this is “something we will be doing next year”.

Student recommendations for improving the course included increasing it to three credits, suggesting to keep the same overall structure, but to offer more topics and speakers. All invited speakers were enthusiastic about the opportunity to speak and volunteered to participate in future course offerings. Several speakers offered ideas for new topics (e.g., hemodynamic monitoring, acute cardiac life support, aggressive goals with cholesterol management) or provided suggestions to expand their topic area (e.g., expanding “Community Cardiopulmonary Resuscitation” into an official training and certification session).

Overall, students indicated that the course increased their knowledge in the field of cardiology, and that it motivated them to pursue further training in this area. Specific comments included, “I found the course very helpful” and “This was the best class I have had in pharmacy school; thanks for doing it! It was fun and I learned a lot!”

### Faculty Reflections

Pharmacy practice faculty who work in large health systems are in an ideal





position to develop elective courses specific to their area of expertise and clinical practice. Significant time is invested in cultivating relationships in their respective practice sites which can readily afford identification of specialists in many topic areas. When potential speakers were initially approached in the developmental stages of this course, they were favorably receptive to the opportunity. In many cases, the speaker had already given similar lectures on the requested topic and their preparation time was minimal. As an added benefit, the speakers could include the teaching experience in their personal educational portfolios that they maintain for their respective clinical ladder at the hospital and the HVC.

The pharmacy faculty member is typically well-versed in the logistics of the practice site and is easily able to coordinate and schedule observational experiences. Not uncommonly, these sites also serve as advanced (P-4) experiential sites. The faculty participating in this course found the speakers to be very forthcoming with the students regarding expectations during their advanced practice experiences while also generating excitement about what the students will experience during those rotations.

The intent in developing this course was to explore cardiology topics from a collaborative perspective with speakers discussing their individual areas of expertise. Interdisciplinary lecturers afforded the opportunity to explore topics to which students may not routinely be exposed. Additional-

ly, it gave students a brief respite from the traditional drug focus typically emphasized in a therapeutics course.

A primary benefit of using a health system as the core component of a health professions' elective course is that it promotes student interaction with other healthcare professionals. The present course increased student awareness of other specialists who share a common goal (patient care), but who accomplish it through other approaches and techniques.

#### Limitations and Future Direction

Students expressed interest in having more on-site experiences within the course such as observational experiences in the cardiovascular diagnostic laboratory, surgery, or cardiac catheterization laboratory. Those observational opportunities are available, however, if the course size is expanded, the greater number of students could be a limiting factor. Future course offerings could potentially provide one or two more observational experiences by dividing the class into sections. Additional course topics could include more formalized medication reviews and a "journal club" component.

#### Conclusion

Development of a cardiology course using interdisciplinary experts from a health system is a practical and efficient means for pharmacy practice faculty to offer an elective course. The pool of diverse specialists is abundant at even moderately sized facilities. The inclusion and participation of those specialists, as observed

in this course and as substantiated by the positive feedback, merits the continued offering of this course in future years. ■

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# Blazing Pharmacy Trails in Uganda

Melinda Young

Last summer, when Meg Melchiors arrived at the small clinic in Ibulanku, a village in Uganda's Iganga District, she discovered medications were being dispensed in small white paper envelopes with cryptic numerical instructions.

When the 25-year-old pharmacy student from the University of Washington asked about an envelope with "1x3" written on it, for example, the nurses told her it could mean either "take one tab every three hours," or "take one tab three times a day." The medication inventory system at the clinic was also followed loosely at best. Nurses generally relied on memory for record-keeping, which posed risks for unintended shortages of important medications when they are in need.

Melchiors, therefore, spent part of her summer working with the clinic's health providers to better organize its pharmacy and dispensing system. She produced a guide for the clinic that covered topics such as medication safety, medication errors, prescription labeling and patient education. Further, upon developing relationships with local villagers, she talked to them about the importance of drug safety.

She did all this through the Uganda Village Project (UVP), an organization founded by the International Federation of Medical Students' Associations that sends students to Uganda to participate in health care service projects. While in the African nation with UVP, Melchiors also collaborated with a team of U.S. premedical and medical students on other projects in the Iganga District focusing on dental care, eye care and nutrition.

The pharmacy project was the first such project that UVP had ever implemented, thanks to Melchiors.

"Before I started, the UVP director asked me if I would be willing to lead a pharmacy project, as the healthcare team had never done work along those lines," she said. "So I was absolutely thrilled to do so."

Melchiors learned that at the Ibulanku Community Health-care Center, there were primarily nurses. There was one doctor who basically worked 24 hours a day and one head nurse who organized and facilitated most of the medical seminars. There was not an official pharmacist. One of the nurses was trained specifically to work in the dispensary



of the center, but she had not received any extra education regarding medication use or management.

In response to the situation, Melchior's goals for the project at the Ibulanku clinic were threefold – to promote that all medications be clearly labeled and explained to each patient; make sure patients are educated properly on their diagnoses, disease states and treatments; and provide the clinic staff with the basic facts about the most commonly used medications.

Ensuring people were as informed as possible was especially important given some of the cultural notions that existed in Uganda. For example, Melchior learned that some Ugandans go to witch doctors for healing and are distrustful of Western medicine. Others believe that a pill – any pill – from a clinic is the answer to any sickness.

For her part, she tried to make the case that drug safety and adherence could help the villagers live longer and healthier lives. One topic she could discuss that generally met with a receptive ear was malaria. In 2006, the disease inflicted 10.6 million Ugandans – more than one third of the country's population – according to the World Health Organization (source [www.who.int/malaria/wmr2008/malaria2008.pdf](http://www.who.int/malaria/wmr2008/malaria2008.pdf)). It killed approximately 47,000 people.

So people listened when Melchior explained that people with malaria who go to a natural healer or don't take their medicines have a diminished chance of survival. She helped them understand that people who go to the clinic, receive their anti-malarials and take them appropriately have a better likelihood of survival.

This dialogue opened the doors for her to talk about drug safety in general. Overall, she said, people were receptive to her.

While the training and resources she provided were a great start, she knows change takes time. That is why she

helped the clinicians and community leaders set long-term goals for maintaining the changes. The villagers were also given specific recommendations and guidelines so that the work of Melchior and UVP could evolve over time to best serve the needs of the community.

"Often, medical relief just serves as a 'band aid' that seems to temporarily solve problems," said Melchior, "but it will not help the community in the future. UVP goes about making sustainable changes by working with community health care providers and leaders to educate and empower them so that changes will last even in the absence of activity of UVP."

Further, she created goals and recommendations for the next team of UVP students to carry on her work. In fact, depending on how things unfold, her work could lay the framework for UVP to implement similar programs in community clinics throughout Uganda.

She plans to return to Uganda after she finishes her residency in 2010 to help UVP try to make this happen. She also hopes to focus on preventing mother-to-child HIV transmission through appropriate use of anti-retroviral medications. And she will help with other health care projects accordingly.

Not only does Melchior hope this will set the stage for a career in international pharmacy, but she also hopes it will allow her to reconnect with the Ibulanku villagers whom she came to love. ■

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# How to get together: A collaborative help network

Peter V Rollason

**Circumstances in Zimbabwe in recent years have been very adverse in the provision of medical and allied services to the public, and this has particularly applied to the elderly and often infirm. This situation has occurred because of a lack of personnel in hospitals and the private sector, which include doctors, nurses and pharmacists, many of whom have emigrated, and also in the total collapse of medical aid systems.**

Another aggravating factor is the total collapse of payable pensions. The availability of prescription medicines has been a matter of great concern, which has been occasioned by the extreme shortage of foreign currency to purchase them. As a word of explanation, some twenty years ago, Zimbabwe was manufacturing, packaging and distributing more than sixty percent of its own sophisticated drug requirements and even exporting to neighbouring countries. But all that has eroded and one would estimate that less than five percent of prescription drugs are being locally produced at present.

While the question of acute medical care is of paramount importance, and somehow has been carried on to a remarkable degree, it is the matter of chronic care that has exercised the minds of those who dedicate their efforts to the welfare of elderly people. However, the ideas and systems offered were frequently bedevilled by duplication of effort, inappropriate advice, and overlaps of similar assistance from different organisations, all of which are coupled with lack of professional resources and personnel.

As a result of all this chaos and confusion, a group of dedicated people decided that a collaborative body was needed in to specifically to coordinate organisations offering aid and identify gaps where assistance is needed. It was realised that this plan could only be implemented on a city-wide level as it would require many individual contacts and personal friendships if it was to become effective. Thus was formed the Bulawayo Help Network.





### What it is

The Bulawayo Help Network's objective is to provide medical care in the broadest sense to chronic patients who are in need, to monitor circumstances of an acute nature and to try to provide assistance wherever possible.

The chronic care facility is operated on a system of weekly clinics. A doctor in private practice will give his services without charge on a given day each week to consult a number of patients at a central point, and to issue the necessary prescriptions for their treatment. These central points are usually located at an elder care centre or somewhere nearby so that patients can be transported there without too much difficulty.

Each patient would expect to see the doctor once a month in most cases, but those chronic patients who are stably medicated and under monitoring need only see him once every three months. The clinics are additionally staffed by volunteer nurses, an occasional additional doctor, and lay members who have varying medical experience. One of

the helpers usually then delivers the scripts on behalf of the patients to one of two pharmacies in the city who then dispense them, and when all are prepared a pharmacist, nurse or experienced health worker physically delivers the medicine to the patient's home and offers counselling and advice, and answers queries.

The majority of the drugs are sourced from a neighbouring country and supplied by pharmacists there without cost. It is quite a complex task in itself to arrange all of this and at the same time keep within the protocols concerning donated drugs as specified by the World Health Organisation – only specifically needed drugs, expiry dates, quality, etc. There is also the matter of transport and customs clearance.

The local pharmacist who fills the prescriptions charges no cost for any donated drugs but levies only a professional dispensing fee for each item provided to cover costs of correct records, stock keeping, times, and controls. If any drugs have to be supplied from available local stock, then the normal dispensed price is charged. These charges are levied against the Bulawayo Help Network, and a monthly summary of all drugs supplied to individual patients together with all accumulated costs is formulated. This system provides adequate statistics for the operation of the scheme and particularly the continued supply of specific drugs. The payout to the pharmacies is made monthly by the Network from donated overseas funding. The recompense to the pharmacists is paid as this scheme forms a reasonable part of their livelihood under present circumstances in the country and often requires their considerable outlay of monies in order to keep the scheme running satisfactorily.

This system operates extremely well and has been the cause of much complimentary comment from the donors of both finance and products from outside our borders. Amongst other things, the satisfaction of service and supply offered to each individual patient is of immense benefit and gives rise to confidence in the medicine received and the care being provided. Patient compliance with their treatment is also much improved. It is also important in that it has become a collaborative effort among the different professions.

Where elective surgery is required for a particular patient, an assessment is done by the consulted doctors who investigate the necessity of the operation, its likely outcome, the time factor, the hospital availability, after care and finance. One particular orthopaedic surgeon makes regular trips from another country at his own expense in order to undertake major surgery like joint replacements.

The provision of acute care for these patients is undertaken by a special medical committee comprising the ►

doctors, nurses, pharmacists, and lay helpers. Dentists, opticians and physiotherapists are contacted as may be necessary and all give financial assistance and excellent service as may be required.

In addition to the medical care, the Bulawayo Help Network supplies food aid to the needy elderly people and this again has contributed magnificently to the maintenance of better health for these patients.

It is obvious from this exercise that collaborative relationships exist between the various medical and allied professions, and these relationships has been the firm basis for the establishment of the Help Network. However it must be appreciated that such co-operation among the various medical professions is not always forthcoming in so many countries. The reasons are obvious. There is never any defined area of operation for so many health personnel, and therefore overlaps in professional practice can and do occur. This may lead to conflict of effort and appreciation and many are the cases of disagreements and arguments, let alone confrontations between such professionals.

### Why it works

When the University was first established in the capital city in the late 1950's, one of the first faculties established was the Medical School. Then a Pharmacy School was set up and very fortunately this was established within the Medical School and not within the Science faculty as is so often the case in many countries. This meant that pharmacists and doctors were being trained alongside each other, and in the first one or two undergraduate years, lectures were often shared. The result was an established rapport between the two professions.

The second useful factor in harmonious relationships between doctors and pharmacists was that of a generally small community where each person got to know their colleagues personally and socially as well as professionally.

The third and most important influence was an arrangement emanating from the two professional societies, the Pharmaceutical Society and the College of General Practice. Each of these bodies held Annual General Meetings, which were mostly quite boring and engendered poor response.

It was just at the time when the College had commenced activity and a much higher emphasis was being placed on continuing education in both professions. They got their heads together and discussed the possibility of joining forces to start an Annual Joint Conference which would take place at differing venues and be mainly concerned with lectures and demonstrations on mutually interesting subjects, and allowing for just a short half day for a pro forma meeting. A joint organising committee was set up and the idea prospered. Such joint Annual Conferences have now been running for more than thirty years and have been an unqualified success. In addition to many papers provided by general practitioners and pharmacists from all differing disciplines, nurses, dentists, medical specialists, physiotherapists, radiologists and many others have willingly contributed their knowledge and expertise and added greatly to a highly successful involvement of an Annual Conference which is the envy of much of the world.

So it is on these three factors that is has been comparatively easy for the Bulawayo Help Network to function so smoothly and in fact even to enhance the friendship and profession co-operation between so many medical and allied professionals. ■

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### Author's Information

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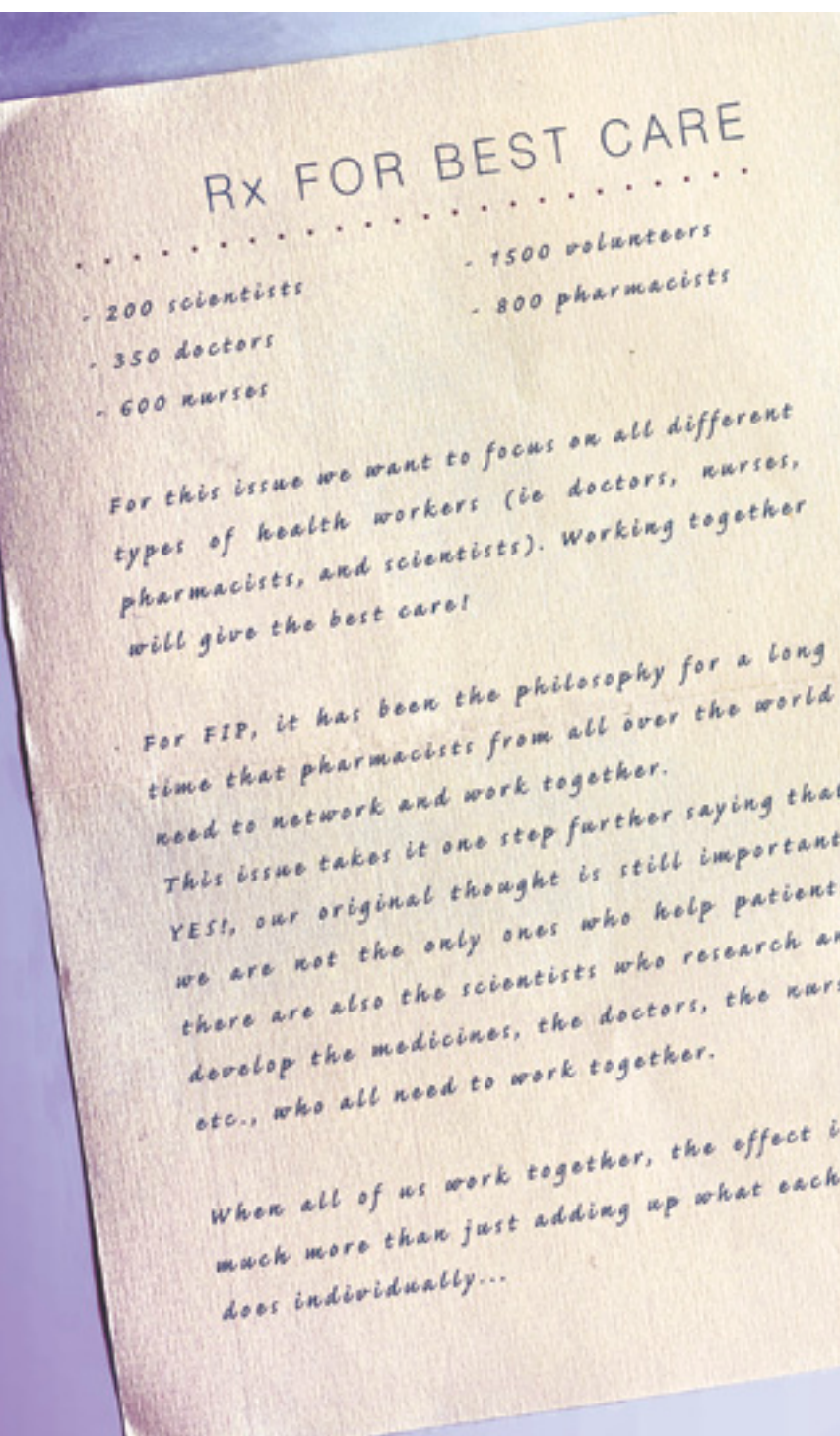
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# Brave new world

Luís Miguel Lourenço



Since the de-regulation of pharmacy ownership in Portugal two years ago (until then only pharmacists could own a pharmacy), much has been discussed about the future of pharmacy and the role of pharmacists in this new era. It is now widely accepted that, in order to foster its role within the health care structure, pharmacies ought to provide services with recognized added value. For example, last October, pharmacies were allowed to start delivering flu vaccinations. ►



For me, as a community pharmacist, implementing this new service was a challenge since a lot of training had to be done and because nothing similar had ever been done concerning vaccination in Portuguese pharmacies. Moreover, as the manager of a private pharmacy, this new service was the beginning of an internal process to make a small shift from a product-based service to a clinical-based service.

### The beginning of the process

In 2007, due to political pressure to allow non-pharmacists to own a pharmacy, the Portuguese government signed an agreement with the major organization of pharmacy owners in Portugal, ANF (Associação Nacional das Farmácias).

This document (which was entitled “Health care commitment”) is the cornerstone of pharmacies’ roles in the healthcare system for the years to come. It includes some changes in the ownership of pharmacies (not restricted to pharmacists only) as well as the new services pharmacies are allowed to provide (vaccines’ delivery (only vaccines not included on the national vaccination programme, ie, those that are not provided for free by the government), health check-ups (hearing impairment, blood analysis...), amongst others). The fact that some of these services had already been implemented abroad and with positive outcomes, both for the patient and the government, contributed to its inclusion on the document.

### Professional involvement

In most settings, nurses deliver vaccinations. However, under the “Health care commitment”, pharmacists and other pharmacy staff were allowed to vaccinate, as long as they had the *proper training*. This *proper training* was not defined by the government nor by any other organization; since the United States had implemented a similar programme, most courses followed their structure and guidelines.

### Learning new skills

Several organizations set up programmes to provide pharmacists the requested training to deliver vaccines. Although some topics were familiar, like immunology, others were new to pharmacists, like administration technique.

The course I attended can be divided in 3 major areas: immunology, vaccines administration and life support techniques:

1. Immunology: the basic principles of immunological response were focused as well as the vaccines that were allowed to be delivered at the pharmacies (ie, not provided for free by the government);
2. Vaccine Administration: participants learned how to deliver vaccinations;
3. Life support techniques: when administering a vaccine, there is always a risk of having some sort of reaction by the patient. During this part of the training participants learnt how to recognize the severity of a reaction and how to handle it.

### Implementing the service at the pharmacy

In order to start the project at the pharmacy, some requisites needed to be fulfilled. Administration of vaccines requires a private room for it, nursing materials should be at hand and all the procedures should be registered.

Some posters promoting the service were used inside the pharmacy and leaflets were provided to the patients. The service was also broadcasted in all major TV channels and radio stations.

Since many patients requested the new service a timetable was set for vaccines administration; this way the number of staff members allocated to the service was balanced with the staff dispensing medicines.

### Feedback from patients

The vaccination project went smoothly at the pharmacy and patients appreciated it. The most often heard comments were that it was comfortable to have the vaccine administered right after buying it and that, due to the long period of opening, the pharmacy was a very convenient place for this sort of service. Although this was an informal survey, ANF collected some data to undertake a formal study of the patients' opinions.

### The importance of the project

Although the project was embraced by many pharmacies across the country, not all decided to implement it. The fact that in some places there are nurses close to the pharmacy and that, in some regions, the number of patients asking for it wouldn't be too high were the major reasons for pharmacies not running the project.

Some pharmacies provided the service for free. For those that did charge, prices usually ranged from one to 4.5 €.

### Improvements

Of course not everything was perfect: sometimes patients had to wait a while to have their vaccines administered if there was a long line. This

happened because patients used to buy their vaccines in the morning so they could look for a place to have it administered during the afternoon (causing mornings to be very busy and afternoons more quiet). Next year, since the word has been spread about this service and patients know that can have their vaccine administered right after buying it, we expect to have this problem solved.

### How the project has been received by other health professionals

Most of the training courses were full due to the high number of interested people, which forced many pharmacy owners to hire nurses to provide the service. Although not only pharmacists were allowed to attend these courses, no official list of the professional background of attendees was released yet by any of the organizations that run the course.

Many discussions were held between pharmacists' and nurses' professional organizations since nurses wanted to be the only ones running the project inside the pharmacies. Since no conclusion was achieved, pharmacies followed the "Health care commitment" guidelines and allowed pharmacists to provide the service.

### Thoughts

Overall, the implementation of the vaccination project was a success. Not only did we start to slightly shift our focus from a medicines only approach to a health care service approach, we also managed to strengthen our relationship with the community.

The challenge of creating a new service motivated all the staff and set the cornerstone of a *changing culture*.

A new era for pharmacy services has started in Portugal and I'm very proud to say I'm part of the change. ■

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*Materials in the pharmacy*







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# The light at the end of the tunnel?

## A hopeful beginning for a malaria vaccine

Ulrike Holzgrabe

Malaria is still one of the most widespread parasitic tropical diseases with its main impact in sub-Saharan Africa. It causes more than 300 million acute illnesses and up to 3 million deaths each year, mostly young children under five years.<sup>1</sup> However, with the development of various routes of transportation and increased tourism to affected regions, malaria has become an even larger problem. Moreover, increasing global temperatures accelerates the problem and the spread of resistance to well-established antimalarial drugs such as chloroquin or mefloquin makes the control and treatment of the disease even more difficult.

Thus, new antimalarial drugs are urgently needed. Quite a lot of innovative ideas are emerging worldwide in the laboratories and getting sponsored by private-public-partnerships (PPP), such as the Bill and Melinda Gates Foundation, Novartis Institute for Tropical Diseases, and the Malaria Project. At this time, no new drugs are in the late-clinical trials. A trial of combination antimalarial therapies in children from Papua New Guinea was conducted against *Plasmodium falciparum* and *P. vivax* applying double and triple therapies.<sup>2</sup> The most effective regimens were found to be artemether-lumefantrine against *P. falciparum* and dihydroartemisinin-piperaquin against *P. vivax*.

Even though the introduction of insecticide-treated bed nets and the artemisinin-based combinations therapies have decreased the incidence of malaria, a safe and affordable antimalarial vaccine would be an excellent addition to the control strategies.

The first immunization experiments were performed as early as 1967 with irradiated sporozoites generating a protective immunity. However, the progress in vaccine development has remained slow, mostly ►



“*Malaria is still one of the most widespread parasitic tropical diseases*”

due to the fact that more than 5,200 genes could code for a protective antigen. This makes the identification of an appropriate vaccine antigen difficult. Half of the approximately 50 candidate vaccines currently studied are based on only three antigens: the circum-sporozoite protein (CSP), the merozoite surface protein (MSP) and the apical membrane antigen 1 (AMA1)<sup>3</sup>. This essay will focus on the most promising of candidate vaccines – those which target the CSP.

Plasmodia, the genus of parasites which cause malaria, have a complex life cycle starting with a female mosquito that injects sporozoites into the blood of a human being. The sporozoites enter the blood stream, migrate to the liver and invade the hepatocytes, all together in less than 30 min. In the so-called liver stage, or pre-erythrocyte stage, the sporozoites mature over a period of 6 to 16 days, and eventually release tens of thousands of merozoites into the blood. They invade the red blood cells where they multiply again and mature within a few days, forming rings and passing the trophozoite stage. They end up as schizonts which eventually burst, lyse the red blood cells and release a new generation of merozoites. This cycle starts again. The blood, or intra-erythrocytic stage, is characterized by the classical acute febrile episode occurring every 48 to 72 hours. Some of the merozoites develop into the sexual-stage gametocytes, which, after taking up by an anopheles mosquito, mature and sexually combine in the insect host in order to generate a zygote. The latter develops into an oocyst, from which sporozoites are produced which can be again transferred to a human being.

#### CSP Antigen

In order to neutralize the sporozoites, vaccines against malaria were designed to target the pre-erythrocytic stages of the parasite by generating an antibody. This antibody prevents sporozoites from invading hepatocytes and elicits a cell-mediated immune response. CSP-based vaccines are among the most promising malaria vaccines in the pipeline and are currently in clinical phase I/IIb.<sup>4,5</sup> This candidate vaccine comprises the C-terminus of the CSP from *P. falciparum* fused to the hepatitis B surface antigen and expressed in the form of virus-like particles (VLPs) in *Saccharomyces cerevisiae*. The purified antigen mixture spontaneously assembles into multimeric particles, named RTS, S (“S” stand for the surface antigen hepatitis B). The vaccine is composed of the RTS, S antigen presented as lyophilized pellets (RTS, S with sucrose as a cryoprotectant per 3 mL monodose vial) and the AS02<sup>x</sup> adjuvant containing 3-D-deacylated monophosphoryl lipid A (MPL) and QS-21 (being a triterpene glycoside from the bark of *Quillaja saponaria*) in either an oil-in-water emulsion or liposomal formulation each in varying amounts (see Table 1). The adjuvant and formulation is critical for the protective immune response which was only obtained from the AS02 formulation. Consequently this system was stepwise optimized as can be seen in Table 1.

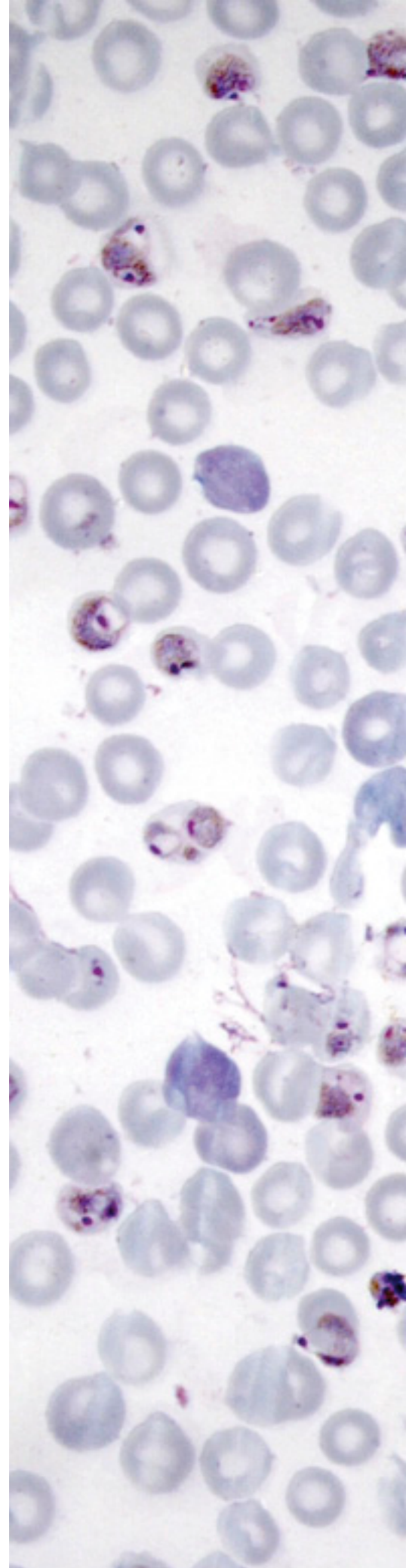




Table 1: Composition of the different generations of the RTS, S vaccine

Vaccine RTS/S+	RTS, S in 12,6 mg sucrose	MPL®	QS-21	Formulation	Dose
AS02A	62.5 µg	50 µg	50 µg	oil-in-water emulsion	0.25 mL
AS02D	31.25 µg	25 µg	25 µg	oil-in-water emulsion	0.5 mL
AS01B	50.0 µg	50 µg	50 µg	liposomal formulation	0.5 mL
AS01E	25.0 µg	25 µg	25 µg	liposomal formulation	0.5 mL

Preliminary clinical trials with the pre-erythrocytic malaria vaccine RTS, S/AS02A protected 30 percent of children against clinical malaria and showed that the vaccine is safe, well tolerated and immunogenic. Similar results could be obtained for the RTS, S/AS02D vaccine in a double-blind randomized trial of 214 children (up to 18 weeks) in Mozambique.<sup>5</sup> This trial conferred 65 percent protection against malaria infection in infants. Now two phase IIb studies using the RTS, S vaccine and the adjuvants S/AS02D and S/AS02E, respectively, were reported.<sup>6,7</sup>

In Tanzania, 340 infants at 8, 12, and 16 weeks received three doses of either RTS, S/AS02D malaria or hepatitis B vaccine intramuscularly.<sup>6</sup> The children also received oral polio vaccine and a preparation consisting of diphtheria and tetanus toxoids, whole-cell pertussis vaccine, and *Haemophilus influenzae* type b vaccine. Malaria infection was cleared with artemether-lumefantrine four weeks before active surveillance was started. The primary objectives were the occurrence of serious adverse events during a 9-month surveillance period. The second objectives were the detection of antibodies against *P. falciparum* circumsporozoite and efficacy against malaria. One month after vaccination, more than 98 percent of infants receiving the malaria vaccine had seropositive titers for anticircumsporozoite antibodies (ELISA). During the 6-month period after immunization, the incidences of malaria infection and disease in the RTS, S group were reduced by 65 percent. No interference with the other vaccine was observed. A correlation between a reduced risk of infection and increased antibody titers, but no association between the incidence of clinically active malaria and increased circumsporozoite-antibody titers was found.

In Kenya and Tanzania, a double-blind, randomized phase IIb trial of the vaccine RTS, S/AS01E<sup>7</sup> compared with rabies vaccine was conducted with 894 infants aged 5 to 17 months. Three doses were intramuscularly given at one-month intervals in order to evaluate the efficacy of the vaccine. The primary end point was fever with a *falciparum* parasitemia density of more than 2500 parasites per µL, and the mean duration of follow-up was about 8 months. The cumulative incidence of clinical malaria (first or only episode) was 8 percent in the RTS, S group and 16 percent in the control group resulting in an efficacy against all clinical episodes of malaria of 56 percent with an anticircumsporozoite antibody titer detectable in more than 99 percent of the recipients. As with the RTS, S/AS02D malaria vaccine there was no correlation between the antibody titer and the protection against the clinical disease. ►

Serious adverse events and local reactions were comparable in both trials, although low-grade fever was more common in the malaria-vaccine group. Even though the antibody titers were different in both studies the protection against infection and clinical disease did not differ whether AS02D or AS01E was used as an adjuvant.

The results of both trials are promising. However, the baseline incidence of malaria was low in each study area because of the introduction of insecticide-treated bed nets and artemisinin-based combination drug treatment.

The vaccine RTS, S/AS01E was developed at GlaxoSmith-Kline Biologicals in collaboration with the Walter Reed Army Institute of Research (DC, USA). The clinical trials have been conducted under a partnership agreement between GSK, Malaria Vaccine Initiative (MVI) and the Bill & Melinda Gates foundation. A multicenter phase III clinical trial is ongoing. It is intended to apply the vaccine in malaria endemic regions only and to launch it in 2012. ■

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# Genomics in the Development of Vaccines

Chandan Thomas, Jon Weidanz, Fakhrul Ahsan and Majid Moridani

Infectious diseases are still among the big killers of 21<sup>st</sup> century. HIV/AIDS, hepatitis B and C, malaria and tuberculosis are the current top killers. Despite having a preventive vaccine, hepatitis B has already infected nearly 2 billion people worldwide, claiming 1-2 million lives annually. Tuberculosis continues to be the tenth leading cause of death and disability worldwide and accounts for 2 million deaths a year.<sup>1</sup> To date, there are no preventive vaccines against other major infectious diseases hepatitis C, HIV and malaria. Hepatitis C, malaria and HIV and complications associated with these three diseases cause about ten thousand, 1 million and 2 million deaths, respectively.

The discovery of vaccines for a variety of infectious diseases including smallpox, cholera, typhoid, diphtheria, pertussis, yellow fever, hepatitis B, mumps and rubella have been successful in preventing the spread of many of these infectious diseases. For instance, because of vaccination, smallpox has been completely eradicated. At present, the World Health Organization (WHO) is working toward the complete elimination of poliomyelitis throughout the world.

In brief, vaccination has been regarded as one of the most effective means of preventing infectious diseases. It is estimated that nearly 3 million deaths annually are prevented by vaccination against infectious diseases.

## Current Advances in Delivery and Development of Vaccines

Vaccine design and development is moving away from the view of “one size fits all” to designing and developing personalized vaccines. Limitations associated with a number of current vaccines have led development research to focus on two main areas: (1) improving the existing vaccine delivery systems, and (2) exploring ►

alternative routes for vaccination. A tremendous amount of research is directed particularly towards improving current vaccine delivery system that include the use of DNA vaccine systems and replacing alum with synthetic oligodeoxynucleotides containing immunostimulatory motifs, Toll-like receptor agonists, poly lactic acid and poly lactic co-glycolic acid based micro and nanoparticulate systems.<sup>2</sup>

Alternative routes for vaccine delivery have received increasing attention to: (1) improve the acceptability for vaccination and compliance by the general population, (2) reduce the spread of infections as a result of the needle reuse and unsafe injection practices, and (3) promote generation of a mucosal immune response in addition to the systemic responses. A number of non-invasive routes which are currently under intensive investigation include oral, nasal, inhaled or pulmonary and transcutaneous routes.<sup>2</sup> For instance, an intra nasal influenza vaccine (FluMist® MedImmuneVaccines Inc, Gaithersburg, MD) was successfully developed and is already available commercially.

Pasteur's principle of vaccine development is based on attenuation and inactivation techniques by which inactivated or killed, or live attenuated and subunit vaccines are produced for vaccination.<sup>2</sup> This process of vaccination is known as direct vaccination because the materials are directly derived from pathogens. However, with the advent of recombinant DNA engineering, molecular biology and immunology, the direction of vaccine development has changed dramatically. The use of genetic engineering led to successful development of the first hepatitis B vaccine based on recombinant DNA technology. The first generation hepatitis B vaccine was developed from purified pathogens collected from the plasma pools of infected donors, who had high antibody levels against hepatitis B virus, also known as seropositivity. The development of vaccines based on Pasteur's principles is not always possible for all pathogens. For instance, microorganisms such as hepatitis C virus, papillomavirus 16 and 18, and the mycobacterium that causes leprosy cannot be efficiently cultivated *in-vitro*. However, this problem can potentially be overcome by using recombinant DNA technology.

To a great extent, the advances of genomic engineering have enabled researchers to use technology such as "reverse vaccinology," wherein the use of molecular biology techniques facilitates identification of antigen candidates for vaccine development. This process eliminates the need of cultivating the microorganism *in-vitro*. In this approach, researchers first identify and select potential gene candidates for vaccine development. Molecular biology techniques are used for cloning and production of large quantities of the genes that needs to be expressed in a microorganism such as *E. coli*. Subsequently, the recombinant proteins are purified as antigens and tested in mice to confirm if they can induce immune responses.<sup>3</sup>

And if successful, it will be tested in humans in a clinical trial.

For example, until the 1990s, the development of a meningococcal B vaccine was thought to be beyond reach because of hypervariable nature of the meningococcus strains and the lack of immunogenicity shown by the polysaccharide antigen that was used in the preparation of the conjugate vaccine. However, the reverse vaccinology using molecular biology techniques has shown a great deal of promise in the development of a vaccine for meningococcus B, which is currently in clinical trials. Because of the success in the development of the meningococcal vaccine, similar approaches have been employed for a number of other pathogens such as pneumococcus, group B streptococcus and Chlamydia. This new era has been justly labeled as "vaccinomics" because it relies on the integration of information from newly established fields of "omics" that includes genomics, proteomics, metabolomics and bioinformatics.

#### Responders and Non-responders – How big is the problem?

Genetic polymorphism refers to variation in the nucleic acid sequence of a gene in a way that there are more than one form of the gene exist in a population and the frequency of the variation is at least 1 percent in the population. A variety of studies have shown that individuals respond differently to drug therapy. For example, genetic polymorphisms in cytochrome P450 enzymes can significantly influence drug metabolism which in turn influences the therapeutic outcomes of that particular drug. Understanding the underlying variations in genetic basis of drug metabolizing enzymes and drug targets can significantly assist clinicians in selecting the correct medication and dosage for the right patient subpopulation. Such an approach can ultimately lead to better drug response, efficacy, compliance and outcome, and minimal toxicity associated with drug therapy.

Similar to interindividual differences observed in drug response, a number of currently available vaccines have also shown significant differences in the magnitude of immune responses in individuals undergoing vaccination. For example, the approved hepatitis B vaccine is given in vaccine doses ranging from 10–40 µg depending on the targeted population. In addition to dose variation, specific segments of population fail to respond to the hepatitis B vaccine, including obese persons, smokers, and immune-compromised individuals. In general 10–15 percent of the population fails to respond to the currently available three-dose vaccine, whereas around 40 percent of adolescent population shows antibody levels that are considered to be protective after one or two doses. Moreover, there have been cases where some individuals have even required more than six doses of hepatitis B vaccination for the generation of immune response.<sup>4</sup>

It has been postulated that a number of factors may be involved in these variations in immune responses. These factors include age, gender, race, amount and quality of the antigen, the dose administered and to some extent the route of administration, and genetics of immune system. Most of these factors can be grouped into the variations caused by biology and genomics of the host and the pathogen. The environmental factors such as smoking, alcohol consumption and diet can potentially alter biology and genomic factors as well. The role of genomics in determining the extent of immune response is still in its infancy with only a handful of diseases investigated in this regard. Some of the most extensively researched infectious diseases include measles, hepatitis B, hepatitis C, human papillomavirus and influenza.<sup>5, 6</sup>

Other vaccines that showed a high rate of non-responders include measles, rubella and influenza. For measles vaccine, during the last large US outbreak, 20–40 percent of those immunized who contracted the disease had been previously vaccinated against measles, indicating that the vaccine used was ineffective in eliciting neutralizing antibodies.<sup>7</sup> A deeper examination revealed specific genetic associations correlated with poor immune responses to measles vaccine. Children vaccinated against rubella have shown immune response variations especially with regards to antibody and T cell responses, which have been linked to host genetic variations.<sup>6</sup> For the influenza vaccine, genetic polymorphisms appear to be important in explaining variations observed for immune responses made against influenza virus.<sup>8</sup>

#### Genetics of Immune System Relevant to Vaccine

Recently, researchers have described five general classes of immune response genes that are critical in the regulation of innate and adaptive immune responses to environmental challenges and vaccination.<sup>8</sup> These gene classes encompass: (1) microbial binding receptors and innate receptor genes (e.g. natural killer receptors, Toll-like receptors, protein kinase receptors), (2) Human Leukocyte Antigens (HLA class I and class II) genes, (3) cytokines and their receptor genes, (4) adhesion molecule and chemokines and their receptor genes, and (5) immune effector molecules. These different gene classes strongly influence T and B cell responses and thus regulate antibody production and the host's ability to neutralize and/or eliminate the microbial agents and destroy tumor cells.

The associations between an individual's genetic makeup and variations in immune response to vaccination is only now beginning to be understood but recent discoveries are proving useful in predicting individual outcome to vaccination. Take for example the *HLA* genes. These are the most highly polymorphic genes in the human genome and play a critical role in establishing T cell and antibody responses against infectious agents. Specifically, the *HLA* system is involved in antigen processing and presentation of peptides that originate from pathogens. Polymorphism

in *HLA* genes has been shown to significantly impact peptide processing and presentation that ultimately affects the type of T cell and B cell responses induced.

A strong association with *HLA* genes has been linked to immune responses in vaccinated individuals. In measles vaccinated individuals, association between *HLA* genes and very high levels of antibodies or hyperseropositive responses have been reported. In fact, a higher frequency of hyperseropositive responders to measles antigens was observed for individuals carrying the class I *HLA-B\*07* allele.<sup>7</sup> In contrast, frequencies of *HLA-B\*44* allele were lower in hyperseropositive than in normal seropositives.<sup>7</sup> The authors also found a significant association with regards to HLA class II alleles, in particular within *HLA-DR*, *DQ* and *DP* loci.<sup>6</sup> Further *HLA* associations have been reported for immune response variations to influenza vaccines.<sup>8</sup>

In the case of hepatitis B vaccination, the presence of *HLA-B46* and *HLA-B15* alleles was found to be higher in non-responders in comparison to responders. Individuals with *HLA-DRB1\*03* allele are less likely to be infected chronically with hepatitis B.<sup>6, 9</sup> Data has also shown that genetic differences play a significant role in determining the extent of immune responses after measles vaccination as compared to mumps and rubella vaccination.<sup>6</sup> Many other examples have shown a link between HLA polymorphism and the immune response against a vaccine

“ This new era has been justly labeled as ‘vaccinomics’ ”

illustrating its significance. Drawing strong associations between *HLA* genes and immune response variation as well as with other classes of immune response genes through immunogenetic profiling will eventually result in greatly improved and much more effective vaccines. This will lead to greater vaccine coverage, fewer failures and adverse responses and ultimately reduction in vaccination costs.

#### Use of Genomics in the Evaluation of Efficacy and Toxicity of Vaccines

With the increasing number of side effects associated with a number of vaccines reported over the years, it has become imperative to develop new technologies that can effectively assist in the development and evaluation of vaccines for efficacy and toxicity. The use of DNA, RNA and protein microarrays provides a number of advantages such as an increased flexibility in the number of genes

and gene products that can be tested in the evaluation of vaccine and immune response over the traditionally used methods which evaluates an overall *in-vivo* efficacy and toxicity response to a vaccine formulation.<sup>10</sup> Such technology can be also used to evaluate and compare the pharmacological and immunostimulatory effect of the vaccine antigen, the adjuvant and the combination on the expression of RNA and proteins. These evaluations can be carried out initially in preclinical studies in animals and later in human clinical trials. Genomics and proteomic studies in vaccine development can provide vital clues regarding the variations in pharmacological outcomes such as inflammation, stress response, apoptosis and carcinogenicity.<sup>10, 11</sup> Furthermore, the genomic and proteomic profiles of vaccinated population can be compared to subpopulation that shows adverse effects to vaccination. Such comparison can be used to identify and validate biomarkers for potential adverse effects to vaccination.

### Summary

The era of immunogenomics has truly arrived and may very well hold the key to future breakthroughs and advances in vaccine design and development and improvement of public health. Such information can be useful in identification of non-responders and individuals at risk of developing side effects, and in understanding the underlying mechanism of immune response to vaccination. Genomic technology also makes it possible to develop vaccines against pathogens that are currently difficult to cultivate in laboratory. ■

### Authors' information

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