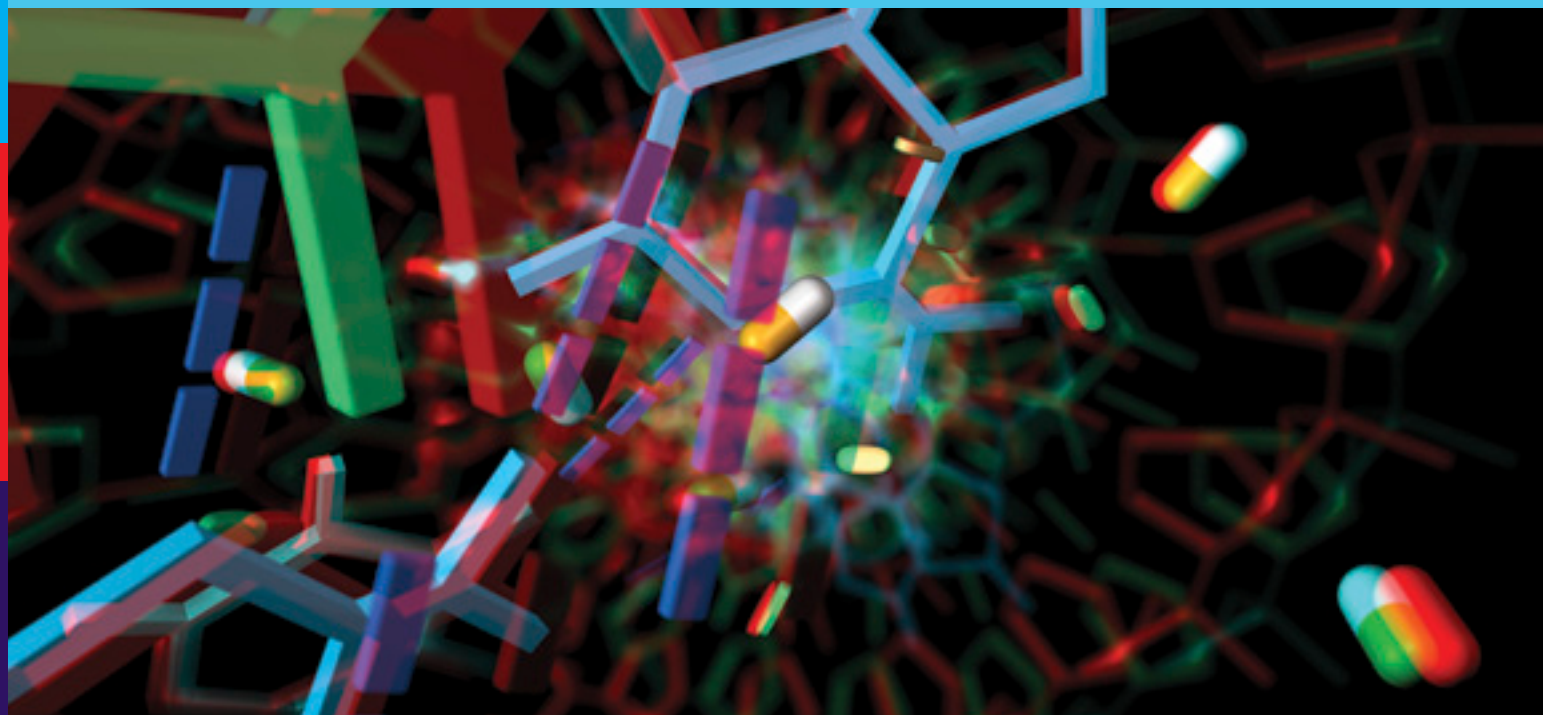


# IPIJ

THE OFFICIAL JOURNAL OF FIP



## PRACTICE

Innovative practice methods for inmates

## SCIENCE

Individualised Medicine – bridging scientific and clinical studies

## EDUCATION

Using science festivals to raise awareness of chronic disease prevention

## VISION AND INNOVATION

What do we see for the future,  
what will take us there?

*Put on your 3D-glasses and discover for yourself!*



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## Dear Reader

### What do YOU see?

The inspiration for this issue of the IPJ, focusing as you see on Vision and Innovation, has come from many sources. Not the least of which are Vision 2020 – FIP's Vision, Mission and Strategic Plan and the true vision and innovation surfacing in the areas of pharmacy practice, the pharmaceutical sciences and pharmacy education, as are exemplified in the articles that follow. FIP was particularly intrigued by the novel practice methods to better serve and involve inmates in their medication regime, as outlined in the Empowering patient minority populations. The authors' research at a prison facility in Australia is both innovative and a call for patients' rights as a core concept of humanity – regardless of previous fault. We look forward to hearing how the project progresses.

There is likely little objection to the notion that the pharmaceutical sciences are the foundation for innovation across our spectrum of pharmacy disciplines. The investigative research and emerging technology taking us into the future will lead to treatments never before imagined. A key question, however, is how will the scientific and clinical branches of research fuse to produce useable

tools and knowledge to positively impact patient care? The report of the joint FIP-JSPHCS Conference on Individualised Medicine: bridging scientific and clinical studies, examines just that.

Over and above our features, this issue offers a new aspect to the IPJ – an article born from a strong reaction to images of hand-held medicines in the previous issue of the journal. The Editor is quick to admit that images of bare hands holding medicines were not once cognitively connected with hand-counting in pharmacies – an unacceptable practice still taking place in many developing countries. FIP thanks the contributors from Management Sciences for Health for their article and bringing this issue to light in hopes of eliminating the practice. They saw something in an image that few others did – is there a better example of “vision”, in all its senses?

The end result of these contributions is an issue that in itself is both visionary and innovative. In a play on words and concept, we are pleased to bring you the first ever 3D version of the IPJ – complete with glasses – a visual concept that not so long ago was at the height of innovation.

Go forth in good vision – and prosper!

**Myriah Lesko** Editor

**Lowell Anderson** Co-Editor



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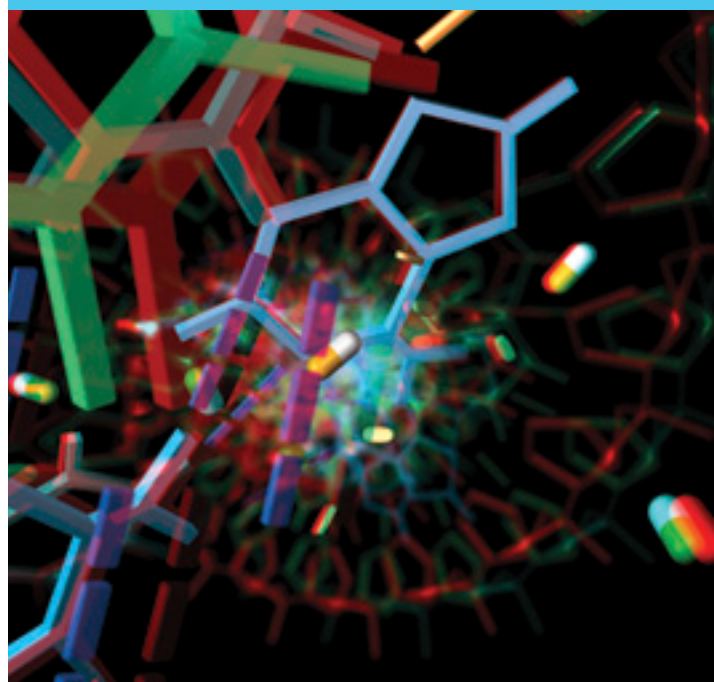
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# Hands Off Medicines

## Enabling good dispensing practices

Judy Wang, Alison Wong, Sarah Morrison, Tina Penick Brock

**The December 2009 issue of the International Pharmacy Journal includes two images with individuals holding medicines in their bare hands, at least one of which is suggestive of a clinician. This image provides a conflicting message when compared with Good Pharmacy Practice (GPP) standards which indicate that “pharmacists and dispensers should not make direct hand contact with medications at any time during the dispensing process.”<sup>(1)</sup>**

Some IPJ readers may not have recognized this as an issue because developed countries typically have counting trays (often multiple units) available in all pharmacies, hospitals and dispensing sites. But in the developing world, the process of counting medicines by (and in the) bare hand is still quite common. For this reason, the images provide an important stimulus for opening a dialogue about the extent of this problem as well as possible mechanisms for both promoting and enabling good dispensing practices around the world.

### Why is counting medicines by bare hands problematic?

Although we were not able to find any published literature linking the bare hand-counting of medicines to negative patient outcomes, it is important to consider the potential impact on patient care when medicines are not handled appropriately. Direct contact with medicines can cause adulteration of the product for multiple reasons, including:

- Degradation by moisture and skin oils. (This could lead to decreased potency and/or effectiveness.)
- Contamination by pathogens. (This could result in infection, which would be especially problematic in regions where HIV/AIDS prevalence is high due to the already increased risk for opportunistic infections in immunocompromised individuals.)
- Cross-contamination of powder residuals from tablets/capsules. (This could contribute to an increased risk for misclassification of allergic reactions and the unnecessary exclusion of viable treatment options in regions where access to essential medicines may already be limited.)

### What is the minimally acceptable standard for good dispensing?

To ensure the integrity of medicines when dispensing, the WHO FIP Good Pharmacy Practice guidelines and United States Pharmacopeia<sup>(1,2,3)</sup> describe the characteristics of a good dispensing environment. This includes adequate equipment, scheduled equipment cleaning and staff hygiene. Adequate equipment is generally considered to be a counting device such as a tray, but could be any clean, flat surface (such as the container lid or plain paper) as long as this can be cleaned or disposed of after use. A counting spatula is also desirable but this could be replaced by a clean spoon, tongue depressor, or dull knife. If clean equipment such as trays and spatulas are not readily available, medicines can be counted by hand if disposable gloves are worn during the process.

Though these guidelines may seem relatively easy to implement, many dispensing sites in developing countries are unable to meet these standards. And despite a long history of informal campaigns to promote appropriate practice, the (bare) hand-counting of medicines remains fairly common practice in Africa, Central Asia, Southeast Asia and several Latin American and Caribbean countries<sup>(4,5)</sup>. Some reasons for this include lack of knowledge about good dispensing practices amongst (untrained) pharmacy support cadres, lack of access to the necessary equipment (eg, counting trays, spatulas and tablet-cutting devices) and limited enforcement of Good Pharmacy Practice.





### What can we really do to improve practice?

There are simple, cost effective ways to promote good dispensing practices. But improving knowledge of these practices solely through informal and isolated campaigns has not appeared to be a sustainable solution. And lack of access to relatively inexpensive supplies has prevented much progress being made globally. Although all pharmacists have a role in ensuring good dispensing practices in their own dispensing sites, professional organizations like FIP have the influence to ensure that a clear, consistent message resonates with a variety of influential stakeholders (who may not be aware of the extent of this problem). Our recommendations for how to move forward include:

1. Working through the FIP Academic Section and the WHO-UNESCO-FIP Global Pharmacy Education Taskforce to promote the inclusion of good dispensing practices in the curriculum for all pharmacy schools and training programs for pharmacy support personnel worldwide,
2. Encouraging the International Pharmaceutical Students' Federation (IPSF) and Young Pharmacists Group (YPG) in collaboration with the FIP Hospital Pharmacy Section and Community Pharmacy Section to create and disseminate a modern "Hands-off Medicines" campaign to promote good dispensing practices,
3. Advocate through the FIP Industrial Pharmacy Section and WHO to pharmaceutical companies in developing countries to coordinate with the local professional societies/ associations and provide adequate numbers of counting trays, spatulas and tablet-cutters with all products procured and delivered and
4. Promoting through the FIP Council good dispensing practice standards that national accrediting bodies can adopt when evaluating local facilities.

We thank IPJ for publishing the controversial photos of medicines held in bare hands as this has enabled us to highlight this important yet neglected challenge for global pharmacy. It is time that all pharmaceutical personnel are

taught the principles of good practice and have access to the supplies necessary to put this knowledge to good use. This relatively simple and inexpensive intervention could have profound implications for patient outcomes. We look forward to continued discussion. ■

### Authors' Information

**Judy Wang, Alison Wong, Sarah Morrison, Tina Penick Brock**  
*Management Sciences for Health*

### References:

1. *Management Sciences for Health. Managing Drug Supply*. 2<sup>nd</sup> Ed. 1997. West Hartford, CT: Kumarian Press
2. *International Pharmaceutical Federation (FIP)*. 1997. Standards for quality of pharmacy services – Good Pharmacy Practice  
 Available online: [www.fip.org/files/fip/Statements/latest/Dossier%20004%20total.PDF](http://www.fip.org/files/fip/Statements/latest/Dossier%20004%20total.PDF)
3. *United States Pharmacopeia Drug Quality and Information Program and collaborators*. 2007. Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide. Rockville, MD: The United States Pharmacopeial Convention. Available online: [www.usp.org/worldwide/dqi/resources/technical-Reports](http://www.usp.org/worldwide/dqi/resources/technical-Reports)
4. **Hafeez A. Kiani AG, ud Din S, et al.** *Prescription and Dispensing Practices in Public Sector Health Facilities in Pakistan: Survey Report*. J Pak Med Assoc 2004; 54(4): 187-91. Available online: [www.jpma.org.pk/Pdf-Download/381.pdf](http://www.jpma.org.pk/Pdf-Download/381.pdf)
5. *Survey of field offices for the Strengthening Pharmaceutical Systems program 2010*; data on file.

# Empowering Patient Minority Populations

## Self medication management program for adult patients in custody

Hanan Abdalla, Patrick Ball

**In custodial environments, once the offenders have been located to a correctional facility they lose most of their privileges, including control over their own activities of daily living (James & Glade, 2002). In the community, someone with a chronic disease may manage their medications, monitor their own progress and report side effects and persistent symptoms. In custody, traditionally prisoners must hand over their medications and then present at set times for 'pill parades', (NSW Health PD2005\_527, 2005). This is disempowering to the patients, inflexible in terms of timing (often leading to meaning sub-optimal therapy and prevents them from actively managing their own health. This results in non-adherence both in custody and frequently, following release. As some patients receive at least one medication to treat a mental illness during their time in custody this non-adherence after release may result in re-offending and further detention (Heilburn, A. 1979).**

A program designed by Pharmacy in Justice Health (JH) at the Long Bay Correctional Complex in Sydney, Australia, was designed to improve adherence to therapy of people with chronic diseases, both in custody and post-release; the project was approved by the Justice Health Therapeutic committee. The program simulates best community pharmacy services for this population; that is, those who are no longer free to manage their own health and being completely managed by Corrective Services staff. This initiative is new in the NSW Criminal Justice setting, but similar programs have been implemented in some UK prisons and in Victorian Correctional facilities. (Holmwood & Rae, 2003 and Victorian Justice Webpage)

"A pharmacy service for prisoners clearly states that the policy and the risk assessment criteria should be developed by local prison D&TC, there should be a process for assessing the risk on an individual basis" and "Medications in use, together with associated monitoring and administration devices, should normally, as a matter of principle, be held in the possession of prisoners" (NHS, medication in-possession, UK, 2005)

The Chief Pharmacist JH recognised that significant nursing time was spent managing "pill parades." Furthermore, inmates entitled to work-release were missing out on this important rehabilitation opportunity. For the elderly and infirm inmates appearing up to four times a day to receive medications was challenging, even if other operating procedures of the facility allowed them to. Clearly the needs of these clients for participation in their own health care were being neither appropriately evaluated nor

assessed. (Kettner, Moroney & Martin, 2000) The correctional environment is a unique community and comparing this situation to medication and personal health management in the community, this group was clearly disadvantaged. (Tansella & Thornicroft, 2001 and Jason, 1997)

The project considered patient diversity such as age, intellectual ability, gender and medication regimen complexity, aiming to:

- Actively involve all those [in custody] capable of self-management to improve their adherence both during their stay and after their release;
- Provide education and counselling about conditions and medications, empowering inmate patients to be responsible for their own health and wellbeing (Nelson, Lord & Ochocha, 2001);
- Reduce the incidence of medication administration errors;
- Reduce the time inmates spent queuing in pill parades" and time the nursing staff spent in administering medications, increasing their availability for direct patient care.

The project included three phases:

- The trial phase was for 4 weeks and recruited 100 patients.
- The review phase was for one week to review data from trial phase and amend the process.
- The implementation phase commenced with a teleconference to brief all users on the requirements, important notices and online user procedures manual (current stage).

*“A pharmacy service for prisoners clearly states that the policy and the risk assessment criteria should be developed by local prison D&TC, there should be a process for assessing the risk on an individual basis”*



The Self Medication Management Program (SMMP) provides a multi-disciplinary approach to patient care. Patient capacity (cognitive and physical) and motivation to self-medicate are assessed before the patient is deemed suitable to commence. (DoHA, National Mental Health Policy 2008) (see Figure 1).

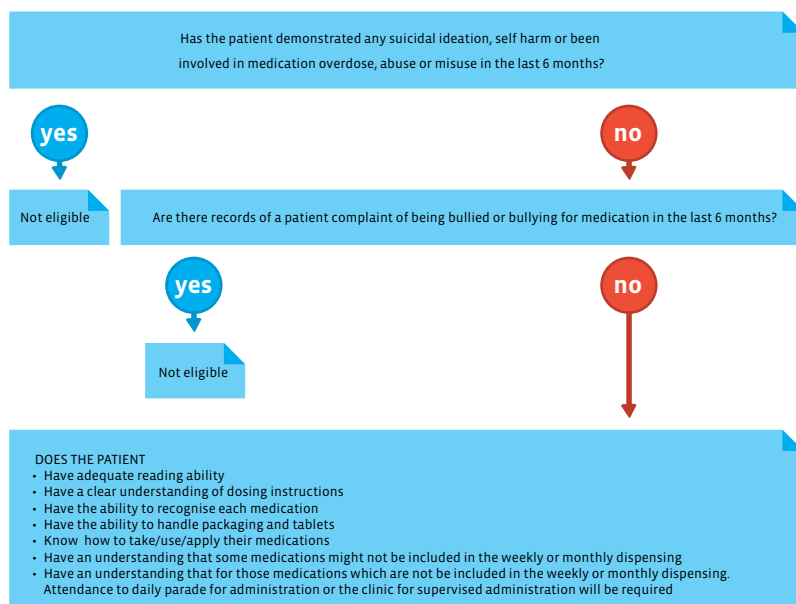


Figure 1 Patient risk assessment form (behaviour suitability)

The decision to include or exclude medications in the SMMP must be made by the prescribing doctor (based on medical condition) and the pharmacist (based on medications). Pharmacists conduct a complete medication review and assess the suitability of the medications for the custodial environment; room temperature, safety of the manufacturer's container, toxicity, ther-

peutic index margin and the requirement for blood or vital signs and ongoing monitoring (AMA, Health Care of Prisoners and Detainees Position statement, 1998). The patient consent form is then completed and kept in the patient's medical file (see Figure 2).

**I WILL BE RESPONSIBLE FOR MY OWN MEDICATION AND AGREE TO PARTICIPATE IN THIS PROGRAM**

I understand that:

1. A nurse, doctor and pharmacist will assess whether the program is suitable for me and my medications
2. If accepted I agree to:
  - a. Collect my medications as arranged by the clinic
  - b. Take my medication as prescribed
  - c. Take full responsibility for the safe keeping of my medication
  - d. Not store up, tamper with or give my medication to other persons
  - e. Return any unused medications to nursing staff
  - f. Advise Justice Health staff of any problems
3. I can obtain medication information when I request it
4. I can withdraw from this program at any time

Justice Health may terminate this program if:

1. I do not comply with the above
2. My medication requires significant change
3. I become unwell

SIGNATURE:	DATE:
WITNESS (RN / MO / DCS officer) SIGNATURE:	DATE:

Figure 2 Patient Consent Form

If there are doubts regarding the patients' comprehension, compliance or if sharing of medications becomes evident, the patient is immediately counselled or removed from the SMMP, whichever is deemed appropriate based on the seriousness of the incident, the patient safety and the safety of others.

All patients are supplied with consumer medication information (CMI) and self-care fact cards (on request). A participating patient's medication chart is annotated with "patient is on the SMMP". Photo identification images of the medications and the supplied quantity labels are affixed on the pack to support CS officers during their searches (see Figure 3).



Figure 3 Photographic Identification of Medications

On handing out the SMMP medications to the patients, nursing staff make an entry on the patient's medication chart, indicating the date of supply and quantity supplied, sign and date. The patient then signs a receipt.

If the medication is changed, the nursing unit manager informs the pharmacy to re-assess the patient's total medication (medication review) and re-assess the new medication for suitability of monthly dispensing. The treating medical officer, nurse or pharmacist as applicable should counsel the patient about his or her medication including indication, dosage and storage requirements. (DoHA, National Mental Health Policy 2008)



Corrective Services and police officers have a duty of care to allow patients access to their medications when they are aware that the person requires prescription medication. However, they are considered to be only acting as custodians or guardians and are not bound by [any] professional obligations, therefore cannot be held accountable or responsible for the issue or effect of the drug (CS Operations Procedures Manual, section 7.2.2.4).

Risk	Likelihood	Consequence	Rating
Suspicious of or actual Self-harm by over use or abuse	Possible	Major	2
Adverse reactions	Possible	Minor	3
Drug interactions	Possible	Minor	3
Medications theft or loss	Possible	Minor	3
Suspicion of hoarding, selling or sharing of medications	Possible	Moderate	2
Non compliance	Unlikely	Moderate	3
Refusal of treatment or medications	Unlikely	Moderate	3
Error in dispensing	Unlikely	Moderate	3
Error in handing the correct medications to the correct patient	Unlikely	Moderate	3

Figure 4 Project Risk Determination

### Project Evaluation

Six months from commencement, the pharmacy instituted an evaluation. Three evaluation questionnaires were lodged, one for the staff and two for patients. The staff questionnaires evaluated practicality and work-load aspects. The first patient questionnaire evaluated service, process and the product they received; the second one evaluated patient safety and the safety of their medications (see Figure 5).

Figure 5 Staff and Patient Questionnaires

#### Staff Questionnaire

##### *Risk assessment forms are easy to use*

Yes x 10

No x 5

##### *Effect on work load during initial recruitment phase*

Yes x 8

No x 7

##### *Effect on work load after the initial phase*

Yes x 9

No x 6

##### *Is the program good to have?*

Yes x 9

No x 6

#### Patients Questionnaire

##### *Do you understand what your medication is for?*

Yes x 19

No x nil

##### *Do you know the procedure to obtain information on your medication?*

Yes x 19

No x nil

##### *Are you happy with this service?*

Yes x 18

No x 1

##### *How does this service help you?*

Yes x 19

##### *Do you have any suggestions to improve this service?*

Yes, may be more male nurses, See the doctor more regularly

No x 17

Figure 5 cont'd

**Patients Questionnaire 2****Do you believe that your medication is safe with you?**

Yes x 44

**Do you have a safe place to secure your medications at all time?**

Yes x 42

No x 2

**Did you experience any incidents of standover from others that compromised the safety of your medications?**

No x 44

**Did you lose any medications since you started having them with you?**

No x 44

**Which is safer having the medications with you or administer them in Pill Parade?**

Safer with me x 43

Safer at pill parade x 1

**Which is more convenient having the medications with you or administer them in Pill Parade?**

With me x 42

Pill parade x 2

**Findings**

The results of the surveys showed that patient satisfaction of being empowered to manage their health as directed by medical and nursing staff, was extremely high.

**Feedback from Staff:**

- "A very good idea and dramatically reduces pill parade time allowing more time for patients and paperwork."
- "makes medication preparation a lot easier"
- "It is great help in maximum security where client movement is less"
- "A great idea, much better than having nursing staff standing at window giving pills for long periods"
- "Extremely good, for staff as well as for patients, giving them responsibility"
- "Much better idea, they are responsible in the outside world, so why not in the inside"
- "The program is much more efficient and empowering; it makes more sense in comparison to pill parade. Thanks for your amazing hard work"
- "Better for the inmates as they can have a sense of self control"
- "Teach patients responsibility towards taking their medications"
- "Good education for the patients"
- "Very good, Exclusion list should be in A-Z order, it should list medications like Avanza, not just say medication require blood test"
- "Makes the day to day run of the clinic, so much easier, therefore we have more time for patients"
- "It's all working well and hopefully to get more patients on the program"

- "Good to have in place, they should be responsible for themselves. More people to participate, increasing the numbers, allow time to organise."
- "A lot better when the paperwork is over, very efficient in compliance and self management."

Patients were willing to learn and participate in their own medication management which contributed to better compliance and better understanding of their own medication.

**Examples of patients' comments:**

- "I can take my pills first thing in the morning at the same time every day"
- "I do not have to wait in line every day, now I get my medication every month"
- "Regular monitoring for my heart condition, ensures the correct dose is given to me, I can then arrange my own scheduled routine for my medications"
- "Saves me coming to the window every day"
- "Making me responsible for my daily meds"
- "Enables me to collect my medications monthly, letting the nurses do their jobs"
- "Yes, my meds are now with me in case of emergencies"
- "Helps me keep track of my meds"
- "It is fantastic as I only have to come once a month, I love the system"
- "I know if I do have any problems, I will be taken care of"
- "As I am living in and working outside the centre, it is so helpful to be able to pick up monthly"
- "Time efficient"
- "I can take it at the right time daily"
- "Its adequate and should be provided to all inmates"
- "Yes, inmates are not interested in the medications I take"
- "No, I take them each morning and I have them with me over night"
- "Pills are safer with me not at the pill parade and it is not a problem with my kind of meds"
- "No problem with safety as it is Glucosamine"
- "I have never had incidents of standover or any one asking me for my meds, not many people know what I am on, I keep my business to myself, thanks for your concerns"

Sixty per cent of the staff reported satisfaction with the process and supported the commencement of the next phase. A random sample of 19 out of 1000 patients was surveyed, of which 95% reported that they became more knowledgeable about their medications and appreciated being involved and in control (*Questionnaire 1*). A second random sample of 42 from 2000 patients found that 98% of patients did not have any security problems with their medications and demonstrated a knowledge of the process, their medication and condition, the ability to work and the convenience and security with being in charge (*Lfe, 1995 and Sozomenou, Mitchell, Fitzgerald & et al, 2000*). The surveys also showed how the paradigm shift in practice affected nursing staff at the beginning and then grew into acceptance once the project commenced. Further, progressively they mastered the required compliance check and patient education aspects (*Thornicroft & Tansella, 1999*).

## Conclusions

The staff involved were initially overwhelmed by the new request of medication safety risk assessment for all patients eligible for the program. However, afterward they gained professional satisfaction and fulfilment due to the time they were then able to devote to clinical services, follow up, compliance and other patient-interactive services. Considering that the patient-group was/is not a stable population, the rate of release is almost equal to reception and the possibility of standover, hoarding and abuse is higher than in the community, an ongoing assessment and evaluation is necessary. ■

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## Authors' Information

**Hanan Abdalla**, *Formal Chief Pharmacist Justice Health NSW, Major Australian Defence Force – Army Canberra Joint Health Command and*

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## References:

- AMA**, *Health Care of Prisoners and Detainees Position statement*, 1998 from <http://www.ama.com.au/print/503>
- Department of Corrective Services Operations Procedures Manual**, section 7.2.2.4, 2009.
- DoHA**, *National Mental Health Policy 2008*, 2.6 participation and inclusion and access to the right care at the right time, from: <http://www.health.gov.au/internet/main/publishing.nsf/content/mental-pubs-n-p0108>
- Eckersley, R.**, 2001. *Culture, health and wellbeing*, in Eckersley, R., Dixon, J. & Douglas, B. (eds). *The social origin of health & wellbeing*, Cambridge: Cambridge University Press, pp.51-70.
- Garling, P.**, 2007-2009. *Caring together, the health action plan for NSW*, from: [http://www.health.nsw.gov.au/pubs/2009/pdf/caring\\_together\\_hap.pdf](http://www.health.nsw.gov.au/pubs/2009/pdf/caring_together_hap.pdf)
- Gomm, R.**, 1999. *Mental health and inequality*, in Heller, T. (ed.). *Mental health matters* Hampshire UK: Open University Press, pp.110-120
- Health Services – Department of Justice** from: <http://www.justice.gov.au/wps/wcm/connect/DOJ+Internet/Home/Prison/Prisoners>
- Heilburn, A.** 1979. *Psychopathy and violent crime*. *Journal of clinical psychology*, 1979; 47:509-516 in Butler, T., UNSW & JH pilot trial, *Treatment of repeat violent offenders with Sertraline 2008*.
- Holmwood, C. And Rae, D.**, (2003). *Prison health – A different place for GPs*, from: <http://www.AustralianFamilyPhysician.Vol.32.No.10.October.2003/reprinted>
- James, E.L. & Glade, F.R.**, (2002). *Drug Court: A Primer for the Family Physician*, from: [http://www.medscape.com/viewarticle/440100\\_print](http://www.medscape.com/viewarticle/440100_print)
- Jason, L.** 1997. *A sense of community, a sense of community in community building*. Values for sustainable future, Connecticut: Praeger, pp.71-87.
- Kettner, Moroney & Martin**, 2000. *Needs assessment. Approaches to measurement, designing and managing programs*. An effectiveness based approach, Thousand Oaks, California: Sage, pp.49-70

**Lfe, J.**, 1995. *Foundation of community work: a social justice perspective, community development*. Creating community alternatives – vision, analysis and practice, South Melbourne: Longman, pp.51-78.

**Meadows, G., Singh, B. & Grigg, M.**, (2006). *Mental health in Australia: Collaborative community practice* (2<sup>nd</sup> edition). Melbourne: Oxford University Press, chapter 7.

**National Prescribing Centre**, UK (2005). *A guide to improving practice in secure environments*, from: <http://www.npc.nhs.uk>

**Nelson, G., Lord, J. & Ochocha, J.**, 2001. *Moving ahead: towards and empowerment integration paradigm in community mental health, shifting the paradigm in community mental health*, Toronto: University of Toronto, pp.19-36

**Palmer, G. & Short, S.**, 2000. *Reforming health policy making, delivery and finance, Health care and public policy, an Australian analysis*, (3<sup>rd</sup> ed.), Melbourne: Melbourne, pp.303-343.

**Payne, J.**, 1999. *Planning your project, researching health needs*, London: Sage, pp.10-24.

**Prisoners – Provision of Medical Services**, PD2005\_527, (2005), from: <http://www.health.nsw.gov.au/policies>.

**Sozomenou, A., Mitchell, P., Fitzgerald, M.**, et al. 2000. *Barriers to and facilitators of consumer, carer and community participation, Mental health consumer participation in culturally diverse society*, 2<sup>nd</sup> eds, Melbourne: Australian Trans-cultural Mental Health Network, pp.59-77.

**Tansella, M. & Thornicroft, G.**, 2001. *The principles underlying community care*, in Thornicroft, G. & Szukler, G. (eds). *Textbook of community psychiatry*, Oxford: Oxford University Press, pp.155-165.

**Whiteford, H.**, 2001. *Can research influence mental health policy?* *Australian and New Zealand Journal of Psychiatry*, 35:428-434.

# Pharmacy Intervention in the Medication-use Process

## The role of pharmacists in improving patient safety

Advid Shah

The “Value of Innovation” is an odd theme when referring to patient safety. This is not a new concept and the ideas to bring about change are dated; yet the implementation of sweeping technologies, some old, some new, that can improve and help save the lives of thousands of patients each year completely suits the International Pharmaceutical Federation’s latest publication of the IPJ dealing with “critical issues challenging the pharmaceutical industry, health professionals and global public health in this new decade.” This article, a truncated version of a paper that was produced during an internship with the FIP in 2009, will explore the difficulties in defining patient safety, pharmaceutical care, the role of pharmacy in the medication-use process and prove our actual use and function in providing patient safety.

### **PATIENT SAFETY**

#### **A standard definition?**

The role of pharmacists has been clinically proven to improve many outcomes regarding patient health, including greater patient safety, improved disease and drug therapy management, effective healthcare spending, improved adherence and improved quality of life<sup>[1]</sup>. Health Canada and its own governing body on patient safety, the Canadian Patient Safety Institute (CPSI), formally established in 2003, acknowledge a lack of a standard definition of what patient safety is exactly making studies and generalizations about patient safety rather vague and difficult to conclude<sup>[2]</sup>. The World Health Organization (WHO), along with input from CPSI, has since developed a conceptual framework in order to build a standardized taxonomy for patient safety definitions that should make future projects dealing with patient safety standardized from researcher to researcher and applicable to a wider, international community<sup>[3]</sup>. The WHO’s new conceptual definition of patient safety reads as “the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment”<sup>[3]</sup>.

The explosive focus on patient care stemmed from a 1999 US report by the Institute of Medicine titled, *To Err is Human: Building a Safer Health System*. This report detailed the costs of medical errors to the US economy and how medical errors numbered higher than deaths due to AIDS, motor-vehicle accidents and breast cancer, combined. The report then went on to describe how errors can be reduced<sup>[4]</sup>. Ten years have passed since that report was published in the US, yet organizations and institutions around the world are still having difficulty identifying, incorporating and utilizing measures to help improve patient safety and reducing errors. The word “error”, itself, brings about actions for prevention and distracts from the main goal of getting the right drug, with the right dose, with the right route, at the right time, to the right patient, a phrase known as “the five rights”<sup>[5]</sup>. Acknowledging that errors will happen due to the human condition is one thing and then blame is easily placed on that individual, however many experts in patient safety see new and existing errors as a fault with the systems that are in place. The systems approach assumes that a number of errors are inevitable and that the work environment can lead to the likelihood of certain errors occurring<sup>[6]</sup>. However, the systems approach says nothing of an individual’s responsibility to prevent medical errors and should not be seen as an excuse for a culture that relies on others to identify





and resolve errors or where errors are seen as being inevitable<sup>[7]</sup>. A Danish report on patient safety and medication errors in 2004 reported up to 0.6% of prescriptions handled in the UK resulted in errors and up to 15.2% of those reached the consumer. More alarming is that 8.7% of those errors can result in fatality<sup>[8]</sup>. Although patient safety may be a relatively new global issue in healthcare, its relevance has been at the forefront in some major countries such as Australia since 1989, in the USA since the late 1990's and the UK since 2001.

### Errors and near misses

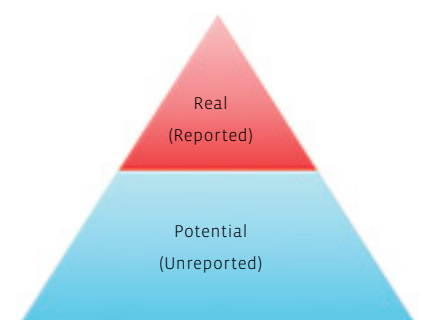
So where do these errors arise from? Many scientists have attempted to answer this question, but the ambiguity of what an “error” is and how it is reported make generalizations difficult. Many of the studies done to date, have looked primarily into hospital error prevention and have identified all major steps in the medication-use process as areas for improvement, the systems approach. More often, the most common errors discovered were in dosing errors, directions that were unclear or missing and incorrect prescriptions<sup>[9,10]</sup>. Other contributing factors include interruptions, distractions, poor working environments (job satisfaction, employee interpersonal relationships, workload, other responsibilities and physical setup) and poorly disseminated information from one healthcare professional to another (poorly written prescriptions, no communication at all, or incomplete information) – a breakdown in seamless care. A new concept in error typing, which further adds to the ambiguity of what an error is, is the term “near misses”.

Voluntary reporting of medication errors and near misses make up what we know of medication errors in general, however, a large proportion of medication errors are unknown. This is what is known as the iceberg phenomenon where what we know presents the tip of the iceberg and what we don't know of medication errors is much like the rest of the iceberg where almost 90% of it is hidden under water (*Figure 1*). However simply filling in more forms is not the only answer as it has been found that response rates decline as those filling out the forms notice their reports are being ignored, no action has resulted from filling out the form, or they mistakenly believe that filling out the medication error report is an admission of carelessness, neglect, or incompetence and thus fear being blamed and held liable<sup>[11]</sup>. Errors are best remedied when all errors, real or potential, are reported and evaluated as part of a continuous quality assurance program. As such, the Danish National Board of Health departed from the usual stance of their healthcare workers voluntarily reporting medication errors and in 2003 enacted the Act on Patient Safety in the Health Service that obligated all healthcare workers to report adverse drug reactions to a national reporting system. In addition, the Danish National Board of Health and all hospital owners are mandated to take the appropriate corrective actions<sup>[12]</sup>.



*Figure 1*

*The Iceberg Phenomenon as related to real (what we see) and potential errors (what is hidden)*



## PHARMACEUTICAL CARE

To understand how pharmacy plays a role in patient safety, one must look at the level of care the profession provides already. The International Pharmaceutical Federation (FIP) amended and adopted Hepler and Strand's definition of pharmaceutical care to read as "... the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve or maintain a patient's quality of life"<sup>[13]</sup>. Thus, one can view pharmaceutical care as a vital component to providing patient care. It seems odd, however, that the practice of pharmaceutical care is relatively a new venture in healthcare itself and even more puzzling as to its slow uptake into the medication-use process. The "five rights" are seemingly the intention of every pharmacist in everyday practice, however human nature and its beauty to distinguish one individual from another based on "imperfections" prevents a robotic and error-free environment from occurring.

### Errors in dual-process reasoning

Looking at the pharmacist, human factors that contribute to medication errors and therefore a breakdown in pharmaceutical care, result from three broad classifications, modal (the way in which errors occur), contextual (dealing with the specifics involved) and psychological. The latter category includes knowledge-based, rule-based, action-based and memory-based errors<sup>[14]</sup>. These four subcategories make up what are known as flaws in dual-process reasoning (Figure 2). As part of this process, System One reasoning is based on previous experience, intuition, association and assumed thinking, that is to say, it is without a lot of thought involved and almost robotic in nature. Rule-based errors, "using a bad rule or misapplying a good rule" and action-based errors, "slips", fall into System One type reasoning errors. Knowledge-based and memory-based errors fall into System Two type reasoning errors which is an analytic, slow and cognitively demanding process, where every situation is treated independently of other past experiences, even if they are exactly the same<sup>[14,15]</sup>. Logically, System Two reasoning would lead to fewer pharmacist' errors, however time constraints, workplace demands, patient demands and the inability for pharmacists to assert themselves and their role in the medication-use process – their value to society – can lead to a failure in this process and therefore result in errors being made.

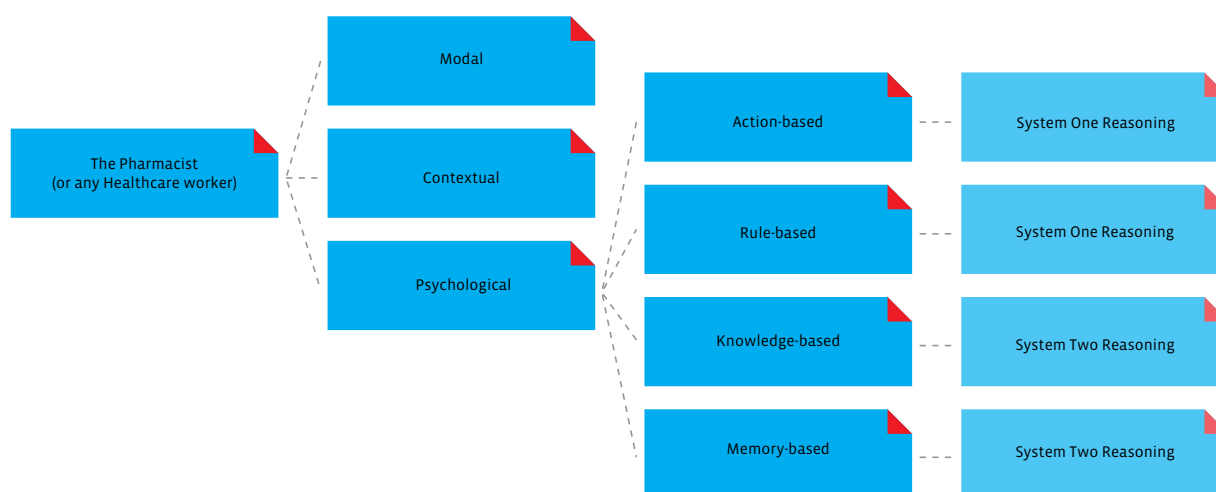


Figure 2 – Concept of dual-processing reasoning that can lead to Pharmacist based errors.

### What pharmacy can do

The role of pharmacy in the medication-use process has been proven to be beneficial in the areas of medication history taking, patient and drug education committees, therapeutic drug committees and integration of technology<sup>[16]</sup>. The profession has long argued over changes to the process itself to include enhanced interdisciplinary collaboration, reduce therapy-related errors and to find well-functioning models and create more of these models as medication demands increase over the years<sup>[17]</sup>. The rate of adoption for new technology can be prolonged up to 20 years with different pharmacies (including acute care settings) adopting varying innovations, formats and systems making communication between healthcare facilities sometimes difficult due to incompatible technologies. In addition, not every technology is necessarily sustainable either economically or through patient or healthcare worker acceptance<sup>[16]</sup>.

### The medication-use process

In order to understand how pharmacists reduce errors, we must look at where in the medication-use process these errors are occurring. The United States Pharmacopeia identifies five major categories in the medication-use process: 1. Prescribing; 2. Transcribing/documenting; 3. Dispensing; 4. Administration; and 5. Monitoring<sup>[18]</sup>. The WHO uses three distinct phases of medication use: prescribing, administration and monitoring<sup>[19]</sup>. The five processes outlined by the USP and the three processes outlined by the WHO can be grouped into three major categories when talking about patient safety and the role that the pharmacist and pharmacy can play when making appropriate interventions to ensure patient safety – either preventatively or after the incidence has occurred. Here, using both of these references, we streamline the USP medication-use processes 1 and 2 to form the first category called prescribing; process 3 will form

the second category called dispensing; and processes 4 and 5 will make up the third category called administration<sup>[18]</sup>. This classification system also allows one to draw links between the level at which the pharmacist's intervention occurred – the location – and which healthcare team would be more likely to be involved (*Figure 3*). Studies have shown that prescribing errors account for roughly 39% of all errors during the medication-use process and are due to a lack of knowledge of the prescribed drug, lack of an established relationship with the patient, mental slips from distractions, or calculation errors. Transcription and verification account for 12% of errors and are mainly due to the inability to read illegible handwritten prescriptions, the use of abbreviations and misusing leading and trailing zeros. Calculation errors, preparation errors and distribution errors contribute to 11% of the errors made during the dispensing stage of the medication-use process. Finally, 38% of errors occur during the administration of medications due to the “five wrongs”, look-a-like packaging, failing to double check, failing to understand what the drug does, unclear medication orders and understaffing<sup>[16,20]</sup>.

### Pharmacy intervention in the medication-use process

To see where pharmacy can and has worked at reduce medication related errors, the FIP investigated the medication-use process as outlined above in the three main categories of prescribing, dispensing and administration, respectively; the errors that can result at each stage of the process; the pharmacy intervention that can be applied to prevent or reduce the number of the errors; and the pharmaceutical organizations that are, in the past or currently, working on improving patient safety at each stage. Available on the FIP's website, are tables that outline the function and application of the pharmacist in the medication-use process and proves how the profession goes well beyond what society believes is the traditional role of pharmacists, dispensing.



Figure 3

*The relationship between the healthcare team and location (team – location) of where the pharmacist's intervention can occur in the medication-use process as set out in this paper.*

### Future roles

The medication-use process is complicated and relies on the support and input from many professional disciplines to work properly and to reduce errors. By creating a culture based on patient safety early in one's education, the premise is set at the beginning to take responsibility of one's actions and realize the consequences of one's actions even though our focus is set on a systems based approach for medication errors and blame. In addition, by consolidating the systems that have a proven history of successfully reducing errors in the medication-use process and by sharing information between pharmacy organizations, the hope is to come up with one standardized process to follow and improve upon. It is important to foster new and novel ideas to improve patient safety and to implement these ideas into the medication-use process as quickly as possible. Of course, issues arise such as territorial rights, differences in the scope of pharmacy practice and interprofessional collaboration, which make sweeping implementation of one standardized and safer medication-use process difficult, however the main result of in-

creasing patient safety is the end goal of each profession involved in the medication-use process, each country's governing body on patient safety and each government looking at reducing medication and healthcare costs. The role of pharmacy in reducing errors that occur during the medication-use process is invaluable, growing and proven to be clinically significant over the interventions made by other healthcare professions. The future role of pharmacy is to assert itself amongst the other healthcare disciplines

as a critically important profession needed to reduce errors made in the medication-use system; to bring about change and make the appropriate interventions where pharmacy has yet to make an impact on (as seen in the missing information on pharmacy interventions in table 1); and to continue to be the most trusted healthcare profession as viewed by the public by expanding the clinical roles of pharmacists. ■

### Author's Information

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### References

1. Canadian Pharmacists Association. (2008). Retrieved 2009 13-November from pharmacists.ca: [http://www.pharmacists.ca/content/consumer\\_patient\\_resource\\_centre/working/pdf/Expanding\\_the\\_Role\\_of\\_Pharmacists.pdf](http://www.pharmacists.ca/content/consumer_patient_resource_centre/working/pdf/Expanding_the_Role_of_Pharmacists.pdf)
2. Gardner J.P., Baker R.B., Norton P. and Brown A.D. (2002 August). *Governments and Patient Safety in Australia, the United Kingdom and the United States: A Review of Policies, Institutional and Funding Frameworks and Current Initiatives: Final Report*. Retrieved 2009 13-November from <http://www.hc-sc.gc.ca/hcs-sss/pubs/qual/2002-gov-patient-securit/index-eng.php>
3. World Health Organization. (2009 January). The Conceptual Framework for the International Classification for Patient Safety (v1.1) Final Technical Report and Technical Annexes. World Health Organization Global Press.
4. Institute of Medicine. (1999). *To Err is Human: Building a Safer Health System*. (C. J. Kohn L.T., Ed.) Washington, DC, USA.
5. Benjamin, D. (2003 July). *Reducing medication errors and increasing patient safety: case studies in clinical pharmacology*. Journal of Clinical Pharmacology , 43(7). USA: SAGE Publications.
6. Longo D.R., H. J. (2005). *The Long Road to Patient Safety*. Journal of American Medical Association .
7. Beso A., F. B. (2005). *The frequency and potential causes of dispensing errors in a hospital pharmacy*. Pharmacy World & Science .
8. Knudsen, P. (2004). *Evidence Report 8: Patient safety and medication errors*. Pharmakon. Denmark: Pharmakon.
9. Prescrire international. (2004). Preventing medication errors. Prescrire international , 13 (72).
10. Feifer R.A., N. L. (2003). *Mail-order prescriptions requiring clarification contact with the prescriber: prevalence, reasons and implications*. Journal of Managed Care Pharmacy , 9 (4).
11. Anderson D.J., W. C. (2001). A systems approach to the reduction of medication error on the hospital ward. Journal of Advanced Nursing , 35 (1).
12. Knudsen P., H. H. (2007). Preventing medication errors in community pharmacy: frequency and seriousness of medication errors. Quality and Safety in Health Care .
13. Wiedenmayer K., Summers R.S., Mackie C.A., Gous A.G.S., Everard M. and D. Tromp. (2006). *Developing pharmacy practice: a focus on patient care*. Handbook – 2006 edition. World Health Organization, Department of Medicines Policy and Standards. Den Haag: WHO/FIP.
14. Aronson, J. (2009). Medication errors: what they are, how they happen and how to avoid them. Quarterly Journal of Medicine , 102.
15. Schroyens W., S. W. (2003). In search of counter-examples: Deductive rationality in human reasoning. The Quarterly Journal of Experimental Psychology , 56 (7).
16. Schneider, P. (2007). Opportunities for pharmacy. American Journal of Health-System Pharmacists , 64 (9).
17. Cooksey J.A., K. K. (2002). Challenges To The Pharmacist Profession From Escalating Pharmaceutical Demand. Health Affairs , 21 (5).
18. USP. (2004). <http://www.usp.org/pdf/EN/patient-Safety/medicationUseProcess.pdf>. Retrieved 2009 12-November from United States Pharmacopeia.
19. World Health Organization. (2009). WHO Patient Safety Curriculum Guide for Medical Students. Retrieved 2009 17-November from World Health Organization: [http://www.who.int/patientsafety/education/curriculum/who\\_mc\\_topic11.pdf](http://www.who.int/patientsafety/education/curriculum/who_mc_topic11.pdf)
20. van den Bemt P.M.L.A., E. T.-v. (2000). *Drug-Related Problems in Hospitalised Patients*. Drug Safety , 22 (4).



# Innovative Partnerships, Expanding Practice

## MTM benefit for University employees

Lowell J. Anderson

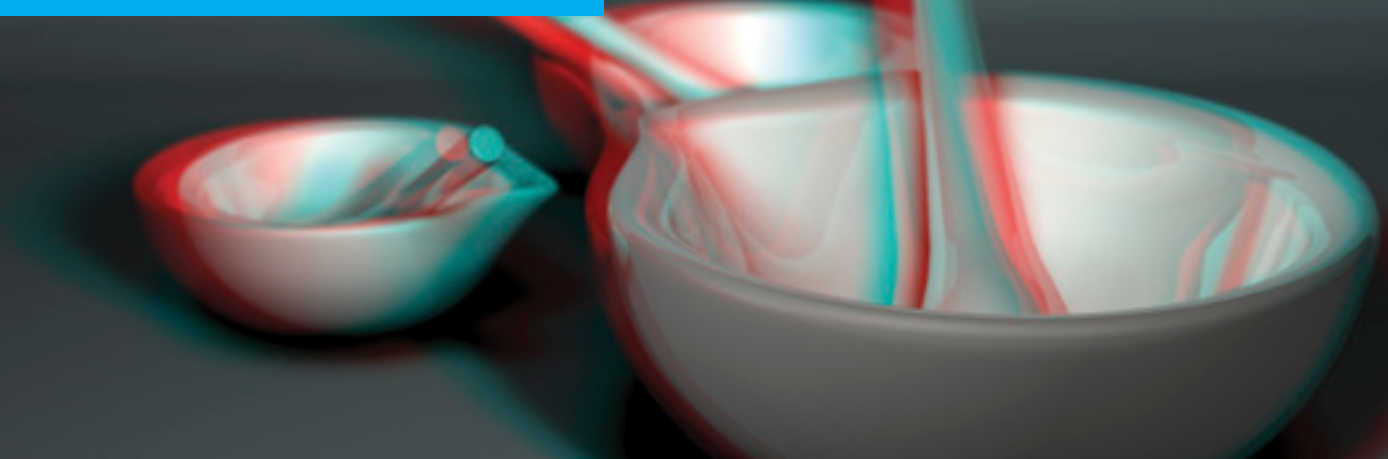
**Much attention is being given to the need for innovation. Certainly the users of health services – our customers and our governments – are looking for ways to improve quality of care and reduce the costs of care. As pharmacists, we are innovative in the use of new technologies in the compounding and dispensing of medicines, as well as how we manage our practices and how we use human resources in our pharmacies.**

Our profession has also adopted the philosophy of “pharmaceutical care” as central to the practice of our profession and we are using its market-level application, medication therapy management (MTM) in our practices. That is an innovation! But, are we being innovative in the way we encourage the purchasers of our services to look at and understand the value of MTM as a services that can improve the quality of health, reduce costs and improve customer satisfaction? Likewise, are we encouraging the consumers of our services to understand the value of our pharmacists provided MTM?

The faculty of the college of pharmacy at the University of Minnesota in the USA took up the challenge by asking the question of itself: Can we use the information that we have about the benefit of MTM to convince the University to offer MTM services by pharmacists as a covered benefit for its 39,000 employees?

Researchers at the University of Minnesota had good evidence that MTM services assist the patient and physician in achieving the desired medicines-therapy outcomes. In a study published in the March/April 2008 issue of Journal of the American Pharmacists Association, pharmacy professors Brian J. Isetts and Stephen W. Schondelmeyer and their associates examined pharmacist-provided MTM to Blue Cross Blue Shield members reported that 637 drug therapy problems were resolved among 285 intervention patients. The types of drug therapy problems addressed were effectiveness, safety and adherence to prescribers’ directions. Many of the resolutions involved additional medicines therapy, or changing the dosage of a medicine. Further, the percentage of patients who achieved therapy goals increased from 76 percent to 90 percent.

Measures from the Healthcare Effectiveness Data and Information Set (HEDIS), a widely used set of performance measures, improved in the intervention group for hypertension by 71 percent, compared with 59 percent in the control group. For cholesterol management, the figures were 52 percent and 30 percent, respectively. Total health expenditures decreased from \$11,965 per person to \$8,197. The reduction in total annual health expenditures exceeded the cost of providing MTM by a 12-to-1 ratio, the researchers reported. ►



This was compelling information. After carefully reviewing the evidence, in March 2009 the University of Minnesota employee health plan (UPlan) added an MTM benefit that includes face-to-face appointments with a pharmacist to assess the patient's prescription medications, over-the-counter drugs and nutritional supplements.

In the University's MTM benefit, providers are pharmacists who are credentialed to provide these services. Any pharmacist who was graduated in or after 1996 can become credentialed without further study. Those who were graduated before that must complete an approved continuing education certificate program. The pharmacist must use an electronic documentation and billing system. The program is open to MTM credentialed pharmacists regardless of their practice location. As a result we have practitioners in independent, chain, hospital and clinic pharmacies. The UPlan MTM benefit differs from most in that all MTM services must be delivered "face-to-face." Many MTM programs rely on telephone call centers for conversations between members and pharmacists. It is our belief that the relationship between the pharmacist and the patient is important in achieving the desired outcomes.

The elements of an UPlan MTM benefit are:

#### Eligibility

Plan members who use four or more prescriptions for chronic conditions can self-refer into the benefit. If the members use fewer chronic prescriptions and are having difficulties due to their abilities or the complexity of the therapy, they may be referred into the program by their physician.

#### Benefit

Program is designed so that the pharmacist, member and physician work together to establish and achieve medicine treatment goals, avoid or minimize undesirable effects from medicines and improve clinical outcomes.

#### Services

The UPlan at the University of Minnesota includes:

- Assessment of the member's health status
- Comprehensive medicine review to identify, resolve and prevent problems related to medicines
- Development of a medicines therapy treatment plan
- Monitoring and evaluation of the member's response to therapy, including safety and effectiveness

- Documentation of the care delivered and communication with the member's primary physician
- Education and training designed to enhance the member's understanding and appropriate use of medicines
- Information, support services and resources designed to enhance the member's compliance
- Coordination and integration of MTM services within the broader health-care services provided to members

#### Member costs

The UPlan provides incentives to the member to use and follow the MTM program. There is no copay or other cost to the member for the consultations with the pharmacist. In addition, UPlan will waive the base copay (currently \$8) for all prescriptions for the first six months after enrollment—a savings to the member of at least \$192, depending on the number of prescriptions being used. The member is expected to work actively with the pharmacist while enrolled in the program.

Worldwide, the growth in expenditures for medicines is an important public-policy issue. Inappropriate use of medicines takes money away from other health services and in countries such as the U.S. where much of health-insurance cost is individual it affects premiums and the ability of some patients to afford to adhere to a prescribed course of medicine therapy.

The faculty of the college of pharmacy in Minnesota recognized the ability of pharmacists in managing the use of medicines and addressing both the cost and quality issues surrounding medication therapy. The faculty was innovative in accepting responsibility for an active role in advancing the practice of pharmacy and improving the quality of the outcomes of the University employees health plan. In the U.S. that is called "Walking the talk." ■

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# Innovation in Telemedicine

## The future of medicine... NOW!



Mahesh B. Kharadi, Dr. Ravindra N. Kamble, Dr. Atmaram P. Pawar

*“Telemedicine is not an evolutionary concept but a revolutionary concept and at the heart of every revolution, there is the need for a sudden massive change, at the core of which is the human mind.”*

Telemedicine facilitates the provision of medical aid from a distance. It is an effective solution for providing specialty healthcare in the form of improved access and reduced cost to the rural patients and the reduced professional isolation of the rural doctors. Telemedicine can enable ordinary doctors to perform extra-ordinary tasks.

Telemedicine has rapidly evolved from a means to full fill outstanding care needs to a platform for delivering innovative and collaborative care by leveraging physicians from multiple sites.<sup>[1]</sup>





## TELEMEDICINE CONCEPT

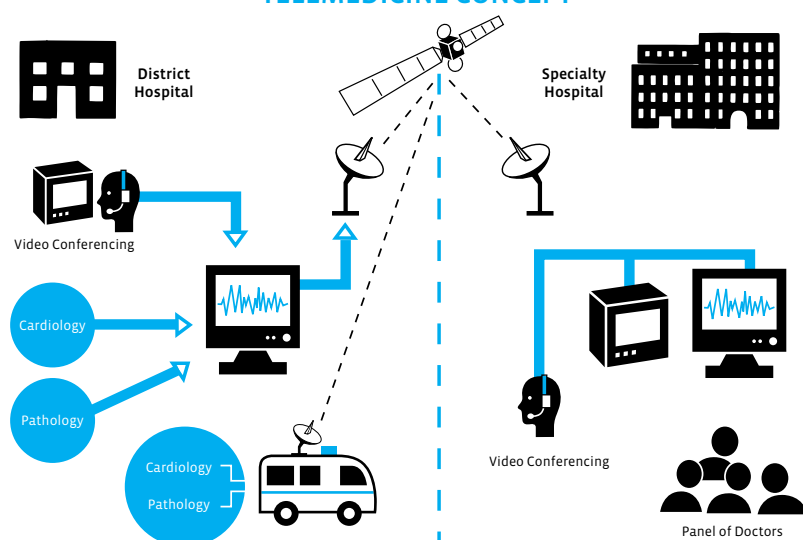
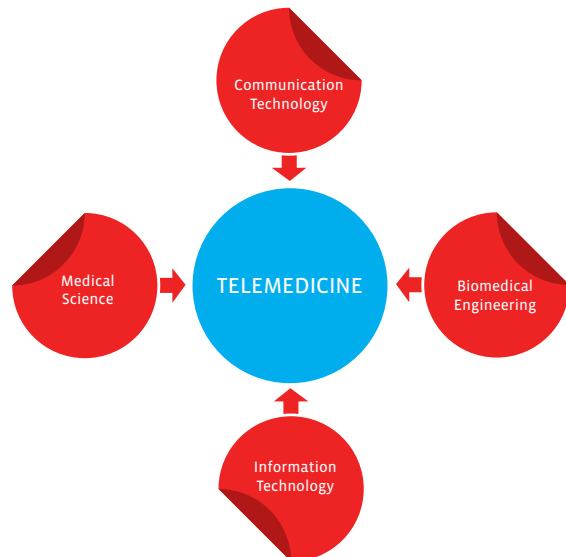


Figure 1 Reaching the un-reached

Extension of Education for Doctors in Rural/Remote areas

General Doctors to learn from specialists and perform effectively

Telemedicine may be defined as “The delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities”<sup>[2]</sup>



Clinical applications of eHealth system are driven by telemedicine technology for communication and consultation of clinical cases between a patient and a doctor or peer-to-peer. Telemedicine can bridge the human resources gap between low-resource (rural) areas and high-resource (urban) areas for effective management of even complicated diseases in remote locations.

Telemedicine is a rapidly developing application of clinical medicine where medical information is transferred through the phone or the Internet and sometimes other networks for the purpose of consulting and sometimes remote medical procedures or examinations. Telemedicine may be as simple as two health professionals discussing a case over the telephone, or as com-



plex as using satellite technology and video-conferencing equipment to conduct a real-time consultation between medical specialists in two different countries. Telemedicine generally refers to the use of communications and information technologies for the delivery of clinical care. “Care at a distance” (also called “in absentia” care), is an old practice which was often conducted via post. There has been a long and successful history of in absentia health care which, thanks to modern communication technology, has evolved into what we know as modern telemedicine. In its early manifestations, African villagers used smoke signals to warn people to stay away from the village in case of serious disease. In the early 1900s, people living in remote areas in Australia used two-way radios, powered by a dynamo driven by a set of bicycle pedals, to communicate with the Royal Flying Doctor Service of Australia. The terms e-health and telehealth are at times wrongly interchanged with telemedicine. Like the terms “medicine” and “health care”, telemedicine often refers only to the provision of clinical services while the term telehealth can refer to clinical and non-clinical services such as medical education, administration and research. The term e-health is often, particularly in the UK and Europe, used as an umbrella term that includes telehealth, electronic medical records and other components of health IT.<sup>[2]</sup>

### Types of telemedicine

Telemedicine can be broken into three main categories: store-and-forward, remote monitoring and interactive services.<sup>[5,10]</sup>

1. Store-and-forward telemedicine involves acquiring medical data (like medical images, bio signals, etc) and then transmitting this data to a doctor or medical specialist at a convenient time for assessment offline. It does not require the presence of both parties at the same time. Dermatology, radiology and pathology are common specialties that are conducive to asynchronous telemedicine. A properly structured Medical Record preferably in electronic form should be a component of this transfer. A key difference between traditional in-person patient meetings and telemedicine encounters is the omission of an actual physical examination and history. The store-and-forward process requires the clinician to rely on history report and audio/video information in lieu of a physical examination.
2. Remote monitoring, also known as self-monitoring/testing, enables medical professionals to monitor a patient remotely using various technological devices. This method is primarily used for managing chronic diseases or specific conditions, such as heart disease, diabetes mellitus, or asthma. These services can provide comparable health outcomes to traditional in-person patient encounters, supply greater satisfaction to patients and may even be cost-effective.
3. Interactive telemedicine services provide real-time interactions between patient and provider, to include phone conversations, online communication and home visits. Many activities such as history review, physical examination, psychiatric evaluations and ophthalmol-

ogy assessments can be conducted comparably to those done in traditional face-to-face visits. In addition, “clinician-interactive” telemedicine services may be less costly than in-person clinical visits.

### Telemedicine benefits

Telemedicine is most beneficial for populations living in isolated communities and remote regions and is currently being applied in virtually all medical domains. Specialties that use telemedicine often use a “tele-” prefix; for example, telemedicine as applied by radiologists is called Telecardiology. Similarly telemedicine as applied by cardiologists is termed as telecardiology, etc.<sup>[6]</sup>

Telemedicine is also useful as a communication tool between a general practitioner and a specialist available at a remote location.

The first interactive Telemedicine system, operating over standard telephone lines, for remotely diagnosing and treating patients requiring cardiac resuscitation (defibrillation) was developed and marketed by MedPhone Corporation in 1989. A year later the company introduced a mobile cellular version, the MDphone. Twelve hospitals in the U.S. served as receiving and treatment centers.

Monitoring a patient at home using known devices like blood pressure monitors and transferring the information to a caregiver is a fast growing emerging service. These remote monitoring solutions have a focus on current high morbidity chronic diseases and are mainly deployed for the First World. In developing countries a new way of practicing telemedicine is emerging better known as Primary Remote Diagnostic Visits whereby a doctor uses devices to remotely examine and treat a patient. This new technology and principle of practicing medicine holds big promises to solving major health care delivery problems.<sup>[5,10]</sup>

### Some specific benefits of telemedicine<sup>[9]</sup>:

To Rural Physicians and clinics (spoke sites)

- Receive education from the specialist/provider
- Better health outcome for their patients
- Enhanced community confidence in local healthcare
- Attend continuing medical education courses from their clinic

### To patients

- Loved ones remain in their community with family support
- Cost savings from not having to travel extensively
- Immediate urgent care
- Confidentiality of specialty examination or visit (Because the patient visits the general practice doctor, he can be seen for any specialty care without anyone else knowing)
- Patient education courses (nutrition, oncology, etc.)
- Properly stabilize patient prior to transport
- Early Diagnosis prior to escalated medical episode

### Rural patients

- Patients that routinely travel to visit doctors in large urban areas tend to purchase their goods and services from those cities; Telemedicine makes it easy.

### To telemedicine providers (hub sites)

- Expand patient outreach
- Major surgical procedures resulting from the initial telemedicine consultation
- Reduction in visits
- Promotion of Hospital
- Charge tuition for clinician education courses (CME, CNE, etc.)

### Telemedicine technology

- Networked programs link tertiary care hospitals and clinics with outlying clinics and community health centres in rural or suburban areas. The links may use dedicated high-speed lines or the Internet for telecommunication links between sites. According to one estimation the number of existing telemedicine networks in the United States is roughly 200, providing connectivity to over 3,000 sites.
- Point to Multi Point Systems – One patient end at a time connected to any of the specialist Doctor's end within the hospital.
- Point-to-point connections using private high speed networks are used by hospitals and clinics that deliver services directly or outsource specialty services to independent medical service providers. Such outsourced services include radiology, stroke assessment, mental health and intensive care services.
- Monitoring center links are used for cardiac, pulmonary or fetal monitoring, home care and related services that provide care to patients in the home. Often normal land-line or wireless connections are used to communicate directly between the patient and the centre although some systems use the Internet.

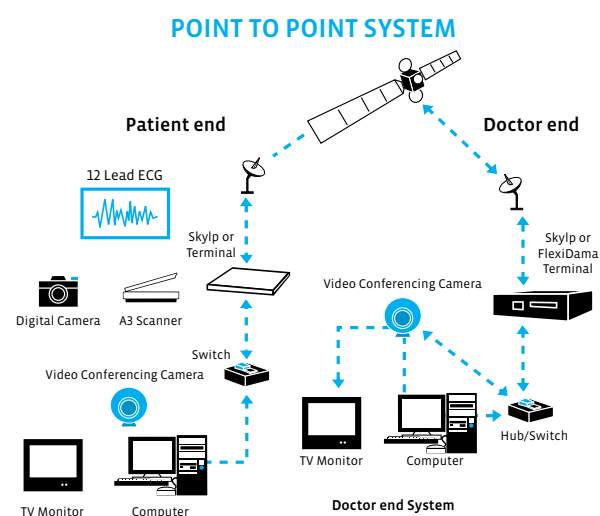


Figure 2 Point To Point system

- Multi Point to Multi Point System – Several patient's end simultaneously connect to different Doctor's end at different hospitals at different geographical locations.
- Web-based e-health patient service sites provide direct consumer outreach and services over the Internet. Under telemedicine, these include those sites that provide direct patient care.<sup>[2]</sup>

### MULTIPOINT-TO-MULTIPOINT SYSTEM

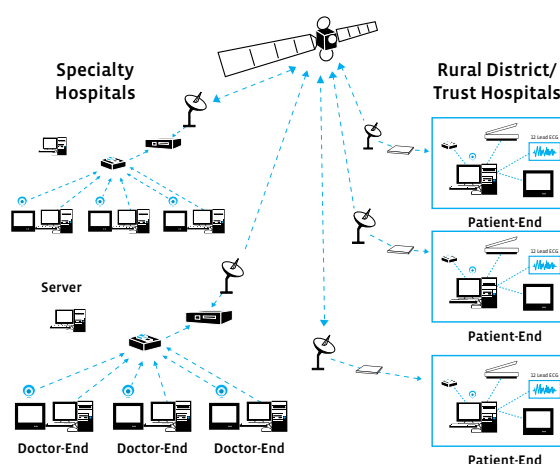


Figure 3 Multipoint –To-Multipoint system

### Major areas of telemedicine technology adopted [8, 9]

Tele-consultation Tele-diagnosis Tele-treatment	The patient with the local doctor consults the specialist, obtains the line of treatment.
Tele-education Tele-training	For Continuing Medical Education, Training for doctors & paramedics from a higher level Hospital/Institution
Tele-monitoring	Regular monitoring for intensive care & emergency care
Tele-support	Support during disaster management

Table 1 Telemedicine Technology

### Telemedicine program – thrust areas

Providing technology and connectivity<sup>[2]</sup>

- Remote/Rural Hospitals and Specialty Hospitals
- Continuing Medical Education (CME)
- Mobile Telemedicine Units
- Disaster Management Support (DMS)

### Challenges to telemedicine

Several obstacles remain with regard to the effectiveness of telemedicine. Legal issues regarding *physician licensing, liability and patient confidentiality* exist. As physicians are licensed by states, this presents a legal problem when physician consults cross state lines. It is necessary in order to fully benefit from telemedicine that states engage

in interstate provision of service. Currently, interstate agreements vary greatly. Several states maintain that physicians must be licensed in both the sending and receiving states. Other states have entered reciprocity agreements with neighbours.<sup>[7]</sup>

*Liability* is an obstacle in providing telemedicine. There is debate related to which physician would be liable for a poor patient outcome, the primary care or the consulting physician. In the case of a poor outcome, it is not clear if the patient should file suit in the residing state or in the state the practitioner is located.

*Cost* is a significant barrier to access. It has been estimated that the start up cost for a rural facility can be \$100,000. In addition to start up costs, consideration must be given to the charge by the consultation team. This may range from \$75-250 per hour, depending on the type and number of consultants involved. Transmission charges can be costly. Some progress has been made in this area with the passage of the Telecommunication Competition and Deregulation Act of 1996. As of January 1, 1998, the Federal Communications Commission (FCC) and states can require affordable, quality communication services. Included is an amendment requiring public and non-profit rural health care provider access to telecommunication service at prices comparable to those paid by urban customers. The rules specifically authorize discounted rates for telecommunication distant charges, toll-free access to the Internet and telecommunication services of bandwidth up to and including Mbps.

*Reimbursement* has been another obstacle in providing telemedicine services. Medicare will reimburse for telemedicine services provided in rural counties that are designated as health professional shortage areas. Most commercial payers do not cover routine telemedicine consultation. Physician reluctance and patient apprehension are also obstacles. Some rural physicians fear the loss of patients to urban facilities. The public and physicians worry about the impersonality of telemedicine.<sup>[4]</sup>

#### The future

The telemedicine endeavour is expanding its outreach and has the potential to open up new frontiers for facilitating rural healthcare in India. Encouraged by the steady growth of its Telemedicine programme, ISRO (Indian Space Research Organization) has also envisioned the development of "HEALTHSAT", an exclusive satellite for meeting the healthcare and medical education needs of the country at large. This satellite, when deployed along with wireless and terrestrial communication links, can bring a large change in augmenting the present healthcare delivery system in the country. Due to the untiring efforts of various departments like the Department of Space and the Department of Information Technology, State Governments, NGOs and Private and Corporate Hospitals/Agencies, the majority of the rural population all over the country will stand to benefit from Telemedicine Techno-

logy that can usher in a revolution for transforming the face of Healthcare in India. Thus, Telemedicine can enlarge the gap between life and death and can extend quality Healthcare to the needy and the under privileged rural, semi rural and urban population at large.<sup>[2]</sup> ■

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#### References

1. *Telemedicine: Theory and Practice*, edited by R. L. Bashshur, J. H. Sanders and G. W. Shannon. Springfield, IL: Charles W. Thomas, 1997.
2. *Telemedicine "Healing Touch through Space"*, ISRO, 2005.
3. **Susan et al.**, *Tele-Education in a Telemedicine Environment: Implications for Rural Health Care and Academic Medical Center*, Journal of Medical Systems, Vol. 23, No. 2, 1999.
4. *"University of North Dakota school of medicine & health science"*, April-1998.
5. **Sood S P**, *Telemedicine adoption in India-The new drivers*, e-health magazine, vol-2, issue-5, may -2007.
6. **Field J.M**, *Telemedicine: A Guide to Assessing Telecommunications for Health Care*, 1996.
7. **Menachemi Nir et al.**, *Factors Affecting the Adoption of Telemedicine – A Multiple Adopter Perspective*, Journal of Medical Systems, Vol. 28, No. 6, December 2004.
8. *Recommended Guidelines & Standards for Practice of Telemedicine in India*, May, 2003.
9. **Michael Ackerman, Richard Craft et al.**, *Telemedicine Technology*, TELEMEDICINE JOURNAL AND e-HEALTH Volume 8, Number 1, 2002.
10. [Telemedicine.com](http://Telemedicine.com)

# The Value of Pharmaceutical Innovation

## Global versus Indian prospective

Dr. T.M.Pramod Kumar, Ravi Valluru, M.P.Venkatesh, Balamuralidhara V. & Gangadharappa H.V.

**Pharmaceutical innovation is a vital part of improving and saving lives around the world. New medicines, vaccines and other medical tools have revolutionized medical practice in the past century, leading to incredible health improvements. Indirectly, these medical technology advances have contributed to economic and social development, by building healthier and more productive societies.**

Innovative pharmaceuticals do not only benefit patients but are an important element of well-functioning healthcare systems. By bringing novel solutions to resolving different public health problems, new pharmaceuticals enable more efficient allocation of resources, leading to savings in the healthcare sector. For example, use of many modern therapies has led to a significant reduction in hospital stays and surgeries, resulting in important financial savings for healthcare systems.

The need for further pharmaceutical innovation is clear and dramatic – improvements in health around the world depend upon this innovation. Faced with evolving public health needs associated with such global phenomena as the aging of societies, epidemiological transition, growing drug resistance for infections or ongoing evolution of viruses, bacteria and microbicides, ensuring the continuity of pharmaceuticals innovation is in the best interest of mankind.

The process of innovation is very complex, lengthy and indeed fragile in nature – the odds are almost overwhelmingly against actually bringing a new and successful medicine to patients. Due to its expertise and experience, the research-based pharmaceutical industry has been able to consistently bring forward new and vitally-needed pharmaceuticals.

More than 100 new therapies have been approved by US, European and Japanese authorities since 1999 alone. Pharmaceutical companies discovered and developed all the most important medicines in use, many of which are considered as the greatest miracles of medicine. This innovative drive has only been strengthened over time and the pharmaceutical industry has never had so many drug and vaccine candidates in its R&D pipeline, as it does today. More than 7,300 compounds are currently under discovery and development within the industry in different phases.

The pharmaceutical industry's successful record in pharmaceuticals innovation is determined by skills, resources and capacities of individual companies, but also to a significant extent by the external environment like Government policies.

Thus, it is extremely important for decision-makers to understand the realities behind pharmaceutical innovation. An appreciation of the complexities of innovation and the factors which are vital for pharmaceutical companies to successfully continue innovating will alert decision-makers as to the possible, unintended negative, consequences of their policies. By drafting policies which support the pillars of innovation, decision-makers will be able to effectively encourage such innovation and promote the improvement of public health in their countries.



### Summary of global pharmaceutical innovation

#### Pharmaceutical Innovation:

Continued medicines R&D is necessary not only for improved treatments, but also to address the many conditions that currently lack an adequate therapeutic option.

- Innovative medicines have created dramatic improvements in saving lives and treating diseases and conditions.
- Innovative drug therapies contribute to efficiencies in patient care, enhancing quality while reducing or eliminating the need for more costly treatments.
- Pharma R&D makes a substantial contribution to economic and social development by spurring advances in healthcare outcomes overall.
- New medicines developed by R&D firms create the building blocks for a vigorous generic drug industry, allowing for significant price competition.

#### Conditions for success in pharmaceutical R&D:

The process of pharmaceutical R&D remains long and complicated. R&D is also becoming more complex due to a combination of scientific and political factors. The financial risks are high because without regulatory approval there is no market.

- R&D costs are rising, particularly for clinical trials, as the focus shifts to complex, multi-symptomatic diseases that require evaluations in larger patient groups and over a longer period of time.
- Innovative new medicines remain a favorite target for government budget cost-cutters, providing a clear and easy target because access to medicines is easy to control compared to other health services that comprise a far larger share of overall spending on health – in most OECD (Organization for Economic Cooperation and Development) countries, drugs represent only around 10 percent of total costs and this has been constant for the last 40 years.
- There is no alternative model or structure able to deliver the R&D output of the research-based pharma industry, a process that has evolved slowly over a century of progress in drug discovery and development.

#### The Pharmaceutical Innovation Platform:

Ensuring a sustained flow of new medicines to patients. An open market condition, bolstered by a strong regulatory environment, provides the enabling environment for a healthy R&D industry.

- Innovative R&D is based on a business model that stands on four critical and inter-connected pillars of performance:
- Efficient markets based on sustainable financing
- Effective intellectual property protection
- Adequate and predictable regulatory requirements
- Intellectual Property Protection (IPP) remains the heart of the entire system of pharmaceutical innovation and efforts to weaken it will only limit the discovery and development of needed new therapies.

#### Spreading the Benefits of Medicines Innovation:

Partnerships and enlightened industrial policy: The moral imperatives to address neglected diseases must be acknowledged but without losing track of the fact that they count for only a very small part of the overall disease burden of developing countries.

- Public-private partnerships that pool research capabilities are a way to overcome the skewed R&D investment climate associated with neglected diseases.
- The research-based pharmaceutical industry recognizes that drugs can only provide part of the answer to the health problems of developing countries. Working in partnership with other private and public sector bodies it is making a notable contribution towards finding and implementing sustainable system-wide reform policies and solutions for these countries.
- Medicines innovation should not be seen as an industrial asset for rich countries alone. The experience of the PIP business model is now being transferred to those developing economies that have the resources, skills and capacities to develop their own pharmaceutical R&D industry.

#### Indian prospective

India has contributed to a great extent to the field of medicine since ages. Indian Pharma industry is one of the fast growing sectors of Indian economy and has made rapid strides over the years.

From being import dependent in the 1950s, the industry has achieved self sufficiency and gained global recognition as a producer of low cost, high quality bulk drugs and formulations. Having proved itself in the international market, India is ready to face the challenge of proving its efficiency as preferred destination for innovation.

The pharma industry will not be in a strong position to capitalize on opportunities unless research and productivity improves. The core challenge for the industry is a lack of innovation, says a Pricewaterhouse Coopers report, Pharma 2020: The vision-which path will you take? (Times of India, June 16, 2007). There are 245 pure vaccines and 11 combination vaccines in clinical development and the market is estimated to be worth as much as \$42 billion by 2015.

The government is likely to exempt pharmaceutical companies from seeking Genetic Engineering Approval Committee (GEAC) clearance for undertaking clinical trials in case of “purified products” of genetically modified organisms (GMOs), used in drugs such as vaccines, interferons and diagnostics. This move will primarily decrease the number of steps in the clearance procedure for pharmaceutical companies.

RBG (Reverse brain gain): Since independence, India has been losing its knowledge resource in terms of migration of its highly qualified persons to other countries-a phenomenon known as ‘Brain Drain’. But the liberalization of

economy and changing industrial, scientific, technological and social scenario in the country since early-1990s have created challenging opportunities for trained/highly skilled personnel to return to India. It is being catalyzed by employment entrepreneurship, opportunities in high-tech areas like information and communication technology, biotechnology, bio-informatics, pharmaceuticals, e-banking, etc\*.

The study has outlined some 'Success Stories of RBD/ RBG Persons'. These covered the areas of production of Hepatitis B vaccine in India (M/s Shanta Biotech), innovative combination of genetics and grain technologies (M/s Avesthagen), synthesis of vaccine for dysentery, pediatric, cardiology, etc.

Another example is the Discovery Research facility of the multinational pharmaceutical company, AstraZeneca, in Bangalore, India and is focused on finding new treatments for tuberculosis. The facility would not have been created were it not for the support of the State of Karnataka and the Government of India.<sup>2</sup>

The buoyancy of the pharma R&D space in India now percolates to the entire spectrum of competencies, from discovery to non-clinical and clinical services, process chemistry and formulation development. What is more, India has emerged as a hot spot amongst Western companies for off-shoring their R&D processes – especially in terms of research process outsourcing, clinical trials and basic research, which have been strengthened by government support and funding. A survey conducted by India's National knowledge Commission shows that only 37% of the large firms have introduced breakthrough innovation and 77% have introduced incremental innovation.

### Challenges and opportunities

#### CHALLENGES

- *Underdeveloped new molecule discovery program*
- *Hue & cry against exploitation*
- *Back lash against outsourcing*
- *IP leakage*
- *Restricted items*
- *No brand value*
- *Safety concerns*
- *Generic competition*

#### OPPORTUNITIES

The Indian pharmaceutical industry has a lot of strengths and hence ample of opportunities. A few important strengths are mentioned below.

*Competent workforce:* India has a pool of personnel with high managerial and technical competence as skilled and largest English speaking population in the world.

*Cost-effective Chemical Synthesis:* It provides a wide variety of bulk drugs and exports sophisticated bulk drugs.

*Legal & financial framework:* There is already an established international industry and business community.

*Information & technology:* world-class educational institutions and established strengths in Information Technology.

*Globalization:* The country is committed to a free market economy and globalization which is continuously growing.

#### Consolidation

The international pharmaceutical industry is finding great opportunities in India as the process of consolidation has started taking place in India.

*Low-priced products:* This has resulted in the Indian pharmaceutical players offering their-products at some of the lowest prices in the world.

*Quality assurance:* The quality of the products is reflected in the fact that India has the highest number of manufacturing plants approved by US FDA (61 plants), which is next only to that in the US.

*Dominance in the market:* Currently, it is the Indian companies which are dominating the marketplace with the local players dominating a number of key therapeutic segments.

*Self-reliance:* Displayed by the production of 70 per cent of bulk drugs and almost the entire requirement of formulations within the country.

*Other strengths:* Low cost of production, Low R&D costs, innovative scientific manpower and Increasing balance of trade in Pharma Sector.

*R&D:* Indian central and state governments have recognized R&D as an important driver in the growth of their pharma businesses and conferred tax deductions for expenses related to research and development. They have granted other concessions as well, such as reduced interest rates for export financing and a cut in the number of drugs under price control, special economic zones (SEZs).

#### Clinical research – India, most significant emerging geography

Indian clinical research industry is estimated at over US\$ 100 million. It complies with ICHGCP protocols

*Labor force:* With one of the largest and most genetically diverse populations in any single country, India can recruit for clinical trials quicker and perform them more economically than countries in the West.

### The Indian generics market

The Indian generics market is witnessing rapid growth opening up immense opportunities for firms. This is further triggered by the fact that generics worth over \$40 billion are going off-patent in the coming few years which is close to 15 per cent of the total prescription market of the US. The Indian pharmaceutical companies have been doing extremely well in developed markets such as US and Europe, notable among these being Ranbaxy, Dr. Reddy's Labs, Wockhardt, Cipla, Nicholas Piramal and Lupin. The companies have their strategies in place to leverage opportunities and appropriate values existing in formulations, bulk drugs, generics, Novel Drug Delivery Systems, New Chemical Entities, Biotechnology etc.

*Ageing and obese population:* An ageing global population is poised to drive pharmaceutical drugs for indications such as Alzheimer's disease.

### Summary of Indian pharmaceutical innovation

It is widely perceived that the 21st century is going to be the Century of Asia and that Asia will play a dominant role in the world economy commensurate with its share of global population and that three of four of the world's largest economies (China, Japan and India) will soon be in Asia. (Report on BRIC in 2007 by Goldman Sachs).

Challenges of Indian Pharmaceutical Innovation has to be addressed appropriately and convert into opportunities. India's Pharmaceutical Industry Research focus of large companies has shifted towards discovery of New Chemical Entities keeping in view the product patent era commenced from 1st Jan., 2005.

Department of Pharmaceuticals (DoP) Government of India, failed to utilize funds allocated in the budget in 11<sup>th</sup> Five year plan. The policy makers have been supportive in terms of bringing down number of steps for clearance of Discovery process and encourage innovation.

### Conclusion

The diseases of the developing world increasingly resemble those of the developed world and a greater affluence is making some countries much more attractive markets. Pharma must improve its R & D productivity, if it is to meet the world's unmet medical needs and capitalize on the market opportunities now emerging. The legal framework in which pharma operates must be altered to promote innovation and discourage imitation. All the countries are working to improve the measurements of this 'intangible', investment. Pharma will have to prove to healthcare payers increasingly interested in establishing best medical practice that its products really work and provide value for money. ■

### References

1. "Innovation and Growth: Chasing a Moving Frontier", edited by **Vandana Chandra, Deniz Ercal, Pier Carlo Padoan, Carlos A., Primo Braga**.
2. *2009 Interim Report on the OECD Innovation Strategy*.
3. *Changing patterns of Pharmaceutical Innovation*, A research report by the NIHCM Research & Educational Foundation, May 2002, [www.nihcm.org](http://www.nihcm.org)
4. Extract from the speech of **Dr.Omkar Shrestha**, in Regional Conference Asia- Responsible Competitiveness- Innovation for future growth. 14-16 Sept.2009, New Delhi, India.
5. *International Federation of Pharmaceutical Manufacturers Associations (IFPMA)*, the Pharmaceutical Innovation Platform, sustaining better health for patients worldwide, Oct.2004, [www.ifpma.org](http://www.ifpma.org)
6. **Lichtenberg F.R.**, *Pharmaceutical innovation, mortality reduction and economic growth*. National Bureau of Economic Research, Working Paper 6569, May 1998.
7. *Opportunities and Challenges for Clinical Research in India*, [www.daneprairie.com](http://www.daneprairie.com)
8. *Pharma 2020: The vision Which path will you take?* Pricewaterhouse Coopers, [www.pwc.com/pharma](http://www.pwc.com/pharma)
9. *Pharma Spectrum*, Jan 18,2010, [www.pharmabiz.com/article/detnews.asp?articleid=53572&sectionid=19](http://www.pharmabiz.com/article/detnews.asp?articleid=53572&sectionid=19)
10. *Pilot Study on: India's Reverse Brain Gain (RBG)* In Liberalized Era Study conducted by Natural Resources India Foundation (NRIF), Catalyzed and Sponsored by Department of Science & Technology (DST), Ministry of Science & Technology, Govt. of India
11. The Korn/Ferry Institute "China Versus India" – Reality Check FOR PHARMA R&D, By **Ling Li, Lan Kang and Shilpa Gentela**, [www.kornferryasia.com](http://www.kornferryasia.com)
12. *Times of India*, June 16, 2007 "India to be in Top 10 Pharma Markets by 2020.
13. *United Nations Development Program*, Human Development Report 2001.
14. *World Health Organisation (WHO)*, Genomics and the world health. Report of the Advisory Committee on Health , Research, Geneva 2002.

# Pharmaceutical Innovation

## And access to medicines

Marina Altagracia-Martínez, Jaime Kravzov-Jinich and Albert I. Wertheimer

**Pharmaceuticals constitute only a small share of health expenditures in**

**developed countries, but they are a much larger share in developing ones.<sup>(1)</sup>**

**In Mexico, it is widely accepted that drug expenditures are about 30% of the total health budget.**

Pharmaceuticals raise productivity of other healthcare inputs, so this sector is vitally important in every country. As the health care system is complex and its components interact with one another, policies affecting one segment will have an impact on the others. Consequently, health reforms designed with the best intentions frequently have serious unintended consequences.<sup>(1)</sup>

The internationalization of research and technology is one key component of the globalization of trade and business, with potentially major impacts on patterns of economic development and public policies worldwide; particularly in the pharmaceutical industry (PI) where innovation processes have changed considerably in the last 15-20 years. One dimensional, linear single-actor type processes are being replaced by multi-dimensional, complex, multi-actor schemes. New players are becoming more important with biotechnology firms and products playing a key role.<sup>(2)</sup>

The PI is one of the leading industrial sectors in many nations. Its extensive research and development (R&D) are sold worldwide and have improved the length and quality of life of countless individuals. However, it is well recognized that “modern medicine” really cures nearly no diseases other than infections. Diseases are controlled, or more accurately stated, the symptoms are controlled for example: hypertension, diabetes, arthritis, cancer, etc.<sup>(3)</sup>

Nevertheless, the PI is criticized for its marketing and pricing practices and even for its R&D priorities.<sup>(1,4)</sup> Especially in developing countries where very limited R&D is done, R&D priorities are not defined by local

health needs and, treatments for neglected disease are frequently not available. Problems confronting pharmaceutical innovation processes and, drug access are usually divided in problems of the developed countries and access to drugs in developing ones. Some authors have reported that for at least 12 diseases, 99 to 100% of all cases globally are located in developing countries.<sup>(5)</sup> The 100% category includes malaria with 24 million sufferers (1996), chagas disease, dengue, encephalitis, lymphatic filariasis, onchocerciasis, schistosomiasis, tetanus, trachoma and trypanosomiasis and, in the 99% category: leishmaniasis, measles, polio, syphilis, diphtheria, leprosy and diarrheal diseases. For tuberculosis and HIV, the percentages are 91 and 65% respectively<sup>(5)</sup> Most of them are prevalent in Mexico (2010).

As mentioned before, the neglected diseases herein prescribed are low priorities for both private and public investors in R&D. The R&D process is expensive, risky and long, regardless of the potential drug indication. For neglected diseases, patent protection and the market secured exclusively for the innovator is insufficient to warrant the R&D investment for the pharmaceutical industry.

The present work has the following objectives:

- a) to make a quick review of the process and products of pharmaceutical R&D,
- b) to briefly analyze the problem of drug access in Mexico as a developing country and,
- c) to propose some recommendations to “solve” the drug access problem for neglected diseases in Mexico.

### Pharmaceuticals innovation

Pharmaceutical innovation ranges from breakthrough treatments for life threatening diseases to minor modifications to “old” drugs.<sup>(6)</sup> Consequently, drug innovation level should be distinguished in order to understand the benefits and costs of new drugs. The US Food and Drug Administration (FDA) classifies all new drug applications (NDAs) on two dimensions: by chemical type and therapeutic potential. FDA used a combined classification in order to measure the level of innovation of NDAs from 1989 to 2000. It was found that only 361 (35%) were new molecular entities (NMEs) or drugs containing new active ingredients.<sup>(6)</sup>

In Canada, the PI is a significant sector of the Canadian economy, representing over \$9.4 billion in domestic production and accounting for 75,000 jobs in 2005.<sup>(7)</sup> The health and economic significance of the PI around the world have enabled this sector to obtain billions of dollars in public R&D investments and tax incentives. Nevertheless, it is often argued that health and economic goals related to pharmaceutical innovation work against one another instead of in harmony.<sup>(7)</sup> One might think that indications of disconnect are found in the current trends of an exceptionally profitable industry and the decreasing number of new drug therapies, as it was previously mentioned based on FDA reports.<sup>(6,7)</sup>

There are researchers who argue that “me too” drugs are not useless and that incremental improvements of medicines are fundamental to enhancing the overall quality of health care.<sup>(8,9)</sup> Nevertheless, increasing the number of medicines within a class might increase competition and lower the costs of medicine in some countries (mainly developed ones) but it increases the drug prices and lack of access in developing ones.<sup>(10,11)</sup>

All pharmaceutical innovations are, at least, linked to local health regulations, economic and drug price policies as well as intellectual property protection (IPP) legislation and foreign agreements.

### Intellectual properties

Trade-Related Aspects of Intellectual Property Rights (TRIPS), negotiated in 1986 through 1994, introduced intellectual property rules into the multilateral trading system for the first time.<sup>(12)</sup> It has now been over fifteen years since the TRIPS Agreement was signed-requiring all members of the newly-formed World Trade Organization (WTO) to implement a set of minimum standards for IPP. The Agreement was a major effort by developed countries to strengthen IPP rights on pharmaceutical innovation throughout the developing world. It was argued that introducing patent rights in developing country markets might stimulate greater R&D investment targeting their specific health needs-areas long neglected.

Many controversies have occurred in the process of application of TRIPS (South Africa and Brazil). A declaration

on TRIPS and Public Health was made, which reaffirmed countries' ability to issue compulsory patent licenses on pharmaceuticals to serve the interests of public health.

Pharmaceutical patents by Indian-based inventors have grown rapidly as a share of all patent applications in the United States; to over 2%-with a similar trend in Europe.<sup>(12)</sup>

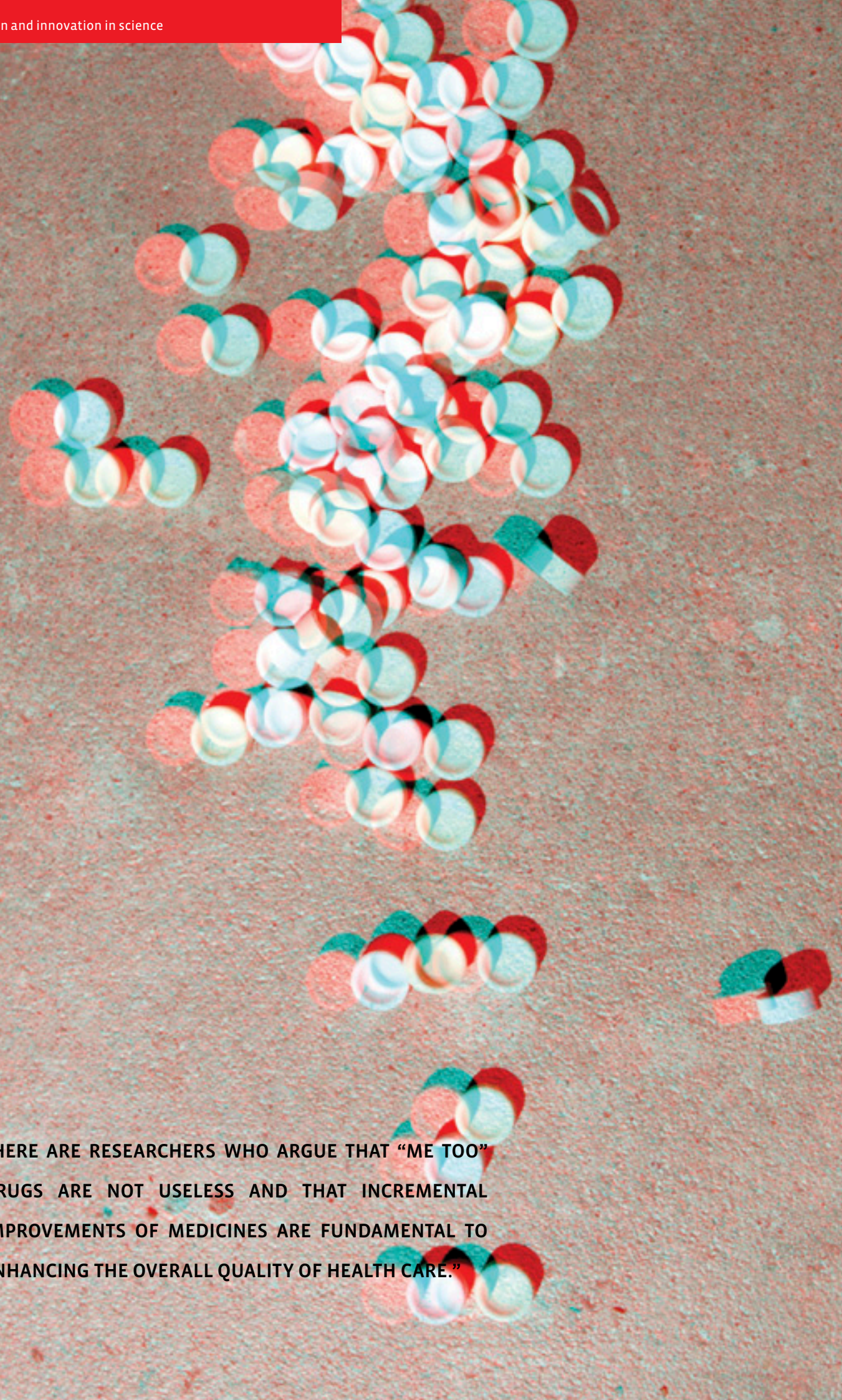
Along with the changes in the global IPP system, there has been a remarkable increase in concern about global health issues and especially infectious disease. In 1997, the US Institute of Medicine warned that, “Even though the majority of people affected by infectious diseases are in the developing world, all nations, even the richest, are susceptible to the scourges of infectious diseases.”<sup>(12)</sup> The heightened awareness and concern about tropical and infectious diseases has led to many R&D initiatives directed at discovering and developing vaccines and pharmaceutical treatments for diseases specific to poor countries and exmple being the WHO's Special Programme for Research and Training in Tropical Diseases (TDR). The TDR has set an agenda and gives grants for basic research, product research, intervention and implementation development and research capacity building (\$25-30 million expenditure since the nineties). Médecins Sans Frontières (MSF) called a working group in 2002 to investigate the feasibility of a “Drugs for Neglected Diseases Initiatives (2002) and Best Science for the Most Neglected (DNDi) is committed to using facilities of the south including the Oswaldo Cruz Foundation/Fiocruz (Brazil), Indian Council of Medical Research (India), Kenya Medical Research Institute KEMRI (Kenya) and the US Centers for Disease Control (CDC) with support from KEMRI and Guatemala studying leishmaniasis, chagas and helmenthic parasites among others.<sup>(12,13)</sup>

### Drug access in Mexico

Despite the fact that the Mexican PI is the largest one in Latin America and occupies the tenth or eleventh place in value of the world pharmaceutical market, up to 10 million or more Mexicans (the poorest) remain without any health care services or access to prescription drugs.<sup>(11)</sup> Illness places a heavy burden on the economy and health care system alike. Some estimates of the economic value of mortality among the working-age population exceed US\$13 billion annually, or approximately 5% of the Mexican Gross Domestic Product (GDP in 2004). Moreover, the elderly population (over 60 years old) is rapidly growing 8% in 2007 and it is estimated to grow to 17.1% by 2030.<sup>(14)</sup>

To measure country level innovation is a complex process that requires the definition of various indicators. Nevertheless, some authors used inputs and outputs indicators and so do we. Inputs include: human and economic resources and research physical infrastructure. Ouputs include number of publications and citations, number of grants between universities and PI, number of patents, etc. ►





**“THERE ARE RESEARCHERS WHO ARGUE THAT “ME TOO”  
DRUGS ARE NOT USELESS AND THAT INCREMENTAL  
IMPROVEMENTS OF MEDICINES ARE FUNDAMENTAL TO  
ENHANCING THE OVERALL QUALITY OF HEALTH CARE.”**



Mexico signed in 1994 the North America Free Trade Agreement (Canada and USA) and using some of the above mentioned indicators the following data were found: very low investment in high education and human resources for innovation and R&D in pharmaceutical and health in comparison with Canada and USA; in 2003 Mexico had 1,349 doctors in health sciences (Ph.D), Canada 8,874 and USA 44,410. Number of individuals dedicated to R&D in Mexico 0.9 per 1000 inhabitants, Spain 8.5 and Korea 8.4. Percentage of the GDP used for R&D in Mexico 0.4, Spain 0.97 and Korea 2.65 (2001). Mexico as a member of the Organization for Economic Co-operation and Development (OECD) is far below the average percentage (2.21) of the GDP used for R&D of the OECD countries.

### Conclusions and suggestions

Drug access might depend on how all the above aspects are combined in order to maintain an innovative and reasonable profitable pharmaceutical industry (PI) and at the same time guarantee immediate access to quality drugs to all citizens and these aspects should coexist in harmony.

Mexico needs to build a scientific and technological capacity to face twenty-first century challenges in innovation; to considerably increase the percentage of its GDP and it might be done by initiatives that include the private and public health sectors and PI, to bind private and public higher education institutions that are conducting R&D in order to strengthen efforts and optimize resources.

Mexico should call together universities and public research institutions to adopt "Equitable Access Licensing" in order that patients have maximum access to medical technologies originating in universities and, participate in international organizations in order to innovate in pharmaceuticals for local neglected diseases that are common with other developed and developing countries.<sup>(15)</sup> ■

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### References

- 1 Schweitzer SO. *Pharmaceutical Economics and Policy*. New York, Oxford University Press, 1997:1-235.
- 2 Jungmittag A, Reger G, Reiss (Editors). *Changing Innovation in the Pharmaceutical Industry. Globalization and New Ways of Drug Development*. Berlin-New York, Springer-Verlag Press, 2000:1-213.
- 3 Jacobsen TM, Wertheimer AI. *Modern Pharmaceutical Industry: A Primer*. Boston, Jones and Bartlett Publishers, LLC, 2010:1-317.
- 4 Commanor WS. (1986). *The political economy of the pharmaceutical industry*. Journal of Economic Literature, 24:1178-1217.
- 5 Kettler HE and Collins C. *Balancing Health Needs and Drug Research Incentives*. Cooperation South, 2002:1-36.
- 6 National Institute for Health Care Management. (2002). *Changing Patterns of Pharmaceutical Innovation*. Accessed at [www.nihcom.org](http://www.nihcom.org). April 2010.
- 7 Morgan S and Mochrie C. (2008). *Pharmaceutical Innovation. Can health and economic goals be met?* UBC Centre for Health Services and Policy Research. The University of British Columbia.
- 8 Wertheimer A and Santella T. *Pharmacoevolution: Advantages of Incremental Innovation*. BIAG Bio-medical Industry Advisory Group.
- 9 DiMasi JA and Paquette C. (2004). *The Economics of Follow-on Drug Research and Development*. Trends in Entry Rates and the Timing of Development. Pharmacoeconomics 22(Suppl 2):1-14.
- 10 Altagracia-Martínez M, Cimoli M, Kravzov J, Castillo R, Espejo O, Wertheimer A I. (2000). *Technical Trajectories and QWERTY Methodology: An Application for Pharmaceutical Innovations*. Journal of Research in Pharmaceutical Economics, 10(1):51-81.
- 11 Altagracia-Martínez M, Kravzov-Jinich J, Guadarrama-Atrizco MD, Rubio-Poo C, Wertheimer AI. (2006). *Consumption and costs of antihypertensive drugs in Mexico: Are diuretic agents a standing technological trajectory?* Research in Social and Administrative Pharmacy, 2:22-37.
- 12 Lanjouw JO and MacLeod M. *Statistical Trends in Pharmaceutical Research for Poor Countries*. 2005:1-33.
- 13 Available at <http://www.cdc.gov>
- 14 Available at <http://www.conapo.gob.mx>
- 15 Kapczynski A, Chaifez S, Benkler Y and Katz Z. (2005). *Addressing Global Inequities: An Open Licensing Approach for University Innovations*. Berkley Technology Law Journal, volume 20.



# Individualized Medicine – Bridging Scientific and Clinical Studies

## FIP-JSPHCS conference summary report

Histoshi Sasaki, Yukinobu Kodama, Majid Moridani, Vinod P. Shah

**This summary report provides a brief overview of the conference “Individualized Medicine: Bridging between Scientific and Clinical Studies” co-sponsored by the International Pharmaceutical Federation (FIP) and the Japanese Society of Pharmaceutical Health Care and Sciences (JSPHCS) held at Nagasaki Brick Hall, Nagasaki City, Japan, in October 2009.**

This summary report provides a brief overview of the conference “Individualized Medicine: Bridging between Scientific and Clinical Studies” co-sponsored by the International Pharmaceutical Federation (FIP) and the Japanese Society of Pharmaceutical Health Care and Sciences (JSPHCS) held at Nagasaki Brick Hall, Nagasaki City, Japan, in October 2009. The term individualized medicine or personalized medicine is widely referred to as the application of genomic and molecular data to target the delivery of health care, facilitate the discovery, validation and clinical testing of novel medications and other health related products. The information can be also used to determine a person’s predisposition to a particular disease or condition, prognostics and therapeutic responses. Goals and objectives of the conference were; 1) to provide an educational opportunity for clinical pharmacists in Japan to learn about the application of pharmacogenomics in individualized medicine; 2) to assess the importance of pharmacogenomics (PGx) and biomarkers in future drug therapy and diagnostics; 3) to discuss the usefulness of genetic testing in predicting pharmacokinetics and pharmacodynamics; 4) to identify new clinical applications for PGx and molecular diagnostics in cancer, cardiovascular and adverse drug reactions; and 5) to discuss the barriers to widespread uptake of individualized medicine in clinical settings.

The conference was organized into three sessions:

- 1) current status of individualized medicine in genome era;
- 2) approach of individualized medicine in near-future; and
- 3) clinical impact of individualized medicine.

The first session “current status of individualized medicine in the genome era” was organized in three talks. Vinod P. Shah, FIP Scientific Secretary, the first speaker, provided an overview on the impact of individualized medicine in pharmaceutical care. He indicated that individualized pharmaceutical care is currently provided by adjusting the dose, dosing interval and therapeutic monitoring; however, the use of genetic information in individualized medicine is finding significant potential in advancing drug development and human health by optimizing drug response, drug efficacy and preventing adverse drug reactions. With rapid accumulation of new knowledge of pharmacogenomics, it can be anticipated that patient care will move from the hit-and-miss or one-size fits all approach to the individualized patient treatment.

Next, Jin-ding Huang presented a talk entitled “the pharmacogenomic consideration in clinical pharmacokinetics”. The presentation highlighted that single nucleotide polymorphism (SNP) can only explain some of the observed inter-individual or inter-ethnic variations for a number of drugs. The extent of gene expression is as important as presence or absence of a SNP when genomic information is taken into account in clinical pharmacokinetics. The expression and polymorphism of CYP2D6, CYP3A4 and CYP3A5 in the liver and intestine and their roles in the metabolism and pharmacokinetics of a number of drugs were also discussed. The conclusion of the talk was that the considerations should be given to variation in gene expression as well as the presence or absence of polymorphism.



The last speaker of this session, Majid Moridani, provided an overview of the building tools and technologies that are currently used in pharmacogenomics. The presentation focused on the principles of target and signal amplifications methods in genomic analyses. A number of examples from each method of amplifications such as polymerase chain reaction, ligase chain reaction, branched chain DNA assay and INVADER assay were discussed. Furthermore, the analytical principles behind microarray technology and a number of FDA approved devices for their use in pharmacogenomics were also discussed. It was pointed out that technology is no longer a barrier in the use of the pharmacogenomics in clinical setting. The major barriers include the complex nature of the data generated at research and development, how to link these data to a clinical outcome to enhance drug efficacy and minimize drug toxicity, the difficulties in validation of biomarkers in clinical settings, cost coverage by insurance, regulatory barriers and the education of health care providers.

The second session was focused on the approach of individualized medicine in near-future. First, Yusuke Tanigawara gave a talk entitled “the pharmacoproteomics and metabolomics in individualized medicine”. The talk provided an overview of his recent studies on chemosensitivity of human colorectal carcinoma against 5-fluorouracil (5-FU) and oxaliplatin using S100A10 protein as a potential biomarker that was associated with the sensitivity of human colorectal cancer cells to oxaliplatin. Data was also presented on quantification of dynamic changes in the total intracellular metabolite

pool after exposure to 5-FU. The talk concluded that the S100A10 protein should be considered as a potential biomarker for predicting oxaliplatin sensitivity and that the proteomics and metabolomics are useful techniques to identify pharmacodynamics biomarkers toward individualized medicine.

Next, Toshiyuki Sakaeda gave a presentation entitled “the pharmacokinetics and PGx in esophageal cancer chemoradiotherapy”. He highlighted a number of difficulties associated with using pharmacokinetics and PGx of 5-fluorouracil (5-FU) and Cisplatin (CDDP) in patients with esophageal cancer by indicating that although global genotyping lists so many candidates with higher predictability of efficacy/toxicity little or no information is available for their use in guiding the therapy in this cancer. The conclusion of this presentation was that monitoring of plasma concentration of 5-FU and genetic profiling are possibly useful tools to ensure the drug efficacy in a 5-FU/CDDP based chemoradiotherapy. Additional in-vitro/clinical investigations are still needed to identify better biomarkers that can be used to individualize 5-FU/CDDP based chemoradiotherapy in esophageal cancer.

The next speaker, Ross McKinnon focused on the status of personalized medicine in the year 2020. While recent years have seen remarkable advances in basic pharmacogenomic research, the extent to which individualized or personalized medicine will emerge as sustainable new therapeutic approach remains controversial. Although long overdue, potential barriers to the clinical uptake of

pharmacogenomics are now receiving closer scrutiny. As a result, a framework is needed for the successful clinical implementation of PGx interventions on clinical and economic outcome in real world settings.

Collectively, advances in pharmacogenomics and targeted therapy demand new approaches in disease management with an emphasis on personalized medicine, there is an urgent need for integrated analyses that embrace the complexity of biological data, including multiple forms of genomic data, in order to explore and understand multiple, interacting and potentially conflicting predictors of drug response and patient prognosis. Importantly, all forms of potentially relevant data should be examined, with a particular emphasis on understanding the interactions, complementarities and possible conflicts among gene expression, genetic, diagnostic and clinical markers. This complexity demands a multidisciplinary approach bringing together relevant skill sets with a focus on individualized care for the individual patients in 2020

In the plenary lecture, Hiroyuki Aburatani gave a talk entitled “genomic medicine with an emphasis on cancer medicine”. Cancer medicine has become more and more personalized, particularly because each cancer and patient is different. Since most of recent cancer therapeutics are designed against certain molecular targets, they should be given only to the appropriate patients who are positive or negative for certain biomarkers. For instance, breast cancer patients who are positive for HER-2 are good candidates to receive trastuzumab. Human genomic variations have been found to be associated with various human diseases, including drug responses and adverse drug reactions. However, examination of individual variation in drug response is still a significant challenge. Despite this, the recent development in genomic technologies has enabled comprehensive analysis of gene expression, DNA methylation and mutation screening. The generated data can be used to stratify the patients as well as to identify new therapeutic targets which can be used to individualize cancer therapy.

The last session of the conference was focused on the clinical impact of individualized medicine. Kenji Tamura highlighted the importance of pharmacogenetics and biomarkers in oncology by giving examples of EGFR mutation in non-small-cell lung cancer, K-Ras mutation in colorectal cancer and BRCA deficiency in hereditary ovarian and breast cancer as biomarkers in predicting clinical efficacy. The conclusion was BRCA1 deficiency, PI3K mutation and the SNPs of EGFR are promising biomarkers but additional studies are needed to validate their clinical usefulness.

The next speaker, Jung Mi Oh discussed the imatinib resistance in chronic myeloid leukemia (CML). Though imatinib is gold standard therapy for patients with CML in chronic and accelerated phases, resistance or refractory CML patients to imatinib arises as a new clinical problem. The most common mechanisms of imatinib resistance

are point mutation and clonal evolution of BCR-ABL. In addition, genetic instability and accumulation of additional genetic abnormalities are suggested as alternative mechanisms for imatinib resistance. Thus, heterogeneous mechanisms might be responsible for disease progression with imatinib resistance. She presented data examining the gene expression profile of leukemic cells that were obtained from patients in the chronic phase and in the blast crisis phase to characterize the molecular mechanisms by which the transition from the chronic phase to the blast crisis occurs in CML. The study indicates that fms-related tyrosine kinase 3 (FLT3) was an important cause of imatinib resistance in CML patients progressing to blast crisis. In conclusion, the use of FLT3 biomarker may facilitate the prediction of disease progression in CML patients and may also help in the development of more appropriate therapeutic modalities.

The last speaker, Ryosuke Arakawa, presented a talk entitled “the molecular imaging of treatment for psychiatric disorder”. He discussed the use of positron emission tomography (PET) to visualize the target molecules of various psychotropic drugs such as receptors and transporters in the living human brain. PET imaging data related to serotonin transporter and dopamine D2 receptor occupancies obtained in phase I clinical trials of antidepressants and phase II clinical trials of antipsychotic drugs were also discussed. The conclusion of the study was that PET imaging can be employed to determine the optimal clinical doses and the pharmacokinetic profiles of psychotropic drugs in clinical trials.

Finally, Majid Moridani gave the participants and speakers closing remarks with appreciation. The conclusion of the conference was that the use of molecular information in individualized medicine has significant potential in advancing drug development and pharmaceutical care. The participants in the workshop discussed various advances and barriers in the spread of the individualized medicine worldwide. The education of clinical pharmacists and the interactive communication among stakeholders were considered of utmost importance. ■

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# Cultures Cross, Minds Meet

Uniting global scientists, highlighting pharmaceutical innovations at the Pharmaceutical Sciences World Congress 2010

**This November, leading researchers in the pharmaceutical sciences will gather in New Orleans, U.S.A to share cutting-edge research, technical and educational approaches at the International Pharmaceutical Federation (FIP) Pharmaceutical Sciences World Congress (PSWC) in conjunction with the American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition. Over 12,000 individuals representing the widest array of disciplines in the pharmaceutical sciences are expected to converge on the Morial Convention Center from Sunday, November 14 – Thursday, November 18 for this meeting.**

Leaders in diverse fields in the pharmaceutical sciences from across the world's universities, pharmaceutical companies and government agencies will offer approximately 115 different scientific and educational sessions aimed at exchanging knowledge and enhancing collaboration between the best minds in the pharmaceutical sciences.

FIP and AAPS offer complementary organizational strengths. FIP provides worldwide standards for pharmacy through guidelines, policy statements and declarations. In addition, FIP actively supports pharmacy and the pharmaceutical sciences in developing countries in collaboration with many other professional societies and international organizations such as the World Health Organization (WHO) and the United Nations. AAPS provides a dynamic international forum for the exchange of knowledge among scientists to enhance their contributions to health by offering timely scientific programs, on-going education, networking opportunities and professional development.

The program, planned by an international committee of prominent scientists, will consist of five days of innovative symposia, short courses, open forums and roundtables that showcase the outstanding research being conducted by members of both organizations. The comprehensive scientific program will be complemented by the unique charm of the meeting venue. The host city of New Orleans features a wonderful blend of American, French and Cajun cultures and the local cuisines are well known as some of the best in North America. PSWC 2010 thus provides an exciting environment for learning and enjoyment.

While the programming is designed to bring forth the most advanced findings in the pharmaceutical sciences into focus, it also examines how these scientific discoveries can be used in translation to pharmacy practice. The wide scope of pharmaceutical science, ranging from drug discovery to clinical utilization, will be discussed and debated among colleagues engaged in various aspects of pharmacy. As an example, a special symposium, entitled "Translation of Pharmaceutical Science to Practice" has been scheduled for Tuesday morning. This symposium, co-sponsored by the American Society of Health Systems Pharmacists, offers a rare occasion in which leading practitioners and scientists will gather to discuss how pharmaceutical science and practice can be synergistic to each other and how one group can inform and educate the other.

The PSWC 2010 will also feature a satellite congress for students and post-doctoral fellows on November 13-14. For our younger colleagues, the PSWC 2010 Congress for Students and Postdoctoral Fellows is a perfect opportunity to meet others with similar interests and goals. The student meeting will take place immediately prior to the official start of PSWC and will offer students the chance to learn from leaders in the pharmaceutical sciences and from each other. Special research, mentoring, educational, career guidance and social sessions are scheduled. Numerous travelships are available for attendees.

Although the depth and breadth of the entire meeting cannot be conveyed in these few pages, the following is a snapshot of what attendees can expect to hear and discuss at the Morial Convention Center. ►

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MINDS MEET

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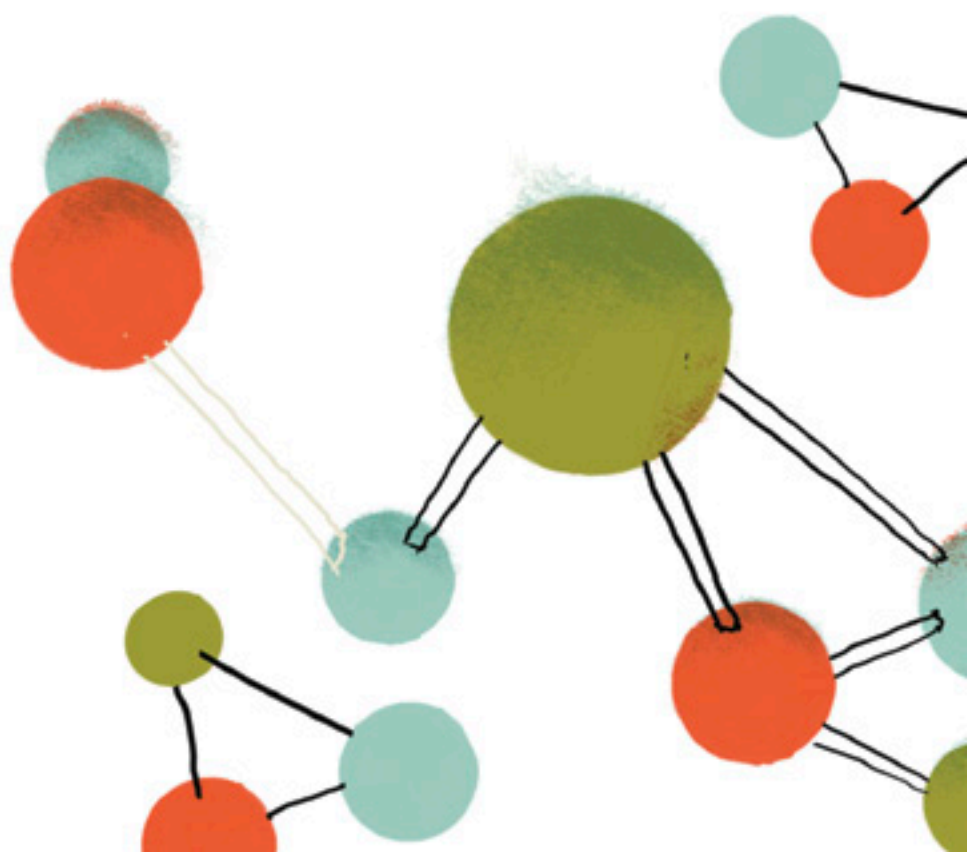
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### Analysis and Pharmaceutical Quality

Over 20 separate programs in Analytical and Pharmaceutical Quality will be presented. Among these are cutting-edge considerations on "Dry Blood Spot Analysis and Novel Sample Preparation" for pharmacokinetic and clinical studies, "Genotoxic and Carcinogenic Impurities: Control and Regulation," "Standards for Essential Drugs," and "Analytical Instrument Qualification: Towards Globalization." A symposium on "Bridging the Gap Between Traditional Medicines and The Western Approach to Natural Products" will address global, regional and national perspectives.

### Biotechnology

The future of biotechnology will be on display at the PSWC 2010 meeting. Of particular note will be a Monday morning roundtable on "Customized Vaccines for the Future," and a Wednesday mini-symposium on "Cutting Edge in Vaccine Delivery." These sessions promise interesting and exciting discussions on the use of vaccines to combat important diseases around the world.

The global nature of PSWC 2010 will be exemplified in a Tuesday afternoon symposium on Biosimilars. This module will cover relevant legislation recently passed by the U.S. Congress, as well as regulations from the European Medicines Agency. Multiple guidelines from Europe, Japan and the WHO have created a challenging environment for the field, which will provide for interesting and engaging discussion.

Other topics of note in this section include:

- The development of anti-cancer drugs based on newly found molecular targets and
- Enhancing understanding of uncommon but important degradation mechanisms encountered during protein formulation development

### Clinical Pharmacology and Translational Research

The wide-spectrum of expertise present in this meeting, including that in chemistry, pharmacology, drug delivery and clinical sciences promises to engender a high level of knowledge exchange and debate about the clinical use of pharmaceuticals. Among the many interesting programs, a symposium jointly sponsored by the American Society of Clinical Pharmacology and Therapeutics will focus on "Phase To Pharmacodynamics Trials in Oncology – a Paradigm Shift in Drug Development." Other programs will discuss "Progress in Modeling Disease Progression" to facilitate clinical drug development and assessment, "Genomics Issues and Solutions in Oncology," and two symposia on "Pharmacogenetics – Found in Translation?"

### Drug Design and Discovery, Medicinal Chemistry and Natural Products

A diverse group of programs will be held to discuss how we can improve on the discovery of new drugs, both from chemical synthesis and from natural products. These programs are represented by sessions such as mini-

symposia on "Pharmaceutical Challenges to Alzheimer's Disease," and "Nuclear Receptors and Their Role in Regulating Physiological Processes," and a sunrise session on "Traditional Medicines in a New Paradigm of Global Health."

Progress on natural products are discussed in programs such as, "Natural Products: Interface between Science and Practice," "Nature's Chemical Diversity: Science and Practice," and "Recent Advances in Natural Products."

### Education and Curriculum

A roundtable discussion will focus on the "Development and Evaluation of Academic Curriculum and Clinical Clerkship for Modern Pharmaceutical Education." This session will enlist experts from around the world to consider the educational needs of future pharmacy professionals. A mini-symposium entitled "Pharmacogenetics: Educating the Doctor, the Pharmacist and the Patient" is intended to bring this modern science into clear perspective for both the health-care practitioner and the patient. The training of future pharmaceutical scientists will be discussed in two sessions: "Sharing Global Best Practice in Educating Pharmaceutical Scientists" and "Safety Sciences – Education and Training."

### Environmental Sciences

Pharmaceutical waste and environmental pollution will be the emphasis of a Wednesday afternoon mini-symposium. Speakers will discuss the effects of pharmaceutical industry on the ecosystem and benign-by-design concepts.

### Formulation Design & Development

Over 25 programs are devoted to this topic of pharmaceutical science. Several sessions are devoted to the new field of nanoparticles, as they apply to pharmaceutical systems. These include a short-course on Sunday entitled, "Nanoparticles from A-to-Z: Achievement in Drug Delivery & Tissue Engineering," which provides a comprehensive overview of this subject. Other sessions focus on the use of nanoparticles in imaging and targeted drug delivery, as well as in clinical applications. Other interesting topics include: "Nose to Brain – Reality or Blowing Smoke?" "Treating Blindness in the Developing World," and "Helping the Medicine Go Down – Pediatric Medicines: Formulation, Manufacturing and Compliance Challenges."

### Global Health

Several interdisciplinary sessions have been designed to address the wide array of issues relating to the discovery, regulatory aspects and quality of pharmaceutical products used in global health. Three symposia entitled, "Pharmaceuticals without Borders" are presented serially on separate days. These sessions will discuss, in turn, "Developing and Delivering Medicines to Underserved Populations," "The Regulatory and Supply Chain Challenges of Providing Medicines to Emerging Markets," and "Ensuring the Integrity and Quality of Medicines Reaching the Patient." A Monday morning roundtable will discuss meeting the

treatment needs of developing countries in global diseases such as AIDS and malaria.

#### **Manufacturing Science & Engineering, Pharmacology and Biochemistry**

Multiple sessions of the meeting will be specifically devoted to the field of Manufacturing Science & Engineering, as well as Pharmacology and Biochemistry. Among the sessions scheduled are those on “Continuous Manufacturing: Benefits and Challenges?” “Imaging Technology for Understanding Process in Pharmaceutical Manufacturing,” “Technology Transfer and Process Validation in the Context of Quality-by-Design,” and “Nanocrystals: Production, Stability and Applications.”

#### **Pharmacokinetics, Pharmacodynamics and Drug Metabolism**

Over 30 programs related to Pharmacokinetics, Pharmacodynamics and Drug Metabolism will be presented. Several programs will be dedicated to each of the following important topics: transport proteins, pharmacogenetics, adverse drug reactions, pharmacokinetic and pharmacodynamic modeling, animal scaling and drug-drug interactions. Other topics include “Molecular Imaging Technologies for ADME-Tox Studies,” and “Metabolomics in Pharmaceutical Development.”

#### **Physical Pharmacy & Biopharmaceutics**

About two dozen programs will be presented in the field of Physical Pharmacy & Biopharmaceutics to enhance our basic understanding of the fundamental properties of drugs as chemicals and when they interact with the body. Among the topics scheduled are: “Development of Effective Fixed Dose Combination Therapies for Global Diseases: Recent Successes and Advances,” “Delivery of Poorly Soluble Drugs: Evolving Science and Technology,” “Improving Pulmonary Delivery of Drugs and Biologics,” and “The Gut-Wall as a Metabolic Barrier to Drug Development.”

#### **Regulatory Sciences, Safety Sciences**

PSWC 2010 will provide an extensive set of symposia that encompass views from multiple regulatory agencies around the world. Members of these agencies and others will provide in-depth information on globalization efforts and the current regulatory environment. Sample sessions include: “Quality Assurance of Medicines: The Detection of Counterfeits and Adulterants,” “Bio-analytical Procedures and Regulations: Towards Global Harmonization,” and “Risk Management Planning: An Essential Component of Pharmacovigilance.”

With approximately 115 programming sessions, the combined 2010 PSWC and AAPS Annual Meeting and Exposition provides the best opportunity for those interested in the pharmaceutical sciences to meet and network with colleagues, learn about and promote breakthrough research and technologies and improve your professional edge. These unique, global perspectives represent the best that FIP and AAPS have to offer. Each member of both organizations and all attendees will benefit from not only the scientific lessons learned, but the cultural ones. The best ideas for improving health through innovation and advances in the pharmaceutical sciences await all that attend. ■

For more information and to register, visit [www.pswc2010.org](http://www.pswc2010.org).



# Broadening the Vision

## Expanding pharmacy education across borders

Abbie Frank

**When I learnt that the University of Minnesota College of Pharmacy was offering a chance to study pharmacy in Velbert, Germany for five weeks, I couldn't pass up the opportunity to do so. I would be spending my first required Advanced Pharmacy Practice Experience (APPE) in a German community pharmacy along with nine other fourth-year pharmacy students. The objectives of the APPE were to study pharmacy in a different health-care system, compare and contrast the best practices of health-care delivery and understand the role of pharmacists in a community setting in Germany.**

Since this was the first time the University of Minnesota would be sending students internationally for an APPE, there was a lot of enthusiasm from the group of students. Our preceptors, Jöchen Pfeifer and Nic Forster, visited the College of Pharmacy in March 2009, for a week-long introductory lecture series. This was a great way for us to meet the preceptors, discuss different health-care systems and learn about what we would be doing while in Germany.

Our time spent at the Adler Apotheke, where Drs. Pfeifer and Forster practice, focused on lectures, discussions and compounding. We worked with the pharmacy technicians making creams, ointments, capsules, suppositories and herbal teas. The preceptors also facilitated lectures regarding the pharmacist's role in the German and American health-care systems. We also divided into small groups and engaged in conversations regarding best practices, pharmacy law and education and expanding the role of the pharmacist for the future.

We also spent a lot of time outside of the pharmacy meeting with different dignitaries, pharmacists and other health care professionals. This offered a unique opportunity for us to create dialogue regarding the developing role of the American pharmacist, the role of medication therapy management and our pharmacy education system. Teaching others about our health-care system enhanced our own understanding. The discussions allowed us to learn from the dignitaries about the foundation of Germany's health-care system and its ideals.

Other excursions during our trip were to different pharmaceutical companies. We had the opportunity to visit

Janssen-Cilag in Neuss, Germany. We also toured Hexal in Magdeburg, Germany, where my great-grandfather was born. Another highlight of my trip was visiting different pharmacies in Germany. Germany has over 21,000 community pharmacies, each legally required to be owned by a pharmacist. Therefore, chain pharmacies that dominate the U.S. retail market are not found in Germany. Also, due to a high density of pharmacies within Germany, each one offers different services that make it unique. We were able to meet with the pharmacy owners, discuss their business models and learn about how it impacts their patient population.

One of the pharmacies we visited offered a variety of patient care services such as blood glucose testing, bone density scans and cholesterol checks. The pharmacist aimed to develop a therapeutic relationship with his patients and provide them with more individualized attention. Another pharmacy was equipped with an automated filling machine that made dispensing extremely efficient. It allowed a pharmacist to spend more time educating a patient on his or her prescriptions. A third pharmacy we visited specialized in pharmaceutical biology. In its backyard, the pharmacy had a beautiful garden full of plants and herbs commonly used in medicinal teas. The garden was a highlight for community members and opened up opportunities to educate patients about pharmaceutical biology and how that could impact one's care.

While in Bonn, we met with German pharmacy students who were attending a national pharmacy student association conference. We reconnected with some of the students for a tour of their pharmacy school at the Heinrich-Heine-Universität of Düsseldorf. Meeting our counterparts from another country was a lot of fun. We were able to see what daily life was like for German pharmacy students, sharing stories and traditions.

During the last week of our stay in Germany, we were very excited to have the unique opportunity to meet with the federal Minister of Health, Ms. Ulla Schmidt. The Minister and her staff warmly welcomed us. It was a wonderful experience to discuss with the Minister about being an advocate for the pharmacy profession, as well as how to promote change for future growth. ►





*Minnesota College of Pharmacy Students visiting Germany*



Looking back on my experience in Germany, it has shaped my future in many different ways. Studying abroad has a special way of affecting one's personal life – the travel, a new culture, different language and experiencing life in a country other than my own. These five weeks also impacted my professional life. I was given the opportunity to do research for my PharmD thesis paper that looks at the expectations and outcomes of an international experience for pharmacy students. The APPE also encouraged me to dive deeper into the world of pharmacy and pharmacy education on a more global scale. To do this, I am enrolling in the University of Minnesota College of Pharmacy's Social and Administrative Pharmacy doctoral program for the fall of 2010.

It is my hope that in the future, pharmacy students will have more opportunities such as mine to study pharmacy abroad. This expands a student's global view of pharmacy practice and allows for learning opportunities not available in the classroom. International practical experiences also encourage the development of professional relationships on a global scale. This network is vital to the future of pharmacy. Currently, there are limited opportunities for pharmacy students to seek out international experiential education. Therefore, an expansion in international learning opportunities should be implemented within colleges of pharmacy all over the world. Partnerships between countries, pharmacy schools and international colleagues should be encouraged and strengthened to create such opportunities through involvement in FIP.

I would like to thank Drs. Jöchen Pfeifer and Nic Forster for the dedication and effort they put into this APPE. These preceptors went above and beyond to make our experience unique and special. The University of Minnesota College of Pharmacy also played a huge role in the success of this program. Without the support of the College, we would not have had this important professional experience. I would also like to thank the group of students I traveled with to Germany. It was a pleasure to work with them over the five weeks and I am grateful for the friendships we made. And lastly, I would like to thank Frau Bister, the manager of Hotel Bürgerstube, for her overwhelming hospitality and care during our stay in Velbert. ■

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# Innovation in Education

## Using the National Science Festival in South Africa to raise awareness of the prevention of chronic diseases

Sunitha C Srinivas, Wendy Wrench, Karen Bradshaw, Catherine Karekezi

**Globally, premature death and disability are increasing rapidly, especially in developing countries due to preventable chronic diseases<sup>1</sup>. The issue of chronic diseases has to be addressed urgently in developing countries that face a double burden of infectious diseases and chronic non communicable diseases (CNCDs).**

Inadequate infrastructure, lack of healthcare professionals and financial resources exert more pressure on the existing healthcare system in addressing the double burden of diseases. The ratio of health care professionals to the population is reported to be eight doctors, 41 nurses and three pharmacists per 10 000 population in South Africa<sup>2</sup>. Of the 23 developing countries selected by the World Health Organization, it was found that South Africa is one of the countries that contribute to 80% of global mortality due to CNCDs<sup>3</sup>. The existing healthcare professional ratio is insufficient to address the dual challenge of treatment as well as prevention strategies such as health promotion.

Among its health objectives, the National Drug Policy (NDP) of South Africa promotes the concept of individual responsibility for health, preventive care and informed decision-making through provision of the necessary training, education and information.<sup>4</sup> It is important that in developing countries with under-resourced health care systems, universities, schools and other non government organisations related to health, work together to develop innovative, proactive methods to provide information to communities in order for individuals to make more informed decisions relating to their health. Pharmacy practice and science are progressing and so too are communication and technology, which are constantly being reinvented for more user-friendly access. It is important that universities utilise progress in an innovative way to reach out to communities “Getting the message across” isn’t the only criteria that should drive this process. It is critical that the right message reaches the community in the most appropriate, accessible and timely manner so that the challenges of addressing the double burden of disease in poorly resourced settings is achieved effectively.



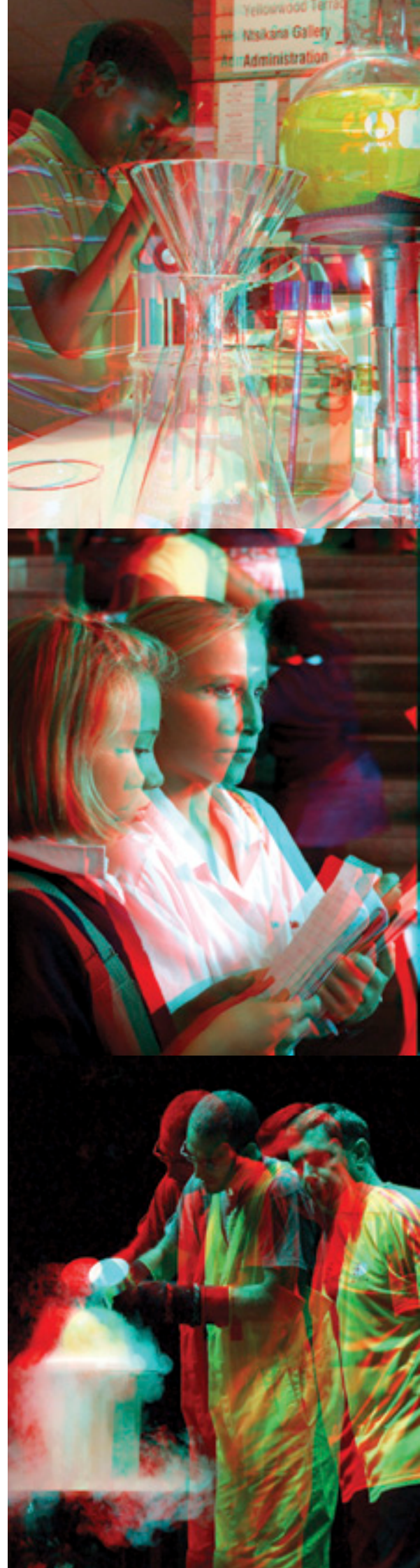
Rhodes University is one of the eight universities offering a Bachelor of Pharmacy degree in South Africa. It is situated in Grahamstown, in the Eastern Cape Province. Pharmaceutical care is a core component of the Pharmacy and Administration Practice curriculum at Rhodes University. In the second year, students are introduced to the concepts of pharmaceutical care, public health and primary health care as well as the role of pharmacists in developing countries. In the third year, students learn more about communication, priority health conditions in primary health care as well as health promotion. Students also conduct research in patient education, chronic conditions or pharmaceutical policy issues. By the fourth year, service-learning forms a key component of the curriculum. Service-learning is a course-based, credit-bearing educational experience in which students participate in an organised service-learning activity that meets identified community goals; and reflect on the service activity in such a way as to gain further understanding of course content, a broader appreciation of the discipline and an enhanced sense of civic responsibility.<sup>5</sup> The Community Experience Program provides an opportunity for students to respond to identified community health needs of Grahamstown by interviewing and educating patients with chronic conditions. This is conducted in patients' homes to increase the students' awareness of various factors that contribute to patient understanding of their condition and medicine taking behaviour. Students then reflect on the interviews as well as how the experience will influence their behaviour as future pharmacists.

The Bangkok Charter identifies health promotion as a key focus area in global health development of communities.<sup>6</sup> Therefore an elective course was designed for final year pharmacy students to raise awareness of the priority health conditions affecting the people of South Africa. As part of the elective in 2009, nine students were required to design an interactive quiz, compatible with custom designed computer software (known as BKnow) and an interactive model on one of the three commonly-occurring health conditions in the Eastern Cape Province namely: Diabetes; Hypertension; HIV and AIDS. Tuberculosis (TB) was included with HIV/AIDS and Obesity with Hypertension and Diabetes. Information about the chronic conditions was summarized on posters and information leaflets. The information leaflets contained a summary of the health conditions as well as tips on healthy living. This information was also translated into isiXhosa, the local language. Board games which focussed on the chronic conditions were also specially designed to actively engage participants.

The computer-generated question and answer quizzes were pilot tested at six schools, both government-funded and independent, to assess their suitability for the intended target audience. Children from grades 8 to 12 evaluated the quiz for each disease condition and changes were made according to the feedback received. Quizzes for younger children which had been pilot tested and used for the Sasol National Science Festival, Scifest 2007 were used again during the national science festival, SciFest Africa in 2009.

Each quiz was designed to collect demographic details of the participants and assess pre-intervention knowledge on the prevention of the condition. Thereafter, information relating to the questions was given and the participant's knowledge was retested with a post-intervention quiz. The aim was to see if there was any change in the participants' knowledge as a result of taking the quiz. The BKnow presenter software was used to integrate multiple-choice questions into a Microsoft Powerpoint presentation. The 'quiz' slides allowed participants to choose one of the given options. Each option was tagged with a pop-up consequence, either congratulatory if that option represented the correct answer, or explaining why the chosen option

Images: <http://www.scifest.org.za>





was not correct. Demographic data of respondents and responses to both the pre- and post-intervention quizzes were logged as Extensible Markup Language (XML). A small interpreter, written in Python, was used to analyze the logged XML and produce tables of responses, which were in turn passed to a statistical package.

The combination of BKnow and Powerpoint offers a reasonably primitive multiple choice system, but with the advantage of being able to leverage the wide base of existing Powerpoint skills for developing presentations. Only very minor changes need to be made to a standard Powerpoint presentation to designate 'quiz' slides. Interacting with the system is extremely simple; only two keys are required and these can be labeled with different colours to further simplify instructions on how to use the system. The system can thus be used by anyone, even those with little or no computer skills and as such is ideally suited to disseminating knowledge in developing countries. Future improvements in the presentation software will allow more dynamic presentations (including video clips, animations and so on) to be screened.

These health promotion materials were exhibited at the national science festival, SciFest Africa 2009, from 25 to 31 March 2009. During the seven day science festival, each day's exhibit focused exclusively on one of the three conditions, except for the last day which focussed on all the health conditions. Thus on each of the first six days of the festival, the quiz and interactive model of only one of the conditions were available. Posters on all the chronic conditions were displayed as part of the exhibit and the information leaflets were available to all who visited the exhibit. For the duration of the science festival, final year pharmacy students participating in the elective and the course co-ordinators involved in the elective, were available to interact with the SciFest attendees. Post graduate students assisted with Blood Pressure (BP) and Body Mass Index (BMI) measurement and a bilingual facilitator was available to interact with non-English speaking visitors and younger children unable to use the computer quiz. By communicating in isiXhosa and using the interactive models and board games, the facilitator was able to inform the participants about the health conditions and lifestyle changes required to promote healthy living.

A cross section of children and adults of various ages, as well as educational, social and cultural backgrounds visited the exhibit at SciFest Africa. A fun, interactive learning environment was created to assess the participants' knowledge and to raise awareness of these priority health conditions among scholars and other attendees. In addition, the exhibit provided information to enable children make informed decisions for healthy living by using games, models, information leaflets and posters. A total of 1361 individuals participated in the quizzes which were well-received by both learners and teachers. The pre-post intervention results showed that there was an increase in knowledge amongst SciFest participants.

Given below is a selection of comments from the participants that illustrate the lessons learned by interacting at the exhibit:

- "Informative, user-friendly, fun-learning"
- "I did not know life sciences could be this much fun!"
- "Very cool and fun way to teach kids"
- "Very interesting, need more things like this to educate people about the disease which is affecting more people"
- "Being healthy can be fun"
- "It was very effective since it was interactive .....it really got the message across!"
- "This is a fun and good way to teach people about diabetes. Especially young people. Well done!"
- "Amazing how common sense is sometimes not so common. This is a good reminder of the things we should be thinking about re: lifestyle"
- "Love the games. They taught me a lot"

The outcomes achieved by this elective included raising awareness regarding the prevention of CNCs while providing a hands-on health promotion learning activity for final year pharmacy students using the principles of service-learning. Student reflection at the end of each activity and a final reflective portfolio capturing the extent to which critical cross field outcomes were achieved helps students to integrate learning activities with service-learning principles into their practice as future pharmacists.

The success of this health promotion activity was evident as it was well-received by scholars, teachers and others attending SciFest Africa. Successful collaboration of the Faculty of Pharmacy course co-ordinators with the Computer Science Department, the Graphics Services Unit and the School of Languages at Rhodes University as well as local independent and government-funded schools resulted in a fun, interactive health promotion exhibit. The opportunity to interact with teachers involved in life orientation at schools from different provinces provided an impetus in motivating and sustaining health promotion activities at schools. It was rewarding to receive feedback indicating that SciFest attendees had gained knowledge, which could positively influence their future health. ■

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**References:**

1. **Suhrcke M, Nugent RA, Stuckler D and Rocco L.** *Chronic Disease: An Economic Perspective*. London: Oxford Health Alliance 2006. ISBN 0-9554018-1-X
2. *Health systems resources*, World Health Statistics 2008. Available at: [http://www.who.int/whosis/who-stat/EN\\_WHS08\\_Full.pdf](http://www.who.int/whosis/who-stat/EN_WHS08_Full.pdf) Accessed 18 October 2008
3. **Abegunde DO, Mathers CD, Adam T, Ortegon M, Strong K.** *The burden and costs of chronic diseases in low-income and middle-income countries*. *Lancet*. 2007 Dec 8;370(9603):1929-38.
4. *Department of Health, January 1996*. National Drug Policy for South Africa.
5. **Bringle R and Hatcher**, 2004. *Implementing Service Learning in Higher Education*. [online] Available from: <http://www.compact.org/advancedtoolkit/pdf/bringle-all.pdf> [Accessed March 27, 2009].
6. **WHO.** The Bangkok Charter for Health Promotion in the Globalized World. [Online] Available from: [http://www.who.int/healthpromotion/conferences/6gchp/bangkok\\_charter/en/print.html](http://www.who.int/healthpromotion/conferences/6gchp/bangkok_charter/en/print.html) [Accessed April 12, 2009].
7. **Ministry of Education.** 2004, The Higher Education Qualification Framework, Department of Education, Pretoria

*In line with the South African Qualifications Authority (SAQA) Act and Institutional policies, all students studying at Rhodes University are expected to achieve the following critical cross-field outcomes: identify and solve problems; work in a team; organize and manage themselves; collect, analyse and evaluate information; communicate effectively; use science and technology; recognize problem solving contexts; reflect on and explore effective learning strategies; participate as a responsible citizen; be culturally and aesthetically sensitive; explore education and career opportunities<sup>7</sup>.*

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# Connecting National Organisations to educational institutes

## Visionary Work in Brazil

Jaldo de Souza Santos

**When I took over the direction of the Federal Council of Pharmacy of Brazil, there was a significant gap between it and the Brazilian pharmaceutical education institutions. I truly felt that this misconnection was resulting in detriments to society, the healthcare market and existing health systems in Brazil.**

Compounding this situation was that societal demands for health services were increasing and diversifying at the same speed, so the market became much more competitive and experienced a phase of expansion thanks to emerging technology. The public health system plunged into a struggle to enforce the principle of universal access to services, specifically outlined in the Brazilian Federal Constitution of 1988.

On the other hand, private health services, no less demanding and competitive, needed to streamline their costs and rationalize the use of products, including medicines, as misuse was and continues to result in health problems, preventable hospitalizations and consequent damages.

Now, who was – and where was – the professional who was at the forefront and took responsibility when faced with these challenges? It was the pharmacist. The problem, however, was that the pharmacy education system in Brazil desperately needed updating if the country wanted to graduate technically and scientifically skilled professionals confident in their knowledge and sensitivity to humanities and social awareness.

Pharmacy education was stuck in an archaic and unproductive system, if we think of meeting new and future professional requirements. The curriculum guidelines that were about to be approved highlighted three sectors, dividing the pharmaceutical profession into three distinct types of professionals. It was then that the Council decided to intervene, opening dialogue with the National Council of Education in a public hearing, ultimately preventing the adoption of the previously mentioned guidelines. The lack of guidance in the formulation of these guidelines was glaring, with some encompassing 2200 hours of instruction and others with 5000. Clearly there was no coherent view on pharmacy education.

All involved in the educational process – teachers, course coordinators, students of Pharmacy and specialists – wanted change, but no one seemed to know how to make it happen.

At that point I gathered in Brasilia, Brazil the leaders in pharmaceutical education to discuss this absolute need for change. What resulted were guidelines that, among other criteria, implemented a more humanistic approach ►

to pharmacy education, which formed the basis of all undergraduate courses, not only those with clinical applications.

The Ministry of Education in Brazil (MEB) accepted these new guidelines and they were discussed in various pharmaceutical education conferences in Brasilia until the publication of the entire, new syllabus for the training of pharmacists. This led to an increase of 4000 hours instruction time (4800 hours/class) and resulted in pharmacy as a five-year of course. And I emphasize that this new schedule was proposed and supported by the Federal Council of Pharmacy, accepted and published by the MEB.

Early in 2010 we signed a partnership with the Ministry of Education in which the Federal Council of Pharmacy will conduct inspections and evaluations of the quality of pharmaceutical education. For this, the Council, through its committees of experts, will examine all courses, verify the registration of professionals entering the market and when enabled, ensure they are practicing under the demands of respectability and credibility put forth by both professional standards and by the community. It is our goal to make clear that pharmacists are part of society and must give back to it.

The Pharmacy course must have a high degree of social relevance. The national curriculum guidelines applied in pharmaceutical education must explicitly describe what will be learnt, but not how to learn – the methodology should be suitable for pharmaceutical training and not set out to merely advance new teaching methods without consideration for the profile of training and its potential to train students.

In relation to the infrastructure, the course must have high level of innovation, following references provided by the partnership projects between MEC and CFF, which indicate the necessary laboratories essential for proper student training and omitting those that do not contribute to the ultimate schooling of future pharmacists.

Although pharmacy education is not a primary task of the Council, given the facts presented we have incorporated into our work the responsibility of presenting an assessment via a technical report, with the analysis of supply, demand and service resulting in a qualitative, positive or negative recommendation for the course. In doing so, we hope to help the colleges of pharmacy in Brazil adapt to changes that in themselves mirror changes in the Brazilian health system and public expectations. We truly want the next generation of pharmacists to better connect and identify with the communities they serve. ■

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