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FOREWORD

The International Hospital Federation vision is to become a world leader in facilitating the exchange of knowledge and experience in health sector management. The publication of a Reference Book each year is a tool to achieve this aim.

The organization of an important congress is another one. Indeed, the activities of the International Hospital Federation are governed by the organization of a major international congress every two years. Two years ago the French Hospital Federation had the pleasure to welcome the 35th Congress. In 2007, the Korean Hospital Association took charge of this event, which took place in Seoul, from 6 to 8 November. Thanks to this initiative, hospital professionals from all over the world had the opportunity to meet them and to discuss on current key issues in health care. This year, the topic of the Congress was “Vision and strategy for ubiquitous health care: Seamless health care across all health care settings and contexts”. Participants attended sessions on hospital information systems, ubiquitous technologies for health care, patient safety, global trends and lessons on hospital accreditation systems, comparative hospital policies, organizational issues in health-care organizations, design and health special sessions, e-business in health care, the role and future of hospital pharmacy, improvement of nursing quality, health information management, improved management of nutrition care process, human resources management, globalization of health care.

Each of those topics is important for health care stakeholders. Human resources is however the major one. The impact of the migration of health workforce is increasing. This phenomenon, which is not new, has dramatic consequences on economic, social and health situations in the developing countries. Indeed, they have to face the burden of poverty with their own health challenges such as HIV and AIDS, and with generally under-resourced health sectors. But the migration of their health professionals has an impact on the costs, quality and availability of such services for local populations. It contributes to the breakdown in health systems. These health care professionals are attracted by the living and working conditions in developed countries, that lack a complete health workforce.

Another topic arouses a strong interest: health information and communication technologies. Indeed, the consolidation and implementation of information systems is at the very core of the ongoing transformation currently taking place in the hospital and health care environment. It is based on health care quality improvement as well as on cost control. Digital revolution is now clearly associated with several objectives: sharing information in the continuum of care; access to databases, facilitating decision-making and prescriptions, limiting risks of avoidable mistakes; operational and financial piloting, better management of resources. Hospital and health care institutions and professionals need a serious involvement in a structured and coordinated development of health information technologies.

This International Hospital Federation Reference Book deals with all of this and much more. Reading it will confront you with the current challenges.

Gérard Vincent
President
International Hospital Federation
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INTRODUCTION

The content of this year reference book is again able to achieve even higher quality and relevance than in previous editions, as it is the ultimate purpose of this publication to never be relaxed and sit back, but rather to always strive for excellence. In this issue we are touching areas of high relevance to the hospital and health services sector by picking examples from different regions of the world.

The content, as said, is covers areas of high importance on the hospital agenda. Such areas are the summaries and perspectives received from Africa, Eastern Mediterranean and Western Pacific Regions respectively. Contributions addressing health regulatory issues from colleagues in New Zealand and the USA respectively, are featured. There are also contributions on the counterfeiting of medicines, a growing and global phenomena that is posing a threat to patient safety.

Patient safety has become one of the prime foci of IHF, and therefore we have joined the WHO Patient Safety Alliance in order to reach out to and share information with our members and partners around the world. We are pleased to publish articles in this edition of the reference book dealing with this important area.

Further, also covered are articles dealing with other important issues relevant to the improvement of quality of health services. The use of global positioning systems, architecture and design, security and access control, are areas where technology play a great role in enhancing quality of services.

Other papers are oriented to the clinical care and care of particular diseases. We will learn from contributions on such different areas as infection control and hygiene, oncology, patient handling, and laboratories.

I wish you fruitful reading and extend my appreciation to all the contributors and the IHF publisher, Pro-Brook, that have made this publication possible.

Professor Per-Gunnar Svensson
Director General
International Hospital Federation

Perseus Voltaire, August 2007
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HEALTH AND DEVELOPMENT IN AFRICA: 
THE CYCLE OF POVERTY AND ILL-HEALTH

ARTICLE BY DR LUIS GOMES SAMBO, REGIONAL DIRECTOR, WHO – REGIONAL OFFICE FOR AFRICA

Health can drive social progress and economic growth and ill-health pushes people into the poverty trap. The severe burden of disease in Africa hampers development and current investment in health is inadequate. African governments need to invest more in health and Africa needs more development support from outside. Scale up tried and tested public health solutions rather than endless experiments. A paradigm shift is needed: need to address underlying determinants of ill-health, such as poverty.

Abstract

People living in the African Region face a heavy and wide-ranging burden of disease, which takes its toll on social and economic development and shortens their life expectancy. The HIV/AIDS epidemic as well as the resurgence of malaria and tuberculosis have swept away improvements in life expectancy in some sub-Saharan countries (see Fig. 1.1). Other infectious diseases and – increasingly – noncommunicable conditions are also a severe burden, while the complications of pregnancy and childbirth take millions of lives every year.

The health services that have evolved in countries in Africa are often not able to address adequately this severe burden of disease. These health systems are weak, reflecting the overall state of the economies in the African Region. In many countries out-of-pocket payments are high in proportion to household incomes and are a major factor driving poverty. The cost of treatment for an adult with HIV/AIDS, in addition to lost income due to time off work, can drag a whole household below the poverty line. Therefore, just as health can drive economic growth, ill-health can push people into poverty and make it very difficult for them to escape the poverty trap. This vicious cycle of poverty and ill-health can be seen in many countries in Africa. Some 70% of the population of sub-Saharan Africa live on less than US$ 2 a day, and 46.5% on less than US$ 1.08 a day (see Fig. 1.2). While poverty has declined in other parts of the world, such as East and South Asia, over the past 20 years, in sub-Saharan Africa the trend has been strongly in the other direction. Between 1981 and 2001 the gross domestic product (GDP) of sub-Saharan countries decreased by 13%, resulting in a doubling in the number of people in the Region living on less than US$ 1 a day from 164 million to 314 million. While Africans represented only 16% of the world’s poor in 1985, by 1998 this proportion had risen to 31%. The trend is likely to continue, with poverty expected to decline over the next 20 years in every part of the world except sub-Saharan Africa, where a dramatic increase is expected.

Progress in human development made by some African countries in the 1970s and 1980s has been sharply reversed by HIV/AIDS and by armed conflict. On top of that, countries in the Region continue to suffer from other emergencies, large-scale migration, famine and economic decline. Chronic diseases are becoming increasingly prevalent in middle-income countries of the African Region, such as South Africa and Kenya. Furthermore, road traffic collisions place a heavy burden on households and, in turn, regional and national economies. For instance, road traffic collisions cost the Ugandan economy around US$ 101 million per year, which is 2.3% of the country’s gross national product (GNP). In addition mental health is one of the most under-resourced areas of public health in the African Region, even though mental health problems are on the rise and mental health services are desperately needed in post-conflict societies to help them achieve stability. In many countries of the Region this area of public health requires more attention than it is currently receiving. Outside the African Region, about two-thirds of deaths are due to noncommunicable diseases. In Africa, by contrast, according to 2002 estimates, 72% of deaths are caused by communicable diseases such as HIV/AIDS, tuberculosis, malaria, respiratory infections, other infectious diseases, and complications of pregnancy and childbirth. These are largely preventable deaths, which account for about 23% of mortality in other regions. The WHO Commission on
Macroeconomics and Health made a powerful case in favour of investment in health – by scaling up known, cost-effective interventions – as an important driver of economic growth. No other region of the world has so much potential to benefit from such investment in health as the African Region.

African economies are growing fast, but not fast enough to achieve the UN Millennium Development Goals (MDGs). The economies of sub-Saharan countries need to grow at an average annual rate of 7% over the next decade to achieve the UN Millennium Development Goal 1 of cutting poverty in half by 2015 (see Box 1), according to the International Monetary Fund. At current rates some countries may succeed, but many will fail. Economic growth and more investment in health will not help countries attain the improvements envisaged by the MDGs alone. More efforts are needed to achieve greater peace and security, good governance, gender equality and sustainable management of the environment. Some countries in the African Region are not far off achieving the MDG targets and may need increased overseas development support to help bridge the gap in economic growth rates. Sub-Saharan countries reported their best economic performance for years in 2004, with an average 5% growth in real GDP, while average inflation fell to below 10% for the first time in 25 years. Oil producers, such as Nigeria and Equatorial Guinea, and post-conflict countries, such as Burundi and Sierra Leone, have seen some rapid though often sporadic growth in recent years.

Economic growth has not always led automatically to improvements in public health in the African Region. Current growth rates are an opportunity for African governments to invest more in health, an investment that would lead to more social and economic stability. Increased investment in public health can reduce the burden of preventable and treatable diseases that – on macroeconomic level – can be a drag on national economies and – on microeconomic level – a drain on household and individual incomes. Health must, therefore, constitute a central pillar of any coherent vision of African development, while increased investments in health should include those in health-related sectors, such as water and sanitation, education and environmental protection (see Figure 3)

**Putting health in the development context**

Development experts have long recognized health as an important moral and social goal. Health is also a key component of a sound development strategy, along with education, economic growth and good governance. As a form of human capital, health is essential to a productive society. Furthermore, the MDG project of the United Nations fully endorses the central role of health in development.

Several studies have sought to quantify the macroeconomic impact of the disease burden (see Table 1). The prevalence of HIV/AIDS for adults aged 15-49 years in the African Region is estimated at about 7.2%. In every other WHO region the average was less than 1%. There is general agreement that the economic and social impact of HIV/AIDS in the African Region has been devastating. The epidemic has drastically reduced the workforce in many countries, while the cost of caring for the growing generation of AIDS orphans could slow down long-term GDP growth by as much as 1–1.5% in countries with high prevalence of HIV/AIDS, such as Kenya and South Africa. Moreover, the older scourge of tuberculosis has made a comeback in many parts of the world.
Southern Africa has become the epicentre of the dual epidemic and both diseases are causing untold human suffering and reducing household income, in turn slowing economic growth in southern African countries. Malaria has been dubbed "an African disease" because 90% of cases occur in this continent. Estimates show that countries with endemic malaria have 1.3% less economic growth per annum compared with similar non-endemic countries, and that in Africa the annual cost of lost productivity and providing treatment is US$ 12 billion.

**Efforts to promote development in Africa**

There have been many regional and international initiatives to promote development in Africa. Some have focused on health as well as education, governance and sound economic policy, while others have focused entirely on health. In recent years both governments in Africa and donors have pledged to provide more money for health and development.

African governments pledged to raise their spending on health to 15% of their annual national budgets at a meeting in the Nigerian city of Abuja in 2001. A year later, the United Nations called on developed countries to increase their overseas development assistance to 0.7% of their GDP by 2015. European countries have pledged to do this, but only a few have done so. By early 2006, Denmark, Luxembourg, the Netherlands, Norway and Sweden had actually honoured that commitment. The debt forgiveness granted by the G8 industrialized countries in 2005 to 23 countries in Africa presents an opportunity for the latter countries to invest more in health, as well as in water, sanitation and education. Following pledges by governments in Africa to invest more in health and health-related sectors, mechanisms need to be set up to monitor spending. Below are some of the major regional and international initiatives to promote development in Africa.

**The Abuja Declaration**

Leaders of African countries gathered in the Nigerian city of Abuja in April 2001 to declare their continent to be in a "State of Emergency" over the HIV/AIDS pandemic. Governments declared that "containing and reversing the HIV/AIDS epidemic, tuberculosis and other infectious diseases" should constitute their "top priority for the first quarter of the 21st century". Their declaration said that tackling these epidemics was an integral part of poverty reduction and sustainable development as well as peace and security, and that the fight against HIV/AIDS was "the highest priority issue in our respective national development plans". In the Declaration, the governments in Africa called for the lifting of all tariff and economic barriers to funding AIDS-related treatment and medicines. For their part, the governments pledged to increase spending on health to at least 1% of their annual budgets.

**NEPAD**

The New Partnership for Africa’s Development (NEPAD) was launched in 2001 by the Organization of African Unity (OAU) to eradicate African poverty, promote sustainable growth and development, help countries in Africa take a more active part in the global economy and improve the status of women in African society. In NEPAD’s 2002 Health Strategy, African governments identified the "huge burden of potentially preventable and treatable disease" as causing "unnecessary deaths and untold suffering". According to NEPAD, the burden of disease in Africa "continues to block economic development and damages the continent’s social fabric". NEPAD recognizes the central role of building and reinforcing health systems to assist in improving health in Africa, but
also that health-care services are “too poorly funded”. The NEPAD health strategy calls on African governments to honour their pledge to raise health spending to a level of 15% of their annual national budgets. NEPAD argues that peace and security are vital for development and acknowledges the devastating impact of war on human health and development.

The United Kingdom’s Commission for Africa

According to a report released by the UK’s Commission for Africa in March 2005, Africa and its partners have a unique opportunity to act now to promote social and economic development in the continent. The report argues that Africa should drive its own development and that it is already doing so through the African Union and NEPAD. The report states that it is in the interests of the rich countries to support Africa’s development agenda to create a more prosperous and secure world. The one-year Commission brought together by the United Kingdom – mainly made up of African political leaders, public servants and private entrepreneurs – sought wide consultation. The Commission calls for more investment in health and development.

The UN report identified four main reasons why some regions are not making enough progress towards the MDGs. The first was poor governance. The second was national poverty traps, a particular problem in the African Region. The third was the presence of pockets of poverty within countries. The fourth was political neglect. The UN report recommends that every government should adopt and implement a national strategy – with the help of bilateral and multilateral donors and organizations – to help each country achieve the MDGs.

G8 Summit 2005

The Group of Eight industrialized countries (G8) agreed to cancel the debt of 18 of Africa’s poorest countries and to increase aid to developing countries by US$ 50 billion at a summit in Gleneagles, Scotland, in July 2005. Of those, 23% in Africa. The G8 lamented declining life expectancy in Africa and pledged to continue to support African strategies to improve health, education and food security. The G8 also pledged to support investment in improved health systems, including the training and retraining of health workers to tackle the major diseases affecting Africa, such as HIV/AIDS, malaria, tuberculosis, polio and other neglected diseases. The G8 pledged to give support for investments in water and sanitation and to comprehensive food security and famine prevention programmes. It also pledged to support African countries in building peace and security, promoting good governance, investing in people, and promoting growth and development.

Conclusion: Making it happen

What should be done to ensure that health development in the African Region plays its rightful role in national development efforts? The answer is that there are tried and tested health-care interventions that work, interventions that enable safe childbirth, treat acute respiratory and diarrhoeal illnesses, and prevent HIV transmission and early death from AIDS. There are established methods of preventing malaria transmission and treating tuberculosis. The results of a public health experiment called the Tanzania Essential Health Interventions Project (TEHIP) suggest that it is possible to achieve dramatic gains in maternal,

<table>
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<tr>
<th>Burden of disease in DALYs*</th>
<th>Mortality rates (arbitrary units) by cause and mortality strata in the African Region</th>
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<tbody>
<tr>
<td>1 AIDS</td>
<td>44 630</td>
</tr>
<tr>
<td>2 Malaria</td>
<td>20 970</td>
</tr>
<tr>
<td>3 Respiratory infections</td>
<td>18 976</td>
</tr>
<tr>
<td>4 Perinatal conditions</td>
<td>10 859</td>
</tr>
<tr>
<td>5 Diarrhoea</td>
<td>11 548</td>
</tr>
<tr>
<td>6 Top five subtotal (1 – 5)</td>
<td>76 083</td>
</tr>
<tr>
<td>7 communicable diseases</td>
<td>39 034</td>
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<tr>
<td>8 Communicable diseases</td>
<td>195 532</td>
</tr>
<tr>
<td>9 Noncommunicable diseases</td>
<td>39 034</td>
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<tr>
<td>10 Injuries</td>
<td>14 974</td>
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Total (8 – 10)                  160 415 

<table>
<thead>
<tr>
<th>Mortality strata (arbitrary units)</th>
<th>Total</th>
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<tbody>
<tr>
<td>Neighbourhood</td>
<td>144 630</td>
</tr>
<tr>
<td>High child, very high adult</td>
<td>144 630</td>
</tr>
<tr>
<td>Medium child, high adult</td>
<td>144 630</td>
</tr>
<tr>
<td>Low child, high adult</td>
<td>144 630</td>
</tr>
<tr>
<td>Very high adult, very high adult</td>
<td>144 630</td>
</tr>
</tbody>
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newborn and child health at little additional cost. Mauritius achieved some of the best reproductive health indicators in WHO’s African Region through providing family planning services, strong political commitment to tackling HIV/AIDS, health promotion, public health education and accurate recording of statistics to gauge changes in health indicators. African governments can avoid some of the burden of noncommunicable diseases that wealthy developed countries now face. While the greatest focus is on the diseases that kill the most people, more efforts are needed to improve on outdated methods of control and cure for neglected diseases, such as sleeping sickness, which also hamper development in African countries.

Some countries are already linking public health and economic interests to tackle shortages of essential medicines, while others may follow suit. For example, some African countries are already using new ways to purchase drugs at reduced prices, such as negotiating low prices for patented antiretrovirals for HIV/AIDS. Other countries are hoping to purchase cheaper generic antiretrovirals from other developing countries, making use of an exemption in international trade law for poor countries that was made permanent at the WTO meeting in December 2005. Farmers in the United Republic of Tanzania are growing the Artemisia annua plant to improve domestic supply of antimalarial medicines. Empowering farmers in the United Republic of Tanzania are growing the Artemisia annua plant to improve domestic supply of antimalarial medicines.

Box 2 | MDG 8: A global partnership for development

MDG 8 calls for international trade and finance that are more equitable and give a fair chance to poor countries. It calls for sustainable development and youth employment as well as better access to essential drugs and communication technology in developing countries. Progress in these areas depends not only on developing countries themselves, but also hinges on policy changes made by wealthy countries, such as debt forgiveness, commitments to increased aid, freeing of market restrictions and relaxing patent protection for lifesaving technology. Some progress has been made in these areas, for example, partial debt relief has been offered to Burkina Faso, Mali, Mauritania, Mozambique, the United Republic of Tanzania and Uganda. Thirty-four of a total of 42 countries in the heavily indebted poor countries initiative are in the African Region. Donor countries have also agreed to harmonize aid and respect development priorities in recipient countries. However, official development assistance declined in sub-Saharan Africa from US$ 34 per capita in 1990 to US$ 21 in 2001. The goal reminds rich nations of their commitment to give 0.7% of their annual income in aid. By early 2006, only Denmark, Luxembourg, the Netherlands, Norway, and Sweden had actually honoured that commitment. However, increased aid can only lead to progress on the rest of the goals if recipient countries improve governance and commit themselves to a policy of poverty reduction.

If the African Region is to achieve peace, prosperity and health for all, African nations and their partners need to act now to implement the many known solutions.

A concerted effort by African governments and their partners is gathering momentum for change and to help the Region come closer to achieving the MDGs (see Box 2). Five key elements are vital for success. First, stronger political will and commitment is essential to ensure solutions are implemented. Second, African nations need to allocate a higher percentage of their national expenditure to health and their partners need to increase aid to Africa to address the lack of financial resources. Third, to draw full benefit from that additional donor aid, African nations need good governance to use it wisely. Fourth, adequate numbers of health-care staff are required across the African Region to provide health care, and governments and their partners need to implement adequate programmes to train, retain and utilize these resources better. Fifth, governments and their partners – domestic and international – need to translate good policies into action. If the African Region is to achieve peace, prosperity and health for all, African nations and their partners need to act now.
References


Patient Safety (PS) is becoming a global public health problem affecting all types of health care systems whether developed or least developed. Adverse events affect all processes of health care systems and levels of care and all aspects from clinical to managerial, from curative to preventive, from the public to the private sectors and from diagnosis to discharge. PS is challenged mainly by the shortcomings in health systems and by the complexity of care processes. In addition patient safety is also challenged by a culture of denial and blame as well as inconsistent reporting and learning. After four years of intensive capacity building, field studies, advocacy, and adoption of a regional patient safety strategy an innovative framework named as "Patient Safety Friendly Hospital Initiative" was developed as an umbrella for all patient safety elements and activities at the hospital setting evolved. Some EMR countries are adopting this Initiative to enhance PS as a national programme.

Responses of EMR countries to global patient safety movement.

Despite the challenges facing patient safety EMR countries have made several efforts in support of PS. One example of these efforts was when EMR countries opted for a regional strategy which was developed in 2004. This strategy was composed of five main axes: the first axis is orientation and raising awareness among the different stakeholders, the second axis is about knowing more about PS and its magnitude and types, the third axis is about research and root cause analysis, fourthly is the development of patient safety models and pilot studies, and lessons learnt from them. The fifth axis is the development of a national patient safety programme building on the other axes of the strategy. A second example of response to enhance PS is the efforts of some EMR countries to address PS by launching quality improvement and quality assurance activities particularly accreditation such as in Bahrain, Egypt, Jordan, Iran, Kingdom of Saudi Arabia, Kuwait, Lebanon, Morocco, Oman, Qatar, Tunisia and UAE. Some of these countries have launched Accreditation programmes. Thus PS as an attribute of Quality is not totally new to many countries. This was an opportunity to seize to sell the idea of Patient Safety Friendly Hospital Initiative (PSFHI). A third example of response to enhance PS is the efforts on prioritizing areas of patient safety in EMR Countries. Focus group techniques during PS meetings and
The goal of PSFHI is to be in line with the national goals of improving quality and performance of hospitals. Its purpose is to establish and foster a culture that is open to learning from errors that strives for best practice implementation. Training courses identified the following priority elements of PS:
- Medication Errors;
- Injection safety;
- Failure to use or act on diagnostic test or device;
- Wrong Site Surgery;
- Post-operative complications;
- Use of inappropriate or outdated diagnostic test or procedure;
- Transfusion Errors;
- Health Facility Acquired Infections (HAI);
- Failure to diagnose;
- Wrong Communication Procedures.

Such prioritizations at the Regional level allows each country to identify its own priorities. A fourth response was strengthening technical cooperation among EMR countries. In this spirit of collaboration with countries has launched the PSFHI. The main purpose of PSFHI as an accountability framework is to support a more just, transparent and open safety culture at the hospital health care.

As in Figure 1 PSFHI has three main related domains/elements: The first is about clear strategic intent of goals, purpose, objectives and targets; the second is ensuring harmony and interaction among main actors or stakeholders namely community, organizations, profession and patient. The third domain deals with important strategic directions of awareness advocacy, leadership and good governance, information exchange through effective communication, learning and action orientation. With such framework PSFHI translates policies into operations at the hospital level requiring that different levels have different roles to play in support of patient safety.

The Strategic Intent of PSFHI: The goal of PSFHI is to be in line with the national goals of improving quality and performance of hospitals. Its purpose is to establish and foster a culture that is open to learning from errors that strives for best practice implementation. The objective of PSFHI is to redesign hospital health care systems to be safer. Targets drive action and give clear directions for action and guide and test commitment of the hospital. Setting targets at hospital level will be determined by the priority components of patient safety. Targets can be specific such as reducing MRSA by a certain percentage or can focus on processes.

Stakeholders/Actors for PSFHI
As depicted in Figure 1 the main stakeholders are the community, the organization, the professional staff and most importantly the patient who is at the centre of the PSFHI. Close collaboration between these stakeholders is in line with the notion of patient safety is everybody’s business. PSFHI creates the opportunity for interaction among these stakeholders in order to fulfill the targets, objectives and purpose of a people-centred health care culture where patients feel comfortable as partners in their own health care, where teams of health professionals are encouraged to work together effectively for the care of each patient, and where there is support for
staff and people to keep learning and to share information. PSFHI ensures compliance of hospitals to involving consumers in improving health care safety through a performance assessment instrument drafted by WHO/EMRO.

PSFHI demands Patient and Public. involvement when the hospital performance is assessed and certified. Hospital builds health literacy for its patients and carers to empower them to make right decisions in their care; involves community in different patient safety activities. and verification; hospital communicates patient safety incident to patients and their carers.; hospital has a patient friendly environment.

Organizing safety programmes is to ensure that the conducive environment created by the national level policies are realised at the facility level. The lessons learnt when reviewing PS in EMR show that at the same time that the MOH is developing it’s policies for PS there is need for bottom up plans at the facility level. Organizational processes take place at policy, managerial and clinical levels:

- At policy level organizational processes support standardisation and consistency of practice, commitment to and investment in systems redesign and information technology management, research to inform systems redesign and a culture that learns from its own mistakes and shares knowledge by establishing legislations for protection of health care providers' rights with regards to confidentiality in reporting.
- At managerial levels actions support best practice based on evidence, teamwork, credentialing and supervision, risk management, audit and reporting, and open disclosure when things go wrong.
- At clinical level initiatives support people in doing the right thing as part of a safe and high quality system with appropriate accountability to individual patients, management and the community.

Strategic directions

As shown in figure 1 in order to fulfill the targets focus should be in raising awareness, building Leadership and Governance, effective communication, learning and action orientation. These directions are not necessarily ordinal. It is justified to launch PSFHI where the leadership of interested hospital are committed to PS. Unless policy-makers and clinicians are convinced that patient safety is a problem, progress in patient safety will not be sustained or effective. A critical mass should be generated and champions of authority figures, public and private sectors, and media need to be developed and involved. A sense of direction and clarity of purpose will thus evolve among the PS stakeholders. Advocacy and raising awareness are continuous processes where a learning network is established that facilitates the sharing of best practices and a proactive research agenda that anticipates risks and learns from adverse events in a synergistic and regular manner. In its advocacy strategy PSFHI continuously advocates for an open environment for safety and accountability and that the user/ patient should be equipped with knowledge on safe practice. Several national and inter-country seminars were held to discuss PSFHI and agree on its roadmap in the participating countries.

Another strategic direction is the lifelong learning of the health care facility to continuously enhance competence of staff, their skill mix and that the hospital learns from all PS incidents reported by making improvements in its performance. Learning through PSFHI is quicker in a setting like the hospital using “patient forums” tools such as routine engagement with the public and users through an institution- wide strategy, and user representation as well as regular hospital level discussion on patient safety as part of quality issues;

Communicating and exchange of information in PSFHI is an evidence-based approach to map safe care. The analysis of such mapping should provide the hospital, the organization and MOH with clear indications on estimating the prevalence of injury to patients caused by their health care; measuring adverse events; judging preventability of these adverse events and assessing disability caused by them.

All previous description of the features of PSFHI should produce results “PSFHI dramatizes solutions not problems”. Actions introduced by the PSFHI implies necessary large-scale changes for organizational shift that places PS and quality at the heart of health services; ensure high authority commitment for Patient Safety through assessing the nature and scale of harm to patients which has started in 2006 by a survey on the frequency and types of adverse events assessment in 30 hospitals in six EMR countries; review responsibilities for clinicians, managers and funders at all levels of the health care system (national, provincial, local and at facility level) to be aligned with best practice to support the PSFHI accountability framework which some EMR countries started; improve capacity of health staff and managers for developing and implementing PSFHI plans; formulating relevant legislations, rules and regulations and resources for patient safety; assess hospital performance using the set of standards, criteria and indicators drafted by WHO/EMRO; develop structural entities which will oversee and support PSFHI.

Actions for better implementation of PSFHI are charted along a time frame at country and regional levels. Recent collaboration with the International Islamic Relief Organization secured a timeline in seven of the low and middle income countries in EMR. This expands PSFHI to cover more EMR countries.

Conclusions

Patient safety is a major public health problem due to systems failures, however it can be an opportunity for improving quality of care. PSFHI emanated out of collaborative work among EMR countries and WHO/EMRO taking a wide range of actions in performance improvement, environmental safety and risk management. It embraces nearly all hospital care disciplines and actors, and
thus requires a comprehensive multifaceted approach to identifying and managing actual and potential risks to patient safety in individual services and finding broad long-term solutions for the system as a whole.

The Patient Safety Hospital Initiative taps the potential of hospital systems and thus offers an entry point to build a safe national health system. To build such a system PSFIH requires a strong networking process and technical cooperation within and among the countries of EMR and beyond. WHO can play a proactive leadership role at national and international arenas to enhance adoption of the PSFIH as part of its agenda to improve health systems performance.

**Author**

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He joined WHO in 1991. Worked as medical officer in urban and rural settings in Yemen. He held several posts as DG Primary health care, DG health services in Yemen. He worked with some international organizations before joining WHO. He worked as WHO medical officer in Pakistan and as WHO representative to Oman. Now he is the coordinator of Health systems at the WHO regional office in Cairo. He is a founding member of some regional associations working in Evidence based Practice, Accreditation and Patient Safety.

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HEALTH AND HEALTH SYSTEMS IN THE WHO WESTERN PACIFIC REGION

ARTICLE BY DR SOE NYUNT-U, DR REIJO SALMELA, AND DR STEVE FABRICANT, WESTERN PACIFIC REGIONAL OFFICE, WORLD HEALTH ORGANIZATION

This article provides a summary overview of the Western Pacific region and provides information on key health indicators for the region. There is also a description of the health-care systems in the region including both public and private sectors and data on the number of beds available against population numbers. The article also considers the response of health systems to the challenges facing them, as well as health-care financing, and the regulation of the health sector. Coverage is given to the health workforce and the impact of globalization and trade on health.

Abstract

The Western Pacific Region of the WHO includes over 1.7 billion people, 27% of the world’s population. Extending from western China to the Marshall Islands, it however excludes North Korea and all the countries except Malaysia that form the wide southwestern arc of Asia. Even without these geographical anomalies it would be difficult to generalize about health and health systems in the region. This is because of its enormous diversity in development: nations of the WPR differ by extremes from very poor to very rich, from market to centrally planned economies, from the least to the most highly industrialized, some with populations in hundreds of millions but many measured in thousands.

It is therefore not surprising that there are very different levels of development in national health systems. Resources for health vary widely, and so do the “outputs” of health systems such as morbidity and longevity. Life expectancy at birth ranges from 54 in Cambodia to 82 in Japan, and infant mortality from 97 to 3.0. Women outlive men by as much as 7 years.

The critical demographic factor in the region is population aging, although this is happening at different rates due to diverse health, fertility and social factors. As seen below, the transition to an older population has already happened in Japan, and China is headed for a similar transition.

<table>
<thead>
<tr>
<th>Country</th>
<th>Life expectancy at birth</th>
<th>Infant mortality per 1000 live births</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td>Males</td>
</tr>
<tr>
<td>Cambodia</td>
<td>54</td>
<td>51</td>
</tr>
<tr>
<td>Lao, PDR</td>
<td>59</td>
<td>58</td>
</tr>
<tr>
<td>Papua New Guinea</td>
<td>60</td>
<td>58</td>
</tr>
<tr>
<td>Marshall Islands</td>
<td>62</td>
<td>60</td>
</tr>
<tr>
<td>Nauru</td>
<td>61</td>
<td>58</td>
</tr>
<tr>
<td>Tuvalu</td>
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<td>61</td>
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<tr>
<td>Kiribati</td>
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<td>Fiji</td>
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<td>Palau</td>
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<td>Philippines</td>
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<tr>
<td>Samoa</td>
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<td>66</td>
</tr>
<tr>
<td>Vanuatu</td>
<td>68</td>
<td>67</td>
</tr>
<tr>
<td>Micronesia, FSM</td>
<td>70</td>
<td>68</td>
</tr>
<tr>
<td>Solomon Islands</td>
<td>68</td>
<td>66</td>
</tr>
<tr>
<td>China</td>
<td>72</td>
<td>70</td>
</tr>
<tr>
<td>Cook Islands</td>
<td>72</td>
<td>70</td>
</tr>
<tr>
<td>Niue</td>
<td>71</td>
<td>68</td>
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<tr>
<td>Tonga</td>
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<td>71</td>
</tr>
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<td>Viet Nam</td>
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<td>69</td>
</tr>
<tr>
<td>Malaysia</td>
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<td>69</td>
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<td>Korea, Republic of</td>
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<td>Brunei Darussalam</td>
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<tr>
<td>Singapore</td>
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<tr>
<td>Australia</td>
<td>81</td>
<td>78</td>
</tr>
<tr>
<td>Japan</td>
<td>82</td>
<td>79</td>
</tr>
</tbody>
</table>


Table 1: Life expectancy at birth and Infant Mortality Rate (IMR) in the WHO Western Pacific Region.
The critical demographic factor in the region is population aging, although this is happening at different rates due to diverse health, fertility and social factors.

Percentage of population under age 14, 1975-2050 (3 WPR countries)

At the same time, rapid industrialization and growing trade is shifting the disease pattern from what has been typical of developing tropical areas to that now prevailing in developed countries. Taking care of the elderly is not an insurmountable problem so long as the working population is growing and the dependency ratio is actually falling, but in the next half century chronic diseases in the elderly could overwhelm health systems in some countries.

Large morbidity differences exist in the region, however, as seen in Table 2. The less-developed countries generally have a higher disease burden, with most DALYs lost to communicable diseases, maternal/perinatal conditions, and nutritional deficiencies. Approximately 60% of the DALYs lost are from premature death, the rest from disability. There are still high rates of malaria in the Pacific, especially in Papua New Guinea, Solomon Islands and Vanuatu, but heart disease and stroke, long regarded as disease and stroke, long regarded as the elderly could overwhelm health systems in some countries.

Available data on the causes of hospital admissions in the WPR are very incomplete, but normal childbirth and complications account for many, the ranking depending on counter-trends of smaller families and fewer home births. Respiratory and digestive system diseases are major causes, and injuries and circulatory system diseases are also significant.

Health systems in the WPR

In the industrialized countries most health care is provided by urban hospitals and clinics, staffed by qualified practitioners and supported by the latest technology. Several countries also have parallel traditional medicine systems. The countries that are still mainly agrarian rely on small rural health centers supported by secondary hospitals in local urban centers and a few tertiary hospitals in the large cities.

Private providers play a large and growing role in most countries in the Region. Drugstores, small private clinics, and traditional healers are favored by poor patients, and many hospitals are privately owned and operated for profit. Not surprisingly, the most developed countries in the region have more beds per capita than poorer less developed countries, as shown in Table 3. The small island nations tend to have higher than average bed ratios due to their dispersed populations. Wealthier countries also tend to have relatively more private sector health facilities. Some countries with few inpatient facilities are well-resourced at the PHC level. Viet Nam, Lao PDR, Philippines, Indonesia and some others have a significant number of inpatient beds available.

<table>
<thead>
<tr>
<th>Country</th>
<th>DALYs lost, all causes (per 1000 population)</th>
<th>Percent of DALYs lost by cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lao, PDR</td>
<td>103</td>
<td>60.4</td>
</tr>
<tr>
<td>Cambodia</td>
<td>135</td>
<td>62.4</td>
</tr>
<tr>
<td>Papua New Guinea</td>
<td>288</td>
<td>53.9</td>
</tr>
<tr>
<td>Kiribati</td>
<td>274</td>
<td>33.4</td>
</tr>
<tr>
<td>Tuvalu</td>
<td>272</td>
<td>29.5</td>
</tr>
<tr>
<td>Marshall Islands</td>
<td>242</td>
<td>25.7</td>
</tr>
<tr>
<td>Nauru</td>
<td>240</td>
<td>17.6</td>
</tr>
<tr>
<td>Solomon Islands</td>
<td>235</td>
<td>14.7</td>
</tr>
<tr>
<td>Mongolia</td>
<td>227</td>
<td>32.2</td>
</tr>
<tr>
<td>Micronesia, FSM</td>
<td>201</td>
<td>25.5</td>
</tr>
<tr>
<td>Fiji</td>
<td>196</td>
<td>19.6</td>
</tr>
<tr>
<td>Philippines</td>
<td>191</td>
<td>11.0</td>
</tr>
<tr>
<td>Vanuatu</td>
<td>184</td>
<td>8.2</td>
</tr>
<tr>
<td>Niue</td>
<td>180</td>
<td>4.9</td>
</tr>
<tr>
<td>Palau</td>
<td>180</td>
<td>2.7</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>166</td>
<td>1.8</td>
</tr>
<tr>
<td>Samoa</td>
<td>165</td>
<td>0.9</td>
</tr>
<tr>
<td>Cook Island</td>
<td>164</td>
<td>0.7</td>
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<tr>
<td>China</td>
<td>154</td>
<td>0.5</td>
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<tr>
<td>Tonga</td>
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<td>0.3</td>
</tr>
<tr>
<td>Malaysia</td>
<td>146</td>
<td>0.2</td>
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<tr>
<td>Korea, Republic of</td>
<td>134</td>
<td>0.1</td>
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<tr>
<td>Brunei Darussalam</td>
<td>129</td>
<td>0.1</td>
</tr>
<tr>
<td>New Zealand</td>
<td>117</td>
<td>0.1</td>
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<tr>
<td>Australia</td>
<td>110</td>
<td>0.1</td>
</tr>
<tr>
<td>Singapore</td>
<td>106</td>
<td>0.1</td>
</tr>
<tr>
<td>Japan</td>
<td>104</td>
<td>0.1</td>
</tr>
</tbody>
</table>

Although the majority of hospital beds in the region are in public general hospitals. China has by far the most district-level referral hospitals and primary health centers in the region. This sometimes can result in overlapping functions and inefficiency, as noted in the box below. To increase efficiency Japan is currently reducing the number of beds, by closing some public hospitals and psychiatric wards. Health system responses Notwithstanding the differences between them, countries in the WPR share common challenges, including poor and inequitable health outcomes, poor access to care, inadequate quality, continuity and integration of services, and poor responsiveness to clients' needs and demands. Health sector reforms to increase the efficiency and effectiveness of health systems were designed to counter the effects of spending cuts in the 1980s and 90s. Donor pressures for health sector reform were sometimes overwhelming. Only the countries least dependent on foreign aid and ideologies, such as Brunei Darussalam, Malaysia and Singapore, have had the luxury of following their own paths.

The Millennium Development Goals (MDGs), approved by 189 governments in September 2000, provide a clear agenda to improve the lives of the world’s poor. Progress towards the MDGs has been mixed across the region. Extreme poverty has declined dramatically due to economic growth, child mortality has been reduced, and the fight against tuberculosis has made great strides. Some MDG targets, such as for malaria, have already been met. Yet rates of progress for other targets have been slow, such as those for sanitation and maternal and child mortality.

A review of seven priority countries found that Cambodia and the Philippines are on track in improving maternal health. Both have achieved at least 50% reduction in maternal mortality ratio (MMR), and China and Mongolia have reduced MMR by 25% to 50% from 1990 to 2002. But halfway between the baseline and target years Papua New Guinea and Viet Nam have reduced MMR by less than one quarter. Among the countries in the Region with a high burden of tuberculosis, only Viet Nam has performed well in both detection and cure. Although exceeding cure rate targets, Cambodia, China, and the Philippines have yet to reach their target rates for case detection.

Multisectoral and decentralized approaches are increasingly being used to combat communicable disease threats. The traditional infectious diseases have been attenuated through immunization programs, access to improved sanitation, and (to a lesser extent) safe drinking water. HIV/AIDS prevention and control requires collaboration of the health, labor, construction, transportation, migration, and police sectors, as well as social research institutions and blood banks.

### Box 1

China’s large rural population is served by a three-tier system. The basic level is the village doctor who often have only rudimentary training. Working on a fee-for-service basis, they diagnose and treat patients, prescribe and sell medicines. The second tier is township health centres or hospitals, with about 25% of all hospital beds in China. Services include deliveries and basic acute treatment and surgery. They tend to have lower bed occupancy rates than county hospitals because of quality and cost concerns. The third tier, the county hospital, is usually the highest level that rural residents use. Independent of the 3-tier system are three important public health services: The Epidemic Prevention Service and the Maternal and Child Health Programme under the MOH, and family planning programmes under the Family Planning Commission. They are increasing problems with overlap, duplication, and lack of coordination between parts of the vertical and 3-tier services. Urban areas also have issues of duplication and inefficiency. One city might have hospitals under several systems but few community-based service facilities, and have weak outreach of public health programmes to the large unregistered migrant population.

### Table: Most and least hospital beds

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th>Total beds/1000 population</th>
<th>Beds in private hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>2004</td>
<td>14.79</td>
<td>Korea, Republic of 2004</td>
</tr>
<tr>
<td>Tokelau</td>
<td>2003</td>
<td>11.76</td>
<td>Japan 2004</td>
</tr>
<tr>
<td>Mongolia</td>
<td>2004</td>
<td>6.02</td>
<td>Macao (China) 2004</td>
</tr>
<tr>
<td>New Zealand</td>
<td>2002</td>
<td>5.81</td>
<td>New Zealand 2002</td>
</tr>
<tr>
<td>Korea, Republic of</td>
<td>2004</td>
<td>5.28</td>
<td>Philippines 2002</td>
</tr>
<tr>
<td>Cambodia</td>
<td>2004</td>
<td>0.57</td>
<td>Samoa 2004</td>
</tr>
<tr>
<td>Northern Mariana Islands</td>
<td>2000</td>
<td>1.02</td>
<td>Hong Kong (China) 2005</td>
</tr>
<tr>
<td>Philippines</td>
<td>2002</td>
<td>1.07</td>
<td>FS of Micronesia 2003</td>
</tr>
<tr>
<td>Lao PDR</td>
<td>2005</td>
<td>1.20</td>
<td>Mongolia 2004</td>
</tr>
<tr>
<td>Guam</td>
<td>2000</td>
<td>1.33</td>
<td>Brunei Darussalam 2004</td>
</tr>
</tbody>
</table>

when done well can influence behavior. Risk perception by the general public, and many people. Mass media can influence present in a manner that can convince communicate and even more difficult to social changes are difficult to major risks. Risk factors that require Tobacco use and underweight are also are the main underlying risk factors causing much of premature mortality. Malnutrition, lifestyle and environment are the main underlying risk factors causing much of premature mortality. Tobacco use and underweight are also major risks. Risk factors that require social changes are difficult to communicate and even more difficult to present in a manner that can convince many people. Mass media can influence risk perception by the general public, and when done well can influence behavior. Awareness against HIV/AIDS in some countries is an example of the significance of mass media in controlling a disease, and “100% condom use” programs have been effective in the region among high-risk groups. Keeping PHC on the health system development agenda is essential for increasing both equity and efficiency. In countries with effective health care networks that have largely resolved problems of access, PHC is mainly seen today as a level of care. In low resource countries where there are still significant access challenges the PHC concept is a system-wide strategy for development with emphasis on the rights to health care, social justice and reducing inequality. Weaknesses in health systems often affect the people who are in most need of services. The poor have more need for healthcare yet face the greatest barriers and opportunity costs. Inequalities in health in the region are being addressed mostly by strategies that specifically target the poor, either by identifying poor households and providing them directly with cash, goods, and/or services, or by redistributing health services preferentially to geographic areas where a high proportion of the poor are living. In addition, focusing on diseases that affect the poor more than others such as tuberculosis, HIV/AIDS, and malaria preferentially improves their health status.

The need for international coordination became evident in the region with the SARS crisis and the current avian influenza threat, which has also brought the agriculture/ veterinary sector into the picture. Health-related sectors such as agriculture, education, industry, trade, and communications are beginning to work together and take the health consequences of their decisions into account when formulating policies. Different modes and priorities are required to cope with changing disease patterns. The most significant response by health systems in the region to changing demographics and disease burdens is an increased emphasis on disease prevention. While aging cannot be prevented, many non-communicable diseases such as diabetes and hypertension can be prevented or mitigated as effectively as most communicable diseases. Malnutrition, lifestyle and environment are the main underlying risk factors causing much of premature mortality. Tobacco use and underweight are also major risks. Risk factors that require social changes are difficult to communicate and even more difficult to present in a manner that can convince many people. Mass media can influence risk perception by the general public, and when done well can influence behavior. Awareness against HIV/AIDS in some countries is an example of the significance of mass media in controlling a disease, and “100% condom use” programs have been effective in the region among high-risk groups. Keeping PHC on the health system development agenda is essential for increasing both equity and efficiency. In countries with effective health care networks that have largely resolved problems of access, PHC is mainly seen today as a level of care. In low resource countries where there are still significant access challenges the PHC concept is a system-wide strategy for development with emphasis on the rights to health care, social justice and reducing inequality. Weaknesses in health systems often affect the people who are in most need of services. The poor have more need for healthcare yet face the greatest barriers and opportunity costs. Inequalities in health in the region are being addressed mostly by strategies that specifically target the poor, either by identifying poor households and providing them directly with cash, goods, and/or services, or by redistributing health services preferentially to geographic areas where a high proportion of the poor are living. In addition, focusing on diseases that affect the poor more than others such as tuberculosis, HIV/AIDS, and malaria preferentially improves their health status.

Engagement and commitment by local communities contribute in many ways to health improvement. By identifying, mobilizing and committing their own resources and advocating more effectively for outside resources, communities build a sense of collective purpose and solidarity and improve their capacity for self-help. Small, action-oriented, local initiatives can be effective and efficient. The “healthy settings” initiatives in the Region (‘Healthy Cities, Healthy Islands, and Healthy Workplaces’) draw on this approach.

Ambulatory care in the most developed countries in the region is provided largely by the private sector. Differences emerge in the hospital sector: hospitals in Hong Kong (China) and Singapore are largely public, while hospitals are largely private in the large social insurance based systems of Japan and Korea. In terms of the private-public mix, these systems span a wide range of ownership and financing combinations. Several countries in the WPR have decentralized their health systems to better respond to local healthcare needs and to devolve financial responsibility to local governments. Large countries including China had long since made this transition out of necessity, as have others with large populations or difficult geographical access. Complementing this trend is the corporatization or autonomization of large public hospitals, often controversial but generally successful. In some countries decentralization has been implemented simultaneously with a reduction in public spending on healthcare.

Health financing: toward better access and equity

Private out-of-pocket spending on healthcare has always been relatively high in Asian countries but privatization was a step backward in some. Millions of the poor and near-poor no longer benefit from free care as hospitals have been corporatized and cut off from central tax-based funding. The most developed countries in the region are far better off than the least developed. Real GDP per capita (adjusted for purchasing power) ranges from $12,830,000 in Australia and Japan to under $3,000 in six countries. Most of the
Box 4

Singapore’s experience with corporatizing public hospitals illustrates the difficulties of this strategy. There have been rapid increases in costs and prices charged to patients, rapid growth in technology and high-tech interventions (especially surgical procedures), and attempts by hospitals to dump high-cost patients and to avoid offering services to low-income patients.

Table 4: Development and health indicators in selected countries in the WPR, 2003 and 2004.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>30,331</td>
<td>2,874</td>
<td>6.4</td>
<td>3.1</td>
<td>9.5</td>
</tr>
<tr>
<td>Japan</td>
<td>29,251</td>
<td>2,944</td>
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<tr>
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<td>87</td>
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Selected WPR countries Percentage of households experiencing catastrophic Out-of-Pocket payment

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<th>Country</th>
<th>Percentage of households experiencing catastrophic Out-of-Pocket payment</th>
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<td>Vietnam</td>
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<td>Cambodia</td>
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<td>Republic of Korea</td>
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<tr>
<td>Philippines</td>
<td>0.78</td>
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*Defined here as the incidence of household payments for health services exceeding 40% of net income after subsistence needs have been met.

FIGURE 5: PROPORTION OF HOUSEHOLDS WITH CATASTROPHIC HEALTH EXPENDITURE

The table above shows that in the WPR region’s population lives in large countries having real GDPs under US$6,000. The wealthier countries have higher expenditures on health, both in absolute terms as would be expected, and also in terms of the percentage of GDP spent on health. Public spending on health is closely related to national income. Wealthier countries have social health insurance (SHI) contributions available for investment in health, as well as more resources from general taxation. The percentage of GDP spent by on health by governments varies from a low of 1.1% in the Philippines to over 6%. Private spending on health varies even more widely and tends to be highest in countries where public spending is low (Viet Nam, Cambodia and China), and also in Singapore. Total (real) health expenditure varies from only US$56 per capita in Lao PDR to US$2,874 in Australia. The Commission for Macroeconomics and Health estimated that in order to achieve the health MDGs a minimum government expenditure of US $4 per person per year is required to provide an essential package of public health interventions. Seven governments in the region currently spend less than US $34.

High private health expenditures do not assure good health outcomes because much is spent on ineffective or non-timely care. Out-of-pocket payment at the time of service can result in catastrophic payments when households need to spend a significant fraction of their net income on health care. In the WPR region 10.5% of households in Viet Nam and 5% in Cambodia experienced catastrophic healthcare events.

The main goal of health financing in the region is for health systems to be funded by prepaid, equitable sources such as SHI contributions and progressive general taxation. Such financing pools risks and can provide health services according to need rather than ability to pay. Near-universal coverage has been achieved by Australia, New Zealand, Japan, Republic of Korea, Singapore, Taiwan, Malaysia, Brunei, Hong Kong (China), and Taiwan through a mixture of various health financing mechanisms. China, Lao PDR, Mongolia, the Philippines, and Vietnam have introduced some form of SHI but face the challenge of extending coverage to the informal sector (and migrants in China), much of the economically active population in these countries.

Most SHI schemes in the region, such as PhilHealth, Korean Health Insurance, Vietnam Health Insurance and the China’s new Cooperative Medical Scheme (NCMS) now use a fee-for-service reimbursement model, with either deductibles, copayments, and ceilings on total reimbursement. Insurers have great
Chinese hospitals earn most of their income from dispensing medicines. New regulations meant to restrict drug profits may lead hospitals to seek other ways to make money. Ultrasound machines appeared in China in large numbers during the 1980s, in part due to the demand for sex-selective abortions which Chinese demographers say account for a large part of the abnormal male-female ratio in the Chinese population. Purchasing power and can improve resource use by means of efficient provider payment methods. Vietnam is considering introducing capitation. The Philippines implemented capitation for an indigent program, and Japan and Korea are developing Diagnostic Related Group (DRG) systems. In countries in the region remaining without SHI, the transition from out-of-pocket financing to universal coverage could occur in stages. During a transitional stage of coverage a mix of cooperative and enterprise-based health insurance and other private insurance would cover the informal sector, with specific employed groups covered by new SHI-type plans, and with limited tax-based financing for a safety net. Ultimately there would be universal coverage through social health insurance for most of the population, and a mix of other insurance and tax-based financing to cover the rest.

Regulation of the health sector

The increasing role of the private sector in the WPR has led to more focus on profitable curative services and neglect of preventive and public health programs. Regulation and guidance appear to be needed to maintain an adequate level of preventive services. Except for countries with well-established parliamentary systems, the capacity of many health ministries in the region to generate legislative proposals is quite weak, even non-existent in the case of the smaller Pacific Island nations. At best, the enactment process is generally lengthy and there is often reliance on ministerial decrees that may not necessarily harmonize with those of other ministries, creating severe challenges for intersectoral health issues. Regulatory weaknesses result in problematic issues such as automatic renewal of licenses. Professional organizations fill this gap but are not completely impartial. Few countries in the region have standards or codes of ethics. Ethical questions arise in communicable disease control. How much coercion and isolation is required for successful control of an infectious disease like tuberculosis? The challenges involved in the equitable provision of HIV/AIDS treatment and care include addressing ethical issues related to expanded access to ART. Cell, tissue and organ transplantation are performed worldwide, reducing lives and the improving quality of life. Trafficking of organs has been detected in some countries in the region, with vulnerable persons being tricked or coerced into donating their organs. 'Transplant tourism' programs operating within the region in effect reduce the access of local people to transplantation. There is clear need for better regulation and monitoring of organ transplantation activities.

Globalization, trade and health

Expanding trade has been a central component of increasing connectedness among countries of the region. Movement of patients to seek treatment abroad is common in small countries, such as in the Pacific, where certain specialized medical services are not available domestically. Meanwhile, countries such as Malaysia, Singapore are actively seeking to attract foreign patients. Hospitals in these countries offer packages of health checkups or elective surgery. By providing services of good quality at prices significantly lower than Western countries, they have seen a steady increase in the numbers of patients from developed countries. The commercial presence in the hospital sector, while still relatively small, is increasing in several countries. Investment is coming from outside Asia, and foreign investors are also active in health insurance. An issue of concern related to foreign investment in this sector is whether these private hospitals and insurers will primarily target only patients who can afford to pay high rates.

The health workforce

An overall shortage of health workers is a basic and critical problem in the region. Besides low production, attrition and restricted staffing levels, other causes are insufficient investment in pre-service education and training, ineffective coordination between the health, education and employment sectors, poor workforce planning, and out-migration due to unattractive career structures and working conditions. The latter has left many Pacific Island countries at crisis level and is also a problem for countries like the Philippines that export doctors and nurses. In some countries the skill mix depends highly on medical doctors and specialists, with some actually having more doctors than nurses. Australia, New Zealand and Pacific Island countries have shortages of doctors in important specialties, and many countries lacked the expertise in epidemiology, infection control, and other specialties to deal with the emergence of SARS and the continuing threat of avian flu.
International hospital perspectives: Global medical tourism

PAVING THE WAY FOR GLOBAL MEDICAL TOURISM

ARTICLE BY JONATHAN EDELHEIT

The Medical Tourism industry is poised for amazing growth. With almost 50 million people in America having no health insurance and the high cost for medical care, the United States is expected to be one of the largest exporters of patients overseas for health care. Although many questions have yet to be answered, Medical Transparency is the key to industry growth and a necessity for hospitals to market themselves to the American patient.

Abstract

The North American medical tourism industry is poised for amazing growth. With almost 50 million people in America having no health insurance, increasingly higher deductibles, and the dramatically high cost for medical care, it is easy to understand why the United States is expected to be one of the largest exporters of patients overseas for care. Since the US is one of the few industrialized countries without socialized medicine, Americans looking for affordable health care coverage are starting to look globally. Several countries have emerged as leaders in medical tourism, such as India, Singapore, Thailand and Costa Rica. Other countries are now racing to establish themselves as medical tourism destinations such as Dubai, the Philippines, South Korea and Taiwan, each creating initiatives and government backed programmes to attract more and more Americans overseas. Billions of dollars are being invested in building new health care facilities and “medical cities” for the waves of future medical tourism consumers. For those with guarded skepticism as to whether people will actually travel overseas for surgery, the cost of health care globally says it all.

The cost differentials for US surgical procedures versus those found internationally together with the well known fact that U.S. health care costs continue to rise, provides a clear indication that Medical Tourism is an industry that is here to stay.

What are the bridges to success for the medical tourism industry to succeed?

It’s all about the patient care – or lack of it. How can patients and collaborating hospitals, insurers and employers be assured they are placing their chips with the best hospitals that are offering the very highest quality care? Is JCI accreditation good enough or are higher standards more appropriate? What about overseas accreditation and government standards abroad? What are the benchmarks, who sets them, and who polices the police? How do hospitals show that they are the best? These questions will be debated for the next several years as this industry unfolds and grows. But the clear answer most in the industry are giving is that “medical transparency” is the real answer for this industry to grow.

Medical transparency

The global marketplace needs the hospitals detailed information on hospital standards, background and outcomes. The differences between hospitals web sites are amazing. Some offer detailed information on physician’s credentials, accreditation, board affiliations, specialties, success rates, and mortality rates. Why do many of the hospitals offer no such information to the public? The Internet, outsourcing, telemedicine and other forces are bringing medical transparency to the forefront. The public globally wants hard data it can use to compare hospital quality and outcomes. In the past, perhaps this information was not necessary, but with the internet and dealing globally, leading international hospitals will have to adapt “transparency” and provide this information in order to attract foreign patients. Otherwise, global consumers will shift and go to hospitals that do disclose their outcomes and standards. In the United States this

<table>
<thead>
<tr>
<th>Procedure</th>
<th>USA</th>
<th>India</th>
<th>Thailand</th>
<th>Singapore</th>
<th>Costa Rica</th>
<th>Mexico</th>
<th>Korea</th>
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<td>$6,854</td>
<td>$11,000</td>
<td>$16,100</td>
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<td>$15,000</td>
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<td>$4,998</td>
<td>$13,000</td>
<td>$11,200</td>
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<tr>
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<tr>
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<td>$2,300</td>
<td>$4,600</td>
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<td>$6,000</td>
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<td>$6,200</td>
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<td>$11,300</td>
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<td>$12,000</td>
<td>$24,100</td>
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* Figures from Medical Tourism Association Report & MTA Member Hospitals – August 2007

Figure 1: COSTS OF SURGERY INTERNATIONALLY
“I came with little hope, but walked away believing in miracles.”

PEACE OF MIND WHEN HEALTH REALLY MATTERS

More than just a leisure destination, Singapore has firmly established itself as Asia’s premier healthcare hub. It is the choice destination for an increasing number of international patients who share a common confidence in a world-class healthcare system that pushes the boundaries of excellence. Together with advanced technology and the latest and safest drugs for better diagnostics and outcomes, all delivered by the region’s leading medical professionals, it’s no wonder healthcare visitors and their families find peace of mind in Singapore during their time of need. www.singaporemedicine.com
International hospital perspectives: Global medical tourism

Hospitals internationally need to remove the internal obstacles in relation to disclosing information to the public as we enter a global health care era, particularly where the focus is getting foreigners to come to your hospitals for care.

Information is easily attainable, and Americans will want to compare their local hospitals’ standards and outcomes of surgical procedures to their international counterpart. Those hospitals that can show they meet or exceed the US standards and outcomes of surgical procedures will find themselves well rewarded as American patients flock to their hospitals.

Hospitals internationally need to remove the internal obstacles in relation to disclosing information to the public as we enter a global health care era, particularly where the focus is getting foreigners to come to your hospitals for care. You can’t just open your doors and expect them to come, you need to earn consumers’ respect and trust.

United States insurance companies and claims payors

Because of unbearable cost constraints of health insurance, employers large and small are putting huge pressure on US based insurance carriers to take bold steps with medical travel. Overseas hospitals are aggressively building International Patient Centres of Excellence, and now embracing the North American baby boomers. The large U.S. insurance companies are the missing link – feeling the heat, yet still hesitant to jump into the choppy, unknown waters of medical tourism. A large portion of America is still stuck on the perception that America health care is the best, but this perception is changing fast. US insurers need hospitals to step up to the plate in regards to quality, standards, and disclosure of hospital data and outcomes in order to create a “comfort level” required for US insurers to become partners with global health care hospitals.

How can international hospitals expand in medical tourism, by forming collaborative relationships in the United States and abroad?

Many forward-thinking hospitals, research organizations and educational institutions have sought partnerships with their counterparts in the United States, such as Johns Hopkins, Harvard, etc. to work on strengthening their positions in patient services, medical research, higher learning, telemedicine and more. Other hospitals have partnered with Medical Tourism companies globally. One simple free, option is joining the Medical Tourism Association, www.MedicalTravelAuthority.com, a non-profit association providing free membership to hospitals and providing member hospital information to the public at no cost. The Association’s goals are simple, to promote medical tourism internationally through an informational website, and through an industry magazine and documentary. Together, hospitals worldwide can help to shape this industry into something extremely positive, establish reliable international standards of care, in addition to generating new sources of hospital revenue. For whomever you partner with, getting connected to reliable US medical Tourism organization can fast track Americans coming to your hospitals.

Author

Jonathan Edelheit is the President of the Medical Tourism Association and Vice President of United Group Programs/OptiMed Health Plans. Mr. Edelheit is a graduate of Villanova Law School. He has been an innovator in cutting edge health-care products in the United States and has been mentioned in over 30 magazines such as Time Magazine, The Wall Street Journal, Newsweek and the International Herald Tribune. Mr. Edelheit was a pioneer in offering low cost health-care products in the United States called mini-medical or limited medical plans. Mr. Edelheit speaks internationally on medical tourism and other United States Health related topics. He was instrumental in founding the Medical Tourism Association and believes outsourcing health care overseas is one valuable asset in solving the American health care crisis.
SPECIAL FEATURE

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ENABLING SAFER PATIENT CARE: AUTOMATIC IDENTIFICATION STANDARDS FOR PHARMACEUTICALS AND MEDICAL DEVICES

ARTICLE BY ULRIKE KREYSA (LEFT) AND JAN DENECKER

Medication errors are an important risk to public health and have a serious economic impact. Counterfeited pharmaceutical products also put people's lives at risk and are an increasing global threat. The need for a traceability solution in health care from point of "manufacture" to point of "care" has never been more important: counterfeit products, faulty batches of drugs or drugs past their expiry date. The soaring costs of treating patients is forcing all related stakeholders to look for more efficient ways of patient care and to increase patient safety.

Automatic Identification and Data Capture (AIDC) and GS1's global, open, and proven standards provide the opportunity to make the health care supply chain more efficient and accurate, and thus safer. The participation of the International Hospital Federation (IHF) and all its members in this 'journey' will be vital.

Abstract

Medication errors are an important risk to public health and have a serious economic impact. Counterfeited pharmaceutical products also put people's lives at risk and are an increasing global threat. The need for a traceability solution in health care from point of "manufacture" to point of "care" has never been more important: counterfeit products, faulty batches of drugs or drugs past their expiry date. The soaring costs of treating patients is forcing all related stakeholders to look for more efficient ways of patient care and to increase patient safety.

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Automatic Identification and Data Capture (AIDC) technologies, using bar codes or radio frequency identification (RFID), in hospitals, can have a very wide range of applications, including point-of-care scanning to match product data to patient data, verification of patient identity via a wrist band, enabling the introduction of robotic dispensing systems, recording implant serial numbers in patient records and central registries, tracking and tracing of individual instruments through decontamination, stock control and supplies management, tracking assets throughout network of facilities...

All these applications enable the realization of associated health and economic benefits: reducing medication errors, preventing counterfeiting, saving costs and increasing the health care supply chain efficiency.

Ensuring the five patient rights: reducing medication errors

The right medication needs to be given to the right patient in the right dose at the right time by the right route. More than 30% of all adverse drug events are preventable and appear to be consequences of medication errors (prescription, transcription, processing, or administration). Adverse events from medication errors represent a significant problem for health care worldwide, as indicated by several studies in different countries. An Adverse Event Study in one country indicated that 9.3% of hospital stays incurred a serious adverse event, with medication errors being the main cause (37.4% of such events). Medication errors are rarely the fault of an individual health-care professional, but rather represent the failure of a complicated health-care system and can occur anywhere in the distribution system, although predominantly during prescription and administration, respectively 39% and 38%. Dispensing and transcription errors account for 11% and 12%. While nurses or pharmacists often intercept about half of the errors originating during prescribing, before they reach the patient, only 2% of administration errors are intercepted.

Automating the prescription and administration processes will thus significantly reduce medication errors. A few examples:

- The Department of Veteran’s Affairs in the USA introduced bar code systems for medication administration in its nationwide network of hospitals in 1999. For example, the VA Medical Center in Topeka has reported that bar coding reduced its medication error rate by 86% over a nine-year period.
- Chelsea and Westminster Healthcare NHS Trust, UK introduced a robotic dispensing system in May 2003. A study in the hospital pharmacy found that dispensing errors were reduced with 67% from 2.7% to 0.9% of prescriptions.
- Brigham & Women’s Hospital, Boston, USA introduced bar code scanning in the preparation, dispensing, and delivery process. Results in error reductions were remarkable: wrong medication and wrong dose/
The World Health Organisation reports that 10% of all drugs worldwide are counterfeit. Other sources estimate that up to 15% of all sold drugs are fake.

Counterfeiting is not a problem that is confined to developing countries, but it is an increasing reality all over the world. In Europe, around 1% of pharmaceuticals are now counterfeit according to the WHO and increasing fast: in 2006, 2.7 million pharmaceutical articles were seized by European Customs, a 384% growth versus 2005. Also the Food and Drug Administration (FDA) in the USA reported "an increase in counterfeiting activities and a more sophisticated ability to introduce counterfeits into legitimate drug distribution channels".

For example in Cambodia, 60% of 1.33 million malaria medications lacking the active ingredient. In fact, the World Health Organisation (WHO) estimates 200,000 people who die each year from malaria perished because of counterfeit medication.

Counterfeiting is more than just an issue of public health. It is also an issue of economics. Counterfeiting has led to a 30% cost reduction in the drug supply chain11. This has resulted in a 30% cost reduction in the drug supply chain11. In the worst case, two packs of drugs with the same serial number would be present in the supply chain, in which case stakeholders would be alerted about this intrusion when the second pack is being cross-checked. Furthermore, the e-Pedigree (an electronic document communicating the custody history of that particular product) also provides additional security to enable tracing where the pack of drugs has been.

Reducing costs and increasing supply chain efficiency

Reducing costs and increasing supply chain efficiency through AIDC and GS1 standards will contribute to keeping soaring health-care costs under control. Manual systems and processes in hospitals are unable to efficiently handle the constant change that occurs with supplies and pharmaceuticals13.

AIDC technologies allow simplifying and improving accuracy in a number of supply chain processes, including order processing, receiving/shipping, management, and inventory management.

One UK trust, deploying a robotic dispensing system, saw a reduction in time spent in the dispensary of 34% for pharmacists and 51% for technicians, enabling far more time to be spent on the wards, working directly with patients and ward staff12.

An AIDC Programme allowed St. Alexius Medical Center Campus, Bismarck, USA to make some manual processes redundant and transition seven full time equivalents to other responsibilities and inventory was reduced by US$2.4 million.

The implementation of an e-prescription process and automatic product identification in San Rafael Scientific Institute in Italy resulted in a 30% cost reduction in the drug supply chain15.

Global Automatic Identification Standards

Global and open standards enable the realization of all health and economic benefits related to Automatic Identification. Open technology-independent standards permit full interoperability and compatibility. End users are not locked into proprietary solutions and R&D...
resources can be freed up for other added value developments once standards have been adopted.

Health care is by nature a global sector, with supply chains that often cross borders. A global standardized system for traceability, from product manufacture to patient treatment, is imperative to comply with the increasing legal requirements for product traceability around the world. In cases of cross border trading, a global identification number can be used to identify that product in any country without any restrictions or errors.

Local needs are incorporated into global standards, but local standards will jeopardise the realisation of the related benefits. Local standards hinder interoperability and compatibility which significantly reduces the economic benefits. Additional R&D and manufacturing resources have to be devoted to meeting heterogeneous local standards.

### An introduction to the GS1 Automatic Identification Standards

GS1 standards are open, global and voluntary.

First of all, the GS1 System of Standards incorporates a set of identification keys. These are numbers identifying products and services and providing access to information held in computer files. These numbers are:

- **Unique:** every variant of an item is allocated a separate unique number.
- **Non-significant:** they identify an item but contain no information about it.
- **International:** GS1 identification keys are unique across all countries and all sectors.
- **Secure:** GS1 identification keys are fixed length, numeric and include a standard check digit.

At the heart of the GS1 System is the GTIN (Global Trade Item Number) identification key. These numbers are allocated by the manufacturer, according to the GTIN Allocation Rules and include a GS1 company prefix assigned to a company by GS1, an item reference assigned by the company and a check digit. The GTIN Allocation Rules have now been enhanced to include specific Healthcare GTIN Allocation Rules.

The GS1 System also incorporates a number of other identification keys, including GLN (Global Location Number), SSN (Serial Shipping Container Code) and GRAD (Global Returnable Asset Identifier).

GS1 identification keys can then be carried on any type of data carrier, a GS1 bar code (linear or 2-dimensional) or an EPCglobal radio frequency identification tag on the specific product or packaging.

The GS1 System provides several types of bar code for use by GS1 members depending on the application. Compared to product coding in for example, a grocery retailer environment, coding of pharmaceuticals has very specific requirements. A large amount of data (product ID, batch/lot number, expiry date) needs to be stored on a small space. It also needs to allow variable information (such as a randomized serial number) to be carried on at high production rates. Unscannable bar codes do not only impact supply chain efficiency, but more importantly, patient safety. Some medical devices, such as surgical instruments and implants, may require direct part marking.

EAN/UPC (e.g. EAN-13) bar codes are ideal in a high volume scanning environment such as supermarkets, but can only carry limited information. Unscannable bar codes do not only impact supply chain efficiency, but more importantly, patient safety. Some medical devices, such as surgical instruments and implants, may require direct part marking.

Another type of bar code, the GS-128 bar code, can carry a lot of information, including attributes (“Application Identifiers”) such as expiry date and lot number, but require a large printing area on the packaging.

GS1 DataMatrix bar codes are the ideal solution for Healthcare. This is a 2-dimensional data matrix symbology enabling, in an efficient way, all of the above requirements. It enables coding more fixed and variable information, within a significantly smaller area than linear bar codes. It also allows error correction to circumvent some degree of physical damage and technologies are available for direct part marking.

EPCglobal is a radio frequency identification (RFID) tag, including a silicon chip, an antenna and the packaging substrate. It also carries identification keys based on a numbering scheme incorporating GS1 identification keys. This carrier can also hold all the necessary information (identification key, attributes, and randomized serial number). Furthermore, reading an EPCglobal RFID tag does not require line of sight, while a bar code needs to be read with a bar code scanner pointing to the bar code.

### About GS1

GS1 is a neutral, not-for-profit standards organization. GS1 is a user-driven organization dedicated to the development of global supply chain standards and to the facilitation of adopting and implementing of such standards. GS1 is driven by more than a million companies, who execute more than five billion transactions a day with the GS1 System of standards. This makes it the most widely used supply chain standards system in the world.

GS1 is truly global, with local Member Organizations in 108 countries, and with Global Offices in Brussels, Belgium and Princeton, USA.

GS1’s diversified portfolio ranges from GS1 Bar Codes to GS1 eCom (electronic commerce tools) to next generation technologies and solutions such as GS1 GDSN (Data Synchronisation), EPCglobal (using RFID technologies) and traceability.

For more information, please visit [www.gs1.org](http://www.gs1.org).
GS1 Healthcare
The GS1 Healthcare user group consists of representatives from all stakeholders: manufacturers, wholesalers, distributors, hospitals, pharmacies, regulatory bodies, trade associations and GS1 Member Organisations.

Its mission is to lead the health-care sector to the successful development and implementation of global standards by bringing together experts in health care to enhance patient safety and supply chain efficiencies.

GS1 Healthcare has a roadmap to adapt the GS1 System of Standards to the specific needs of the health-care sector.

User-driven Work Teams are currently going through this standard development process, which is planned to be finalised in 2008.

For more information or to join us, please visit www.gs1.org/healthcare.

What’s next?
GS1 Standards have already been recognized by many governmental bodies around the world, including the FDA in the USA, the Shanghai FDA in China, the Ministries of Health in Australia, Brazil, England, Japan, New Zealand, and many more. The Council of Europe’s Expert Group on Safe Medication Practices has issued a report “Creation of a better medication safety culture in Europe: Building up safe medication practices” - Expert Group on Safe Medication Practices, Council of Europe - 2007.


The implementation of AIDC throughout the health-care supply chain based on global standards to read them, all health-care stakeholders have to continue to work together towards a standardized implementation of AIDC in a hospital. Otherwise, hospitals have to re-package into unit-dose packages and re-label them. This not only incurs additional and un-reimbursed costs, but may also introduce a new source of error.

To crack the chicken-and-egg issue (which comes first, unit-dose packages with bar codes or RFID tags or the implementation by hospitals of the systems to read them), all health-care stakeholders have to continue to work together towards a standardized implementation of AIDC in a hospital. Otherwise, hospitals have to re-package into unit-dose packages and re-label them. This not only incurs additional and un-reimbursed costs, but may also introduce a new source of error.

To crack the chicken-and-egg issue, which comes first, unit-dose packages with bar codes or RFID tags or the implementation by hospitals of the systems to read them, all health-care stakeholders have to continue to work together towards a standardized implementation of AIDC throughout the health-care supply chain based on global and open standards. The participation of the IHF and all its members in this “journey” will be vital.

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IMPLEMENTING BARCODE TECHNOLOGY STRATEGIES TO IMPROVE PATIENT CARE: IMPACT AND LESSONS LEARNED

ARTICLE BY THOMAS W COOLEY

Abstract

Patient and medication safety have become a major quality of care improvement focus for many hospitals. Brigham and Women’s Hospital, Boston, Massachusetts, USA, began a multi-year project beginning in 1993 to decrease medication errors and adverse drug events throughout the medication use process to improve patient care and outcomes. The application of new technologies were designed and implemented with the contributions of pharmacist, nurses, physicians and information system specialists. These new technologies included computerized practitioner order entry, barcode point-of-care systems, wireless medication order communications and mobile hardware. Reductions in medication order, distribution and administration errors have been demonstrated by implementing these technologies.

Brigham and Women’s Hospital (BWH) is a 747-bed academic medical centre affiliated with the Harvard Medical School. It is a founding member of Partners Healthcare Enterprise, an integrated health care system comprised of academic and community hospitals in the Boston, Massachusetts area. The hospital treats over 45,000 patient admissions annually where more than six million medication doses are dispensed from approximately 2 million physician medication orders. We describe here our attempts to maximize information technology with the goals of increasing patient safety, reducing medication errors, and improve patients’ outcomes.

Background
In the early 1990s, BWH placed a major focus on developing technology to improve medication and patient safety. In 1993 computerized practitioner order entry (CPOE) demonstrated decreases in serious medication error rate by 55%. Improvements in clinical decision support, and therapeutic ordering guidance in CPOE continued to present day, but challenges in the medication use system continued.

In 2000, a forty-member multi-disciplinary project team began a critical evaluation of the entire BWH medication use process. With senior hospital leadership support for improvement, the team evaluated the complex inter-play of all electronic and manual medication use systems. The major final recommendations to improve medication and patient safety included:

- redesign the Pharmacy Information System as a web-based application able to use barcode technology in the preparation, check and distribution of medications;
- develop an electronic medication administration record (eMAR);
- implement barcode point-of-care system (BPOC) at the patient bedside.

Redesign of the Medication Use Process
The BWH redesign of the Pharmacy system began in 2001, prior to eMAR design and development. Barcode technology was incorporated in the medication preparation, checking and distribution processes. During development of the new systems, a study was completed to assess the accuracy of the pharmacy distribution processes prior to the new system being introduced. Of 19,000 medication doses dispensed from the pharmacy and observed for selection and distribution accuracy, a pharmacist’s initial check intercepted 393 (2.03%) errors. However, a second recheck revealed errors missed by the first pharmacist. An additional 179 errors were discovered showing that 0.93% (179/19,338) of medications dispensed would have reached a patient in error. For a hospital dispensing 6 million doses annually, this represented over 57,000 Pharmacy dispensing errors. The incentive to improve accuracy in dispensing was confirmed.

The design of the new pharmacy system had several components to help assure an improvement in medication safety:

- Bi-directional interface with the future eMAR.
- Ability to prioritise the review and approval of physician orders.
- Incorporation of barcode scanning in medication preparation, checking and
During development of the new systems, a study was completed to assess the accuracy of the pharmacy distribution processes prior to the new system being introduced. Of 19,000 medication doses dispensed from the pharmacy and observed for selection and distribution accuracy, a pharmacist’s initial check intercepted 393 (2.03%) errors.

Establish a repackaging centre for the bar coding of medications.

Use of full-size laptop computers on mobile carts for nurses at the bedside.

BWH eMAR development focused on creating an application for nursing that would improve the safe administration of medication to patients while fitting into nursing workflow and patient care processes. A development group comprised of nurses, pharmacists, physicians and information system analysts and developers began work in 2003 to meet this goal. A 10-month, phased rollout beginning in November 2004 was completed by August 2005 to the majority of BWH inpatient care units (27 intermediate units, three mother-baby units and nine ICUs). The eMAR had the following major components:

- Eliminates transcription to paper MAR.
- Prioritises medication administration.
- Uses barcode scanning at the bedside to assure the 5-rights of safe patient medication administration.
- Provides real-time clinical lab data associated with specific medication orders.
- Bi-directional wireless communication to Pharmacy and CPOE systems.

In preparation for the new eMAR rollout to the nursing staff, extensive training with barcode scanners, laptop PCs, and the eMAR application were necessary and critical to the BPOC success. Nurses were required to attend a four-hour training class supplemented by computer based training modules. During eMAR implementation on each nursing unit, on-site eMAR experts were provided, comprised of nurse ‘Super-Users’; Information System (IS) analysts, and extensively trained pharmacists. Super-users were interviewed and selectively chosen for the project based on their motivation, clinical and interpersonal skills. The super-users were given extensive training in the new application and then returned to their specialty practice areas during eMAR implementation. This provided them with a better understanding of existing workflows issues, allowing them to incorporate this into training fellow nurses on the eMAR and use of the barcode technology. They provided both clinical expertise and eMAR application knowledge. This combination of talent allowed close, personal interaction between colleagues that enabled successful teaching and learning.

**Results**

The implementation of the BPOC at BWH required changes in workflow, use of new equipment, and application of a new technology to the medication distribution and administration processes. This impacted every practitioner involved in the ordering, preparation and administration of medications.

The ability to scan medications efficiently did require practice and was discovered to be more an art than science.
given current level of image scanner capabilities. Placement and quality of barcodes also impacted efficient and rapid processing of medications through the medication use system. Practitioners with clinical skills, who did not take shortcuts in documentation or patient care, engaged the new system well, accepted the learning curve required to gain the safety benefits of the BPOC, and strove to work within the new system. Others who were not as skilled in scanning, hurried in patient care, or easily frustrated with experiencing less than optimal performance of the new system, created process work-arounds, or chose not to perform required scanning steps.

Work-arounds discovered in BPOC implementation included:

- Not scanning entire quantity of medication required for order, i.e., scanned same medication multiple times instead of each individual medication.
- Cutting and pasting National Drug Code (NDC) information from Pharmacy database instead of scanning.
- Photocopying drug package barcodes for use during preparation and distribution instead of scanning product barcodes.
- Pharmacist skipping final check scans, i.e., “Send now, worry about the scan later.”
- Over-using manual and emergency over-ride options during medication administration scanning.
- Not scanning the patient ID bracelet at the bedside, but attaching it to the patient chart outside the patient room.
- Administering medication from a “stash”, then scanning Pharmacy-supplied medication after administration process is complete.

Continued reinforcement of the safety and accuracy reasons for implementing barcode scanning, additional on-site training, hardware and software enhancements, and responding to user feedback for improvements were all used to decrease, minimize or stop work-arounds. Eventually, user confidence and performance within the new system and improvements in efficiency of both hardware and software have led to decreasing work-arounds.

The new closed-loop medication administration system drove many practice changes to take place for physicians, nurses and pharmacists. Processes that would have been verbally communicated, or performed without documentation, now had to be “codified” into the new BPOC system since all medication ordering and any associated action taken on those orders had to reach the eMAR from CPOE and Pharmacy system. Initially at BWH over forty-four required software changes in the existing CPOE were identified to enable correct order information flow to eMAR.

The training and education costs were significantly higher than expected at the beginning of the project, but were vital to the success of BPOC implementation. Nurses routinely cited the Super-user training model as a positive aspect of the project (‘clinicians must teach clinicians’).

Staff, especially the end-user nurse, must be used in the evaluation and decision-making process regarding hardware to be used on patient care units, and software functionality. Complete and thorough usability testing led to greater BPOC acceptance once it went live. In addition, other staff, including medical staff, must be engaged early in screen designs, implementation decisions and staff training.

Impact of New BPOC System

Pharmacy and Nursing services performed post-implementation studies. Pharmacy demonstrated an 85% dispensing error reduction during their distribution processes by implementing medication barcode scanning. This decrease in dispensing errors also represented a 63% decrease in potential adverse drug events. Results from a cost-benefit analysis of the Pharmacy system using bar coding indicated a net five-year cumulative benefit of $3.2M, with break-even point reached within one-year after going live on the system.

The Nursing Service performed a concomitant study to examine nurse’s satisfaction with the new BPOC by comparing satisfaction levels before and after its introduction. Using a 16 item, 6-point Likert scale, 1,087 nurses satisfaction scores were assessed in three areas; efficacy, safety, and access. Pre-conversion, nurses were satisfied with the new BPOC (Avg. Likert score = 4.1). Post-conversion, nurses were more satisfied (Avg. Likert score = 5.1).

Conclusions

In summary, we have found efforts to ensure patient safety and reducing medical errors can be achieved by implementing BPOC technology and supporting systems, but requires practitioner commitment, information technology resources, and time. Our work has shown reductions in Pharmacy dispensing errors, and reductions in nursing administration errors. We were able to achieve this by completing a four-year plan of improvements. While many clinicians embraced the safety movements others have sought ways to circumvent the safety measures. We conclude that this represents a piece to a very complex puzzle (a small step in a long journey) towards ensuring patient safety during hospitalization. Future work includes implementing BPOC and
eMAR in hematologic-oncology patient care units, Emergency Department and procedural areas. In addition, we will further close the medication use process loop by implementing wireless programming of smart pumps from direct interfaces with the pharmacy and eMAR information systems.

Author

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HOW TO TRANSFORM A SUPPLY CHAIN TO ENABLE TRACEABILITY WITHIN A HOSPITAL: A TRACEABILITY PILOT AT THE UNIVERSITY HOSPITAL OF DIJON, FRANCE

ARTICLE BY FRANÇOIS BISCH

Abstract

In hospital environments, logistics is often the missing link in product traceability. Implementing GS1 standards not only allows you to prevent logistics from being the missing link in product traceability, it also contributes to the security of care services and allows health practitioners to focus on their core business: providing care.

With more than 6,300 people representing more than a hundred activities relating to patient care and 1,665 beds and places, the University Hospital of Dijon is the biggest player in terms of public health in the Bourgogne region. This major hospital is organised into medical sectors, and a new 80,000m² building associated with a logistics platform, currently under construction, will contribute to improvements in taking care of patients as of 2009.

In the past, health establishments were autonomous, functioning almost as an autarky. Now, they are customers and suppliers of numerous supply chains that contribute to health services. While the supply of manufactured products and the compounding of medicines immediately spring to mind, other more discrete production processes contribute to the functioning of hospitals: the preparation of meals is one area that is particularly concerned with food traceability. The central sterilisation of instruments and medical devices is another very important area in terms of traceability, characterised – as in the case of laundry – by an internal transport loop constituted of the distribution of ‘clean’ items and the collection of ‘dirty’ ones. As for the collection of samples for analysis and the increasing amount of waste, this puts the hospital upstream in the corresponding supply chains.

This opening of hospitals to the economic world especially calls into question identification habits. While international identification – which does indeed exist – appears to be a solution that is practically ready to be adopted and deployed, it is still necessary to ensure its operational relevance in a hospital environment.

At the University Hospital in Dijon, together with the external partners SAVOYE and MEDINORMA we carried out research on a well-controlled circuit: instruments going back and forth between operating theatres and central sterilisation. This led to the operational traceability pilot for the transportation of sterilised goods, which has been in operation for the past three years.

Recognition of logistics operations

The first benefit of the Traceability Pilot was, and still is, the recognition of the existence of logistics operations within health care establishments. This awareness opens the way to make logistics services more professional. Logistics operations are ensured on a daily basis by discrete and devoted staff, without whom hospitals would grind to a halt.

This discretion is reinforced by the very secondary aspect of these necessary logistics operations compared to the nobility of providing care. Especially in a context which very often escaped a regulatory framework. But more recently, quality measures are being implemented in this environment.

This recognition is necessary to explain the requirements regarding the registration of the containers used, the formalisation of the circuits, the people involved and the associated actions, and a minimum processing of information.

Enable traceability and traceability records

Recording the departure or arrival time of a container considerably reduces alleged transport disputes. Traditionally, what a carrier says has little value compared to what a health practitioner or doctor may say. We have observed a decrease of two-thirds in the number of complaints regarding lateness or items going astray, and consequently, the good level of internal carrier services, much better than that perceived by the addressees and addressees.

Better knowledge of the location of the
The first benefit of the Traceability Pilot was, and still is, the recognition of the existence of logistics operations within healthcare establishments.

Transport containers used for other purposes by the care units resulted in a decrease in equipment renewal through the reduction of this type of removal.

Finally, this control process allowed integrating the associated information in the management applications of the addressee and addressor processes. In particular, the issuing of transport orders and DESADV despatch notes.

Even though they contribute to patient safety, these requirements were unknown to health practitioners and had little chance of being taken into account when expressing the needs preceding computerisation.

**Lessons learned**

The main costs are those related to data acquisition equipment and developing or purchasing processing software. In particular, the number of collection points or of the people involved to be equipped directly impacts the necessary investment.

It seems quite obvious that equipping a person or a vehicle with a mobile reader may be better than equipping all the reading points with fixed readers. Furthermore, if Radio Frequency Identification (RFID) is chosen rather than traditional bar codes, RFID tags and readers are still much more expensive that barcodes. They also require more readings and controls to transform the data read by an antenna into usable information. Indeed, the volume of magnetic fields is difficult to superimpose on the geometric forms usually used, such as doorways or transport containers. The first detection of the electromagnetic beacon must be confirmed by a second, if only to be certain of the direction. The collection of numerous unnecessary electromagnetic signals requires appropriate middleware to retrieve the information of interest or can be greatly reduced if the addressor system can focus on the correct objects to be monitored, by issuing a transport note.

GS1 standards have provided for a DESADV despatch note to notify the addressee and to allow him to prepare for his delivery and to collect the traceability data of the products sent. In the same way, the transport note allows the carrier to prepare the shipment and to collect the traceability data from the objects to be transported, i.e. the containers.

Success depends heavily on taking into account the numerous operational details. It is essential to take these into consideration in order for staff to adopt these new ways of working.

Staff motivation is generally reinforced by the recognition resulting from the possibility of them demonstrating their professionalism.

**Validation of GS1 standards**

The Traceability Pilot allowed our hospital to validate the relevance of the GS1 standards for the security of our transported goods and the effective creation of the traceability link which may be missing between two production processes.

Adopting global standards is reassuring
The current deployment of e-procurement solutions and WMS (warehouse management system) are based on GS1 standards, since the two software packages chosen (Achat Pro and LMT Logistic Manager 7) are the basic programmes for GS1 standards. In the context of our hospital, this will cover the majority of products purchased, including all medication and medical devices.

This deployment will be supported by the implementation in our hospital of GS1 identification keys for locations or functions (GLN – Global Location Number) and for returnable assets (GRAI – Global Returnable Asset Identifier). The doors of the 4,300 locations in the new hospital with 777 beds, called ‘Bocage Central’ and currently being constructed, will all have a bar code corresponding to the GLN’s (Global Location Number) already allocated to these locations.

Future perspective
The French National Committee of the Directors-General of the University Hospitals (la Conférence Nationale des Directeurs Généraux de CHU) has chosen the GS1 System of Standards to be implemented throughout their supply chains.

In fact, the validation of the relevance of GS1 standards in our hospital has also led us to envisage an extension to all related activities in our hospital.

Our calls for tender already explicitly ask the suppliers for the GTIN (Global Trade Item Number) of the products proposed, and to be able to send a DESADV (Despatch Advice) as of 2008.

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Special report: Global standards and patient safety

THE DEPARTMENT OF HEALTH AND CODING FOR SUCCESS IN ENGLAND

ARTICLE BY DR. HELEN LOVELL

The Department of Health in England and its associated agencies are convinced of the potential benefits of Automatic Identification and Data Capture (AIDC) technologies. This article sets out why and how patients and the health-care system could benefit if AIDC and coding standards are adopted more widely. It is for NHS organizations, industry and technology suppliers to take up the challenge and drive the agenda forward, and the Department of Health and its agencies are taking forward a programme of action in support of this. Actions include:

- Recommending that all manufacturers of medicines and devices should provide a Global Trade Item Number (GTIN) on products;
- Recommending that NHS organizations adopt GS1 coding for new applications;
- Membership of GS1 for all NHS organizations in England;
- Demonstrator projects;
- Further guidance and best practice information.

Abstract

There is evidence of real improvements to patient safety when coding systems are used to match patients to their care – fewer medication errors, a reduced risk of wrong-site surgery, a more accurate track and trace of surgical instruments, equipment and other devices, and much better record keeping. Using coding to manage supplies and purchasing electronically can cut costs dramatically as well as improving efficiency.

Benefits for industry include effective track and trace, and supply chain efficiency; coding is also a weapon in the fight against counterfeit products.

It has been calculated that in the UK about 10% of inpatient episodes result in errors of some kind, of which about half are preventable; and of 8 million admissions to hospital in England each year, about 850,000 result in patient safety incidents which cost the NHS about £2 billion in extra hospital days.

The Charing Cross Hospital installed an automated dispensing system in the pharmacy in winter 2003–04. Its impact on a range of outcome measures was assessed through a before-and-after study:

- Dispensing errors were reduced from 2.7% to 0.9%.
- Time taken to pick items was significantly reduced.
- Stock control was improved, with fewer items ordered outside the regular ordering times and fewer items supplied as ‘to-follow’. There was a dramatic improvement in stock discrepancies.
- There was a 23% increase in storage capacity.
- The system had no impact on time taken for labelling and assembly of prescriptions, and there was no change in turnaround time for discharge prescriptions.

One Trust deploying a robotic dispensing system saw a reduction in time spent in the dispensary of 34% for pharmacists and 51% for technicians, enabling far more time to be spent on the wards working directly with patients and ward staff.

An RFID tagging system has been implemented at the day-case unit at the Birmingham Heartlands Hospital, to improve safety and efficiency as patients go through surgery. Patients have a digital photograph taken when they are admitted to the unit, and this is embedded in their EPR. They are given a wristband with an RFID tag containing their identification details. The system has saved time and enabled more patients to be treated on each list. As a result, cost savings are estimated at £270,000 per year. Patient satisfaction is high, and they are happy to be photographed and tagged as a means of ensuring they receive the right treatment. The Trust has now decided to invest in the system throughout all its theatres.

The NHS is also a major purchaser of all manner of goods and the scope for enhanced supply chain efficiency is significant. In Leeds Teaching Hospitals NHS Trust, the cardiac catheter laboratories have switched to an AIDC-based stock control system. The value of stock held has reduced from £1.6 million to £700,000, including 983 product lines. Orders are placed twice weekly on an electronic system instead of twice daily on a paper system, dramatically reducing both staff time and the costs of the purchasing process from up to £7.05 per line to just 39 pence.

Automatic Identification today in the UK

The medicines and medical devices industries have already made significant progress on coding products to voluntary standards. Most medicines already have a...
Figure 1: Schematic diagram showing how AIDC can impact on healthcare systems and processes.

- Medicines supplied with Unique Product Code (UFC) and GS1 Global Trade Item Number (GTIN)
- Supply chain tracked through external database
- Batch and expiry date recorded
- Medicines dispensed in pharmacy
- Admission verification of right patient-right medicine

Pharmaceutical manufacturer

Manufacturer

Database for tracking and verification of medicines and devices

Device manufacturer

Hospital pharmacy

Pathology Radiology

External laboratory

Surgical procedures

On the sterilisation centre

Process for tracking and verification of surgical instruments

- Sterilisation centre
- Code on sterilisation pack
- Sterilisation verification and recording
- Consent to surgery
- Consent to surgery

Special report: Global standards and patient safety

GS1 Global Trade Item Number (GTIN) product code on the patient pack, but this needs to be on all medicines. Product codes are not used as systematically for devices, but this too needs to change. NHS Purchasing and Supply Agency recommended in 2004 that all products supplied to the English NHS should have a GTIN, and manufacturers need to act on this.

Use of AIDC within the NHS is inconsistent at present, focused on individual projects rather than used generically throughout the system. There is a need to share learning and encourage the evaluation of projects to ensure that benefits are quantified and the most beneficial approaches adopted more widely.

Robotic dispensing systems in hospital pharmacies are one of the most widely used applications at present. These systems suffer from the need to input data manually when a new medicine is received for the first time. The electronic Dictionary of Medicines and devices (dm+d) will be upgraded to include bar code information for each product. This will enable robotic systems to call down details of new products automatically, without them having to be input manually.

Application of codes within the NHS more widely could benefit from a more systematic approach – e.g. to identify medicines or other items manufactured within hospital laboratories for use within other organizations. Connecting for Health will work with the GS1 standards organization to enable each NHS organization to have a globally recognized organizational identifier, and to provide the support necessary to enable coding to be implemented within the organization. Demonstrator projects will inform wider implementation.

Much can be done to facilitate further uptake of AIDC within the NHS. Individual applications of AIDC, such as automated dispensing in pharmacies and bedside verification systems, can make significant improvements to patient safety on their own. It is also clear that wider benefits will come through as the IT infrastructure across the NHS develops in the coming years.

Coding standards and regulatory perspective

The case for coding is compelling, but all stakeholders need to work to commonly agreed standards if the benefits are to be realized fully. Standards for coding have developed over time through voluntary action across industry. There are a number of different standards and associated organizations, but the most widely used is the GS1 System, owned and managed by GS1, which is a not-for-profit membership organization. The GS1 organization has established a Healthcare User Group which is reviewing and revising the GS1 standards for healthcare products worldwide. The work is due to be completed in 2008. In the meantime, existing GS1 standards are being used by the majority of manufacturers and many health organizations that have implemented coding systems.

The Department of Health recommends that the GS1 System should be adopted throughout the healthcare system in England, both for manufactured products and for coding systems used within healthcare settings, such as patient identification codes on wristbands. The GS1 (EAN.UCC) system will offer the most appropriate coding structure for most applications in the NHS.

We have considered whether any action should be taken to require manufacturers to code products using a given standard through regulations. Medicines and medical devices are subject to European legislation. The use of coding is not currently mandatory. Under existing medicines legislation, the UK may be able to introduce national requirements for unique identifiers but this would need to be compliant with wider EU law.
The use of auto-identification is recognized internationally as a useful tool for patient safety, supply chain efficiency and the fight against counterfeit products. Work is under way in the World Health Organization (WHO), the Council of Europe and several EU fora.

Mandatory requirements for medical devices would need to be negotiated at European Union (EU) level. These would be complex and lengthy processes.

Manufacturers, while keen to see a level playing field with the same requirements applying to all of them, also operate in European and wider global markets. Different labelling requirements in different countries would be complex and costly to administer, and an EU-wide, or even global approach would be preferable. This is also an area where technology continues to develop and regulation may restrict helpful developments.

The use of auto-identification is recognised internationally as a useful tool for patient safety, supply chain efficiency and the fight against counterfeit products. Work is under way in the World Health Organization (WHO), the Council of Europe and several EU fora.

In England significant progress has already been made through voluntary actions, and standards for coding by manufacturers should continue to develop on a voluntary basis. The work of the GS1 Healthcare User Group to review and update GS1 standards for healthcare products is welcomed. The Department of Health endorses fully the NHS Purchasing and Supply Agency recommendation that all supplies to the English NHS should have a product code following the GS1 standard bar code format, and recommends that all manufacturers of medicinal products and medical devices adopt this approach.

**References**


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Helen Lovell has been a career civil servant at the Department of Health in England since 1998. In that time she has worked on a variety of aspects of health and social care, including children’s services, reconfiguration of health services, dentistry, and most recently in the Healthcare Quality Directorate, where projects include auto-identification and clinical audit.

Prior to joining the Department of Health she spent three years at the Engineering and Physical Sciences Research Council, managing the Medical Engineering research programme. She trained originally as a scientist, with a first degree in Chemistry (Bristol University) and PhD in natural product synthesis (Cambridge University).
THE NEW ZEALAND GOVERNMENT PERSPECTIVE ON AUTOMATIC IDENTIFICATION AND GLOBAL STANDARDIZATION – THE MEDICATION SAFETY PROJECT

ARTICLE BY ELIZABETH PLANT AND DR BRUCE ANDERSON

The New Zealand Medication Safety Project is an initiative to reduce medication errors by introducing bedside verification of medications using a standardised barcode point of care (BPOC) system. For successful information verification to occur, other systems will need to be changed or introduced. For example, hospital pharmacy information systems, the introduction of e-prescribing, e-medications chart or e-medications records, introduction of a system of medicine reconciliation and repackage pharmaceuticals as unit dose with barcodes. These measures will reduce the number of adverse medication events and with that reduce the number of patients adversely impacted by those events.

A cost utility analysis was carried out to support the project concept. It is estimated that the gross cost over 12 years of a proposal to introduce and then operate the new medicine management systems in District Health Board (DHB) hospitals would be in the order of $101 million. The gross cost of the project will be offset firstly by a potential saving over the first 12 years of about 1,050 lives; preventing about 2,800 people being subject to permanent disabilities; and about 29,000 shorter term disabilities. In addition, a reduction in adverse medication events will mean patients do not need to spend additional time in hospital recovering from the event. As a consequence this will free up resources allowing them to be allocated to other areas of health priority.

Global standardization for Auto-ID is an essential component in ensuring that internationally these types of projects can be duplicated and standardized.

Health and disability services in New Zealand are primarily funded by the Government through taxation. The planning, purchase and provision of services in local regions is the responsibility of District Health Boards (DHBs). These DHBs are responsible to the Minister of Health who has overall responsibility for the health and disability support system.

The New Zealand Government has committed funding to a national project which aims to support health professionals in the medication administration process by introducing bedside verification of medication using Auto-ID Barcode Point of Care. This will reduce the number of adverse medication events and with that, reduce the number of patients adversely impacted by those events.

The types of systems that it is proposed to introduce do not remove the need for clinical judgement; rather it supports staff by bringing to their attention a potential error directly before administration. Health care workers will still need to use their judgement before deciding the appropriate course of action to take following a warning. They also still need to talk and listen to patients. Those normal interactions won’t change.

Global standardisation for Auto-ID is an essential component in ensuring that internationally these types of projects can be duplicated and standardized.

Medication safety

Those working in the New Zealand health sector are dedicated professional people who strive to provide the best care possible to their patients. However, errors can and do occur despite the best efforts of staff and organisation. Medication errors continue to be a recognised problem in the New Zealand health and disability sectors.

An extrapolation of results by the New Zealand Quality of Healthcare Study (NZQHS) suggests that in New Zealand each year, about 5,000 patients are subject to medication errors. As a result of these errors about 150 patients die, over 400 are permanently disabled, and nearly 3,500 are disabled for less than one year. The magnitude of medication errors estimated in New Zealand is consistent with that experienced in other countries. The actual number of adverse medication events is unknown and regardless of possible issues with the development of these estimates of medication errors, it is important to act now regardless of whether the impact is 100, 1,000 or 10,000 deaths, permanent disabilities or other patient impacts.

Potential medication errors occur throughout the medication process, starting on admission when a clinician records a patient’s medication history. Throughout the medication process, when the clinician prescribes medication to a
An extrapolation of results by the New Zealand Quality of Healthcare Study (NZQHS) suggests that in New Zealand each year, about 5,000 patients are subject to medication errors.

Prescriptions are either transferred to the hospital pharmacy or dispensed from ward-based stocks. When prescriptions are sent to the pharmacy they are transcribed into the pharmacy information system, the pharmacy then fills, checks and dispatches the medication to the ward. Alternatively or in conjunction, many hospital pharmacies supply medicines via an imprest system – this is a storage cupboard in the ward which is pre-filled with an agreed selection and quantity of medicines. (Some have automated systems such as Pyxis). Nursing staff access this stock according to what is prescribed on the medicine chart i.e. there is no guide to ensure the correctness of the medicines chosen.

The final checks are undertaken usually by nursing staff just prior to the patient receiving the medication and these checks are known as the “five rights” – the right medication is given to the right patient in the right dose at the right time by the right route. Conversely, a patient may be injured when:

- the wrong medication is given to a patient or by administering a medication to the wrong patient;
- the wrong dose is given;
- the medication is administered to a patient who is known to be allergic;
- the medication is administered incorrectly or using the wrong formulation (e.g. orally instead of by injection);
- the medication is administered at the wrong time or when doses are missed completely.

As an enabler to increasing the penetration of patient safety systems in the United States, the Food and Drug Administration mandated the use of linear barcodes on unit of dose for drugs ordinarily used in hospitals. This has allowed for a rapid expansion of the number of hospitals implementing barcode point-of-care and associated medication safety systems. When implemented these systems have significantly reduced the number of medication errors and consequently prevented large numbers of patient deaths and injury.

This project proposes to implement a barcode verification of medication at the point-of-care into New Zealand public hospitals. For this to occur, the project would also change some hospital pharmacy information systems, introduce e-prescribing, e-medication chart e-medicine reconciliation and repackage pharmaceuticals as unit dose with barcodes. In isolation, each of the components is likely to improve medication safety but the maximum gain is to be obtained from implementing all systems in a coordinated manner. These data capture, decision support and checking systems have been successfully implemented in many hospitals in the United States and other countries.

A comprehensive bedside verification of medication using a barcode point-of-care system might work as follows:

- The hospital gives the patient an identification bracelet with a barcode on it. The information in the barcode uniquely identifies the patient and allows for data relating to that patient to be captured and synchronised for example by linking the patient, and clinical staff, to his or her computerised medication record (or on the patient management system). In the future, the system would link to a more comprehensive electronic medical record.
- A medication history is developed with the patient and if needed their General Practitioner. This information is continually updated and then made available (or accessible) at each transition in the patient’s care.
- Prescription pharmaceuticals and certain over-the-counter drugs would have a barcode on drug packaging/labels and would be available at the unit of dose. The barcode would contain the pharmaceutical’s unique identifier number.
- A clinician creates a computerised medication prescription and decision support is available to them at that time flagging incorrect doses, or potentially dangerous interactions. This prescription is transferred electronically to the hospital pharmacy, where a second series of consistency checks is undertaken (e.g. does the prescription match the stated application of that drug and in the correct dose for the patient?). If no problems are encountered, the medication is dispatched to the ward or profiled into automated drug distribution cabinets available at ward levels.
- The hospital ward has barcode scanners or readers integrated with the hospital’s computer systems and are linked to the hospital’s patient management system, pharmacy, the patient’s electronic medication record and stock inventory.
- Before the medication is administered to a patient, the staff member scans the patient’s barcode and a barcode on their own staff identification tag.
- The staff member scans the medication provided by the hospital pharmacy. This scan validates that it is the correct patient, checks that the drug is the same as that prescribed for the patient, in the correct dose, formulation etc.

At each stage of the sequence, information is compared to the patient’s electronic medication record. If there is a problem, an error message alerts the staff member, requiring them to stop, investigate and inform the patient. As an example, bedside verification could prevent a patient from receiving medication intended for someone else, a child from receiving an adult dosage of a drug, or prevent a patient from mistakenly receiving a duplicate dose of a drug he or she had already received. A bedside verification of medication system also records the time that the patient receives the medication, the person administering and the location of administration. The information collected will ensure more accurate medical records.
While the key patient safety tools in this initiative is the barcode point of care (BPOC) checking, there are several other systems that support this approach. For example, BPOC requires drugs to be packaged at the unit of dose level and each medication is individually wrapped and the wrapper has a barcode containing information that uniquely identifies the drug and dose. It is proposed that in the short term unit dose packaging machines be purchased. BPOC systems need to be interoperable with electronic prescribing or electronic medicine charts, patient management and pharmacy information systems. The linking of these systems allows for data to be compared and for checks to be made with other sources of information (such as decision support tools).

It is estimated that the gross cost over 12 years of a proposal to introducing and then operating bedside verification of medication in DHB hospitals would be in the order of $101M. The gross cost of the project will be offset firstly by a potential saving over the first 12 years of about 1,050 lives; preventing about 2,800 people being subject to permanent disabilities; and about 29,000 shorter term disabilities. Secondly, in financial terms reducing the incidence of medication error will reduce the need for those subject to the adverse medication events needing to spend extra time in hospital. On average, those subject to a medication error need to spend an additional 7.5 days in hospital on top of the days required for the original health problem. Preventing this unnecessary time in hospital could eventually free up about $20million of resources each year for other priorities. The total net discounted saving over 12 years would be in the order of $115million.

While no plans are currently being considered, it is likely in the future Auto ID (barcode use) on pharmaceuticals and health supply chains could be mandated by New Zealand Government regulation. Global standardisation of Auto-ID is essential to prevent duplication or confusion to arise internationally. Bedside verification in a process that would benefit global health care organisations and where possible should be standardised and available internationally.

Conclusions
The New Zealand Medication Safety Project in New Zealand described here is aimed at reducing the number of adverse medication events and as a consequence reduce the number of patients adversely impacted by those events. This will reduce the number of patient deaths, and disabilities caused by medication error. In addition the project will support health professionals in the medication administration process by introducing bedside verification of medication using Auto-ID Barcode Point of Care.

Bedside verification is a process that would benefit global healthcare organisations and where possible should be standardised and available internationally. Global standardisation of Auto-ID is essential to prevent duplication or confusion to arise internationally.

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Bruce Anderson, PhD Manager, Governance, Ministry of Health, New Zealand.

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1 Costs and benefits have been discounted at 3.5% unless stated otherwise.
2 In this paper, the terms medication and drug are used interchangeably.
4 Dorland’s Illustrated Medical Dictionary (26th Ed.)
5 A barcode provides information that is reliably read by a computer. A barcode helps automatic data capture. Technically a barcode is a data carrier for the information encoded in the black and white stripe of a linear barcode or the pattern of dots on a “two dimensional” barcode.
6 Costs and benefits have been discounted at 3.5 percent unless stated otherwise.
HOSPITAL MANAGEMENT AND DEVELOPMENT

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**ADVANCING HEALTH-CARE SYSTEM PERFORMANCE WITH GEOINFORMATICS**

**ARTICLE BY SETH WIAFE**

**Abstract**

Health-care systems represent robust and demanding information environments that require comprehensive infrastructure capable of addressing inadequacies in existing systems. Although several modern geotechnologies have been available for over three decades, most healthcare systems and public health agencies have incorporated only a limited number of these innovative technologies into their routine practices. Understanding geoinformatics capabilities in the health-care industry as a decision support system in responding to health-care challenges associated with assessment, assurance, and policy development is needed.

Geography is important in understanding the dynamics of health causes and spread of diseases. Any attempt to advance quality improvement in health care requires geospatial consideration and implementation of geoinformatic science and technologies such as geographic information systems (GIS), global positioning systems (GPS), and remote sensing applications. Recent progress in geotechnologies has intensified the need for evidence-based spatial decision support systems (SDSS) in health-care practices. A GIS integrates data from multiple sources, providing the ability to analyze and visualize how data relates over space and time. The use of a GIS requires the creation of geospatial databases, appropriate hardware and software acquired, applications developed, and all components installed, integrated and tested before users can use it. This usually occurs after a thorough needs assessment and analysis of the benefits of GIS for the organization. This paper provides a snapshot of the benefits of GIS and related technologies and how they are being used in health-care systems.

**Geoinformatics in health care**

Health geoinformatics combines spatial analysis and modeling, development of geodatabases, information systems design, human-computer interaction and networking technologies to understand the relationship between people, environments, and health effects. GIS provides the opportunity of linking databases to maps, creating visual representation of statistical data, and analyzing how location influences features and health events on the earth’s surface.

Within the last decade, the world has experienced some catastrophic events that clearly provide evidence of the importance of state-of-the-art health information systems (HIS). The events of 11 September 2001, provided an enormous evidence of the need for spatial information in rescue missions and emergency preparedness efforts. Since “9/11”, several health agencies have adopted GIS for immediate rescue, response, and long-term recovery efforts. Plans to process data and train personnel to prepare them for emergencies before they occur have been developed. The Severe Acute Respiratory Syndrome (SARS) outbreak took public health experts by surprise while establishing an insurmountable fear among communities everywhere. SARS was present in 28 countries by affecting over 7000 possible cases with over 600 deaths between November 2002 and May 2003. The success of containing SARS was attributed greatly to the Global Outbreak Alert and Response Network (GOARN), an electronic network developed by Health Canada, used extensively by World Health Organization (WHO) since 1997 as an early warning system. Mapping technology was used to help victims in December 2004 after a massive earthquake struck Sumatra island and triggered a tsunami that killed more than 230,000 people in a dozen countries, including 160,000 in Indonesia’s province of Aceh. As a collaborated effort, Mercy Corps, working with the University of Washington and the Pacific Disaster Center, used GIS mapping technology to plot everything from village survival rates to access to destroyed fish ponds.

Compared with other public services as natural resource, urban planning and transportation, it is evident that the full capacity of GIS in health-care management has not been fully explored. There is limited evidence that GIS are being formally considered or regularly used in strategic decision-making in any major health-care planning system. Several initiatives that advocate the inclusion of GIS operations at different stages of health-care planning and management have been noticed. In 2003, GIS was recognized as an emerging information technology that can be used to enhance the ability to prepare for and
Making health data timely, accessible, and linking them to various public and private data systems will solve many of the health information challenges facing health-care systems.

Respond to public health emergencies. Several organizations including the WHO are committed to support countries in the adaptation and integration of GIS within their respective health-care programmes. In an address to his staff, the Director General of WHO, Dr Lee acknowledged that, “Health information is the glue that holds a health system together.” WHO plans to establish a health metric network to fulfill the health information inadequacies.

Making health data timely, accessible, and linking them to various public and private data systems will solve many of the health information challenges facing health-care systems. Successful adoption of GIS by health-care managers and policy-makers depends on understanding the spatial behaviours of health-care providers and consumers in the rapidly changing health-care landscape and how geographic information affects these dynamic relationships.

Geoinformatics in emergency response

In most cases, linking emergency resources with victims creates a geospatial challenge. A big part is the fragmentation of emergency services and lack of a central communications clearing house. To address this challenge, Loma Linda University Medical Center (LLUMC) has developed an integrated Advanced Emergency Geographic Information System (AEGIS) that can be accessed anywhere. AEGIS allows all emergency resources to be fully coordinated as a web-based situational awareness system for use in all emergency medical services. AEGIS monitors and maps the location and status of emergencies, locates victims and emergency response personnel, and tracks other factors such as prevailing weather conditions that can impact emergency response on a real-time basis.

AEGIS overlays traffic congestion and accidents on freeways to plot the fastest routes to area trauma centres. All authorized emergency responders can access AEGIS via the Web or by using a basic cell phone or in-vehicle unit. AEGIS has contributed in reduction of response and transport time from a half-hour or more to just minutes at a time when minutes mean lives saved.

GIS provides high quality patient care management

Ensuring delivery of high quality care requires care givers to have the necessary accurate and timely information and the ability to visualize them at their fingertips. Hospitals that have developed patient/bed management systems that operate during non-surge periods are in a better position to provide critical information to local incident management during unanticipated disaster surges. Downey Regional Medical Centre (DRMC) has implemented a GIS-based patient care and room management applications using location as an integral data component. This system facilitates capturing of vast array of information of patients’ admission, switching rooms, discharge, and moving from in-hospital to outpatient care. With information centralized, automated and networked, data accuracy is vastly improved and retrieval speed tremendously enhanced. On a broader scale, linking hospitals in local, statewide and multi-state systems will enable health-care surge capacity the ability to adequately prepare and respond to mass-casualty events and other regional public health emergencies.

GIS in disease outbreak and surveillance

Global health experts believe that the world is now closer to another influenza pandemic than at any time since 1968, when the last of the twentieth century’s three pandemics occurred. WHO uses a series of six “phases of pandemic alert” as a system for informing the world of the severity of the threat, and for the need to launch intense preparedness activities. A review of current disease surveillance systems indicates a lack of consistency across systems regarding data integration, management, and adoption of information technology. Incorporating GIS in any disease surveillance system enhances its ability to provide accurate and timely information that is more efficient and less cumbersome.

Defining suitable locations for health-care services

Access to health care is a significant factor that contributes to a healthy population. Accessibility and utilization of health care depends largely on having the appropriate health-care resources in the right place at the right time. GIS has been used in a number of situations to estimate the optimal location for a new clinic or hospital to minimize distances potential patients need to travel taking into account existing facilities, transport provision, hourly variations in traffic volumes and population density. Through the USAID-funded Partners for Health Reform plus (PHRplus) Project, stand-alone GIS-enabled HIS and mapping tools have been developed to support the Yemen Ministry of Health officials to understand health issues visually, and make decisions more easily. Four GIS applications have been developed, the health facility viewer, health facility targeting, health care accessibility, and health risk index. These applications demonstrate sophisticated use of health information to enhance facility utilization, improve distribution of preventive and curative care, and provide evidence-based rationale for targeted assistance and service delivery.

Resources required to implement a GIS

Developing a GIS requires investment in computer hardware, GIS software, networking environment, data, procedures, and trained staff. Staffing for a GIS programme is critical as it is not easily feasible to directly expand the local health-care staff positions to fill the GIS need. Areas where expertise is needed include GIS project management, GIS database skills, and application development. Training of the health care workforce in general computing, database principles, and GIS are essential for increasing efficiency of use.

Conclusion

Several dimensions of health and human services can benefit from the adoption of geoinformatics as a way of improving health and be in a better position to prevent and respond to public health...
emergencies. There is a need for health-care systems to create new types of information that are both clinically relevant as well as place and time sensitive in response to large scale emergencies. When appropriately implemented, GIS could potentially act as a powerful evidence-based practice tool for early problem detection and solving while modifying clinically and cost-effective actions in predicting outcomes, and continually monitor and analyze changes in health-care practices.

Author

Seth Wiafe is an Assistant Professor and Interim Chair of Environmental and Occupational Health department and Academic Director of Health Geomatics Program. He served as health GIS marketing coordinator for ESRI’s Health and Human Services Solutions group from 2002-2005. Wiafe received his Bachelor of Science in Public Health (BSPH) degree in Health Geographics from Loma Linda University School of Public Health in June 2002 and Master of Public Health (MPH) degree in Environmental and Occupational Health in 2004. Wiafe is also a medical technologist and served as the Director of Clinical Laboratory Sciences at Gimbi Adventist Hospital, Ethiopia 1992 to 1999. He served as listserv administrator of Pacific Public Health Training Center (PPHTC) from 2002 – 2005. He is involved with both local and international projects relating to Geographic Information Systems (GIS) health applications, including the partnership for quality medical donations (PQMD) mapping project, LLU mobile mapping project, African American Health Initiative (AAHI) project of San Bernardino county. He serves as co-investigator for the LLU Center for Public Health Preparedness and the Regional Academic Center of Excellence in Environmental Health.
DESIGNING STRONG LINKS TO NATURE

ARTICLE BY TYE FARROW

Abstract

One of the most pressing obstacles facing health care designers is the gap between the business of healthcare and fundamental human desire to connect with nature during the healing process. Two Canadian projects are embracing a holistic design approach: the Credit Valley Hospital in Mississauga, Ontario and the Thunder Bay Regional Health Sciences Centre in a remote northern community. Achieving a harmonious balance between fiscal restraint and tangible relationships with nature, these projects raise public expectations for what health care environments should be: nurturing, human-centred investments in cultural and physical infrastructure.

A major challenge facing health care designers today is the apparent conflict between the business of building hospitals and the proven human desire to connect with nature during the healing process. Health care organizations actively promote themselves as the patient’s advocate. For over twenty-five years, such terms as “patient-focused care” and “natural environments” have been popular with hospitals and health care designers around the globe. Yet is it possible that fiscal cuts paired with pressures to improve efficiencies in care delivery have reduced these fundamental principles to empty words?

To help close this gap, it is imperative that designers, executives, and stakeholders work together and consistently ask the tough questions of everyone involved: “Do we have the courage to advocate for and deliver integrated places that truly provide healing and hope?”

Two Canadian projects are helping address these fundamental issues: the Credit Valley Hospital in suburban Mississauga, Ontario and the Thunder Bay Regional Health Sciences Centre in a remote northern community. Achieving a harmonious balance between fiscal restraint and tangible relationships with nature, these projects raise public expectations for what health care environments should be: nurturing, human-centred investments in cultural and physical infrastructure.

Raising the bar

Completed over several phases, the new 320,000 sf, 386-bed Carlo Fidani Peel Regional Cancer Centre at the Credit Valley Hospital includes the province’s first fully integrated ambulatory clinic and cancer care facility. Also included is a 72-bed complex continuing care wing; an 18,000sf rehabilitation facility; a 60,000sf wellness centre; a maternal child and laboratory wing; and emergency room renovations.

At the outset of the design process, cancer patients were asked about their priorities for the new treatment area. “Our waiting spaces should give us hope,” they responded. When asked what would give them hope, they replied, “Something that is alive!”

Faced with this devastating illness, such responses emphasize the importance of strong connections with nature. In the harsh Canadian climate, however, therapeutic links to nature require more than views to the outdoors and abundant daylight. As the design draws on shapes and symbols that evoke protection, resilience and strength, the first impression is of a wellness research institute, rather than a place for processing sick people.

Credit Valley’s main lobby and cancer treatment areas convey the message “you are in good hands.” Believed to be one of the most intricate wood assemblies in North America, there is nothing timid about this design - a self-assured approach that instills confidence in the quality of care one can expect here. The case for wood was easily justified as the sustainably-harvested Douglas fir members cost less than equivalent steel, while providing superior aesthetic value. Powerful arching forms soar skyward, suggesting a human-scale cathedral in the...
it is imperative that designers, executives, and stakeholders work together and consistently ask the tough questions of everyone involved: “Do we have the courage to advocate for and deliver integrated places that truly provide healing and hope?”

midst of a bustling hospital. Patients, staff and visitors gather in this sheltered sanctuary to share news and talk through emotional issues.

Natural light also plays a key role. The atrium incorporates large triangular glazed sections at its cleaves. Internally, a series of multi-storey light wells illuminate ambulatory clinics deep within the block while similarly glazed, wooden mini-atriums bring light to the radiation treatment waiting areas below.

While the qualitative benefits of nature seem self-evident, an innovative research study project sought to quantify this relationship. Completed for the Ontario Hospital Association Change Foundation, the study utilized evidence-based design and function analysis to determine the impacts of design on patient and user satisfaction and movement; the first such study in a Canadian health care facility.

While the data is currently being quantified, results indicate a positive direction in the level of satisfaction, efficiency and effectiveness. Satisfaction with physical comfort, information, communication, education and respect for patient preferences also increased in the new site. On the staff side, gains were observed and therefore (by extrapolation) for patients. Staff had more time for treatment, education and supporting patients. These are all positive outcomes that the CVH will continue to build on and improve upon.

At the recently completed Thunder Bay Regional Health Sciences Centre, the team also embraced a similar holistic approach. The 680,000 ft², 375-bed acute care facility has been hailed internationally as a design benchmark that redefines the notion of a community hospital.

Thunder Bay is a community of approximately 120,000 in north-western Ontario Canada on Lake Superior. Rather than renovating its two existing local hospitals, it was decided that the municipal monies would be best spent on one single regional facility. As a result, the project operates a regional cancer centre, maternal child services, mental health centre and is a base hospital serving a northern region the size of France.

Conceptually, the building is organized in a “T” configuration. Oriented north-south, patient wards are located on the east side with clinical departments on the west and north. At the crutch of the T is a public plaza with the main entrance.

There is a powerful attraction to this design that draws patients, staff and visitors who gather to share their thoughts and talk through emotional issues. Its function goes far beyond the standard requirement for circulation and waiting areas. The concourse thus reflects a vital new role of the hospital as a place that fosters learning and understanding.

**Heroic innovators**

While the design team is of course a key factor, it is by no means a singular effort. Every client and stakeholder has the latent capacity to create extraordinary, uplifting spaces for staff, patients and the community. It is important then that we actively encourage everyone to expect more from their built environment.

When Thunder Bay CEO Ron Saddington knew he had “just one chance to get it right” he recognized the importance of attracting support for a facility that would change the course of
To endure this bumpy journey, he took advantage of every opportunity for open dialogue with stakeholders. By doing so, legitimate, thoughtful concerns would not be overshadowed by the negative “noise.” He also cautioned his Board not to waffle in their resolve to proceed with the vision as planned and after attracting a critical mass of support, he made it known that dissent would not impact the final building. Staying focused on the future turned out to be a worthwhile investment. As a result of his tireless commitment, Mr. Saddington now leads a revitalized organization. The facility has attracted international attention and awards as a beacon of future health care design. There is a consistent message that comes from people who get a chance to view the site: Wow! “My chief-of-staff tells me that it’s a pleasure to come to work in the morning,” reports Mr. Saddington. “This hospital lifts our spirits.”

Similarly, Credit Valley Hospital’s ambition was to be “the finest hospital in Canada in the hearts and minds of people they serve.” This bold intention emerged from an intense period of soul searching and dialogue. President and CEO Wayne Fyffe also seized the unique opportunity to raise the bar for health care delivery internationally. Confronted with pressure to conform to conventional design standards, Mr. Fyffe was faced with several key challenges:

- Improve care in a cost-containment environment.
- Foster an integrated team care delivery model.
- Reduce costs and waiting times associated with patient transfers.

To achieve these goals, one fundamental question kept everyone focused: “What are the most basic needs of our fellow humans when they are worried or feeling vulnerable?” The answer was in understanding the quantitative value of design from a business perspective. “The lobby has a function and that function supports the business we are in: serving the physical needs of our patients” says Fyffe. “Also, the design energizes our staff and makes them proud to be here, we have no trouble recruiting the best talent; and we accomplished this within normal cost parameters.”

If we are to fundamentally alter the way the world views health care design we must first redefine what a hospital environment can be. And while the journey from creative concept to realization is often a bumpy and uphill challenge, the commitment on the part of the entire management and design team has been justly rewarded with legacy-building facilities that are also a showcase of concern for the well being of patients and the entire community.

**Author**

Tye Farrow is a senior partner at Farrow Partnership Architects in Toronto. He is a recognized leader in creating architecture that lifts the human spirit while advancing clients’ business goals. Drawing on themes from nature, he has designed award-winning projects across Canada and around the world. Recently, the Stockholm-based World Congress on Design and Health identified him as global leader who is making “a significant contribution to health and humanity through the medium of architecture and design.”

His groundbreaking approach to promoting wellness at The Credit Valley Hospital and The Thunder Bay Regional Health Sciences Centre is viewed internationally as setting a new standard for health care design. Building on his clients’ highest aspirations, he encourages them to join his pursuit of design that demonstrates true compassion for health care patients, staff and families.

Currently he is design team leader for the Providence Legacy Project in Vancouver (joint venture with Buxby, Perkins + Will), the Colchester Regional Hospital in Truro, Nova Scotia and the National Oncology Centre in Trinidad and Tobago.

Tye Farrow’s work has been published in the British journals Architectural Review, AD Architectural Design and HD Hospital Development. In 2003 The Globe and Mail designated him as one of Canada’s Top 40 Under 40; recognizing the “best and brightest” in Canada. He is a frequent presenter at international conferences on the value of human-centred design.

Tye holds a Bachelor of Architecture degree from the University of Toronto, and a Master of Architecture in Urban Design from Harvard University.
THE 411 ON THE ROAD TO HEALTH CARE

ARTICLE BY SHEILA MURRAY

Abstract

“All progress is precarious, and the solution of one problem brings us face to face with another problem.” Although Martin Luther King, Jr., was describing the 1960s American civil rights struggle, his words also aptly depict the state of healthcare reform today across the globe. In their quest to meet the greatest challenges, the critical shortage, the ideas for solving them and to find a panacea for healthcare ills, industrialized countries have been forced to re-evaluate their healthcare priorities to balance competing needs. The last two decades have provided exceptionally ripe conditions for reform, as healthcare demands have risen against a backdrop of increasingly limited resources so that health expenditures now regularly outstrip growth in gross domestic product (GDP) across most countries in the OECD (Organization for Economic Cooperation and Development) (Appleby 1993). And as the baby-boomer population has aged and worker tax bases have dwindled, governments have struggled to efficiently utilize available resources in order to fund an equitable level of care for their citizenry (Appleby 1993; Blank and Burau 2004).”

When your car slams into another or you faint and don’t know why or you experience excruciating chest pain, most likely those close to you will call 911 to get medical help fast! When you live in the United States, more often than not, help in various forms arrives in minutes. But what does one do when experiencing similar circumstances in industrialized countries; countries where efforts to fight HIV/AIDS, tuberculosis, malaria and other diseases have little to no desired effects, where patient care is jeopardized because qualified health care professionals are in short supply. A national phenomenon that has consequences for all countries, the shortage pervades all settings—hospitals, primary care facilities and public health and community clinics so that it’s not so easy to dial 911 in Third World Countries, and if one does, who is there to come?

And so, welcome to HealthConnections International, a company dedicated to giving American health care professionals the opportunity to live and work outside the US in another culture apart from military bases or volunteer organizations. Sheila Murray, President, has over a quarter century of practical health care recruiting experience both nationally and internationally; experience that in 1996 spurred her with the impetus to establish HealthConnections International to respond to the need in many countries for health care workers that are in short supply; a shortage that has progressed at an alarming rate. Citing the words of Lao Tzu, the father of Taoism, “Give a man a fish and you feed him for a day; teach him how to fish and you feed him for a lifetime” as incentive, Murray expanded her service to include recruitment training and consulting to address this shortage on a local level and give health care facilities the tools to recruit their own staff so they can compete globally.

HealthConnections International is committed to securing positions for health care professionals in other countries; they will contribute expertise, knowledge, and high-quality patient care to the health care facility; at the same time, they will expand their knowledge and have a competitive advantage in the global marketplace.

An innovative new element conducted by HealthConnections International is its full-service consulting and training program, the “Methods of Recruitment for the Health Care Professional”, one designed to provide attendees with the tools to create a plan of action that will increase their ability to fill vacancies and have a steady supply of candidates; candidates that learn to help themselves.

The program was designed specifically for health care professionals who find themselves responsible for recruiting staff but were never given the tools; a program that can also be used in cooperation with a Human Resources recruitment function to implement better staffing enrollment and increase their focus and ability to attract candidates on a consistent basis. Training, conducted on-site with existing staff, easily evaluates the current process, while the consulting services aspect offers clients real world solutions and hands-on assistance.

Additionally, the workshop explores how to attract candidates, where to find them, and then examines why they would want to work in a specific facility or country.

References

PATIENT PRISONER SECURITY
– A CALL TO ACTION

ARTICLE BY THOMAS A SMITH

Abstract

Taking care of prisoner patients poses severe challenges as pointed out in the article by Tom Smith, Immediate Past President of the International Association for Healthcare Security and Safety (IAHSS). Health care facilities can take proactive steps to minimize the potential for adverse incidents related to the care of prisoners. This article reviews the circumstances relating to the tragic shooting of a security officer last year in Blacksburg Virginia, USA and provides an outline for all hospitals to use to evaluate patient prisoner security issues.

We live in a time where evil wears many faces...” That was the opening of the eulogy at Derrick McFarland’s Memorial Service by his best friend Jason Goldman. Derrick McFarland was a security officer at Montgomery Regional Hospital in Blacksburg Virginia and was killed by a prisoner as he escaped from custody in the early morning hours Sunday, 20th August, 2006. As President of the International Association for Hospital Security (IAHSS) last year I had the great honor to represent the association at meetings and conferences around the US and Canada. Unfortunately one of those functions included Derrick McFarland’s funeral. This tragic and needless killing by an escaping prisoner is one of those events that should serve as a wakeup call to any health care facility (HCF) that treats prisoner patients. Among the thousands of prisoner patients treated at health care facilities around the world each year, there are those who are clever, desperate and strong enough to defeat security measures or take advantage of complacent prison staff or uninformed clinical staff. When prisoners escape from custody while in a HCF, at minimum, the public confidence in the facility is affected and in the worst case injuries and fatalities occur. Such incidents happen often enough for health care managers, security directors, law enforcement and corrections staff to review their policies and evaluate the risk of treating prisoner patients. If you treat prisoners in your facility, you should evaluate your forensic policies now and take reasonable measures to reduce the risk of treating prisoner patients.

In an article posted on Roanoke Times web site, jail officials reveal how William Morva overpowered a deputy early that Sunday morning. A segment from the article is listed immediately below followed by a suggested outline for use in evaluating prisoner security at your facility. Read this if you ever have prisoner patients in your facility.

Sheriff’s department Capt. Robert Hall, who oversees the Montgomery County Jail, stressed that officials were still piecing together accounts of the events for an ongoing investigation but said he didn't want to hide anything about what happened.

At 10:15 p.m. Saturday Morva told jail staff he fell out of bed and injured his right wrist and ankle. He was examined by medical staff at the jail. They recommended he be taken to the Montgomery Regional Hospital.

He left the jail, supervised by a sheriff's deputy, at 11:46 p.m. Because of his injuries, Morva's right wrist was not cuffed, Hall said. His left wrist was attached to a chain on his waist. The deputy took leg irons in case they were needed in the hospital but did not attach them to Morva because of his ankle injury.

Hall said that at the hospital, X-rays were taken of Morva's ankle and wrist, which were both diagnosed as severely sprained.

Morva then asked to use the bathroom and was taken to a one-toilet room while the deputy waited outside in the hallway. After going to the bathroom, Morva said he needed help pulling his pants up because of his injury.

When the deputy went in to help him with his pants, Hall said, Morva hit him over the head with a metal toilet-paper container, knocking him unconscious.

Morva then took the deputy's gun and, once in the hallway, shot hospital security guard Derrick McFarland and shot through a locked glass door to escape about 2:35 a.m., Hall said.

McFarland died from his wounds. Morva also is accused of killing Sheriff's Deputy Eric E. Sutphin Monday during his long flight from police.

Jail policy is for one officer to oversee one inmate during transfers unless the inmate is deemed a security risk, Hall said. It's up to medical staff to decide if a prisoner should not be cuffed because of the risk of further injury.

This guy had been here over a year,” Hall said of Morva, “and there was no
Requiring hospital security or police officers to conduct an initial risk assessment upon admission and to check in with police or prison officers and nursing staff on each patrol is a very good way to improve communication and compliance with your policies.

Indication of anything out of the ordinary with him as far as – security-wise,” Hall said. The policy is being reviewed and, in the meantime, two deputies will guard an inmate during any transfers from jail. Hall said Sheriff Tommy Whitt is meeting with hospital staff to discuss procedures. “If anything needs to be changed, we’ll change it,” Hall said.

What can be learned from the death of this fine security officer? What would you do now had this incident occurred in your facility? Let’s learn from this event and “If anything needs to be changed”, do it now.

Here are a few suggestions for areas to consider when reviewing your policy:

Communication
Communication between the agency guarding prisoners, security/police and clinical staff is one of the most important elements of prisoner security in a health care facility. Designate who is responsible for liaison between forensic and hospital staff. Meet with local law enforcement and correction agencies in your area to discuss and evaluate procedures. Do not rely on these agencies to provide complete security. Hospitals have a responsibility to implement reasonable security procedures for prisoner patients in their facilities. Security procedures are often spelled out in contracts between the custodial agency and the hospital. How do you communicate these agreed upon procedures to hospital and forensic staff members? Make sure your facility trains those that need to know of these policies. How do you inform the custodial officers of Forensic Policies? There are usually many Law Enforcement and Correctional agencies in each jurisdiction. HCFs should not completely rely on those agencies to communicate hospital forensic policy to their officers. A brochure targeting these individuals should be developed and reviewed with each forensic staff member as patients are admitted and throughout the patient stay. Requiring hospital security or police officers to conduct an initial risk assessment upon admission and to check in with police or prison officers and nursing staff on each patrol is a very good way to improve communication and compliance with your policies. Most facilities have patient risk assessments in place for victims of assault, domestic violence, child abuse or elder abuse. The same processes may be used to help evaluate prisoner risk and to improve communication between the custodial agency, security and clinical staff. Attached is a sample policy and record form that may be tailored to any HCF.

Restrains and custody levels
Custody levels may change from day to day depending upon level of risk. Know how your local agencies handle and communicate initial and modifications to custody levels. How many restraints are necessary? Are restraints secured to bedrails or to the bed frame? Are male prisoners treated differently than females? Some of these questions may seem ridiculous. However, speaking from experience, they need to be asked and staff needs to be reminded of the basics. Make sure your policy distinguishes between a prisoner restraint and clinical restraint and has a process to manage conflicts. Clinical and security needs must be balanced. One does not necessarily always overrule the other.

Physical security
Evaluate physical security for the primary locations forensic patients are treated. The emergency care, inpatient areas, and clinic spaces are all locations to consider. Inpatient forensic patient guards should be reminded of important physical security measures such as positioning in relationship to the door and avoiding being trapped by the prisoner.

Weapons security
Assess your policy regarding weapons allowed in your HCF. Are police and prison officers allowed in elevators, bathrooms or other confined spaces with prisoners and weapons? Some policies address these situations and do not allow weapons and prisoners together in confined spaces. When there are two officers one turns over his or her weapon to the second officer. In some cases weapons lockers are available. Do officers have other weapons (pepper spray, baton, Taser, etc…) available to them in addition to a handgun? A handgun should not be the only tool in the toolbox in the event additional force is necessary during a struggle. Some organizations have a philosophy attempting to remove weapons from all law enforcement and corrections staff. In most cases this is an unrealistic expectation that is not practical and in conflict with most agency policy. Unless a highly controlled environment is created, such as a locked mental health unit, police and prison staff will not disarm, nor should they.

Parking and transportation
Assess entrance points for prisoner patients. Evaluate security measures in place and consider the value of having designated entrance points vs. random access points. Consider a designated holding area for prisoner patients and build in physical security measures.

Inspect
There is an old military saying, “Do not expect what you do not inspect”. Inspect and make sure you know what is happening on the ground in your facility. Since this incident the IAHSS has developed a guideline for HCFs to use when evaluating procedures involving patient prisoner patients. These guidelines may be found at the IAHSS website http://www.iahss.org.

Author
Thomas A Smith, CHPS, CPP is a member of IAHSS and has worked in the health care field since 1981. During this time, Tom held a number of positions in a variety of health care facilities including a community hospital, inner city medical center, and a large teaching university based health care system. These organizations provided a variety of experience working with many different health care security models including contract security, proprietary security, and an in-house police department. During his career, Tom has held many different local offices in professional security and safety organizations and is currently the IAHSS Immediate Past
President. He has been a programme speaker for a number of professional organisations including IAHSS and has contributed to a number of professional publications and training manuals including the IAHSS Security Officer Basic Training Manual and Supervisor Training Manual.

Tom holds a Bachelor of Science degree in Security Administration and Law Enforcement from Northern Michigan University; is a Certified Healthcare Protection Administrator; Certified Protection Professional; and is appointed as a Special Police Officer by the State of North Carolina.

In 2007 Tom received the prestigious the IAHSS Philip A Gaffney Faculty Chair Award. In 1999 Tom received the Award for Management Excellence from his employer, UNC Health Care System and was nominated for the North Carolina Governor’s Award for Excellence in 2000.

References

HEALTHY CHOICES IN HOSPITAL VENDING MACHINES AND CANTEENS?

ARTICLE BY CHRISTINE HANCOCK, KATY COOPER AND KAREN SIEGEL

Abstract

Chronic diseases such as diabetes, heart disease, cancer and chronic lung disease are responsible for the majority of deaths and disabilities in developed and in most developing countries. Confronting this global epidemic requires society-wide interventions – including in workplaces and health-care settings. As part of this effort, hospitals could be taking a lead in providing appropriate food and beverages to visitors and hospital employees, as well as patients: this article is a call to action to create healthier food environments in hospitals.

Box 1 | The burden of chronic disease

- Mexico has the highest rate of diabetes of any large country (6.5 million diabetics in a population of 100 million).\(^1\)
- CVD treatment cost the UK health service £16 billion in 2004.\(^2\)
- The proportion of the disease burden (measured in disability-adjusted life years, DALYs) from non-communicable diseases in developed countries is around 85% in adults and is increasing in other regions – the proportion in middle-income countries has already exceeded 70%.\(^3\)
- Globally diabetes cases are predicted to rise from 246 million today to 380 million by 2025.\(^4\)
messages, including those who might not otherwise be reached – particularly the socioeconomically disadvantaged. Messaging can take the form of health education (e.g. health-promotion posters), or may be more subtle: hospitals are places dedicated to health, and the whole environment should therefore reflect the importance of healthy living. In this context, providing only HFSS food and drink options is entirely inappropriate, and sends a very ambiguous message.

“It is difficult for me to comprehend why many hospitals provide food and drink for their staff, patients, and visitors, much of which is almost the opposite of what the medical profession encourages us all to eat in order to be healthy. I simply cannot understand it” – Outside member of the advisory boards of several major US hospitals.

Hospitals as employer

Hospitals and health-care centres are a major employer worldwide. As employees often spend as much as 60% of their waking hours in their place of work, the food options made available to them by employers can greatly impact upon their diet and long-term health. This is particularly true of large institutions such as hospitals, where there may be no local food outlets other than those provided on-site. The UK’s National Health Service, for example, is one of the largest employers in the world, employing over a million people – but 45% of NHS employees are lower earners.10 Healthy million people – but 45% of NHS employers in the world, employing over a

Box 2 | Integrated best practice in Denmark

Sygehus Vendsyssel, a public hospital in northern Denmark, is targeting primary prevention at employees and visitors as well as patients. The initiatives are all coordinated at executive level – without this high-level support “the rooting of practices and priorities in health promotion won’t happen”, according to the hospital’s chief, Ingeborg Thusgaard.

- There is a complete ban on smoking in the hospital.
- The central canteen, open to employees and visitors, codes healthy food options with a green ‘traffic light’.
- Vending machines sell only salads and sandwiches.
- High HFSS products are sold only in the hospital’s kiosk, and this is currently under review.
- High-sugar soft drinks are available to undernourished hospital patients on prescription.
- New patients’ nutritional needs are assessed and appropriate advice given on recommended behavioural change. Screening for smoking, alcohol use and physical activity is to be added in 2007.
- Employees are offered fitness facilities and sport classes, and can consult a dietician during work hours, free of charge.
- At staff meetings, cake has been replaced by fruit.
- Everyone visiting the hospital premises is invited to take a walk around specially marked routes.

Access to healthy options

An argument put in favour of HFSS foods in hospitals is that they are often cheaper than healthier options, and are therefore affordable to all who visit. While socioeconomic disadvantage is a source of health inequalities in society more widely, this should be tackled – not perpetuated – in health care settings, perhaps by providing subsidised healthy foods.

It should be recognised, of course, that not all hospitals provide food for patients or visitors, particularly in developing regions. Where this is the case, family members are expected to provide food for patients – and whenever possible clear advice should be given on the importance of good nutrition for the overnourished as well as the undernourished.

What can be done? A call to action

There are a number of practical steps that could be considered by hospital managers, government and supplier companies to create a healthy food environment in hospitals. Significant recent advances in the school food environment11 could be replicated in

Box 3 | Community Interventions for Health

The CIH project” is an initiative of the Oxford Health Alliance, which seeks to use the same methodology to reduce the risk factors in four settings – schools, workplaces, communities and hospitals/health-care centres – in sites in countries as diverse as China, India, Mexico and the UK. A major component of CIH is to promote healthier practices by educating clinicians and hospital management teams to improve the hospital food environment.
health care settings.

- Facilitate healthy choices by strongly promoting the healthiest options. Vending machines can include healthy snacks and drinks (such as nuts, seeds, water and fruit juice), which should be more prominently displayed than the HFSS products.

- Government can encourage hospitals to develop standards on the availability of healthy foods (as often already exist for food hygiene) – including reviewing the requirements for franchises for canteens, shop vendors and vending machines.

- Encourage self-regulation of the suppliers of vending machines and canteen food, as has happened in the United States around vending machines in schools.1

- Provide incentives (e.g. franchises) to food companies that are reformulating/developing healthier products.

- Provide food that is culturally appropriate.

- Provide clear nutritional information on all canteen food – this will encourage consumers to consider their food choices more carefully.

- Consider subsidising healthy foods for patients, family members who bring food to hospitals, and employees, whose lifestyle choices may lead to their falling ill from preventable chronic diseases in the future. While there is a great diversity in the nutrition issues faced by hospitals in different parts of the world, it is also clear that the global availability of cheap HFSS foods is becoming endemic and will contribute to increasing obesity and consequent health problems. Where better to promote health than in places that exist to improve the health and wellbeing of the people who step through its doors? Change requires effort from all parties – government, hospital managers and health care professionals, service companies, multinational food and beverage companies, patients’ organisations and NGOs – to work together to create a healthy food environment in hospitals and in the wider community.

Conclusion

Hospitals are an important environment in which to encourage healthy eating – among patients and also among hospital employees, whose lifestyle choices may lead to their falling ill from preventable chronic diseases in the future. While there is a great diversity in the nutrition issues faced by hospitals in different parts of the world, it is also clear that the global availability of cheap HFSS foods is becoming endemic and will contribute to increasing obesity and consequent health problems. Where better to promote health than in places that exist to improve the health and wellbeing of the people who step through its doors? Change requires effort from all parties – government, hospital managers and health care professionals, service companies, multinational food and beverage companies, patients’ organisations and NGOs – to work together to create a healthy food environment in hospitals and in the wider community.

Authors

Christine Hancock is a director of the Oxford Health Alliance (OxHA), a UK-registered charity that enables collaboration between experts and activists from a wide range of disciplines – health professionals, urban planners, food manufacturers, academics, young people – to raise awareness and change behaviours, policies and perspectives of the epidemic of chronic disease at every level of society (www.oxha.org). From 2001 to 2005 she was president of the International Council of Nurses.

Katy Cooper is a project manager at OxHA, focusing on designing healthy environments. She is also working on the interactive website @FOUrJo – we encourage you to share online your experiences of hospital food environments (www.4ourjo.com).

Karen Siegel is an associate with MATRIX Public Health Solutions, Inc. and serves as the CIH Data Coordinator.

References


2 If these risk factors were eliminated, at least 80% of all heart disease, stroke and type 2 diabetes would be prevented; over 40% of cancer would be prevented. WHO, Preventing Chronic Diseases: A Vital Investment p. 18 (http://www.who.int/chp/chronic_disease_report/en/index.html).

3 See also Subrucke et al., Chronic Disease: An Economic Perspective (Oxford Health Alliance, 2008).

4 See, for example, The Economist, 11 August 2007: http://www.economist.co.uk/world/international/displaystory.cfm?story_id=9118917

5 Health Economics Research Centre, Oxford University: http://www.herc.ox.ac.uk/pubs/bibliography/Luce-no-Pernigo2005.


7 International Diabetes Federation: http://www.idf.org/home/index.cfm?node=8B9-69588-C352-F253-8787-F58B-C29A165A.

8 There are, of course, occasions when energy-dense foods are appropriate – for undemanding patients or for those on treatments such as chemotherapy.


11 For example, Jamie Oliver’s efforts in the UK: http://www.jamieoliver.com/schooldinners.

12 ‘The Alliance for a Healthier Generation (a partnership between the Clinton Foundation and the American Heart Association) has facilitated change in the US school food environment, by working to create guidelines for healthy school beverages and foods. These guidelines have been adopted by the American Beverage Association and PepsiCo, Coca-Cola and Cadbury Schweppes, the largest beverage suppliers in the US, as well as the Campbell Soup Company, Dannon, Kraft Foods and Mars. ‘To see UK NGOs as an example: The Soil Association, The King’s Fund, Slow Food (global), Health Care Without Harm (which has three chapters: US/Canada, Europe, and Global South).
ICT DEVELOPMENTS

067 REVIEWING THE INTEGRATION OF PATIENT DATA: HOW SYSTEMS ARE EVOLVING IN PRACTICE TO MEET PATIENT NEEDS
RICARDO J CRUZ-CORREIA, PEDRO M VIEIRA-MARQUES, ANA M FERREIRA, FILIPA C ALMEIDA, JEREMY C WYATT AND ALTAMIRO M COSTA-PEREIRA

077 SPONSORED FEATURE: CREATING A NEW HEALTH-CARE PARADIGM ONE PEN AT A TIME
ANOTO GROUP AB

079 DEVELOPING A CONCEPTUAL FRAMEWORK FOR E-HEALTH READINESS ASSESSMENT TOOLS FOR DEVELOPING COUNTRIES
SHARIQ KHOJA, RICHARD SCOTT, MOHSIN M, AFM ISHAQ AND CASEBEER AL
Anoto digital pen and paper technology provides the healthcare sector with a secure, efficient and cost-effective solution for capturing patient information in a user-friendly way.
REVIEWING THE INTEGRATION OF PATIENT DATA: HOW SYSTEMS ARE EVOLVING IN PRACTICE TO MEET PATIENT NEEDS

ARTICLE BY RICARDO J CRUZ-CORREIA, PEDRO M VIEIRA-MARQUES, ANA M FERREIRA, FILIPA C ALMEIDA, JEREMY C WYATT AND ALTAMIRO M COSTA-PEREIRA

Abstract

The integration of Information Systems (IS) is essential to support shared care and to provide consistent care to individuals – patient-centred care. This paper identifies, appraises and summarises studies examining different approaches to integrate patient data from heterogeneous IS.

Methods

Eligible studies

Only studies describing or evaluating IS implementation for integrating patient data from heterogeneous IS were selected.

Review team

The review team was composed of three Computer Scientists, namely Ana Margarida Ferreira, Pedro Vieira Marques, and Ricardo Cruz Correia, one medical doctor Filipa Canário Almeida advised by health informaticians experienced in systematic reviewing, Jeremy Crispin Wyatt and Altamiro Costa Pereira.

Search methods

Studies were searched between September and October 2005 in the bibliographic databases. Since there is no specific standardized MeSH term, we developed a search string that includes the concepts of patient record, computers and data integration or sharing. Only articles with an abstract in English were included. Given the significant evolution in ICT in the last decade, only studies published after 1994 (the last ten years) were included. Three distinct bibliographic databases

This review appraises studies examining the different approaches to integrating patient data from heterogeneous IS. Special attention is given to the type of integration engine and the type of integrated data. Articles published in the English literature between 1995 and 2005 with abstracts available were reviewed. We aimed to specifically review the integration of patient data, and how systems are evolving in practice to meet patient, professional and organizational needs.

A patient record is a set of documents containing clinical and administrative information regarding one particular patient, supporting communication and decision making in daily practice, and having different users and purposes. Clinical care increasingly requires health-care professionals to access patient record information that may be distributed across multiple sites, held in a variety of paper and electronic formats, and represented as mixtures of narrative, structured, coded and multimedia entries. In hospitals, information technologies tend to combine different modules or subsystems, resulting in a best-of-breed approach. Integration of health-care Information Systems (IS) is essential to support shared care in hospitals, to provide proper care to mobile individuals and to make regional health-care systems more efficient. However, to integrate clinical IS in a way that will improve communication and data use for health-care delivery, research and management, many different issues must be addressed. Consistently combining data from heterogeneous sources takes a great deal of effort because the individual feeder systems usually differ in several aspects, such as functionality, presentation, terminology, data representation and semantics. It is still a challenge to make electronic health records interoperable because good solutions to the preservation of clinical meaning across heterogeneous systems remain to be explored. Over the years different solutions to these problems have been proposed and some applied. Many of these solutions coexist in today’s healthcare settings and are influenced by technology innovation and changes in healthcare delivery. Some of these solutions use differing standards and data architectures that may prove to be the greatest obstacle to semantic interoperability.

ICT developments: Interoperability

International Hospital Federation Reference Book 2007/2008
were searched: Medline (via Pubmed), ISI (ISI Web of Knowledge) and IEEE (IEEE Xplore). The query search string used in each database was ((medical or clinical or patient) and record*) and (comput* or digital or electronic*) and (integrate* or link* or sharing or share or shared).

This search method found 2,443 articles in Pubmed, 961 in ISI and 414 in IEEE Xplore, a total of 3,818 articles. After eliminating duplicate articles 3,124 were selected.

Selection of studies for the review
All four reviewers from the review team were involved in study selection. Six combinations of reviewer pairs were defined, due to the large number of articles found. The first selection was based on the study title. Each pair of reviewers read 512 titles. The study was considered eligible when at least one of the reviewers considered that the title mentioned one of three key concepts:

- Patient Records (e.g.: patient record, EPR, EHR, EMR, clinical documents – CDA, administrative database).
- Integration (e.g.: IS integration, record linkage, information sharing).
- Distributed environment (e.g.: e-Health, distributed health care, shared health care).

A total of 923 of 3,124 articles were selected in this first selection on title alone.

The second phase of the study selection was based on abstracts. Again, six combinations of reviewer pairs were defined. Each pair of reviewers read 154 abstracts. The inclusion criterion in this phase was that articles should fulfill all three of the following conditions:

- describe or assess IS implementations;
- integrate patient data from various IS;
- describe the technology used to integrate.

To maximize specificity, only selection by both reviewers was considered adequate. In cases of disagreement a third reviewer was called to decide. A total of 84 out of 923 articles were selected to be read entirely. These 84 articles were grouped into 69 distinct integration projects to avoid the distortion created by multiple papers describing the same project. All statistical analysis is based on projects and not on articles. Some of articles (n = 13) were descriptions of project plans or architecture models that were not already implemented on a real scenario nor even as a prototype. These projects were also excluded, leaving only 56 projects. Figure 1 is a flowchart illustrating the different stages of paper selection.
variables

Figure 2 illustrates the stages of a generic integration of heterogeneous IS. The variables examined in this review are related to these stages and intend to describe the content where the integration takes place (country, date, area covered, institutions involved, type of final users), the type of data integrated and the technology used (standards, communication methods, integration model, repositories of data, client applications).

The variables are:

- country where the system is implemented;
- date of article publication;
- area covered by each project (country, region, hospital, department);
- institutions involved as sources for patient data integration, i.e., institutions that own feeder systems to integration (departments, hospitals, primary care, private clinics, private labs, patient health portals) – multiple values are accepted;
- what type of medical data is integrated (lab orders, lab results, prescription orders, diagnosis or problems, procedures, admission letters, discharge letter, transfers letters, referral letters, medical images, biosignals) – multiple values are accepted;
- medical informatics standards used (e.g.: HL7 – Health Level 7, CDA – Clinical Document Architecture, GEHR – Good European Health Record, SCIPHOX – Standardized Communication of Information Systems in Physician Offices and Hospitals using XML, DICOM - Digital Imaging and Communications in Medicine, MML – Medical Markup Language) – multiple values are accepted;
- communication method (DICOM, DDE – Dynamic Data Exchange, e-mail, computer agents, Web services, Direct

Table 1: Frequencies (and percentages) for each variable analysed among the 56 data integration projects reviewed

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<td>P 7, 9, 12, 14, 15, 21, 25, 29, 29, 30, 31, 33, 37, 39, 40, 49, 53, 54</td>
</tr>
<tr>
<td>Primary care</td>
<td>18 (33)</td>
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<td>5 (26)</td>
<td>11 (61)</td>
<td>.029</td>
<td>P 8, 12, 15, 16, 17, 22, 27, 29, 31, 34, 35, 38, 40, 41, 44, 48</td>
</tr>
<tr>
<td>Health portal</td>
<td>4 (8)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>4 (17)</td>
<td>.054</td>
<td>P 13, 20, 34, 49</td>
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<td>Private labs</td>
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<td>0 (0)</td>
<td>1 (4)</td>
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<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
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<td>User groups</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health professionals</td>
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<td>5 (100)</td>
<td>18 (100)</td>
<td>19 (100)</td>
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<td>P 4, 8, 9, 10, 13, 14, 15, 17, 18, 20, 22, 25, 27, 34, 35, 36, 37, 39, 40, 41, 42, 43, 44, 46, 47, 48, 49, 50, 51, 53, 54, 55, 56</td>
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<tr>
<td>Medical users</td>
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<td>1 (20)</td>
<td>8 (44)</td>
<td>1 (11)</td>
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<td>P 9, 16, 17, 18, 20, 29, 31, 34, 35, 36, 37, 38, 40, 41, 43, 44, 48, 49, 54, 55, 56</td>
</tr>
<tr>
<td>Nurses</td>
<td>4 (10)</td>
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<td>2 (11)</td>
<td>1 (5)</td>
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<td>P 38, 42, 55, 56</td>
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<tr>
<td>Other health prof.</td>
<td>5 (12)</td>
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<td>4 (22)</td>
<td>1 (5)</td>
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<td>P 10, 18, 31, 42, 44</td>
</tr>
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<td>Patients</td>
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<td>10 (58)</td>
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</table>

Table 1: Frequencies (and percentages) for each variable analysed among the 56 data integration projects reviewed
### Table 1: Frequencies (and percentages) for each variable analysed among the 56 data integration projects reviewed

<table>
<thead>
<tr>
<th>Type of model</th>
<th>n</th>
<th>Type of data integrated</th>
<th>n</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Semantic – all</td>
<td>21(44)</td>
<td>Diagnostic and problems</td>
<td>40(77)</td>
<td>68.6%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Images</td>
<td>35(67)</td>
<td>67%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lab results</td>
<td>34(65)</td>
<td>65%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discharge</td>
<td>33(62)</td>
<td>61%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Procedures</td>
<td>31(60)</td>
<td>58%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Admission</td>
<td>25(48)</td>
<td>48%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Transfers</td>
<td>16(31)</td>
<td>29%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Referrals</td>
<td>10(19)</td>
<td>19%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lab orders</td>
<td>9(17)</td>
<td>17%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bio-signal</td>
<td>9(17)</td>
<td>17%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Missing</td>
<td>4(7)</td>
<td>7%</td>
</tr>
<tr>
<td>Medical informatics standards</td>
<td></td>
<td>67%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Type of data integrated**

- **Diagnostic and problems:**
  - 40 (77) patients
  - 13 (26) patients
  - 21 (75) patients

- **Images:**
  - 35 (67)
  - 4 (7)
  - 14 (25)
  - 17 (31)

- **Lab results:**
  - 34 (65)
  - 6 (11)
  - 11 (20)
  - 17 (31)

- **Discharge:**
  - 33 (62)
  - 2 (3)
  - 12 (21)
  - 19 (34)

- **Procedures:**
  - 31 (60)
  - 4 (7)
  - 9 (16)
  - 18 (34)

- **Prescription:**
  - 25 (48)
  - 4 (7)
  - 8 (15)
  - 16 (30)

- **Admission:**
  - 25 (48)
  - 8 (15)
  - 16 (30)
  - 18 (34)

- **Transfers:**
  - 16 (31)
  - 2 (3)
  - 6 (11)
  - 8 (15)

- **Referrals:**
  - 10 (19)
  - 0 (0)
  - 3 (5)
  - 7 (13)

- **Lab orders:**
  - 9 (17)
  - 0 (0)
  - 3 (5)
  - 6 (11)

- **Bio-signal:**
  - 9 (17)
  - 1 (2)
  - 6 (11)
  - 2 (4)

- **Missing:**
  - 7 (13)
  - 0 (0)
  - 3 (5)
  - 2 (4)

**Medical informatics standards**

- **HL7 (includes CDA):** 23 (48)
- **ICD-10:** 11 (22)
- **Other:** 8 (16)
- **GEHR:** 3 (9)
- **HL7:** 1 (2)
- **Missing:** 24 (48)
database access, CGI – Common Gateway Interface, CORBA – Common Object Request Broker Architecture, DHE – Distributed Healthcare Environment) – multiple values are accepted;

**type of integration model for semantic interoperability** (direct communication ie. when the systems create different interfaces to connect to each other; middleware ie. when an application programming interface is made available to talk with the central repository; semantic ie. when all possible data has a predefined message template, both semantic and syntax is known; generic ie. when the document structure accepts a certain degree of evolution without re-defining the whole template) – adapted from Bernstein et al.8 – only one type of model is accepted;

**type of data repository** (File System, Database, PACS – Picture Archiving and Communication System, LIAP – Lightweight Directory Access Protocol, Virtual repository system) – multiple values are accepted;

**how data are made available to users** (client application or web browser) – multiple values are accepted;

**how data are made available to other IS** (Web services, CORBA or others) – multiple values are accepted;

**user groups** (health professionals – medical users, nurses and other ICT developments: Interoperability Repository database direct access 9 (20) 4 (80) 1 (13) 4 (24) .083 P 2, 23, 26, 28, 32, 39, 41, 46, 54
Web services 8 (27) 0 (0) 1 (13) 7 (41) .042 P 5, 6, 16, 20, 33, 38, 49, 52
CDRBA 4 (13) 0 (0) 2 (25) 2 (12) * P 14, 27, 33, 47
E-Mail 3 (10) 0 (0) 1 (13) 2 (12) * P 15, 20, 34
DISCM 3 (10) 0 (0) 1 (13) 2 (12) * P 25, 31, 43
DDE 3 (10) 0 (0) 2 (25) 1 (6) * P 7, 14, 34
DHE 3 (10) 0 (0) 2 (25) 1 (6) * P 19, 47, 48
CGI 3 (10) 2 (40) 0 (0) 1 (6) .082 P 32, 39, 55
Agents 2 (7) 1 (20) 0 (0) 1 (6) * P 11, 26
Missing 28 (50) 2 (100) 12 (60) 14 (48) .063 P 2, 3, 5, 6, 9, 10, 13, 15, 16, 17, 18, 19, 20, 23, 25, 26, 27, 28, 30, 31, 32, 35, 36, 39, 41, 42, 43, 44, 49, 47, 48, 49, 55, 56

**how data is made available to users**

**how data is made available to other Information Systems**

†: single variable with mutually exclusive response categories
‡: multiple variables with dichotomous response categories (yes or no)
*: not statistically significant
§: linear-by-linear association chi-square test used (except in variable type of model)
?: models used for semantic interoperability: direct communication when the systems create different interfaces to connect; middleware when an API is used to talk with the central repository; semantic when all data has a predefined message template; generic when the document structure accepts evolution without re-defining the whole template. P value calculated using Pearson association chi-square test.
### Table 2: Integrated IS included in the review, Country in which installed, number and date of publications

<table>
<thead>
<tr>
<th>Project number</th>
<th>System name (or location)</th>
<th>Country</th>
<th>Number of publications</th>
<th>Publication date</th>
<th>References</th>
</tr>
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<tbody>
<tr>
<td>P1</td>
<td>Aarhus County</td>
<td>Denmark</td>
<td>1</td>
<td>2005</td>
<td>[8]</td>
</tr>
<tr>
<td>P2</td>
<td>Allina</td>
<td>USA</td>
<td>1</td>
<td>2004</td>
<td>[13]</td>
</tr>
<tr>
<td>P3</td>
<td>Argonautia</td>
<td>Germany</td>
<td>1</td>
<td>1999</td>
<td>[14]</td>
</tr>
<tr>
<td>P4</td>
<td>CareHaven</td>
<td>China</td>
<td>1</td>
<td>2001</td>
<td>[15]</td>
</tr>
<tr>
<td>P5</td>
<td>CareWeb</td>
<td>USA</td>
<td>2</td>
<td>[1998, 2000]</td>
<td>[16, 17]</td>
</tr>
<tr>
<td>P6</td>
<td>Chih</td>
<td>Germany</td>
<td>1</td>
<td>2004</td>
<td>[18]</td>
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<tr>
<td>P7</td>
<td>Cleveland – USA</td>
<td>USA</td>
<td>1</td>
<td>2000</td>
<td>[19]</td>
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<tr>
<td>P8</td>
<td>Clicks</td>
<td>Israel</td>
<td>1</td>
<td>2003</td>
<td>[20]</td>
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<tr>
<td>P9</td>
<td>Clinical Desktop (former Spectrum)</td>
<td>USA</td>
<td>1</td>
<td>2002</td>
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<tr>
<td>P10</td>
<td>Clinical Management System</td>
<td>China</td>
<td>1</td>
<td>2005</td>
<td>[22]</td>
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<tr>
<td>P11</td>
<td>Daegu – Korea</td>
<td>Korea</td>
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<td>P12</td>
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<td>Switzerland</td>
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<td>[1998, 2005]</td>
<td>[24-28]</td>
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<td>Greece</td>
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<td>[31–34]</td>
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<td>P42</td>
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<td>[1997, 2001]</td>
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<td>[87, 88]</td>
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<td>P53</td>
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<td>Spain</td>
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<td>2002</td>
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<td>P54</td>
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<td>2001</td>
<td>[91]</td>
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<td>P55</td>
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<td>Web-EBP</td>
<td>Brazil</td>
<td>1</td>
<td>2001</td>
<td>[93]</td>
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</table>
clinicians, clerical staff and patients) – multiple values are accepted.

**Time intervals considered**

To analyse time trends, we divided the total period up into three shorter periods because of the small overall number of projects identified. The first period includes projects with their last publication in 1994–1999, the second period with their last publication in 2000–2002 and the third period with their last publication in 2003–2005.

**Statistical analysis**

The statistical analysis was performed with SPSS® version 14. P values in Table 1 were calculated using Pearson and linear-by-linear association chi-square tests with significance level of 0.05.

**Results**

**Study selection**

The agreement rate for the first phase was 83%, and for the second phase was 77%. The number of different IS implemented was 56. Table 2 lists all integrated IS considered in this review, their country, number of publications and period of publication. Countries with the most published projects were the USA (15), Germany (8), Greece (6), Denmark (4) and China (4). Most IS (71%) have just one publication. 52% of the IS had their last publication in the period 2003–05, and 36% during 2000–2.

**Trends**

**Area covered by integration**

59% of the IS covered only a region, while 29% covered a hospital, 9% a department and 4% a whole country. There was a downward trend in publications related to projects that cover a hospital from 57% until 1999, 35% in 2000-02 and 17% in 2003-05. The number of projects covering a region or country has increased over the years, and currently represents 76% (p = 0.037).

**Institutions involved in the integration**

Most of the integrated information comes from hospital IS (69%), with departmental (40%) and primary care (18%) IS representing the next two most frequent institution types. Four projects (8%) integrated information from health portals, all were published in the most recent period considered (2003–05).

**User groups**

As expected, all information systems provided access to health professionals. Two recent projects claim giving data access to patients3,9. Medical doctors are more often referenced as users (48%) than nurses (10%).

**Integrated data**

77% of the projects integrated diagnosis and problems, 67% medical images, 69% lab results, 63% discharge notes and 60% procedures. There has been an increase in projects integrating referral letters (from 0% until 1999, to 18% in 2000-02 and to 25% in 2003-05).

**Type of models**

Regarding the type of integration model, although the number of projects found using a predefined message templates (semantic – all data structured) and middleware are very similar (44% and 40% respectively), it seems that there is a trend to use more predefined message templates (40% in 2003-05) and fewer middleware solutions (31% in 2003-05). This tendency is clearer, if the values of the projects using messaging (both “Semantic – all data structured” and “Generic – structure and data dynamic”) are added, representing 54% in 2003-05. Direct communication to databases is very low (10%) and more flexible messaging is now appearing (12% in 2003-05).

**Messaging standards**

HL7 is the most frequently used messaging standard (68%). It seems that CDI is becoming the reference to use inside HL7 (22% in 2003–05). DICOM is becoming less used when compared to other standards, which is understandable as it is mainly for images. Nevertheless, DICOM is no more the only success example of standards use in medical communication protocols. Other standards have very low usage nowadays (19% in 2003-05).

**Communication method**

Recently (since 2000) more different technologies have been used to establish communication (3 until 1999, 8 in 2000-02 and again 8 in 2003-05). Web services have increasing importance (p = 0.042), whilst Database direct access and Common Gateway Interface have decreasing importance.

**How data are made available for users**

92% of the Information Systems use a Web browser to deploy their applications, whilst only 19% give user access through client-server applications.

How data are made available for other IS 88% of the IS use Web services to communicate with other systems, whilst only 13% use CORBA. The absolute number of systems using Web Services has grown from zero until 1999, two in 2000–2 and 5 in 2001–05.

**Current status (results regarding 2003–05)**

Currently there are more projects carrying out regional integration, especially between hospitals and primary care. Referral letters are mentioned in 7 of the 29 projects described in articles published in 2003–05. It is also clear that patients are also becoming active participants because they appear for the first time as a user group in more recent projects.

Regarding integration models, messaging between systems, both Semantic and Generic, is lately used more frequently (58%) than middleware (31%). Databases are still the most common method for data storage (36%). Communication between integrated systems uses many different technologies with Web services being used in 41% of the projects. The most common user interface by far is the Web browser (90%).

**Discussion**

Our results show an increasing number of publications describing projects which integrate data from multiple Information Systems. This is in agreement with our initial assumption about the interest in improving the communication of health related data to support person-centred health care. As the number of heterogeneous health IS grows, their integration becomes a priority. Moreover, we may be witnessing an increasing interest in regional integration between heterogeneous health-care information systems across different institutions, to
help communication between the different stake holders (primary and secondary care doctors, nurses and patients). This is also supported by the increasing communication of referral letters.

It should be noticed the efforts being put into integration in countries like Germany, Greece and Denmark which are trying to implement nationwide healthcare integrated networks feed by heterogeneous information systems.

Messaging technologies (in particular HL7) are more used than middleware solutions (like ICOM or CORBA). Web based technologies (web-services and web-browsers) support most of the projects, indicating that these new technologies are quickly adopted in healthcare institutions. Nevertheless, it is obvious that many distinct technological solutions coexist to integrate patient data.

The concept of message passing appears to be radically different from the conventional concept of procedure calls or operation invocation, but the difference is more one of pedagogical emphasis than of semantics. Message passing emphasizes the remoteness of the object and the caller’s lack of knowledge of the code body which will be executed. However, any procedure call can be viewed as an exchange of messages. The main difference is both approaches is the reliance on open Internet standards like HTTP, XML, SOAP, WSFL, UDDI and WSFL by the Web services (messaging), in contrast with to DCOM and CORBA solutions (middleware) that resulted many times in single-vendor implementation requirements.

One key omission from the literature reviewed is that most of the project publications failed to mention any type of error detection. We feel that is mandatory to verify the quality of integrated data, so that instead of propagating data errors, alerts regarding data quality can be triggered and correction processes can take place.

**Limitations**

One of the main limitations of this review is lack of detail reported in most of the articles, and especially the non existence of any impact evaluation of the technologies they describe, despite the enormous cost of such systems and the evident change in working practices that they entail. The percentage of missing values for each time interval varied between 0 and nearly 50% depending on the type of variable analysed and interval of time considered.

Another limitation is only considering papers published in the last ten years may exclude early work on integration at the hospitals, although we feel it is justifiable given the significant evolution in ICT in the last decade.

Although we feel that grouping the papers into projects is essential to decrease the bias of multiple publications of the same project, on some of the papers it was difficult to determine if they were describing the same project or not.

**Conclusion**

Currently people have more mobility, longer lives and health care is more shared than ever before. It is clear that Information Systems are evolving to meet people’s needs by implementing regional networks, allowing patient access and integration of ever more items of patient data. We conclude that patient information is becoming more accessible as there are more integrated IS which are more likely to involve primary care and a wider range of patient data.

Web based technologies and messaging technologies are supporting most of the current integration projects, indicating that these new technologies are quickly adopted in health-care institutions. Many distinct technological solutions coexist to integrate patient data, using differing standards and data architectures which may difficult further interoperability.

**Acknowledgements**

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**References**

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Kinnunen PM, Dufey RB. The use of digital imaging and communications in medicine (DICOM) in the integration of imaging into the electronic patient record at the Department of Veterans Affairs. J Digit Imaging 2000, 13(2 Suppl 1):133-137.


Health-care organizations struggle every day with volumes of time-consuming handwritten forms that must be processed, in order to get the information gathered together in one place quickly and securely. This is a particularly important task when patients’ lives are at risk. Anoto AB, the inventor of the first commercial Digital Pen and Paper technology, has made huge strides for the health-care industry in providing a unique electronic data capture technique.

Anoto’s cutting edge applications are allowing doctors, nurses as well as homecare providers to capture and transform handwritten data, notes and drawings into digital formats. There are numerous examples of how this can allow health-care organizations to work more efficiently. This article will present some of them.

Quality of homecare is improved

The Digital Pen has been employed in Stockholm, Sweden, to digitally register the arrival and departure of homecare providers, so as to ensure that the elderly patients are visited every day. Furthermore, as a part of an academic research thesis in Linköping, Sweden, the Digital Pen has been used by palliative patients that have chosen to spend the last part of their life at home to keep in constant contact with their doctors and to manage their levels of pain.

"Apart from an improved accuracy in pain treatment, patients took a greater part in their own care and had a sense of increased security. I believe that the pain assessment method by use of digital pen technology helped them to create better value of their last period of life", says Dr. Leili Lind, author of the PhD thesis.

Benefits for the emergency care

Bethesda Emergency Associates in Maryland, USA, provides emergency medical services to a community of almost one million people, including children and adults suffering from trauma, stroke and heart attack. The physicians face the challenge of diagnosing and treating a myriad of emergencies on the spot, while simultaneously keeping track of charts and getting patient documentation entered into the hospital computer system. In such a fast-paced environment, it is critical for all documentation to be verified as accurate and complete. The doctors desired a solution that could manage all this as well as reduce the computer time and increase the time devoted to patients. Since they are working at a non-profit community-owned hospital, price and functionality were also key factors. At first, tablet PCs were considered but then deemed to be too heavy to carry around all day, too cumbersome to use (with many drop-down screens) and very expensive to implement and maintain.

Instead, the physicians decided to choose the easy-to-use and cost-effective Anoto Digital Pen and Paper solution. And now, they can use the solution to record
patient information on charts created on paper printed with the Anoto dot pattern and then transfer the information electronically into the hospital’s medical records system in seconds. This way, doctors complete their charts as usual during the patient examination including diagnosis, care and medical history and with no obvious intrusion from a tablet PC or computer.

“I’ve seen technological advances come and go throughout my career. None have been as easy to use or have actually improved my efficiency like this”, says Robert R Rothstein, MD, Medical Director of Bethesda Emergency Associates.

American nursing homes content with the Digital Pen
A growing concern in the health care of today is the rapidly increasing number of elderly people in society. Due to brilliant innovations in the last 50 years, people are enjoying longer lives. The rising number of people in need of care, has resulted in a demand for creative ways of reducing the long-term care costs. The aim is to find solutions that allow the elderly to stay in their own homes or nursing homes for as long as possible, while improving the quality of care. In the long run, improving the management of handwritten patient records, often initiated outside the hospital, will become vital. This new paradigm positions Digital Pen and Paper as a perfect solution, due to its low costs of implementation and its exceptional ease of use (requiring no special training), as well as its utter efficacy.

Nursing homes in the USA are finding the Digital Pen and Paper solution very valuable in keeping track of patients and their charts. The Anoto Technology has so far been deployed in more than 14 American nursing facilities with many more on the way. Digital Pen Systems, an Anoto partner, develops applications for many of these. Its project “On-Time Quality Improvement for Long-Term Care Initiative” facilitates daily resident documentation with the help of Digital Pen and Paper. Clinicians can document all of their resident care on customized flow sheets to prevent, track and manage pressure ulcers (bed sores) at the nursing, unit and facility level.

At the nursing home Country Villa Health Services in California, they are delighted with the Digital Pen and Paper solution, since it allows the use of existing work such as standardized documentation and proven clinical reports in accelerating quality improvement.

“We were able to redesign CNA (Certified Nursing Assistant) documentation and implement the Digital Pen solution all in less than three months, providing access to clinical reports immediately”, says the director Alan Gibson.

According to Gibson, this is also the first time frontline staff has been engaged so closely in a quality improvement effort. And as a bonus, staff motivation has been greatly increased, creating a more vibrant working atmosphere for everyone.

Technology also useful in new drug approval

The prospect of long-term care would not exist without the exciting work being done today by pharmaceutical companies. The road to approving a new drug is certainly a lengthy process. Clinical trials for a new drug, require extensive, detailed research studies where its safety and efficacy is put to the test. Actelion Pharmaceuticals, headquartered in Switzerland, conducts clinical trials on a global level, using Anoto Digital Pen and Paper. The company is currently recording data for 12 trials throughout Western Europe, the USA, Australia and Israel.

Over the past 25 years, the average cost of developing a new drug has soared from $138 to $802 million. For pharmaceutical companies like Actelion, every successful step to improve efficiency and quality, directly contributes to sustained competitiveness that can be measured in realized revenue.

Clinical trial investigators at the company use the data collected with the Digital Pen on a daily basis to adjust drug dosage and to document results. In addition to providing faster and more secure data capture, the application also ensures traceability of collected data and gives trial investigators more personal time with the patients in testing.

“Most doctors don’t like typing on a keyboard while examining a patient. They would have to look at a screen instead of into the eyes of a patient… Doctors like this solution because it feels like using a normal pen”, says Massimo Rainerti, at Actelion Pharmaceuticals.

The solution was very well received by trial study doctors for its ease of use, and it also helped Actelion to attain successful clinical trials faster and to monitor them more closely. The result was a significant time reduction, representing millions of euros for the company. The Digital Pen and Paper solution has thus provided Actelion with a significant competitive edge.

As can be seen from this article, there are many different areas of usage for Digital Pen and Paper technology. The presence of the technology in health care is growing and has been duly noted. As the health-care sector is quickly evolving, prosperous health-care organizations, whether hospitals, nursing homes, long-term care facilities or medical centres, must streamline operations if they wish to stay competitive. Anoto, with its Digital Pen and Paper technology, is dedicated to support such organizations in improving the quality of their medical records and their workflow processes. The results are substantial and provide measurable productivity advantages. For more detailed cases, please visit www.anoto.com.

About Anoto Technology

The pen contains an integrated digital camera, an advanced image microprocessor and a mobile communications device that tracks and records every stroke made on the paper. The pen works with paper that has been printed with Anoto’s hardly visible matrix of intelligent dots. This pattern plots the exact path of the Digital Pen. Data stored in the pen can be transferred to any computer via a USB port, and the data can be used locally on a single computer or routed to a back-end system in a hospital. Every upload records the exact time the document was written, who wrote it, and the identity of the paper form used.

The Anoto Digital Pen offers advantages over a traditional EMR (Electronical Medical Record) in that it does not require any clicking through multiple screens or typing and it eliminates lost or down-coded charts. In addition, the software automatically verifies all of the data for completeness and billing purposes, including a physician’s signature, and prompts key questions whenever there is a concern.
DEVELOPING A CONCEPTUAL-FRAMEWORK FOR E-HEALTH READINESS ASSESSMENT TOOLS FOR DEVELOPING COUNTRIES

ARTICLE BY SHARIQ KHOJA, RICHARD SCOTT, MOHSIN M, AFM ISHAQ AND CASEBEER AL

Abstract

e-Health is being used to address the long-standing issues of lack of access to and quality of health care among different populations. To increase the chances of success, it is important to assess the readiness of health-care institutions before implementing e-health programmes. This paper describes the process of creating a conceptual framework that can be used for developing e-health readiness assessment tools for health-care institutions in developing countries. Three sources of information were used to create the conceptual framework, namely: literature search, review of existing tools, and expert opinion. Several determinants of access to e-health in developing countries were identified and included in the conceptual framework to develop e-health readiness assessment tools for health-care institutions. The tools developed based on this framework can also be used as part of the planning process of any e-health programme in the health-care institutions of developing countries.

Developments in Information and Communication Technology (ICT) in the latter half of 20th century have accelerated socio-economic activity across the world. The use of ICT in health care is also referred to as “e-health”, which has been defined by World Health Organization (WHO) as “the cost-effective and secure use of ICT in support of health and health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge and research”.

Use of e-health in developing countries carries a number of risks, along with the anticipated benefits. The biggest risk of using technology is the unintended widening of the gap in health status and knowledge between different sectors of the population, thereby increasing rather than addressing health inequity. One method to avoid this divide is for governments and healthcare institutions in developing countries to assess and prepare themselves for change before adopting programmes that require use of ICT. This process of preparation for e-health related change is also referred to as “e-health readiness”. E-Health readiness is measured by assessing the relative status of governments, health-care institutions, or users in those areas most critical for adoption and success of programmes using ICT. Tools have been created to assess e-readiness in areas other than health care, for both developed and developing countries. However tools available for the health-care environment focus mainly on issues of relevance to developed countries. Some of these tools are already being piloted in parts of Canada. Realizing the huge differences in access to ICT between developed and developing countries, it is necessary to understand the factors determining access to e-health in the health-care institutions of developing countries, and build a conceptual framework considering these determinants that can be used in developing “e-health readiness assessment tools” for developing countries.

This article presents the process of creating a conceptual framework for e-health readiness using multiple sources of information. This conceptual framework was later used to develop e-health readiness assessment tools for public and private health-care institutions in developing countries. These tools were also validated in health-care institutions of Pakistan.

Materials & methods

For the development of conceptual framework for e-health readiness in developing countries, this study utilized three sources of information, namely: 1) literature review; 2) existing scales; and 3) expert opinion. The main purpose of using multiple methods was to identify all possible determinants of access to e-health in health-care institutions, and understand their relevance to the health-care institutions in developing countries. Following is the process of using each of the sources:

1. Literature review: The literature search was designed to: (1) review the concept of “readiness” and its relationship to the process of change; (2) understand the relationship of readiness with ICT implementation in health-care and other areas; and (3) locate and review current tools that assess e-readiness in different fields and in healthcare. Using Ovid and PubMed bibliographic search engines, a formal literature search of the “Medline” database was performed for English language peer-reviewed journal articles published between 1990 and 2005. Abstracts were reviewed for relevance, and full-texts of relevant articles were obtained. Since limited formal literature was available on e-health readiness assessment in health-care institutions, a Google search was performed to identify reports from any current and recently completed projects in e-health readiness.
ICT developments: e-Health in developing countries

2. Existing scales: Existing e-readiness assessment tools, applied within and outside of health sector, were identified. Three existing scales were reviewed that either measured e-readiness in developing countries (CID’s readiness for the networked world), 7 or measured e-health readiness in healthcare institutions (Jennett P and North Network).3,4

3. Expert opinion: A group of faculty members from the University of Calgary and partners from the institutions in Pakistan, who had experience in the field of e-health, were involved in the study as experts. Three partner institutions were identified from different sectors in Pakistan. Each of these institutions led e-health implementation in terms of projects in e-health, and had established links with government and other public and private healthcare institutions.

In order to develop the conceptual framework for e-health readiness relevant to health-care institutions in developing countries, an advisory committee was formed. This committee comprised of faculty members from the University of Calgary, AB, Canada, and three institutions in Pakistan. The committee supervised the process of developing the framework and provided feedback in relevance of identified issues with the conditions in developing countries. Their collaborative work was facilitated through ongoing e-mail discussions, teleconferencing (at least once a month), and web-based on-line presentations and discussions (every second month), throughout the course of the project. Face-to-face meetings were also conducted with the members during the fieldwork in Pakistan. Ethics approval for the study was obtained from the “Conjoint Health Research Ethics Board” at the University of Calgary.

Results
Information gathered from different sources suggested that apart from the availability of ICT, there are several other issues that determine access to e-health. These are either specific to, or have a higher impact in, developing countries. The literature search identified many articles and reports that list different barriers to ICT use. For example, according to a report from Children’s Partnership, significant barriers to the use of ICT include: lack of urgently needed local information, literacy barriers, language barriers, and cultural-diversity barriers. These and other “determinants of accessibility”7 can be grouped under the following headings:

a) Appropriateness of technology: The technology must not only appropriately address the pre-assessed needs of the organization or community, but also the local conditions. The behaviours and aspirations of people must be identified and the local social dynamics and interests considered while developing programs using ICT.8,9

b) Affordability: It is important to know if the suggested technology is affordable for the government, health-care institutions, or community. This includes the affordability of equipment, installation, training, maintenance and ongoing support. Another important aspect is the affordability of personal computers and Internet for the general population, which is much higher in many developing countries compared to costs in the United States or Canada.

c) Capacity: Health-care providers and other users, including the general population, require appropriate skills to use the technology and Internet. Appropriate capacity must be available locally to ensure ongoing support and further training. Inequity in access becomes more evident as the amount and variety of health resources available over the Internet increase, and people need more sophisticated skills.10

d) Relevant content: The information available should be relevant to local needs and must be in a language easily understood by the target audience. This problem is more common with Internet sites, which are mostly in English.11

e) Integration: The literature suggests that people are less likely to use technology if it does not become part of their lives.12 It is therefore important for both health-care providers and users to know how the introduction of technology will impact their current job.

f) Socio-cultural factors: It is useful to understand any limitations to the use of technology due to sex, race, or other socio-cultural factors. One example of the influence of socio-cultural factors is that women and children (especially girls) are the most vulnerable groups in terms of health, but have least access to ICT.13

g) Trust: It is important for the planners as well as users to have full confidence in the proposed technology, and they should also understand the implications of its use.14 While technology can be a significant driver of community development, it can also become a barrier due to mistrust and fear among people. It is therefore important to use simple and well-tested technology in such programmes, so that people can focus on its utility rather than its operation.15

h) Legal and regulatory frameworks: It is crucial to understand how laws and regulations affect the use of technology and what regulations are required to foster ICT use.16

i) Political will: It is necessary that politicians and key policy-makers should understand the importance of using e-health and be ready to enable its integration with existing health-care systems.17

Some other important factors of readiness were identified during the review of existing scales and discussions with experts in the advisory committee. These factors include:

a) needs-assessment;

b) dissatisfaction with status quo;

c) key issues in planning of e-health initiative, such as buy-in from senior management, identification of champions, involvement of all stakeholders, and development of implementation and evaluation plans.

Applying the conceptual framework in developing e-Health readiness assessment tools

Based on the conceptual framework developed in this study, separate tools were developed for health-care providers and managers, working in the health-care institutions in developing countries. Each tool contained four major categories of items to determine if an institution was prepared to implement e-health interventions. Each category addressed some of the identified determinants of access to e-health, and measured these determinants by a combination of 3-4 items. The categories for the tool for health-care providers included: 1) Core-readiness; 2) Learning readiness; 3) Societal readiness; and 4) Policy readiness.
This tool contained a total of 21 sections and 50 items. In the tool for managers, the category of “learning readiness” was replaced by “technological readiness.” This tool contained a total of 23 sections and 54 items. Each item can be rated using a five-point Likert-type scale, and thus identifies areas of improvement for the planners. The total e-health readiness score can also be calculated by adding the scores for the entire tool. The total score would act as an internal yardstick to determine the placement of an institution at different stages between prepared and not prepared. Complete tools have been reported as a separate paper.14

Discussion

The conceptual framework addresses key determinants of accessibility to e-health for health-care institutions in developing countries, along with some other important planning issues, such as needs assessment, implementation, and evaluation. Consideration of these issues in the development of any e-health readiness assessment tools would enable the planners to develop a comprehensive plan for a particular e-health intervention that will allow greater access to staff of different sexes and levels of service, and clients of different sexes and socioeconomic strata. This in turn would help address the issue of digital divide, which is so prominent in the context of developing countries. Addressing these issues at the individual level ensures that the preparedness of health-care organizations, both within Pakistan and in other developing countries, will allow greater access to staff of different sexes and socio-economic strata. This in turn would help address the issue of digital divide, which is so prominent in the context of developing countries.9

The tools developed through this conceptual framework (reported in a separate paper),14 contain items that appropriately assess the preparedness for each of the determinants, at both the individual and the organizational levels. Addressing these issues at the individual level ensures that the preparedness of individual planners, implementers, and users is assessed appropriately. Addressing the determinants at the organizational level means that the institution has appropriate infrastructure, teams, and policies in place to deal with each of the issues at an appropriate time. Both individual and organizational readiness are essential and mutually dependent.

Since the conceptual framework developed in this study is based on the determinants of access to e-health in the context of developing countries, this should be applicable to most geographical areas and institutions in these countries. Focusing on “access to e-health” and studying its determinants in the context of developing countries would facilitate the development of tools that are comprehensive and complete. Also, the use of multiple sources of information for developing this conceptual framework brought different perspectives and diversity of ideas into discussion, and increased the richness of this framework. Study of some previously developed tools provided an opportunity to build on existing knowledge, whereas the inclusion of international e-health experts and partners from Pakistan in the advisory committee helped in making the framework more appropriate to the socio-cultural situations in Pakistan and similar developing countries. This claim was endorsed by most of the participants during the in-depth interviews conducted during validity and reliability testing of the tools developed as a result of this study (reported in separate papers).14,15 This study provides significant evidence that this conceptual framework is valuable in the development of practical e-health readiness assessment tools that can be used successfully to assess e-health readiness of health-care organizations, both within Pakistan and in other developing countries.18

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References

CLINICAL CARE FOCUS

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CLEAN CARE IS SAFER CARE: THE FIRST GLOBAL PATIENT SAFETY CHALLENGE – A CALL TO ACTION TO ALL HEALTH CARE FACILITIES AND HOSPITALS OF THE WORLD

ARTICLE BY JULIE STORR, GERALD DZIEKAN, AGNES LEOTSAKOS, DIDIER PITTET AND BENEDETTA ALLEGRANZI

Abstract

In the 2006/2007 edition of the IHF Reference Book, Sir Liam Donaldson, chair of the who world alliance for patient safety provided an overview of the first global patient safety challenge, clean care is safer care. In the article Sir Liam outlined a vision that during the life of the global challenge, improvements for cleaner and safer care would be initiated for over half the world’s population. This paper describes the progress made since the launch of the first global challenge in 2005, and illustrates the need for continued close working with health-care facilities through the who regional and country offices to ensure that the momentum generated results in patient safety improvement at the patient level.

The World Alliance for Patient Safety is a relatively new WHO programme, launched in 2004 as a direct result of World Health Assembly resolution WHA55.18. The resolution urged Member States to pay the greatest possible attention to patient safety. The various programmes of the Alliance are concerned with promoting awareness of and building political commitment for patient safety in health care. Within the ten programmes of the Alliance are contained a number of specific technical projects designed to improve patient safety. Against this backdrop the first of a series of Global Patient Safety Challenges was issued in October 2004, concerned with the prevention of Health Care-Associated Infection (HAI) through the promotion of clean safe care in relation to blood safety, injection safety, safe water and sanitation, safe clinical procedures with the entire Challenge underpinned by a focus on improved hand hygiene.

A new Global Patient Safety Challenge is issued on a two-yearly basis, with the lifespan of each Challenge varying according to the complexity of the patient safety issue being addressed. The intention is that Global Patient Safety Challenges are concerned with an issue of universal significance and relevance, thus providing Member States with a vehicle for demonstrating commitment to patient safety per se.

The First Global Patient Safety Challenge: Clean Care is Safer Care: In the face of compelling evidence that something as simple as better hand hygiene by health care workers can impact on the global burden of disease due to HAI, the First Global Patient Safety Challenge, Clean Care is Safer Care aims to:

- raise awareness of the issue of health care-associated infection;
- create a global movement - through a concerted effort to mobilize countries at the political level, to take action to reduce the burden of infection in health care, and as a direct result of awareness raising activity; high level ministerial commitments (country pledges) are one important method of mobilizing country actions;
- develop the first ever WHO Guidelines focusing solely on hand hygiene improvement;
- develop, test and make widely available technical resources and tools to aid implementation of hand hygiene guidelines. The tools of the implementation strategy can assist each level of the health-care system starting with individual health-care facilities and transcending the sub-national, national and at the regional level.

To achieve these aims, the World Alliance for Patient Safety works with the WHO Regional and Country Offices and a range of stakeholders, to influence action at the health-care facility level which might result in long lasting behaviour change in health care workers and ultimately increased safety and reduced infection. This is summarized in Figure 1. At its simplest, the outputs of the Challenge offer countries a “road map” for a coordinated national approach to tackling health care-associated infection starting with better hand hygiene. Its overall focus is on ensuring the clean, safe care of patients – all of the time and wherever health care takes place.

The WHO Guidelines on Hand Hygiene in Health Care (Advanced Draft) The WHO Guidelines on Hand Hygiene in Health Care (Advanced Draft) present a comprehensive account of the history of

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hand hygiene improvement, and bring together all of the evidence relating to the most effective long-term strategies for success. Robust research studies and expert opinion support the premise that improved hand hygiene practices significantly reduce the risk of transmission of pathogenic microorganisms in health care and thereby have the potential to dramatically decrease the burden of disease among patients in terms of HAI.

Hand hygiene is frequently cited as the most important measure to achieve a reduction in health care-associated infection in health care settings and the WHO Guidelines present the case for this. Getting better at hand hygiene compliance reduces the incidence of health care-associated infection. The Guidelines present some stark statistics of relevance to all those involved in patient care: in terms of HAI.

Figure 1: Diagrammatic representation of the First Global Patient Safety Challenge

The multimodal hand hygiene improvement strategy

The first global guidelines to focus solely on hand hygiene in health care were made available in early 2006 in an advanced draft form and in line with WHO protocol will remain so until field testing is complete. The Guidelines are available as a web monitored download. Emerging from the Guidelines, a WHO Multimodal Strategy has been developed. The strategy has five core components and a Guide to Implementation outlines a five-step framework for implementation (Figure 2).

Table 1: Implementation Tools and Field Testing

<table>
<thead>
<tr>
<th>Multimodal strategy component</th>
<th>Examples of some of the Implementation Tools</th>
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<tbody>
<tr>
<td>System change</td>
<td>Facility situation analysis Guide to local production of the WHO Alcohol-Based Handrub Formulation Ward structure survey</td>
</tr>
<tr>
<td>Training and education</td>
<td>Training DVD “the Five Moments” Hand hygiene brochure and pocket leaflet Summary leaflet of the Hand Hygiene Guidelines</td>
</tr>
<tr>
<td>Observation and feedback</td>
<td>Observational compliance monitoring tools Suite of evaluation surveys Data analysis tools</td>
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<tr>
<td>Reminders in the workplace</td>
<td>“Five Moments” posters Suite of posters Information sheet</td>
</tr>
<tr>
<td>Creating a safety culture</td>
<td>Templates for communicating with senior managers Advocacy material Information leaflets</td>
</tr>
</tbody>
</table>

Figure 2: The Implementation Framework
Around forty implementation tools have been produced to assist countries and facilities in reducing HAI through better hand hygiene.

**Implementation tools and field Testing**

Implementation tools are categorized according to the components of the multimodal strategy, as illustrated in the table below.

The implementation strategy is being field tested in each of the WHO Regions, with six pilot sites in facilities in Bangladesh, Hong Kong, Costa Rica, Russia, Mali and Pakistan. Additional field testing is occurring as a result of the overwhelming number of requests from countries to be a pilot site. The WHO Complementary Test Sites (CTS) are comprised of individual health-care facilities, and in some cases entire nations have enrolled all health-care facilities within a country to test the implementation of the WHO Multimodal Strategy. By enrolling as a CTS facilities gain access to a state of the art toolkit for improvement and an exclusive community web platform for learning and sharing information and ideas.

**Integration of hand hygiene improvement with other WHO Safety Programmes:**

In May 2007, nine patient safety solutions, developed by the WHO Collaborating Centre on Patient Safety (Solutions), were launched. Hand hygiene is one of these nine solutions. The solutions are based on interventions and actions that have addressed patient safety problems in some countries – and in this instance Solution 9 is based on the WHO Guidelines on Hand Hygiene in Health Care (Advanced Draft).

The First Challenge is also working closely with the WHO Patients for Patient Safety Programme to ensure that patients and carers remain at the heart of hand hygiene improvement strategies. A global survey of patients’ views on the extent to which patients should be involved in hand hygiene improvement has recently concluded and results will be made available via the Challenge website.

**Summary**

The First Global Patient Safety Challenge, Clean Care is Safer Care has generated significant momentum within a very short time, mobilising countries, health-care leaders, patients and patient organizations and technical experts to support the work through positive action. Measurement of the impact of the technical guideline-related work is being undertaken through a robust pilot site evaluation. Countries, professional organizations and individual health-care facilities with a desire to implement a hand
hygiene improvement programme now have available to them a blueprint for action.

Encouragingly, to date countries representing over three quarters of the world’s population have committed to tackle health care-associated infection and a growing number of countries are or have implemented national and sub-national campaigns for hand hygiene improvement (see Figures 3 and 4).

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Further information:
The Implementation Tools: http://www.who.int/gpsc/implementation/en/
Complementary Test Sites: http://www.who.int/gpsc/country_work/pilot_testing/en/index.html
Additional Information: http://www.who.int/gpsc/resources/en/
Countries committed to tackling HAI: http://www.who.int/gpsc/statements/countries/en/index.html

Countries committed to addressing HAI as at July 2007

Countries committed to address HAI as at July 2007

Countries committed in 2005, 2006 and 2007

Countries planning to commit in 2007

Countries interested to commit in 2007

Pledge: 17 July 2007

Figure 3: Countries committed to addressing HAI as at July 2007

Figure 4: Test sites and national/sub-national campaigns

As at June 2007

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MANAGING THE FINANCIAL AND HEALTH RISKS OF EXPOSURE TO BLOOD BORNE VIRUSES

ARTICLE BY GRAHAM JOHNSON

Abstract

The procurement processes in the UK National Health Service (NHS) has changed. The emphasis is on a cost effective approach to the purchasing and supply of goods. This, along with the standardisation of products and equipment means that there is a need to ensure that the procurement process is driven by evidence based decisions. This should incorporate a risk assessment to address the needs of the end user with an assurance that patient safety needs are met.

To address this, many National Health Service (NHS) Trusts have adopted a partnership arrangement, involving clinicians, management, finance and other stakeholders which ensures a commitment to the introduction of new practices, procedures and products.

Exposure to blood borne viruses

With the invasive nature of surgery and increased exposure to Blood Borne Viruses (BBVs) during surgery, there is a high risk of transfer of pathogens. These can be transferred through contact between surgical patients and the surgical team, resulting in post-operative blood borne infections (BBIs). Both patients and the surgical team need to be protected from this risk.

It has long been accepted that health-care workers, and surgeons in particular, have a moral, ethical and legal duty of care to reduce the incidence and prevalence of Surgical Site Infections (SSIs) and BBIs within the Operating Theatre environment.

Almost 250 years ago Obstetrician, John Walbaum, donned gloves manufactured from the small bowel of a sheep, making him possibly the first clinician to recognise the need for barrier protection during surgery. That was in 1758, since then the wearing of gloves has become common practice by members of the surgical team in their efforts to protect themselves and their patients from the adverse consequences of potentially infective pathogens.

Health and safety implications

The Personal Protective Equipment at Work Regulations 1992 sets out the regulations for wearing personal protective equipment, such as surgical gloves, designed to protect the user from occupational injury. This together with the Health and Safety at Work Act and the Management of Health and Safety at Work Regulations place a legal obligation upon employers to protect the health of health-care workers (HCWs).

Specific legislation regarding the control of BBVs is also included in the Control of Substances Hazardous to Health Regulations (COSHH).

An implicit requirement of this legislation is the need to assess the risk of occupationally acquired health risks for employees, and that where the risk is apparent, control measures must be put in place to protect health.

Amongst these are:

- Avoiding the use of and exposure to sharps such as needles.
- Adoption of safer needle devices and the avoidance of re-sharpening.
- Prevention of puncture wounds, especially where there is a known risk of pathogen transmission.

By far one of the greatest risks to members of the theatre team is that of contamination from a glove puncture from a needlestick injury (NSI). It is often a conception that a NSI means an injury resulting from a needle. A needlestick injury is defined as "the par literal introduction into the body of a health-care worker, during the performance of his or her duties, of blood or other potentially infectious material by a hollow-bore needle or sharp instrument, including but not limited to, needles, lancets, scalpels and contaminated broken glass".

Incidence and prevalence of needlestick injuries

Recent figures supplied by the Health Protection Agency (HPA) have revealed that the incidence of exposures to BBIs is still unacceptably high. The first documented case in the UK of a health-care worker acquiring HIV following an occupational injury was in 1984. Following this, a passive surveillance system was established, involving healthcare workers in England, Wales and Northern Ireland for exposures to HIV. This was changed to a more active surveillance system in July 1997, and was expanded to include hepatitis B and hepatitis C.

Between 1996 and 2004, 2140 incidents of significant exposure to BBVs were reported to the agency. 47% (997/2140) of these health care workers were exposed to hepatitis B and hepatitis C.

International Hospital Federation Reference Book 2007/2008  e99
The report also commented on a needlestick injury surveillance project in 14 NHS hospitals in the UK, initiated by the Royal College of Nursing (RCN), which revealed a reported injury rate of 17.6 injuries per 100 occupied beds. This implies that when taking into consideration the underreporting of these incidents, over 100,000 NSI may occur within the NHS each year.

A recent study in the US reported as many as 700,000 needlestick injuries occur each year and that the national economic burden of NSI is estimated to be US$ 65 million. A further study suggests these numbers underestimate the true cost for several reasons, as they only examined short-term costs. The study only used self-reported data and did not include the cost associated with treating the side-effects of HIV drugs.

Financial implications

With the current dilemma between procurement striving to keep costs to a minimum and surgeons demanding an appropriate level of safe protection from the rising rates of BBV’s, any measure which reduces the financial burden that occurs from NSI far outweigh the costs of future HIV infections.

The evaluation of the health-care worker includes a medical history and details of any existing medication must be considered appropriate, health care workers should need not be subject to any modification of their working practices, for example avoidance of exposure-prone procedures. (Exposure-prone procedures are defined as: procedures where the worker’s gloved hands or fingertips may not be completely confined anatomical space where the instruments inside the open body cavity or hands may be in contact with sharp instruments inside the open body cavity or hands may be in contact with sharp)

Post exposure prophylaxis (PEP)

All NHS trusts in the UK should as part of their clinical governance arrangements, have policies for dealing with a NSI and many adapt these from legislation set out in The Health and Safety at Work Act, COSHH Regulations, and the Management of Health and Safety at Work Regulations.

Commonly these policies would follow a risk management approach designed to answer the following questions: Would HIV transmission have taken place? How likely is it that it did? Is immediate treatment required? What discussions and support does the injured HCW require?

Further reading of a HPA article ‘Eye of the Needle’ details a more in-depth approach to occupational exposure and it is clear from their findings that such steps would remove the health-care worker from their practice for a considerable time and incur a financial burden upon their organization.

Occupational exposure to known or suspected HIV-infected materials is always stressful and for some, extremely so. It is recommended that PEP ideally should be commenced as soon as possible after the event. If a longer interval has elapsed following possible exposure, this may not be a contra-indication to starting therapy.

Following exposures for which PEP is considered appropriate, health care workers will need time to discuss the balance of risks in their particular situation and should be offered appropriate psychological support. They should be informed that knowledge about the efficacy and toxicity of drugs used for PEP are limited.

It is important that their views about PEP are taken into account and that their preferences about who this should be discussed with are respected. In particular, there may be someone in whom they have trust and to whom they would like to be referred. Expert advice through the NHS should always be sought when needed.

The evaluation of the health-care worker includes a medical history and details of any existing medication must be established. All exposed health-care workers should be encouraged to provide a baseline blood sample for storage and a follow-up sample for testing with baseline samples being retained for two years. An HIV test should be carried out at 8-12 weeks and six months and the health-care worker would be informed of the retention policy at the time the sample is taken.

PEP should normally be continued for four weeks and every effort taken to facilitate adherence to a full four-week regimen. The duration of the course, or the drugs used, may need to be modified if problems of tolerance and/or toxicity are encountered.

Nausea is a common problem, and the prescription of prophylactic anti-emetics should be considered. If severe nausea is experienced and is a deterrent to taking PEP, expert advice should be sought.

Regular medical/occupational health follow-up during the period of PEP is necessary to monitor acceptability and possible toxicity of the preparation(s). Close follow-up and encouragement, ideally on a weekly basis at least, from an experienced occupational health practitioner, is likely to help improve adherence and deal expeditiously with concerns and complications.

The advice of local experts would be sought when necessary and the employer advised that any need for sickness absence associated with adverse effects of PEP drugs following an occupational exposure, should preferably, not contribute to an individual’s sickness absence record.

The affected HCW occupationally exposed to HIV will require follow-up counselling, post-exposure testing and medical evaluation whether or not they have received PEP. They would be encouraged to seek medical advice about any acute illness that occurs during the follow-up period. Illnesses characterized by fever, rash, myalgia, fatigue, malaise or lymphadenopathy may represent a seroconversion illness. Some of these symptoms may, however, be side effects of antiretroviral medication.

Pending follow-up and in the absence of seroconversion, health-care workers need not be subject to any modification of their working practices, for example avoidance of exposure-prone procedures. (Exposure-prone procedures are defined as: procedures where the worker’s gloved hands may be in contact with sharp instruments inside the open body cavity or confined anatomical space where the hands or fingertips may not be completely visible at all times.)

Advice should, however, be given about safe sex and avoiding blood donation during the follow-up period.

What to prescribe

Antiretroviral agents from three classes of drug are currently licensed for first-line treatment of HIV infection, namely:

nucleoside analogue reverse transcriptase inhibitors (NRTIs);
non-nucleoside reverse transcriptase inhibitors (NNRTIs);
protease inhibitors (PIs).

Zidovudine (an NRTI) is the only drug to date which has been studied and for which there is evidence of a reduction in risk of HIV transmission following occupational exposure. It continues to be
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References

Sensors depicted are for illustrative purposes only.
reasonable that zidovudine is included in all first choice PEP regimens.

In HIV-infected patients, combination drug therapy has proved more effective than zidovudine alone in reducing viral load. In theory, a combination of drugs could increase the potency of post-exposure prophylaxis and offer increased protection, in view of the increased prevalence of resistance to zidovudine and other antiretrovirals.

Information about the virus present in the source patient and, if known, any sexual partner of the source patient, will be relevant when choosing appropriate PEP drugs. Similarly, information about the source patient’s (and his or her sexual partner’s) previous and current antiretroviral therapy may also be important. Any information available in the source patient’s medical record about antiretroviral therapy may also be used to inform choice of PEP drugs.

Following exposure it is recommended the health-care worker receives a combination of the following drug therapy:

- Zidovudine 250mg (£3.18 per 60 tab pack12)
- Lamivudine 150mg (£1.52 per 60 tab pack)
- Nelfinavir 1250mg (£2.73 per 300 tab pack)

While the above regimen is recommended for emergency starter packs, other NRTI and PI combinations could be considered when the physician considers them more appropriate for individual patients.

Side effects

All of the antiretroviral agents have been associated with side effects. Many of these can be managed symptomatically. Side effects of the NRTIs (e.g. zidovudine and lamivudine) have been mainly gastrointestinal (e.g. nausea, vomiting). Malaise, fatigue and headache have also been reported. Some experts consider that stavudine may be substituted for zidovudine as a means of reducing adverse effects, and others consider that zidovudine should not be omitted from any PEP regimen.

Both NNRTIs licensed for treatment (nevirapine and efavirenz) are associated with short-term toxicity. Nevirapine has the potential for severe rashes (which may be confused with rash associated with HIV seroconversion) and sometimes Stevens-Johnson syndrome. Nevirapine is described in the BNF as being for progressive or advanced disease. Efavirenz is associated with neurological side effects but has a lower incidence and severity of rash.

PEP and tests

PEP should ideally be commenced as soon as possible and it is recommended that this should be within one hour of the incident. If a longer interval has elapsed, PEP has been given in cases 1 to 2 weeks following the exposure, but this overall effectiveness is likely to be reduced. PEP in most cases consists of taking three drugs for a period of 4 weeks. The exception to this is if a woman is or could be pregnant, which means that only Zidovudine (AZT) will be given.

A baseline blood test will be taken for storage for two years. After exposure to HIV, it takes approximately 8-12 weeks to develop antibodies to the virus. This is known as the “window period.” An HIV antibody test result is only deemed accurate if this time span has elapsed. It is recommended in occupational exposure that a further test is performed at 8-12 weeks and six months following the incident.

As HIV can be transmitted during this “window period” it is important to take appropriate precautions in an individual’s personal life, such as not donating blood or other body fluids and using condoms to reduce sexual transmission.

If one of the above members of the health care team experiences an injury from a NSI, other factors need to be considered. This would include the cost of cover for the absent employee for an indeterminate time, including overtime payments or agency fees, with the addition of any litigation costs which could be immeasurable.

If the injured person was a Surgeon then far greater costs could be incurred. An extended period of absence would result in operating lists being cancelled and waiting lists extended. Ultimately the individual could face the scenario of losing their career.

The above scenario is centred on costs of losing a member of staff from possible infection from a patient, however in a recent “Communicable Diseases Review” two investigations had to be carried out on patients operated upon by surgeons who were infected with HIV. In the first review, 310 patients had to be screened with 20 (6%) having acquired Hep B from the surgery carried out by Dr X.12

In the second report,11 a total of 31 patients were tested. Dr A had 16 patients requiring testing and Dr B had 15. Only two of Dr A’s patients tested positive and all of Dr B’s were found to be negative.

Interestingly Dr X and Dr A, according to the reports, did not practice the use of double gloving, however Dr B routinely wore two pairs of gloves for all of his surgical procedures. These cases highlight the further costs that can occur from BBVs. Neither of the above reports outlined the financial cost of screening all of the patients or any compensation that may have been paid.

However it is reasonable to assume that the organisation for whom these Doctors were employed would have incurred heavy financial burden.

Evidence given so far has only outlined the quantifiable costs of NSI and possible infections yet there is little question that exposure to blood borne pathogens via NSI exacts a significant emotional and psychological toll on the victims, the cost of which is difficult, if not impossible to quantify.

Health-care workers who are injured by needlesticks face the uncertainty of their
infection status in the immediate period following the injury, and, once the news is known, face whatever life-changing, long-term consequences are associated with the disease they may have contracted. A 2005 study found that 29 out of 110 nurses who sustained a sharp-related injury sought emotional counselling in the year following the injury.

A more recent 2006, detailed case study described two nurses who received needlestick injuries from an HIV-infected patient. Despite testing negative for HIV antibodies more than 22 months after their injuries, both nurses displayed symptoms consistent with post traumatic stress disorder (PTSD): insomnia, ongoing depression and anxiety, nightmares, and panic attacks upon returning to the work environment where the injuries were received. Although these may be extreme examples, the authors maintained that the long-term emotional consequences of needlestick injuries are likely to be unappreciated.

Many studies nowadays are focusing on the need for double gloving and evidence is incontrovertible that double gloving represents the minimum standard for reducing the incidence of perforations. It would be easy to say that to double glove for all surgery would solve the problem. However, there are a number of factors which affect the rate and distribution of glove perforations, for example, the type of surgery, length of surgery and hand dominance of the glove wearer.

An article in 2005 suggests the nature of the operation being carried out is probably the most significant causative factor of glove perforation. Few studies exist which compare rates of perforations for different surgical specialities. However, one study has found orthopaedic surgery to have the highest incidence of perforation, closely followed by gastrointestinal surgery. Vascular, urology and thoracic surgery were found to have comparatively low perforation rates.

The Cochrane Review

The much lauded Cochrane Review of surgical gloving practice was first published in 2002 and provided information on the effectiveness of gloving measures taken to reduce perforations during surgery. The Royal College of Surgeons of England released a statement in 2004 endorsing the findings of the review and the Association for Perioperative Practice has based its guidelines for practice on the review. The review compared the effectiveness of single gloving with double gloving, double gloving with perforation indicator systems and double gloving with glove liners.

The Cochrane Review found nine high quality trials which compared single with double gloving. All of these trials were carried out in low risk surgical specialities. The nine trials examined a total of 5,264 gloves. Single gloving was found to have a perforation rate of one in 11 gloves (9% of gloves perforated) and double gloving was found to have a perforation rate of one in 31 inner gloves (3% of inner gloves perforated). Further evidence is as follows:

- perforation rates of 11% vs 3% for single gloves and double inner gloves, respectively, in low-risk surgery (e.g. vascular, gynaecology, obstetrics), equivalent to more than one perforation in every five pairs of single gloves;
- 77% vs 21% detection rate for colour indicator gloves vs standard double gloving;
- only a 1% perforation rate for double-gloving plus liner vs 28% for double gloving alone in high-risk surgery;
- similarly, a 4% perforation rate for cloth inner gloves vs 27% for double gloving;
- zero perforations for triple gloving vs 5.3% for double gloving in high-risk maxillo-facial surgery.

The review found that wearing two pairs of gloves during low risk surgery offers significantly more protection against perforations than single gloving. Though double gloving has been shown to offer more protection than single gloving, this practice has met with some resistance from surgeons who believe that their dexterity and comfort has been compromised. However, several studies show no reduction in dexterity and the Cochrane review found that wearing two pairs of gloves did not result in the glove wearer sustaining more perforations.

Identifying glove perforations is a particular problem for two reasons. Firstly, surgeons considerably underestimate perforation rates and therefore do not look for holes. Secondly, perforations are difficult to detect. Perforation detection during surgery can be improved by using a glove puncture indication system.

One commercial, proprietary indication system involves wearing a green-coloured pair of latex gloves underneath a standard pair of latex gloves. In the event of a perforation, fluid from the operative field seeps between the layers of gloves through the perforation and the site becomes highly visible. A comparison of single, double and indicator gloves in Finland found that the risk of contamination from blood was 13 times higher when using single compared with double gloves. Surprisingly, the combination of two regular gloves was much less efficient than double indicator gloves when compared with double gloving. The report recommended double gloving in orthopaedic surgery in general and also in long arthroscopic procedures.

The Cochrane Review found that during standard double gloving, glove wearers detect only 25% of glove perforations but 74% of perforations are detected when wearing this indication system.

There are no studies which sufficiently describe the relationship between gloving practice and number of transferred pathogens to patients or to members of the surgical team. Therefore it is up to the individual to determine by way of a risk assessment, their own level of acceptable risk for glove perforations. Individuals should not base their method of gloving practice on the current generalisation that orthopaedics is a high-risk speciality and almost all other specialties constitute low risk. Instead they should assess each procedure in particular, operations involving bone and metal work, deep cavities, confined spaces and procedures which last more than one hour have the highest incidence of perforation.

Conclusion

The need to control costs in the NHS on the purchase and supply of gloves has to be measured against the equally important area of risk management in the prevention of surgical suite infections, blood borne infections and needlestick injuries.
Using evidence based purchasing policies to ensure that personal protective equipment and medical devices meet the demands of operating department personnel is an important aspect of the management of occupationally acquired infections and injuries. The benefit of using control methods such as safer needle devices and double gloving incorporating an indication system, are important measures which will help to reduce the incidence of these health-care incidents.

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Roles of Laboratories and Laboratory Systems in Effective Tuberculosis Programmes

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Abstract

Laboratories and laboratory networks are a fundamental component of tuberculosis (TB) control, providing testing for diagnosis, surveillance and treatment monitoring at every level of the health-care system. New initiatives and resources to strengthen laboratory capacity and implement rapid and new diagnostic tests for TB will require recognition that laboratories are systems that require quality standards, appropriate human resources, and attention to safety in addition to supplies and equipment. To prepare the laboratory networks for new diagnostics and expanded capacity, we need to focus efforts on strengthening quality management systems (QMS) through additional resources for external quality assessment programmes for microscopy, culture, drug susceptibility testing (DST) and molecular diagnostics. QMS should also promote development of accreditation programmes to ensure adherence to standards to improve both the quality and credibility of the laboratory system within TB programmes. Corresponding attention must be given to addressing human resources at every level of the laboratory, with special consideration being given to new programmes for laboratory management and leadership skills. Strengthening laboratory networks will also involve setting up partnerships between TB programmes and those seeking to control other diseases in order to pool resources and to promote advocacy for quality standards, to develop strategies to integrate laboratories’ functions and to extend control programme activities to the private sector. Improving the laboratory system will assure that increased resources, in the form of supplies, equipment and facilities, will be invested in networks that are capable of providing effective testing to meet the goals of the Global Plan to Stop TB.

The laboratory has always played a critical role in diagnosing tuberculosis (TB) and monitoring its treatment. In the new millennium, the strength of the laboratory network is often a direct reflection of the success of TB control programmes. Developed countries have taken advantage of new technologies that provide rapid detection, identification and drug susceptibility testing of Mycobacterium tuberculosis, hastening the decline of the prevalence of the disease when combined with good management and support of TB programmes. In contrast, many developing countries are burdened with high rates of TB and struggle to provide good-quality microscopy, with access to culture and drug susceptibility testing (DST) being scarce to non-existent. For a long time, countries have demonstrated effective TB control using microscopy-based diagnosis and monitoring combined with well-managed treatment programmes. However, inadequate management and support of TB programmes and the laboratory networks are hindering progress against the disease. Also, the complications stemming from the HIV epidemic and multidrug-resistant TB (MDR-TB), especially in Africa and eastern Europe, prevent effective TB control that relies entirely on microscopy-based case detection and management. Effective control involves access to laboratory services at every level, which requires managing and supporting laboratory networks that provide reliable and consistent decentralized services. Although laboratory strengthening is beginning to gain higher priority on the TB agenda, as reflected in the new Stop TB Strategy, more efforts are needed to improve access to and utilization of existing diagnostics as well as to develop and implement new technologies.

Modern techniques such as fluorescence microscopy (FM), use of liquid cultures for isolation and DST, and amplification for detection of and/or for study of drug resistance are expensive, labour-intensive or relatively slow. Increased interest has therefore emerged in developing new diagnostics and in efforts to introduce modern diagnostic methods in developing countries. The Foundation for Innovative New Diagnostics (FIND) is now applying a systematic approach to research and development for new diagnostics. Focusing solely on finance, techniques and new diagnostics, however, often ignores the need for well-trained staff, quality management systems and other prerequisites that underpin the standards of practice in developed countries. Clinicians will continue to forgo existing laboratory testing services and diagnose and treat empirically in situations where there is a lack of trust and credibility concerning the quality of laboratory results. Such failures to have adequate quality standards highlight the urgent need to focus also on strengthening the laboratory system in parallel with efforts to implement new techniques and methods. The problems of MDR-TB and the recent outbreaks of extensively drug-resistant TB (XDR-TB) provide a compelling rationale for increasing capacity for culture and DST services. In turn, the complexity of providing such services is driving discussion and analysis.
The problems of MDR-TB and the recent outbreaks of extensively drug-resistant TB (XDR-TB) provide a compelling rationale for increasing capacity for culture and DST services

of how to build laboratory capacity that far exceeds the training, human resources and networks required for microscopy centres. For countries where TB laboratory services are integrated with general laboratory services or where there is a large private sector, there is also a question of whether national tuberculous programmes can successfully improve the quality of and access to laboratory services in the absence of combined efforts by all health programmes to support a general initiative of laboratory capacity-building.

Past efforts to provide a separate and parallel system of TB microscopy practices, records and monitoring may be insufficient to meet the demands of improving TB laboratory services in the context of changing health systems.9

There is growing recognition that the quality of TB laboratory networks serves as either the catalyst or rate-limiting step for further progress in TB control. This paper outlines some of the key technical and organizational challenges associated with microscopy, culture, DST and the corresponding safety issues. The different components of successful laboratory services will also be examined, concentrating on human resources, research, quality management systems and laboratory network structure.

Microscopy

Microscopy remains the mainstay of rapid TB case detection, especially for those patients who are most infectious to others, with the bacterial load involved often reflecting the extent of disease requiring immediate treatment. In most countries, especially those with the highest burden of TB, the direct Ziehl-Neelsen (ZN) smear is still the most common test. However, its sensitivity depends on the diligence of the technician and on use of the appropriate technique. The co-epidemics of HIV infection and TB, especially in Africa, and concerns that the ZN smear has lower sensitivity in those with HIV infection, have stimulated interest in practical methods to improve microscopy.10-12 Industrialized countries often use concentrated smears and FM, a combination showing high yield also in low-income, HIV high-prevalence countries, but requiring greater resources.13 Further operational research to demonstrate the effectiveness and acceptance of this diagnostic combination under field conditions is required before it can be widely recommended.13,14 Also, external quality assessment (EQA) programmes are needed to ensure that smears are performed and interpreted correctly and that all microscopy centres achieve an accepted level of performance.14 Effective EQA programmes are, however, labour-intensive and complex, requiring dedicated staff for onsite supervisory visits and to recheck results for a relatively large workload of smears.14-16 Although international guidelines recommend rechecking a blinded random sample of smears, many regions and countries have either not fully implemented rechecking or still use unblinded rechecking, the results of which are ineffective and misleading.16-18

The implementation of EQA for microscopy has the advantage not only of strengthening laboratory networks but of improving diagnostic quality.11 Systematic review by a laboratory expert is probably the most important component of strengthening network management, but is often limited by the cost and time involved. In integrated health systems, one solution is to broaden the scope of onsite supervision to include review and monitoring of other testing and diagnostic services, such as those for HIV, malaria, biological chemistry and haematology. Although such an integrated review would provide less attention for TB, it is a more efficient and cost-effective use of human resources, and reflects the common practice for laboratory accreditation in many high-resource countries.

Culture methods and drug sensitivity testing

The use of culture methods for TB diagnosis and of DST are standard practices in high-resource countries; however, many low-resource countries still struggle to provide culture methods for priority needs such as drug resistance surveillance (DRS), extrapulmonary and childhood TB, and MDR-TB. There is considerable debate about the feasibility and cost of providing culture for routine detection of TB cases in the high-prevalence setting, not to mention what is the most appropriate diagnostic algorithm to use.19 However, many high-burden countries have not even developed the basic capacity for accurate and reliable culture for DRS and diagnosis of MDR-TB, as shown by the lack of data on drug resistance in most of the high-burden countries.20 Additionally, national TB programmes need to promote appropriate use of the current limited culture capacity so that priority requests are met and TB laboratory services are made available throughout the country, and not just in selected urban areas.21 Recent outbreaks of XDR-TB have helped to focus attention on the selection of DST for diagnosis as well as for surveillance. The use of direct specimen testing for rifampin resistance using nucleic acid amplification tests (NAAT) avoids the difficulty in providing rapid, comprehensive and accurate DST for diagnosis using culture methods. NAAT also offers the promise of centralizing testing services without the “cold chain” transport systems required for culture.22 However, cross-contamination or false positives.22 Also, DST and NAAT require training. EQA and standard practices to achieve the levels of accuracy required to establish credibility and to justify the resources needed to further expand services.

Human resources

Management of microscopy networks and referral laboratories for culture and DST require highly skilled laboratory scientists, who are either in low supply or often unwilling to work in low-paid government jobs. For many countries the human resources crisis is limiting laboratory services at all levels. At the
Successful integration of disease control providers have also been responsible for public initiatives to work with private mandatory reporting of cases of TB and quality standards and regulations, with resources, factors such as laboratory systems, including laboratories, which provide high-quality care and services. Although the quality of care correlates with resources, factors such as laboratory quality standards and regulations, mandatory reporting of cases of TB and other infectious diseases, and specific public initiatives to work with private providers have also been responsible for successful integration of disease control programmes with private health care.28-30

Laboratory network structure

The challenge to developing effective laboratory networks must take into account the evolving structure of the health-care system. Most high-resource countries have large private health-care systems, including laboratories, which provide high-quality care and services. Although the quality of care correlates with resources, factors such as laboratory quality standards and regulations, mandatory reporting of cases of TB and other infectious diseases, and specific public initiatives to work with private providers have also been responsible for successful integration of disease control programmes with private health care.28-30

However, in many countries with a high burden of TB, there is a struggle to monitor and assure the quality of testing and reporting in the growing private laboratory sector. In such settings, the national TB programmes and national reference laboratories (NRLs) must develop strategies to enrol private laboratories in EQA programmes and require reporting and referral of TB cases. However, it is unlikely that these bodies alone will be able to secure both national legislation and the resources to establish programmes that only monitor TB testing in private laboratories. This will probably require efforts to establish partnerships with other health programmes to lobby for national laboratory standards and sufficient structure to implement regulations. A key issue is the organization of the TB laboratory services in relation to the national TB programme and the general health services. The traditional model is to have the NRL located within the national programme. An advantage of this arrangement results from the close cooperation between the two, which assures that the laboratory activities are closely aligned with the needs of the programme and receive appropriate support. The disadvantage of having a “stand-alone” TB NRL versus a TB section in an NRL facility with integrated laboratory services is that it can result in a rather small national TB laboratory with limited staff and service support. A larger integrated NRL offers many smaller countries the opportunity to share services such as support staff, equipment and supplies, and provides a greater critical mass of laboratory peers who can share technical expertise. An integrated NRL may also benefit from sharing quality assurance, information technology and specimen transportation functions. The choice may be even more pressing at the intermediate level. For individual programmes, many countries cannot raise the human and other resources required for quality assurance and other tasks at this level. The concern associated with having a TB section within an integrated NRL is to assure that the laboratory activities and support are closely aligned with the national programme. Furthermore, the laboratory requirements may be so much higher than those of the general services or other programmes that integration will be difficult. Representatives from all sectors of the health-care system should look strategically at what is the best structure for expanding and improving laboratory services.28-30

Laboratory safety

Safety is a continuing concern for laboratory staff at all levels who work with specimens and cultures containing M. tuberculosis. It is the responsibility of the NRL and the national TB programme to address such concerns through a combination of training and education to help promote risk assessment and safe practices, and also to support reasonable safety improvements with respect to equipment, supplies and facilities. Microscopy carries a low risk if direct smears are prepared carefully in well-ventilated areas.30 Rather than purchase biological safety cabinets that are difficult to maintain, microscopy centres should invest in simple cabinets or “fan boxes” that are relatively inexpensive and efficiently exhaust air without filters, provided that they have sufficient extraction power.30 When suitably installed, such cabinets can offer a level of protection that reassures technical staff. The process of culture, identification and DST has well-defined risks of causing laboratory-acquired infections. These risks present a challenge to countries in terms of supporting appropriate facility design and engineering, training and adherence to safety practices, and use and maintenance of biological safety cabinets. As countries expand their culture capacity, there will be a need for guidance and decisions on minimum safety standards that are affordable and sustainable.

Quality systems

The quality of testing services for TB remains a major barrier for microscopy, culture, DST and newer NAAT methods. Many countries are still struggling to expand effective EQA to all microscopy centres, both public and private. Effective EQA is even more important in the presence of HIV infection, with concerns that many patients will have paucibacillary specimens requiring detection of only a few AFB to make the diagnosis of TB. In the meantime, EQA...
TB laboratories also play a pivotal role in performing research, especially operational research that supports evidence-based decisions for guiding laboratory practice. The research on TB diagnostics and treatments may be the most practical approach to immediately improve test sensitivity, while further evidence is being obtained on the appropriateness of methods such as PM and concentration techniques, and new diagnostics are tested. EQA is one component of quality and there are proven programmes for measuring performance of microscopy and DST. One of the most effective is mentorship of NRLs by supranational reference laboratories and exchange of strains between them in order to measure performance in support of global drug resistance surveillance. Culture performance is often harder to measure, and existing EQA programmes do not necessarily estimate sensitivity in this respect. The low efficiency of culture methods in some settings is illustrated by surveillance for drug resistance, where some laboratories may have difficulties in isolating M. tuberculosis from smear-positive specimens. These quality problems cannot be solved only by EQA and must be dealt with by total quality management systems that include all the components involved: documents, records, personnel, standards, facilities and quality control. In this respect, one critical difference in many developed countries is the presence of laboratory regulations or accreditation programmes. Until countries develop, implement and monitor laboratory standards by regulation, a minimum step is to develop an accreditation process for NLRLs.

Research

TB laboratories also play a pivotal role in performing research, especially operational research that supports evidence-based decisions for guiding laboratory practice. Whenever possible, such research should be performed in the field in low-resource settings, where the conditions represent the situation in most countries with a high burden of TB. In contrast, research performed in academic centres that have human and material resources that differ from those in public-sector services in low-resource countries may not always provide reproducible results under programme conditions. Research carried out to improve diagnostic methods and techniques can be published in the literature and guide countries’ decisions about implementing changes in technology and procedures. Many NRLs have the interest in and the capacity to perform operational research, and can be encouraged to carry it out if provided with training in research methods and by developing partnerships with research-focused institutions such as universities. It is important, however, to ensure that the NRL and other institutions balance research activities with priority initiatives to monitor and support the laboratory network. Financial and other incentives that are only available for research activities lead to misplaced priorities and neglect of the daily support that laboratory networks provide for TB control.

Conclusion

Laboratories are not just technologies, equipment and buildings; they are people and systems that manage the processes and standards required to produce accurate and timely results. Successful implementation of new diagnostic tests will still require functional networks of laboratories with trained and motivated staff, quality management systems and safe working environments. The Global Plan to Stop TB calls for 800 new culture and DST facilities at an estimated cost of US$ 700 million to reach its 2015 targets. The Global Fund to Fight AIDS, Tuberculosis and Malaria can help with these costs; however, there will also have to be a corresponding requirement for attention and investment in people, organizations and systems to successfully expand services. Resources for commodities are increasing; nevertheless, currently neither funds nor efforts are directed towards addressing the human resources needed for EQA, guidance and processes to establish and enforce quality systems, practical and reasonable safety standards and steps to determine optimum organizational structures and requirements for TB laboratory services. Rather than assuming that technological developments are the only way to improve TB diagnosis, international organizations and countries should work immediately to strengthen laboratory leadership and systems through shared guidance at the global level. The solutions, in the form of technical guidance, effective quality assurance, systems and capacity building are all-attainable, but will require a new focus on the laboratory as a system. Also needed is coordination and support from organizations and countries in the Stop TB Partnership to develop the people and networks in tandem with improvements in facilities, equipment and methods. A new focus on expanding and strengthening laboratory systems for quality-assured services, that is microscopy, culture methods and DST, will help achieve the targets for global TB control.
References


CIRCULATING TUMOR CELLS IN BREAST CANCER: BLOOD WILL TELL

ARTICLE BY GEORGE W. SLEDGE

Abstract

Predicting survival in advanced breast cancer has a long and problematic history. Both physicians and patients care about survival prediction, although for somewhat different reasons. The patient's interest springs from the most human of motives: how long have I got? Will I see my child graduate from school? Will I live to see the birth of my grandchild? Physicians naturally wish to provide patients guidance on these matters, and in addition, find prognostic information useful in determining appropriate therapeutic options.

Unfortunately, physicians have never been very good at predicting survival. Breast cancer is a disease with sometimes astonishing heterogeneity with regard both to natural history and therapeutic response. Indeed, therapeutic response and natural history entwine to a confusing degree. In addition, the rapidly evolving therapeutic landscape can render older prognostic categorization irrelevant; compare the fate of the HER2-positive patient a decade ago versus today.

This issue's article by Budd and colleagues represents an attempt to solve the prognostication problem through the application of a novel technology. It is one of several recent articles from the same group of investigators examining the role of circulating tumor cells (CTC) in patients with advanced disease. To summarize this work, the presence of high CTC counts (5 per 7.5 mL of whole blood) is associated with shorter progression-free and overall survival in the metastatic setting, and their continued presence following the initiation of a new therapy similarly predicts impaired therapeutic response and overall survival.

The current article extends the prior work by comparing CTC measurement with standard radiographic measures of disease progression as prognostic indicators. The population of patients studied was receiving either front-line or second-line therapy for metastatic disease, all with measurable disease. It is a representative population with regard to estrogen receptor and HER2 status, but unrepresentative in having few patients with bone-only metastatic disease (a function of the requirement for radiographically measurable disease).

In this study, both CTC and radiographic measurements provided independent prognostic information. CTC measurements obtained four weeks after the initiation of therapy clearly provided prognostic information in (early) radiographic nonprogressors, suggesting that the assay might well provide important information. This much seems solid. The study raises questions as well as answering them, some of which are discussed below.

What do CTC measurements really measure? At its simplest level, the assay used in this study measures circulating cells that express epithelial cell adhesion molecule (EpCAM). In primary and metastatic breast cancers, EpCAM is expressed at levels that are 100- to 1,000-fold greater than in benign epithelial cells, and is implicated in tumor invasion and migration. EpCAM has been suggested as a potential therapeutic target for patients with advanced malignancies, with clinical trials of anti-EpCAM antibodies having been done in breast cancer.

With regard to CTC measurements, however, a deeper level question should be asked: what does it mean to have circulating EpCAM-positive cells? There are two possible answers to this question. CTC measures could reflect the volume of metastatic disease in the patient with breast cancer, or they could reflect tumor biology (a summation of factors such as aggressiveness, drug resistance, and mutation).

In this and previous studies, tumor load, as measured radiographically, did not correlate with CTC measurements, with the caveat that radiographic measurements are not a perfect surrogate for tumor volume (nor even particularly reproducible). In contrast, this and other studies suggest that the presence of EpCAM-positive CTCs denotes the presence of aggressive pathobiology.

What are the benefits and disadvantages of CTC measurement? The benefits of CTC measurements, as used in this review, are straightforward. The technique employed was highly reproducible and standardized across multiple sites. Indeed, the reproducibility of CTC measurement in the Budd study, as opposed to that of standard radiographic techniques (even in the hands of expert radiologists), is striking. Assay reproducibility has been the downfall of many a prognostic factor, and the care given to this issue is to be congratulated.

The disadvantages of the technique represent the opposite side of the coin: reproducibility is dependent on the use of proprietary technology, and the use of this technique does not replace (at least at present) standard radiographic examination. Routine use of this approach...
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would therefore increase the cost of patient evaluation.

Does finding out bad news earlier really help? The old Baconian dictum that "knowledge is power" appeals to many clinicians and patients. Early discovery of tumor progression might allow earlier therapeutic intervention with follow-up therapy, leading to improved patient outcome. Although an appealing concept, there is no current data supporting this approach. The use of (admittedly crude) radiographic and serologic measures of metastatic disease in the postadjuvant setting failed to improve overall survival when compared with minimalist follow-up in two large randomized trials7–7. Similarly, cancers that progress early on front-line chemotherapy frequently have multidrug-resistant phenotypes and lower response rates to second-line chemotherapy compared with cancers undergoing initial disease response. Therefore, we lack any compelling data to suggest that measurement of CTCs will improve outcome. What we are left with is the possibility that finding failure at an early point in time will decrease the toxicity and eliminate the expense of ineffective agents.

What is the future of CTC measures? I have argued above that finding bad news earlier does not make the news less bad. Useful early intervention depends on the existence of effective agents specific to the patient’s cancer. CTC measures that would allow therapeutic individualization represent at least a partial approach to this problem. An initial example of this approach is provided by the analysis of CTC HER2 expression, in which recent work has suggested the conversion from HER2 negativity in the primary tumor to HER2 positivity in circulating cancer cells8, 9. It is unknown whether this conversion can be turned to clinical advantage. Similarly, a test that would predict benefit to a specific chemotherapeutic agent (e.g., “agent A is failing the patient; use agent B” or “eliminate agent A from combination A + B; it adds nothing”) would offer enormous cost savings and prevent significant unwanted toxicity. The increasing ability of modern molecular biology techniques to pull more and more data out of smaller and smaller numbers of cancer cells bodes well for progress in this area.

The Breast Cancer Intergroup of North America currently plans to study the role of CTCs in a prospective randomized trial (S0500). This trial will test the strategy of changing or maintaining therapy for patients with metastatic breast cancer based on elevated CTC measurements after the first cycle of chemotherapy. S0500 will evaluate overall survival as its primary end point, and as such, will measure the most clinically important patient benefit of therapy. If successful, it may show us whether the “blood will tell” an important predictive truth.

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References
PROTON TREATMENT FOR CANCER

A REPORT FOR THE UK NATIONAL RADIOTHERAPY GROUP

Abstract

The following article is a report to the National Radiotherapy Advisory Group made in April 2006 on the use of Proton therapy in England. England has no modern high energy Proton treatment facility for cancer patients. This contrasts with most other European countries where such centres are either available, being commissioned or planned. The Clatterbridge Hospital proton unit, whilst highly successful as a national referral centre for choroidal melanoma has insufficient beam energy and infrastructure to treat a wider range of cancer patients. The report recommends that two modern Proton treatment facilities and national referral centres are set up in England. Patient numbers for accepted clinical indications are sufficient to justify this. Some capacity must be allowed for clinical research. There is now strong evidence that the significantly improved dose distribution delivered by modern Proton radiotherapy beams represents a safer and more effective treatment than the best available x-ray (photon) therapy for a range of paediatric and other rarer cancers or unusual clinical situations.

Radiotherapy with x-rays (photons) is an essential component of modern cancer treatment. The fundamental principle is to deliver a sufficiently high dose accurately to a cancer target and areas of potential spread. Because of the known effects on adjacent normal tissues/orans, it is essential to limit the dose. X-ray based radiotherapy passes through the entire body, contributing to late toxicity, ranging from organ dysfunction to radiation-induced second malignancy. Altered growth in cured children is particularly important. These complications cause reduced quality of life and incur additional costs associated with their treatment.

Proton and Particle therapy is now highly topical and the literature expanding, provoking significant debate. There is understandable anxiety about heavy particle therapy in the clinical community given the UK experience of neutron treatment some 25 years ago. The promotion of neutron radiotherapy by enthusiasts was based on higher relative biological effectiveness (RBE of neutrons = 3-5) but important clinical trials in the UK demonstrated extremely high morbidity rates. The dose distribution of neutron therapy is very poor by any modern standards; being roughly equivalent to 250 kV x-rays and contributing to the poor results.

There is no demonstrable excess toxicity with protons which have an RBE - 1.1 and well understood radiobiological properties. The benefits are based entirely on highly superior dose distributions.

It is widely accepted that Protons are the treatment of choice for certain categories of ocular tumours, and are available to NRB patients. The Cyclotron at Clatterbridge produces 62MeV Protons, which are inadequate to treat deeper cancers and so would not be able to support a wider range of treatment indications.

The same benefits of superior dose distribution and tumour control rates exist for other tumour sites. In a climate of prioritised resources, the increased cost of charged particle therapy in other clinical situations is matched by large enough medical benefits in order to be justified. The first fixed beam proton facilities have largely been superseded by multiple rotating gantry systems within several treatment chambers, all supplied with charged particles from a single synchrotron/cyclotron.

A case for basic science research is not the remit of this report but there are opportunities for partnership funding and for additional revenues in a new UK facility.

Choice of particle

Most of the Heavy Charged Particle Therapy experience has been with Protons. Over 40,000 patients have now been treated worldwide with Proton beams, mainly for eye cancers. Protons have an improved dose distribution but little extra biological effect compared to photons. However there is increasing clinical experience – with encouraging results – using Light Ions such as Carbon ions in the Japanese government-funded Centre in Chiba e.g. in early stage Lung Cancer with high local control rates rivaling surgery. Carbon ions have a much higher biological effect (= 3-5 times that of photons), which is theoretically useful in the treatment of hypoxic and intrinsically radio-resistant cancers, and a further dose-distribution advantage c.f. protons. There is however at present no unequivocal evidence that ions are better than Protons.

Any new facility could also have the capability to produce ions heavier than Protons; particularly Carbon Ions as there is scope for future clinical and basic biological and physics research. However, the production of carbon-ion beams of the required energy for deep-seated therapy increases the cost by a factor two or three. This would need to be supported and funded by Research Councils.

It is recommended that Protons should be used for the basis of any proposed UK Particle Treatment Centre.

Advantages of Proton Therapy

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- University of Florida Proton Therapy Institute, Jacksonville, USA
- University of Pennsylvania Health System, Roberts Proton Therapy Center, Philadelphia, USA
- Westdeutsche Protonentherapiezentrum, Essen, Germany
- Centre de Protonthérapie de l’Institut Curie, Paris, Orsay (France)
- The Oklahoma ProCure Treatment Center, Oklahoma City, USA
- United Proton Therapy Facility, Rome, Italy
- Westdeutsche Protonentherapiezentrum, Essen, Germany
- Centro de Protonterapia de l’Institut Curie, Paris, Orsay (France)
- The Oklahoma ProCure Treatment Center, Oklahoma City, USA
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is very strong. There are many ocular, skull base and paraspinal tumours done in other countries. The evidence of doubt whether phase III trials will be prospective trials or case series. It is The published literature is of phase I/II controlled) trials of protons vs. photons.

Intensity Modulated Radiotherapy (IMRT) enables dose to be “painted” onto an irregularly shaped tumour volume defined by modern cancer imaging. Whilst modern conformal photon-beam treatment of choice. There is clinical situations to make Proton therapy the sufficient large in certain clinical treatment techniques. This difference is compared with the most modern photon toxicity to critical structures when distribution to minimise normal tissue significantly improved accuracy and dose distribution to minimise normal tissue toxicity to critical structures when compared with the most modern photon treatment techniques. This difference is sufficiently large in certain clinical situations to make Proton therapy the treatment of choice. There is clinical consensus for referral of certain categories of ocular tumours within the UK. Similar improvements in dose distribution and potential favourable outcome can be shown for a wider range of cancers e.g. skull base, paraspinal and paediatric cancers particularly where target volumes may be very close to dose limiting critical structures. Teenage girls and young women with Hodgkin’s disease treated with radiotherapy to the chest have a significantly increased risk of radiation induced breast cancer in the long-term. Patients treated in this way in the UK have recently been recalled to implement a screening programme for the early detection of breast cancer. This highlights the very real effect of avoidable integral dose. One of the ways in which this can be achieved in some tumour sites is with Proton therapy:

Clinical demand for Proton Therapy
Clatterbridge treats 100 – 130 patients a year with malignant melanoma in the conserved eye. Approximately 15-20 other patients are referred for proton treatment abroad. Accurate figures are unavailable as there is no central registry or referral system. Obtaining funding for treatment abroad is complex, time consuming and pursued only where patient and clinician motivation is strong.

Worldwide, Proton fractionation patterns have been similar to photons for large field sizes, but considerably fewer treatments are used in some instances, e.g. 4 treatments for eye cancers. Fractionation has major implications for
the treatment capacity necessary for England and the UK as a whole. There is now some clinical and radiobiological evidence that suggests it may be possible to reduce the number of fractions in certain clinical situations. This would reduce the overall capacity required, time away from home and costs. Fractionation should be subject to future clinical trials to ensure that morbidity is not increased. For capacity-planning calculations the safe assumption would be to start with standard fractionation. The proportion of all radiotherapy patients for whom proton therapy is essential is very small (<1%). The figures given in the tables below reflect the overall numbers of specific cancers for whom the clinical case is overwhelming. Whilst there may be advantages and reduced treatment morbidity in wider clinical scenarios, further justification is necessary from clinical trials designed to look at cost-effectiveness. Radiotherapy in children often requires general anaesthesia and preparation or playtherapy time. These reduce throughput, so that in capacity calculations a “weighted fraction” factor of 1.5 x normal fraction time is used in the tables below. The figures below are supported by data from the National Registry of Childhood Tumours.

There are certain widely accepted indications for proton therapy; where proximity to critical dose limiting normal tissues and/or in children growth, vision, hearting and mental retardation effects, or risks of second malignancy are paramount. For skull base chordomas and chondrosarcoma or paraspinal tumours there is very little acceptable alternative treatment. These clear initial High Priority indications are listed below (Table 1) and are estimates for the UK with a population of 60 million. This equates to 8 patients per million of population. There is a further group of cases where proton therapy provides a superior dose distribution with reduced risk to critical normal tissues. For example, cases where previous radiation, atypical anatomy or prosthetic implants would lead to poor options with standard radiotherapy. These have been added to the indications in Table 1 to define a total number of cases where the indication is strong and if protons were available it would be difficult not to refer for treatment (Table 2). This total equates to 23 patients per million of population. Again, the figures are based on a UK population. The figure of 1386 patients annually compares with a total of approximately 216,000 radiotherapy treatment courses in the UK and reflects just less than 1% of total caseload.

The Italian CNAO project has similarly estimated proton demand and for “category 1 – strong indication” also identify a figure of 1% which tends to validate our estimation”. The categories of tumours and sites listed are consistent internationally. Additionally, there are a wide range of clinical situations where the improved dose distributions are attractive but where the results of clinical trials are awaited with interest. These include prostate cancer, left-sided breast cancer where the heart is at risk, oesophageal cancer, hepatocellular cancer and in gynaecological cancers where radioisotope use may not be feasible. The demand for proton therapy could increase substantially22.

Clinical capacity required to meet demand

For photon therapy 4.5 fractions per hour, or 13 minutes treatment time is recommended as standard. Proton therapy cases will be biased heavily towards complex delivery with immobilisation. A standard treatment time initially of 25 minutes may fall with greater experience over time to 20 minutes; paediatric treatment complexity includes time-weighted fractions.

For a national referral centre(s) it should be assumed that capacity is maximised and that it worked a minimum of 8 hours per day and 50 weeks a year (to allow servicing, repairs etc). Some bank holiday periods might be accommodated by treatment at weekends or twice daily to compensate.

From these figures a number of fractions per treatment chamber per day can be calculated. The treatment facility at the MD Anderson Hospital (USA) aims to treat 2500 patients per year within 3–5 years using largely gantry based chambers23. They have assumed long, 10–12 hour working days with shift working. Whilst this maximises the use of capital assets there will be increased staff costs and revenue. This balance should be explored in planning a future service. Some additional treatment capacity should be built in for clinical trials.

**Table 1: Capacity required in terms of treatment chambers.**

<table>
<thead>
<tr>
<th>Treatment Courses</th>
<th>High Priority</th>
<th>Strong Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chamber 1</td>
<td>495</td>
<td>1395</td>
</tr>
<tr>
<td>Chamber 2</td>
<td>1492</td>
<td>4705</td>
</tr>
<tr>
<td>Chamber 3</td>
<td>4095</td>
<td>1395</td>
</tr>
<tr>
<td>Chamber 4</td>
<td>3.7</td>
<td>9.2</td>
</tr>
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</table>

**Table 2: Numbers of patients for whom proton therapy is available.**

<table>
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<tr>
<th>High Priority</th>
<th>Strong Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult</td>
<td>Paediatric</td>
</tr>
<tr>
<td>Chamber 1</td>
<td>44</td>
</tr>
<tr>
<td>Chamber 2</td>
<td>22</td>
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<tr>
<td>Chamber 3</td>
<td>25</td>
</tr>
<tr>
<td>Chamber 4</td>
<td>38</td>
</tr>
</tbody>
</table>

*Note: Treatment capacity could increase substantially with accommodation being required.*

**Table 3: Capacity required in terms of treatment chambers.**

<table>
<thead>
<tr>
<th>Treatment Courses</th>
<th>Initial High Priority</th>
<th>Strong Indication</th>
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</thead>
<tbody>
<tr>
<td>Chamber 1</td>
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<td>1500</td>
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<td>Chamber 2</td>
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<td>Chamber 3</td>
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**Table 4: Initial capacity.**

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<th>Treatment Courses</th>
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<th>Strong Indication</th>
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<tr>
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<td>Chamber 2</td>
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<td>Chamber 3</td>
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<tr>
<td>Chamber 4</td>
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<td>1500</td>
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</tbody>
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**Table 5: Numbers of patients for whom proton therapy is available.**

<table>
<thead>
<tr>
<th>Initial High Priority</th>
<th>Strong Indication</th>
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<tbody>
<tr>
<td>Adult</td>
<td>Paediatric</td>
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<tr>
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<td>Chamber 3</td>
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<td>Chamber 4</td>
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*Note: Treatment capacity could increase substantially with accommodation being required.*

**Table 6: Initial capacity.**

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<thead>
<tr>
<th>Treatment Courses</th>
<th>Initial High Priority</th>
<th>Strong Indication</th>
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International Hospital Federation Reference Book 2007/2008
clinical indications but perfectly adequate for physics research and industrial applications.

Gantry Systems Isocentric rotating gantry systems are now available. These are large, weighing from 100 tons for Protons to 600 tons for some light ion facilities and must be situated in correspondingly large buildings. They are more expensive than a fixed beam, costing an additional €20M per room, with half the cost being for the gantry and half for the building. Gantries allow a wider range of treatments, a 50% faster throughput of patients and a better solution for more complex geometric treatments. They allow multiple fields to be used in the same way as for photon treatments. They allow further development of this technology. The most recent centres, e.g. MD Anderson and Munich, each have 3 gantries and 1 fixed beam room. In some proposed low-cost centres in the USA, fixed beams and robotic couches are suggested mostly for prostate cancer; a market driven approach with no evidence of improved outcomes. It is recommended that for a future UK centre it would be necessary to have a minimum of 2 gantry chambers and 2 other chambers one of which should have a fixed beam and robotic couch system. The remaining chamber could be either a gantry or fixed beam depending upon funding, academic or industrial partnerships or research projects involving ions.

**Technical advances**

The method used to spread the dose out to achieve a plateau of uniform dose in the past has been “passive scattering” and provide wide circular or rectangular beams. More recent technology exists to create smaller beams and deposit dose at individual voxel-sized targets defined by good imaging techniques. This is a significant advantage but a spot scanning beam may have even greater importance since the scattering foil used in passive modulation can produce neutrons resulting in a total body dose to patients particularly important in second cancer induction. Lifespan of Technology Given the high initial capital costs this becomes an important factor in terms of net treatment costs. Some cyclotrons have functioned for 50 years. Synchrotrons may have a shorter lifespan but still in the order of 30 years. Gantries ought to last in principle for 20-30 years. The first gantries are now over 10 years old at Loma Linda University Hospital in California. Consequently, the capital cost could be depreciated over a longer time span than for standard linear accelerators, where 10 years is utilized.

**Site and description of facilities**

A proton facility acting as a national referral centre for the specific groups of patients defined above will require a wide range of supportive infrastructure. Referral Pathway Appropriate patients will be identified by existing Cancer Centres, tertiary based MDTs and allied services. Whilst videoconferencing and electronic transfer of diagnostic scans and pathology could be used for referral and acceptance, definitive decisions and final dose-planning would occur at the Proton Centre. Some shared care could be proposed with referring Cancer Centres for follow up. A greater degree of centralization of paediatric malignancy is likely to occur – following the recent NICE guidelines – and would facilitate high quality prospective data collection on late treatment morbidity. The United Kingdom Children’s Cancer Study Group (UKCCSG) already co-ordinates national protocols and guidelines for children with cancer, and this arrangement would ensure that appropriate referrals for children would be made from individual paediatric oncology centres to the proton facility. Clinical Relationships Strict
referral criteria – including clinical, histopathology and radiology reviews – will ensure that only appropriate patients will be referred; excellent communication between the dedicated medical and nursing staff in the proton centre and the referring centre will be required. A close link in terms of staff, buildings and other equipment to a major radiotherapy centre means that large-scale duplication could be avoided. This would enhance levels of care and reduce costs. This ‘Host’ centre would need sufficient capacity to ensure timely access to simulation, CT, MRI and CT/ PET. The number of paediatric cases requires some dedicated new staff but safe levels of care can be achieved only if the centre is sited with good access to general paediatric services and specific paediatric oncology. The current requirement for synchronous chemotherapy would continue in many patients. Centre design would need to allow for the time and space constraints of anaesthetised children, with adequate recovery rooms. Some cases may require photon therapy to drainage lymph node areas making integration with a host radiotherapy centre essential. Proton Centres should be involved in NCI trial clinical trials. Trials may involve comparison with conventional photon treatment but patients drawn from the catchment population of the host centre. A wide range of multidisciplinary care should be available for these complex patients. This would include general surgery, DNT, neurosurgery, orthopaedics, ophthalmology, specialist radiology and pathology.

**Technical support**

There are two models for a new centre for technical and engineering support. The Centre could undertake its own maintenance, systems engineering, hardware and software upgrades, safety systems and development work required to maintain clinical and research capacity. The alternative is to buy a complete turnkey system with follow-on service contracts from a commercial vendor, which transfers considerable risk away from the clinical service. The relationship with that commercial vendor within the public/private partnership therefore becomes vital. The Centre would need some ‘in-house’ dedicated technical and engineering support. Access to a wider pool of expertise in Radiotherapy Physics again makes the relationship with a Host radiotherapy centre a key factor. Recruitment and training will be mutually enhanced. The immobilisation technology, dosimetry and physics aspects will need to be robust to ensure a safe clinical service. As part of national referral centre dedicated IT and data management with good clinical audit and quality assurance are essential.

**General support**

Patients and carers will be travelling from significant distances and need accommodation for as long as 6 weeks or more. Medical assessment, counselling, preliminary immobilisation arrangements and planning scans could be performed in a single visit. The patients might then return for their more prolonged treatment stay after a suitable time interval. Accommodation should be provided for most patients. At Clatterbridge, cheap local hotels/ travel lodges are used for self-caring eye patients. The patients for other proton indications are different with potentially higher dependence levels so that an alternative model is necessary. With more prolonged treatment, temporary acute reactions arising from either treatment or problems from other co-morbid conditions may occur. Although both paediatric and adult patients will need to be of good performance status to justify treatment, they will have a higher degree of dependency and likelihood for some medical or nursing intervention. Independent hotel accommodation seems inappropriate for all patients. A hostel within the hospital environment seems most appropriate with some on-call cover from the host centre. The numbers of patients on treatment at any one time is clearly dependant on fractionation and for calculations an average of 30 fractions is assumed. The numbers in Table 4 illustrate the effect of both one and two centres being made available. Funding arrangements for both hostel and travel would need to be addressed. The current discrepancy between Scotland and England in commissioner agreement to cover travel costs is noted. Academic Links The advantages of close working with a University Department of Engineering and Physics lie in the opportunities for partnership and research. It potentially opens avenues to new funding support as well as ensuring that the centre remains able to offer the latest technical advances. The building of a fixed-beam chamber for research allows capacity for industrial activity and income. Radiotherapy and Cancer Biology links would be an advantage. Physical Sitting Proton therapy should be based on a National Referral pattern, with caseload and patient access dictating where a Centre should be built. After a first centre is built a second would be based on capacity requirements but should be sited to make geographical access for patients easier. An alternative is to ensure that adequate space is available for an expanded number of treatment chambers in an initial facility. This report can only make recommendations for the provision of services to England, which constitutes 84% of the 60 Million UK population. It seems unlikely that independent centres can presently be justified for Scotland, Wales or Northern Ireland but in siting a facility it would important to bear in mind patient access from these countries and the Republic of Ireland. Our strong recommendation is that any centre(s) should be sited close to an existing Integrated Cancer Treatment Centre with adequate patient support, medical and physics expertise. Close links to University Physics, Engineering and Cancer Biology would be advantageous.

**Staffing**

The justification for a dedicated workforce is contained elsewhere. The posts necessary to support each centre are contained in Table 5. For medical staff this includes the Host staff costs. Host staff costs are not included as potential business models are variable. The total is therefore estimated at £1.7M per annum.

**Commissioning mechanism**

**Patient selection**

To ensure clarity about indications for proton therapy and ensure equity of access, it is recommended that a consensus group is formed to devise tight diagnostic and evidence based criteria. Whilst the majority of the diagnoses given within the lists in section – are clear-cut, criteria for access in categories such as the difficult anatomy and re-treatment, would need to be assessed by physical dose distribution comparisons and
medical benefits are judged to be high. Within existing NHS frameworks this would most appropriately fit within the National Institute for Health and Clinical Excellence (NICE)\(^29\) whose remit includes:

- health technologies - guidance on the use of new and existing medicines, treatments and procedures within the NHS
- clinical practice – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.

Such a group, with informed input regarding radiation dose, would provide the basis on which National Commissioning and referral could take place.

**Service commissioning**

In order to ensure coordination, funding, appropriate selection a Proton service would need to come within the remit of the National Specialist Commissioning Advisory Group (NSCAG)\(^30\). Many rare and specific cancers are already treated within NSCAG e.g. Choriocarcinoma, Ocular Oncology, Primary Bone Tumour, Psuedomyxoma and Retinoblastoma. It should be noted that at least 2 of these diagnoses come within the list of tumours likely to be treated with protons. A set of clinical guidelines, procedures and protocols of care would allow the Centre to relate to NSCAG. Such systems are essential to ensure compliance with agreed protocols. Web based referral forms, videoconferencing access and electronic transfer of diagnostic images would allow rapid access and acceptance for patients. Specific considerations within Cancer Waiting Time targets will be necessary as the overall pathway will be complex.

It would be essential that multiple Centres worked to shared access, protocols and audit standards NSCAG funding would ensure top sliced funding streams for the service and equity of access for patients. It would be inappropriate for this service to come within the Payment by Results (PBR) Tariff system. However if concurrent proton therapy was necessary within the Host Centre this could be reimbursed by PBR.

**Costs**

The extended lifespan of the basic equipment has a significant impact on capital investment and treatment costs. The present cost for a patient treated at Clatterbridge Centre for Oncology is approximately £12,000 for 4 proton fractions. Costs will be significantly affected by centre design, construction and configuration, length of working day and fractionation. Estimates internationally seem remarkably consistent. Treatment costs are likely to be up to 2.4x a complex photon treatment cost for protons\(^1\)\(^3\) with Carbon Ions being a factor of 5-10 x more expensive than photons. The Japanese are moving towards a fixed cost of £15,000 per patient regardless of fractionation. A European model of £1,000 per fraction would require adjustments for different fractionation regimes. The basis of the new HRG system for radiotherapy due to be introduced in 2008 recognises the considerable resource and cost involved in preparation, planning and delivery of complex treatments. So a minimum cost regardless of fractionation seems a sensible model with fractionation factors added. Estimates for a long (20 – 36) fractionated course will consequently be £24,000 – £28,000. If the full referral numbers identified in section 5.6 of patients with a strong indication are treated the total costs would be in the order of £36M. This represents 20% of the 2004/5 NSCAG budget which would clearly need adjusting. Whilst these costs may seem high they should be seen in the context of new drug costs recently adopted such as adjuvant Herceptin for Breast Cancer (£25,000 for 1 year with a total NHS impact of £107M) and Imatinab for palliative GIST patients (£22,000 for 1 year if responding). There are industrial uses in component testing, semiconductors and radioisotope production, etc that would attract significant income to a Centre, with use of equipment overnight and at weekends.

**Cost effectiveness**

There is some published literature on cost effectiveness\(^1\)\(^6\). The cost of either failing to cure a patient, e.g. repeated complex surgical procedures, or the cost gain of avoiding morbidity is important in Advice to NRAG\(^23\) evaluating proton therapy. The extant data using detailed evaluation suggests that protons are cost effective in a wide variety of clinical indications. However detailed prospective data on treatment effects, risks and costs are not available. It is likely that cost savings are more likely with the defined classical proton therapy targets. Recent data on the increased risks of second malignancy with conventional photon therapy may alter the comparison to the benefit of protons. The most detailed analysis relates to paediatric cancer and the treatment of medulloblastoma where a reduction in IQ loss and growth hormone deficiency were
the most important factors in cost effectiveness leading to a cost saving of £20,000 and 0.68 quality adjusted life years per patient.27

Management of the interim period
A small number of patients are referred for proton therapy abroad. Some of these are not even receiving the full benefit since a 25%-75% mixture of proton and photon therapy is used in Europe. The cost for a recent patient treated in France was £21,820. With increasing acceptance of the criteria for referral within the initial high priority group it is anticipated that the demand from clinicians, patients and families will increase. As it will be some years before a large UK proton therapy exists, work on commissioning arrangements and referral criteria should be established without delay. The establishment of a relationship with one or more proton centres abroad is necessary to streamline the practical and clinical aspects of referral and care. Once a UK proton therapy centre has been agreed and funding arrangements secured, a commissioning period of 3 years is anticipated. Critical staff (clinicians, medical physics and radiographers) should be sent in increasing numbers to gain experience in the centres abroad and to support patients from the UK.

Stakeholders and bids
There is very significant interest from Academic, Engineering and Applied Physics bodies within the UK (EPSRC), PPARC). This involvement is attractive to foreign equipment manufacturers and potentially encourages investment. There are established collaborative research groups such as the UK Research Network on Biomedical Applications of High Energy Ion Beams, the British Accelerator Science and Radiation Oncology Consortium, Academic Clinical Oncology and Radiology Research Network (ACORN), National Cancer Research Institute (NCRI) and Cancer Research UK (CRUK). The European Network for Light Ion Research (ENLIGH)T was influential in achieving respective National approval to construct four centres although defunct after the end of the grant. (Heidelberg Ion Therapy (HIT); the Centro Nazionale di Adroterapia Oncologica (CNAO) in Pavia; Advice to

NRAG 25 MedAustron in Wiener Neustadt; and ETOILE in Lyon. CERN is at present trying to coordinate European activities and re-form a network. Partnership with equipment manufacturers has been productive in setting up clinical facilities in other countries. Even in the USA it is clear that the significant initial capital cost has led to wide public / private partnerships to establish a new centre. The MD Anderson partnership is between Investment Banks, Healthcare Facility Developers, Charitable funds, Research Funding Bodies and equipment manufacturers.28 A similar model might be the most successful method of achieving a UK centre without capital cost provision by the DH. The success of any proposed UK centre would require a coordinating body to bridge the gap between government, finance, industry and research. The involvement of Research Funding Bodies such as the NCRI and CRUK is essential. However it is clear that no bid will be successful without a clear signal from the DH that Proton Therapy is regarded as a National Healthcare priority and an appropriate infrastructure put in place for referrals and revenue funding. There are several examples of successful major PFI schemes for Major Oncology and Radiotherapy centres.29 The Ministerial Industry Strategy Group (MISG)30 has been successful in bringing together Government and the Pharmaceutical Industry. There is considerable potential and scope for a cross-governmental department collaborative project arising from the terms of reference of the Healthcare Industries Task Force (HITF)31 which has already identified that the UK is slow to adopt new technology. The DTI already supports International Particle Physics research at CERN. Proton Centres would be a suitable opportunity to address both the Health of the Nation and the Wealth of the Nation, blending healthcare with clinical, engineering and physics research along with technology development and services to industry. Any clinical Proton facilities would be complimentary to new initiatives for longer term development of proton beams, such as through the Basic Technology Programme (Research Councils UK).
References

documents
ERGONOMICS FOR THE HOSPITAL SETTING

ARTICLE BY CRAIG SHEPHERD

Abstract

The correct incorporation of ergonomics into the hospital can bring true cost savings when set against injuries incurred by hospital staff. In this article, advice is given on hazard prevention controls, patient lifting equipment and "engineering out" high risk events.

Earlier this year President Bush signed into law SJ Res 6. This action repealed the Occupational Safety and Health Administration’s ergonomics standard and marked the first time the Congressional Review Act was implemented. Numerous reasons for the repeal were noted including the overall cost and compliance challenges for businesses. The President stated that his Administration would continue to work on a “comprehensive approach to ergonomics” that would respond to the concerns brought forth with OSHA’s standard.

Regardless of one’s position on this issue, the nice thing is that many more people are talking about ergonomics and gaining a better understanding of what ergonomics is all about. Both sides of this issue can agree that even though OSHA’s ergonomics regulations were repealed, problems still exist and there is much ergonomics has to offer. This is readily apparent when one looks at data regarding musculoskeletal injuries in the health-care industry. Safety and health statistics compiled by the Bureau of Labor Statistics continue to show a high number of sprains and strains among nursing aides, registered nurses, and orderlies.1 The majority of these incidents involved the back.

The problem for this population is that they are often exposed to physical demands that are the result of handling tasks unique to their industry. Traditional body mechanics principles are not always easily applied to positioning or transferring patients.2 Nurses, nurses aides, and orderlies often find themselves in situations requiring extended reaching with a load (as in reaching across the bed to position the patient or prepare for transfer), lifting loads with a flexed low back, and twisting with a load. All of these are risk factors for low back injury. Add to these awkward postures the possibility of an abrupt change in the load during a transfer, and it is easy to see why musculoskeletal injuries continue to be prevalent. In any injury prevention programme, it is important to focus on developing a safety culture within the facility. This safety culture differs from a programme. A programme usually denotes a process that has a beginning and end, while a culture is an ongoing way of life that permeates the organization throughout. This culture should consider all feasible means of avoiding injury. The hazard prevention controls it could consider are:

- Engineering controls – use of equipment/technology.
- Behavioural or work practice controls – training, body mechanics, or other joint protection principles.
- Administrative controls – policies/procedures geared toward injury prevention.

These might include staffing ratios, job rotation or job enlargement. The use of personal protective equipment would be a fourth area of consideration. Numerous studies exist that demonstrate the value of focusing our efforts on “engineering out” ergonomic risk factors through the use of available technology. Hospitals that have focused their efforts here have realized significant reductions in injuries associated with the noted risk factors. In a study conducted over a three year period at a large long-term care facility, back injuries were reduced approximately 74% with a prevention programme using mechanical lifting devices.3 A variety of assistive devices are available that can control for risk factors associated with patient handling:

- Sling lifts work well for maximum assist type transfers. These can be on portable units or ceiling mounted.
- Standing assist lifts have a sling that is looped under the patient’s arms. It is a useful device for chair transfers and toileting where the patient can weightbear to some degree.
- Sliding assists such as air flow mattresses and sliding sheets reduce the coefficient of friction and, hence,
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Ergonomic equipment purchases often pay for themselves exponentially over time. The amount of equipment and training required could be controlled by considering the concept of lift teams.

Less force is required to perform the task. There are also stretchers with built-in transfer devices.

Bed design – a number of advances in this area allow such things as converting a bed to a chair with the touch of a button. This eliminates the handling required with bed to chair transfers. This is of particular benefit with those patients requiring maximum assistance.

There is additional cost associated with the purchase of equipment. This investment, however, often pales in comparison to the true cost of lost-time injuries. Ergonomic equipment purchases often pay for themselves exponentially over time. The amount of equipment and training required could be controlled by considering the concept of lift teams. These teams are trained in the use of special equipment and techniques. They respond throughout the hospital and can reduce risk to the larger care giver population. This can also free-up nursing staff to attend to other responsibilities.

Given the current state of nurse staffing, this is an intriguing concept for some hospitals. A six-month pilot programme at an Ohio hospital demonstrated a 100% reduction in nursing injuries on one unit using this concept. This entire process of developing a safety culture must begin with a firm commitment to resolving the real problems. High risk job tasks must be identified through job hazard analysis. Recommendations based on this analysis must be made. High risk jobs must be re-designed to “engineer out” risk factors associated with them. Finally, a method must be in place to measure the effectiveness of the abatements selected.

Emphasis must be placed on management commitment and employee involvement in the process. There should also be an understanding that ergonomic principles can be applied to all areas within the hospital setting. Proper analysis and design of computer workstations, nursing stations, food service areas, maintenance, laundry, and transport areas can yield significant benefits for those employees as well. A good way to get your hospital-based ergonomics programme started, is to perform a job hazard analysis of tasks that have a high injury correlation. Data can be gathered from OSHA 200 logs, staff input, and incident/injury reports among others. Select abatement measures that have the greatest likelihood of reducing or eliminating the problem. A pilot study involving the abatements selected for a chosen high risk area is an excellent way to demonstrate effectiveness and cost/benefit factors. The results of your study may serve as motivation for other departments.

References