2006 ISO General Assembly - Open Session on Electronic Healthcare and Standards

Held as part of the 29th International Organization for Standardization (ISO) General Assembly

Ottawa, Canada on 2006-09-14

Final Report Submitted to Industry Canada

December 20, 2006

Revised January 11, 2007

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1. Introduction

This report has been prepared by the Standards Council of Canada (SCC) for Industry Canada. It summarizes the presentations and outcomes of three sessions presented as part of an Open Session on Healthcare held in Ottawa on September 14, 2006.

2. Background

This Open Session on Healthcare called "Healthcare – Global Challenges and Opportunities for International Standards" was held as part of the 29th General Assembly (GA) of the International Organization for Standardization (ISO). The Standards Council of Canada (SCC) hosted the 29th ISO General Assembly and related meetings in Ottawa, Canada during the week of 10-16 September, 2006. This was the second time that ISO held a General Assembly in Canada. The first Canadian hosting was in 1982 in Toronto. One hundred and seventeen (117) of one hundred and fifty six (156) member bodies attended this year. Canada was one of ISO's 25 charter members when it was created at a meeting in London in 1946.

The Open Session was attended by over 460 representatives. Of these, about three quarters were official ISO delegates representing about 120 countries. The others were Canadians invited from industry, government, academia, consumers and the general public from across the country.

The panel of speakers included Canadian and international experts in the healthcare field, and addressed a range of globally relevant topics related to healthcare technologies and services for the developed and developing world.

The ISO General Assembly meetings were held at the Château Laurier, however, the Open Session was held at the Ottawa Congress Centre.

The day was co-moderated by:

- Elma Heidemann, former Executive Director of the Canadian Council on Health Services Accreditation; and,
- Phil Hassen, Executive Director of the Canadian Patient Safety Institute.

3. About the SCC and ISO

The Standards Council of Canada is a federal Crown corporation with the mandate to promote efficient and effective standardization in Canada. Through the collaborative efforts of the SCC and its partners, standardization is contributing to the social and economic well being and health and safety of Canadians. As Canada's national standardization body, the SCC represents national interests at ISO.

The mandate of the SCC is to promote efficient and effective voluntary standardization in Canada, where standardization is not expressly provided for by law and, in particular, to

a) promote the participation of Canadians in voluntary standards activities,

b) promote public-private sector cooperation in relation to voluntary standardization in Canada,

c) coordinate and oversee the efforts of the persons and organizations involved in the National Standards System,

d) foster quality, performance and technological innovation in Canadian goods and services through standards-related activities, and

e) develop standards-related strategies and long-term objectives, in order to advance the national economy, support sustainable development, benefit the health, safety and welfare of workers and the public, assist and protect consumers, facilitate domestic and international trade and further international cooperation in relation to standardization.

Further information on the SCC can be found at www.scc.ca.

ISO is a non-governmental organization with 156 members (one per country) and the world's leading developer of international standards. It maintains close working relations with many other international and regional bodies, including specialized organizations representing industry, consumers and regulators. ISO's library includes nearly 16,000 standards and standards type products, produced by approximately 700 committees and sub-committees. Further information on ISO can be found at www.iso.org.

ISO's work by sector is summarized in the following table:

Table 1: ISO Production by Sector (as of December 31, 2005)

	Sector (per International Classification of Standards)	Draft and Final Draft Int'l Standards		International Standards			
		New	Total	New	Pages	Total	Pages
1	Generalities, infrastructures and sciences	210	204	98	5 435	1 406	49 761
2	Health, safety and environment	142	131	59	2 267	658	20 252
3	Engineering technologies	654	550	378	18 662	4 099	169 843
4	Electronics, information technology and telecommunications	385	298	205	15 631	2 447	161 132
5	Transport and distribution of goods	250	229	131	5 180	1 710	44 918
6	Agriculture and food technology	98	95	43	1 386	954	20 335
7	Materials technologies	446	418	265	9 221	3 943	93 121
8	Construction	68	60	41	2 717	311	11 068
9	Special technologies	40	24	20	797	121	3 064
	TOTAL	**2 293**	**2 009**	**1 240**	**61 296**	**15 649**	**573 494**

Source : www.iso.org

4. Organizing the Open Session on Healthcare

Planning the one day Open Session was done within the context of planning the ISO General Assembly which took approximately two years. The Open Session was co-planned by the SCC (Begonia Lojk, Manager Standards Governance) and ISO Central Secretariat (Béatrice Frey, Head of ISO Central Secretariat).

The theme of *healthcare* was jointly selected by ISO and SCC in the fall of 2004. It was deemed a globally relevant and timely topic for the standards community. In the fall of 2005, the SCC established a programme committee to act as an advisory body to develop concepts for the Open Session, including the format, topics, potential speakers and moderators. The committee was chaired by B. Lojk of SCC. It included seven members (of eight invited), consisting of representatives of each of the standards development organizations which SCC accredits, the Chairman of SCC's committee on ISO matters, a representative from Health Canada, a representative of SCC's Governing Council, and a representative of SCC's Committee on consumer matters. Most individuals had a background in healthcare standards. The invitation letter is included in Annex A.

The committee met by teleconference on three occasions:

- December 21, 2005
- January 10, 2006, and,
- January 19, 2006.

SCC and ISO then met in person in Geneva the week of March 20, 2006 to finalize the Open Session programme. Over the next month, speakers and moderators were contacted.

The final programme was designed to highlight the key issues related to standardization, and to provide perspectives from various regions of the world, including a developing country. Speakers were identified with the assistance of other international members of ISO.

The Open Session promotion was done through ISO which issued a brochure to the international delegates. In addition, SCC prepared and sent 400 copies of a larger brochure to attract Canadians from various sectors. SCC also issued media releases of the events.

5. Delivering the Event

Staff from all branches of the SCC were involved in the delivery of the event, including registration, setting up and support for the "cyber café" with 20 computer workstations available for delegates for use throughout the week, room monitors, note takes, meeting logistics, hotel accommodations coordination (3 main hotels, plus 3 secondary hotels for overflow), on-site coordination of promotion and media (interviews with CJOH, Ottawa Citizen Editorial Board, official welcome of VIPs), etc.

For the Open Session, three SCC staff were assigned as note takers, four as room monitors (to assist delegates), and the SCC lead plus an assistant were on site to work

with the moderators, speakers and ISO personnel. Simultaneous interpretation was provided in English, French and Russian, the three official languages of ISO. A speakers breakfast was held the day of the Open Session with the ISO Secretary General per ISO tradition to ensure all international speakers are well coordinated.

SCC's lead met with the moderators the evening prior to the Open Session to prepare final details of how the day would be managed.

6. Setting the Context

At the onset of the Twenty-first Century, the reality of globalization and international integration is changing the very concept of global healthcare. The rise of electronic-dependent medical technologies and the need to coordinate health care responses quickly and efficiently across borders and across oceans has all come with a significant rise in cost to government and industry alike. As governments across the planet attempt to restrain the rapid rise of healthcare expenditure, different methods of cost reduction and streamlining are being examined and implemented in efforts to help reduce redundancy and avoid the wasteful usage of time and resources of healthcare professionals.

In Canada the rising cost of healthcare coupled with an overall aging population, a growing shortage of healthcare professionals, and an ever-changing medical needs environment (e.g., SARS, AIDS, Avian Flu, etc.) has caused both the healthcare industry and government at all levels to consider new and different methods to respond to the health and medical needs of the Canadian public. One such area that has proven repeatedly beneficial has been the use of various components of Canada's National Standards System.

7. Speakers

Speakers were asked to discuss the role of International Standards in terms of how these have contributed to advancing healthcare, and what some of the challenges as well as opportunities might be for the international community of standards and conformity assessment.

The panel included speakers who provided an international perspective, such as the World Health Organization (WHO), as well as experts on healthcare policy, regulation, e-health, and those involved in the delivery of services within the hospital environment as well as homecare.

The agenda and speakers were as follows:

Challenges in Healthcare Worldwide

- Dr. Timothy E. Evans, Assistant Director General, Evidence and Information for Policy, World Health Organization (WHO)

Voices for Change in Healthcare

- Dr. Neil Yeates, Assistant Deputy Minister, Health Products and Food Branch, Health Canada

Standards Advancing Healthcare in Developing Countries

- Mamadou Sidibé, Technical Advisor to the Ministry of Health, Mali

E-Health – Integrating Information Technology into Healthcare

- Richard C. Alvarez, President and CEO, Canada Health Infoway (CHI)

Putting Patient Safety First – Quality in the Hospital Setting

- Dr. Thomas H. Clutton-Brock, Department Head, and Senior Lecturer in Anaesthesia and Intensive Care, University of Birmingham, UK

Standards as a Tool for Health Policy and Regulation

- David Rowlands, Manager, Health Informatics, National E-Health Transition Authority, Australia

Medical Devices – The European Approach

- Norbert Anselmann, Head, Standardization Unit, Enterprise and Industry, Directorate-General, European Commission (EC)

Bringing Healthcare Back to the Home

- Dr. Toru Watsuji, Sharp Corporation, and International Society of System Health Science, Japan

Dr. Timothy Evans of the WHO was not able to attend in person and instead provided his opening address by video presentation.

Assistant Deputy-Minister Neil Yeates of Health Canada Health Products and Food Branch presented Canada's perspective on Healthcare, setting the stage for a discussion on leadership and policy issues.

An interesting developing country perspective was then provided by Mr. Sidibé of the Ministry of Health of Mali.

The next presentation, also by a Canadian, focused on e-health and the challenges of health records. Mr. Richard Alvarez, President and CEO of Canada Health Infoway provided that. The next one turned the focus on quality and hospital safety, looking at the challenges of managing data from the perspective of Dr. Thomas Clutton-Brock, an anesthesiologist from the University of Birmingham in the UK.

The afternoon session examined health policy and regulation; one providing the Australia perspective on health policy and standards, by David Rowlands, Manager, Health Informatics, National E-Health Transition Authority, Australia.

The other session provided the European Union's approach to regulating medical devices and the use of standards, by Norbert Anselmann, Head, Standardization Unit, Enterprise and Industry, Directorate-General, European Commission (EC).

Finally, the day was capped off by a presentation from a Japanese expert, Dr. Toru Watsuji, Sharp Corporation, and International Society of System Health Science, Japan. He explained a pilot project providing homecare through electronic means aimed at addressing the challenges of an aging population.

Annex B provides the Open Session programme and the presentation abstracts. This information and the presentations [1] are also available on the ISO website at:

http://www.iso.org/iso/en/commcentre/presentations/ga/gaopen/2006healthcare/index.list

The available presentations are being submitted with this report under separate cover.

8. Themes

In discussions with Industry Canada prior to the Open Session, it was determined that three themes were of interest:

- Electronic healthcare;
- Standards as a Tool for Health Policy and Regulation; and,
- Putting Patient Safety First- Quality in the Hospital Setting.

The following elaborates on each of those three themes.

E-Health – Integrating Information Technology into Healthcare

Presentation - From standards for medical records, to standards in e-health services and delivery, certification of healthcare professionals and the accreditation of medical facilities speakers explored the link between standards and the growing need for e-health initiatives in Canada. In an age of innovative health technologies, limited resources and international health issues, electronic interoperability offers myriad applications and solutions for healthcare providers and institutions. With a population of nearly one million healthcare professionals in Canada and 40,000 separate medical record systems, the obstacles facing Canadian health services were well illustrated.

Challenges - There is an urgent and growing need to better manage health information, moving from a paper-based to an electronic system. This is especially true within Canada where, in 2006, only 23% of physicians use electronic records to track their patients. This is in contrast to the UK and the Netherlands where the number of physicians using electronic record management approaches 89% and 98%[2] respectively. This movement to the use of e-based healthcare has become global in scope and is being demanded by consumers to be more transparent and timely, while simultaneously taking into consideration increasing levels of self-care for an aging and mobile population. It is a fact that any electronic system implemented will need to rely on architectural support and interoperability supported through a robust standards development system.

Other challenges raised by the panel include the relationship between Codex, the WHO and ISO in setting standards, the codification of best practices, privacy of health

[1] The complete presentation by Clutton-Brock was not available publicly for privacy issues, given that it consisted of several pictures of individuals in hospital settings. The summary slide of conclusions is being provided with this report under separate cover.

[2] http://www.cmwf.org/publications/publications_show.htm?doc_id=419208

information, and ensuring that the needs of developing countries are also addressed in any standards development.

Recommendation - In implementing electronic healthcare there is a need to re-engineer the industry, change the way we manage the information while keeping costs in check. Some opportunities exist to create clear, more meaningful relationships between Standards Development Organizations, vendors, clinical professions, and consumers at large. Given its global reach and in particular its engagements with both the developed and developing nations, ISO is particularly well-situated to provide the requisite strategies and fora for countries to embark on developing standards-based solutions to health informatics.

Standards as a Tool for Health Policy and Regulation

Presentation - Standards are recognized as an integral part of "Smart Regulation" and associated changes to the Canadian regulatory process. In the healthcare context, standards can be utilized as an effective tool to reduce administrative costs, promote and ensure system interoperability through accreditation of institutions and professionals, demonstrate regulatory compliance, implement quality or environmental management systems (QMS and EMS respectively), demonstrate the competence of healthcare personnel, and open new markets for medical device manufacturers.

Challenges - Yet even with the opportunities listed above, the panel identified many key challenges in developing standards in healthcare. There is a need for standards training, maintenance, conformance, education, implementation, and access to adequate resources throughout the standards life-cycle. Another key obstacle identified was the need to broadly engage stakeholders from the medical field in standards and regulatory development in order to assist in building a global solution. ISO and many of its Member Bodies were identified as having available expertise and experience that could be brought to bear to the needs of Canadian government health policy and regulation.

Recommendation - Given the requested desire for more transparent and timely healthcare, one of the recommendations coming out of the session was for ISO to consider standards development for primary care and prevention strategies. There is also an opportunity for ISO to partner with existing professional healthcare groups as well as clusters of nations who are experiencing similar health-related issues.

Putting Patient Safety First – Quality in the Hospital Setting

Presentation - The sophistication and complexity of hospital-based medical care is increasing constantly and is growing intertwined with a persistent drive to improve efficiency and productivity. In addition, patient's needs are changing: life expectancy is increasing, fewer conditions are considered truly incurable, and patients rightly expect both a high and dependable level of safety and quality in the healthcare they receive.

Effective use of standardization in health regulation and industry will allow for medical knowledge to become more accessible, and for health practitioners while remaining up-to-date and far less dependent on specific technology. The adoption of standardization practices will streamline and reduce redundancy within health education and training

programs, allowing skills to be more transferable both within and between countries. In the development of effective regulations and standards, the involvement of clinicians and their expertise is essential. Standards developers, regulatory officials, and medical personnel bear the responsibility to improve communications in order to facilitate this key element of the development process.

Challenges - Despite the opportunity standards represent to the medical community, many challenges exist. The first is that there is a high-level under-appreciation within the medical industry of the standardization system. This is partially due to a need for more medical practitioners to take part in the standards development process and in related health care regulatory activities. Secondly, medical staff at all levels also require additional education on the use of standards in their fields. Training in standards, as well as clarity of the standards themselves, would be essential to prevent mishaps. Moreover, these standards would need to be internationally accepted to allow for maximum benefit to be achieved in patient care (i.e., universal training of medical staff, greater availability of medical equipment, personnel and reduction in cost-of-care).

Recommendation - In putting patient safety first, ISO recommended ensuring that appropriate connections between standardization and national health strategies be established. This would be accomplished through liaising at the national and international level with health regulators, accreditation agencies, clinicians and industry to promote the use of voluntary standards in a healthcare system context, as well through collaboration with other standards development organizations to optimize resource and programs.

9. Question and Answer Session and Wrap-up Comments

Two question and answer sessions were held, one just before lunch and one at the end of the day, prior to wrap-up. The questions, answers, comments and wrap-up discussion are presented below using the speakers' own words:

Question: Canada does not have a federal agency that sets and defines standards for accreditation. How are we going to implement complex standards and systems into resource challenged regions?

Answer: To start, these standards will be implemented at the most advanced facilities within the country. This will act as a "spring board" for other regions. One place is better than none, then we can expand as possible. It will be learn as you go.

Question: Are hospital departments registered to ISO 9000 in Canada?

Answer: Some medical facilities in Canada are registered to ISO 9000.

Question: If a federal organization sets the accreditation criteria based on ISO standards for laboratories, what prevents ISO from setting those standards too high for developing countries?

Answer: ISO actually looks to set the bar at a minimal level and consults developing country members when drafting or adopting standards. This allows members to openly discuss best practices at the global level.

Question: Can sectoral issues within the healthcare industry be included as a focus for ISO standardization? (e.g., process standards, self care, health promotion etc.)

Answer: It was stated that there exists a need for more awareness given to primary care and prevention at the ISO. To this end, it was agreed that sectoral health care issues would be future topics for discussion at the ISO.

Question: How will the Infoway project affect mental healthcare in Canada (both that which is currently covered and that which is not)?

Answer: E-Health would be available with patient consent.

Question: Is it a Canadian initiative to have ISO 9000 implemented in Canadian hospitals?

Answer: Yes, it is definitely an initiative. It may be more widespread than indicated by the delegate from BC. In BC, it took 18 months to achieve ISO 9000, and two iterations.

Moderator follow-up question: Are you asking for a repository of information for Canadians to access?

Answer: Yes, that would have been a tremendous help, something to allow for the transfer of information.

Question: Regarding the medicalisation of many of the healthcare systems across the world, there is a need for inter-sectoral transfer of information. Sometimes it is the very basic, very simply solutions that make a difference. How do we position standards to have a high impact? How can standards impact the greater population? Maybe we need to promote healthcare and hygiene.

Answer: The implementation and promotion of primary healthcare is essential across the board, however, there is also a need to implement a more elaborate perhaps technology based solution so that healthcare can be dealt with in the future.

Infrastructure needs to be developed and implemented. Training on how these are to be used and training for updating credentials are essential.

Prevention and primary healthcare are priorities, but we also need to implement the infrastructure to allow growth.

Question: Is there an opportunity for ISO to reach out internationally to associations and work being done by member bodies and bring this together for all?

Answer: (none – question was a suggestion and noted).

Question: What is the WHO doing to recruit health care professionals and make sure that resources are available for developing countries?

Answer: It is a major problem. It is one of the essential elements not only in quantitative terms but in qualitative terms. Efforts are being made in certain areas to entice professionals to the developing countries.

A program is in place to bring experts in for 2-3 weeks to teach expertise in areas of certain specialities.

Comment: We need good inter-sectoral cooperation to ensure clean, healthy water.

Comment: Note the importance of infrastructure and make sure you take it into account when implementing standards.

Comment: Standards empower people who may have less expertise; the reliability of prescripting people in their homes. Standards contribute to making things right but they cannot fix all problems. We need to take care of the workforce or we will not have a healthcare system.

Question: How will e-health benefit mental health professionals?

Answer: Privacy of patient information is key. There is a major pilot project in BC on how to implement e-health into the mental health field. Access to information is based on patient approval.

Question: What plan should a developing country have to promote quality? Is there a standard available for primary care?

Answer: It is difficult to have one standard that will address primary care. Most standards will reflect quality of care – have a contract with WHO for services. Standards for public safety are difficult and very new across the world. One of the most important things is what is quality: What do you need (structure) for quality? What do you need to do for quality (process)? What results do we want?

The process for standards for public health is far-reaching and encompasses many sectors and areas.

Wrap-up Comments

There needs to be clarification between what is under ISO and the WHO purview. The WHO has primary responsibility for healthcare standards. ISO has it for products, management, etc.

Note the importance of privacy with respect to electronic health records.

Developing countries are users and developers, therefore, we need to make sure that developing countries are involved with implementation.

Tim Evans (WHO) clearly summarized the issues that make up healthcare and the complexities.

We have noted the following:

- the importance of electronic data collection and its use;
- patient safety;
- the quality and process management concerns to make things more efficient;
- the importance of training and certification, also for upgrading training;
- the need to attract resources;
- the importance of harmonization; and,
- that there is a role that ISO can play in approving healthcare standards.

10. ISO Resolution and Conclusions

There was a consensus that healthcare needs to be further understood, in particular, issues with respect to accreditation and standards setting. Some such activities in certain countries and regions are not currently aligned with ISO's mandates and processes. Further discussion would advance the identifying differences, so as to assist in overcoming obstacles when necessary.

FAA, Boeing, Airbus, Embraer and Bombardier don't compete over safety. Safety is an expected social and business ethic, and should not be a means to assign or achieve greater competitive market value. Similarly, ISO should foster a non-competitive, multilateral drive for standards-based improvement in healthcare.

ISO should strengthen its awareness of ongoing issues in developing countries, and work to ensure its processes and products better meet the needs of these countries.

Certainly, the role of governments is understood with respect to supporting standards development, but ISO has an opportunity to work more closely with governments in the strategic implementation of standards to the benefit of society at large.

The Open Session was discussed the following day at the ISO General Assembly which passed the following resolution:

ISO Resolution 12/2006- Open Session on Healthcare

the ISO General Assembly,

- *referring to the open session "Healthcare – Challenges and Opportunities for International Standards",*
- *thanks the moderators Elma Heidemann and Philip Hassen for their efficient handling of the session and the speakers for their most interesting and challenging presentations which underlined that the range of possible areas for the contribution to healthcare expected from International Standards is exhaustive,*
- *asks Council to review the following recommendations resulting from the open session and to take appropriate action as to their implementation:*
- *to ensure that appropriate connections between standardization and national health strategies and programmes, in particular in relation to e-health systems and the dissemination of good management practices,*
- *to promote the use of voluntary standards in the context of healthcare systems,*
- *to liaise at the national and international levels with regulators and policy makers in health sector, such as the World Health Organization or the Global Harmonization Task Force, as well as with healthcare accreditation agencies, clinicians and industry,*
- *to collaborate with other standards development organizations in order to optimize resources and programmes,*
- *to promote the use of ISO standards as a tool for the improvement of health services in developing countries.*

Annex A

Invitation Letter to Members of Programme Committee

Standards Council of Canada
Conseil canadien des normes

To: See attached list

November 28, 2005

Reference: International Organization for Standardization General Assembly, Ottawa, September 10th to 16th, 2006 – Open Session Program Committee

Dear Sir/Madam:

I would like to invite to participate in a committee which will provide input to the SCC on an Open Session on Healthcare to be held in September 2006. This session is being held as part of the 29th ISO General Assembly which is being hosted by the SCC in Ottawa. The last hosting of the ISO General Assembly (GA) by the SCC was in Toronto 1982. In 2006, we expect about 375 delegates from 144 countries.

The schedule of key meetings is:

September 11, 2006 – Technical Management Board (TMB) meeting
September 12, 2006 – ISO DEVCO (Committee on developing country matters) meeting
September 13, 2006 – ISO GA day 1
September 14, 2006 – ISO Open Session (host country selects theme)
September 15, 2006 – ISO GA day 2 (closing)
September 16, 2006 – ISO Council meeting

Other than the ISO Open Session, all meetings will take place at the Château Laurier. The Open Session will be held at the Ottawa Congress Centre. There will also be social events such as an opening reception and a closing (Gala) dinner.

All meetings are closed to registered country delegations, except for the Open Session which will provide us with an opportunity to reach out to other Canadian stakeholders with a world-class event. The theme for the Open Session is "Healthcare". This theme has been arrived by mutual agreement between ISO and the SCC and is deemed as reflecting international as well as Canadian interests and priorities.

The ISO Open Session is considered part of the ISO GA (the "open" part), and as such subject to consultation and acceptance by ISO Central Secretariat. It is our hope to work collaboratively and propose a program which will meet their expectations and allow us to demonstrate Canadian leadership.

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As part of this committee, you would bring your knowledge of the healthcare sector, your ideas on how to organize the sessions and your knowledge of potential speakers (national and international). We expect most of the meetings to take place by teleconference, so no travel is anticipated. We would like to schedule the first meeting in mid-December, before the holidays so that we can proceed to finalize a draft program in early January. We are expected to have a draft program to ISO by mid to late February. They have made a suggestion that we consider "health technology" and "health services" as two separate streams, but the program committee is free to discuss this and other options. As well, ISO expects 2-3 speakers to be from Canada, with the others being from other standards bodies and international organizations.

I hope that you are interested and able to participate. Should you not be able to participate due to time constraints, your input is still very much welcomed by e-mail or otherwise. Please confirm your acceptance to Mr. Dean Brookes (dbrookes@scc.ca, (613-238-3222 ext. 452).

I look forward to hearing from you.

Begonia Lojk, P.Eng.

Manager, Standards Governance

c.c. Michel Bourassa, Sandy Watson

Annex A

Distribution List

ISO Open Session Program Committee

1. Standards Development Organizations (BNQ, CGSB, CSA, ULC)
2. Grant Gillis, Canadian Institute for Health Information and CNC-ISO Chair
3. David McKinnon, SCC Council and former CEO Ontario Hospital Association
4. Janet Hazelton, Nova Scotia Nurses' Union and CPIC
5. Marta Caris, Health Canada and CPIC

Annex B

Programme, Presentations, and Abstracts

14:00 **Standards as a Tool for Health Policy and Regulation**

Mr. David Rowlands, General Manager, Health Informatics, National E-Health Transition Authority, Australia

14:30 **Medical Devices – The European Approach**

Mr. Norbert Anselmann, Head, Standardisation Unit, Enterprise and Industry Directorate-General, European Commission (EC)

14:50 **Bringing Healthcare Back to the Home**

Dr. Toru Watsuji, Manager, Corporate R&D Group, Business Development Dept., Sharp Corporation, Japan

15:10 **Question Period and Wrap Up**

16:00 **Closing**

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Healthcare

Global Challenges and Opportunities for International Standards

Venue: Ottawa Congress Centre, Salon E*

14 September 2006

*Three-minute walk from the Fairmont Château Laurier Hotel (see map).

Health – it is our most precious commodity and when you stop to think about it, there may be no other issue that unites us more closely as human beings. As new technologies, changing demographics, and public safety issues reshape our world, they also impact our collective health.

Healthcare demands global cooperation, global solutions and global standards. The ISO Open Session on Healthcare, as part of the 29th ISO General Assembly being held in Ottawa, is an opportunity to build international consensus on some of the significant health challenges facing the world today, and to consider the role and capacity for International Standards to address these evolving concerns.

Canada is a fitting backdrop to address these pivotal issues because it shares many challenges being faced by other nations such as meeting the healthcare needs of an aging and diverse society, and ensuring that it can provide the same quality of service in its cities and in rural and remote communities.

Topics and speakers for the ISO Open Session have been selected to reflect the breadth of standards-related healthcare issues affecting developed and developing economies – from patient safety to electronic health records and homecare. Healthcare experts from Canada and around the world will draw on these and other examples, to demonstrate how International Standards may increasingly have a positive impact on healthcare practices and policies. The event will provide participants from various professional and cultural backgrounds who represent different viewpoints the opportunity to come together to develop a truly global perspective on our current healthcare challenges and to contribute to the ongoing dialogue about the future direction for standards in healthcare.

PROGRAMME

08:45 Opening

09:00 **Challenges in Healthcare Worldwide**
Dr. Timothy E. Evans, Assistant Director-General, Evidence and Information for Policy, World Health Organization (WHO)

09:30 **Voices for Change in Healthcare**
The Honourable Tony Clement (invited), Federal Minister of Health, Canada

10:00 **Standards Advancing Healthcare in Developing Countries**
Speaker to be confirmed

10:30 **Refreshment Break**

11:00 **e-Health – Integrating Information Technology into Healthcare**
Mr. Richard C. Alvarez, President and CEO, Canada Health Infoway

11:20 **Putting Patient Safety First – Quality in the Hospital Setting**
Dr. Thomas H. Clutton-Brock, Head of Department and Senior Lecturer in Anaesthesia and Intensive Care, University of Birmingham (United Kingdom)

11:40 Question Period

12:30 **Lunch**

Presentations and Abstracts

All presentations and abstracts are available electronically at:

http://www.iso.org/iso/en/commcentre/presentations/ga/gaopen/2006healthcare/index.list

1. Challenges in Healthcare Worldwide - Abstract

by Timothy E. Evans, Assistant Director-General, Evidence and Information for Policy, World Health Organization (WHO)

We live in a very complex healthcare landscape which can be summarized in the following grand challenges in systems performance:

- **Scale** – Safe, proven and cheap interventions not reaching those in need;
- **Distribution** – Those with unmet needs are disproportionately those with lesser means;
- **Protection/Safety** – Too many are worse off through encounters with the health system;
- **Systems capabilities** – Primitive frameworks and responses to dealing with complex challenges.

In order to address the above challenges, the combination of national as well as regional and global mechanisms from an intersectorial perspective is required.

As the relevant specialized agency of the United Nations, the WHO plays crucial role in this area. This includes standard-setting activities, in liaison with other organizations such as the Global Harmonization Task Force (GHTF), with respect to food, biological, pharmaceutical and similar products, as well as diagnostic procedures.

2. Voices for Change in Healthcare - Abstract

Abstract of speech by Neil Yeates, Assistant Deputy Minister, Health Products and Food Branch, Health Canada

Mr. Yeates will describe the structure of Canada's health care system, how it has evolved, and where standards have been used to strengthen health service delivery.

He will also share some thoughts about what comes next – the directions that Health Canada is pursuing to ensure that Canada's regulatory frameworks continue to serve in the best interests of Canadians in the decades to come.

Right now, one of the federal government's five key priorities is to work with provincial and territorial governments to ensure that all Canadians not only receive medically necessary services, but that they receive them within clinically acceptable wait times.

Toward that end, the Government of Canada is focussed on developing a patient wait times guarantee. While the details remain to be worked out, the approach will be based on set standards and benchmarks and the exchange of best practices.

Where it is in Canada's best interest, the Government of Canada will also endeavour to harmonize its practices with those of other nations. We recognize the inherent value of standards, at both a national and international level. High-quality standards, often developed by subject-matter experts in academia, industry, the health care field and user groups, have enormous potential for good.

3. Standards Advancing Healthcare in Developing Countries - Abstract

by Mamadou Sidibé, technical adviser to the Ministry of Health of Mali

Context

Globalisation and the liberalisation of trade are factors that have pushed industries everywhere to conform to international standards in order to gain access to markets. The resulting increase in the range of products available also enables consumers to make an informed choice in line with their expectations.

The imperatives of safety, the patient-doctor relationship (with the patient now seen as a user of care services) and the ever rising cost of medical treatment have led all concerned to seek standards as a means of limiting the risks. In this regard, we can mention, for example, the safety of blood products, the safety of anaesthesia practice, the consent of the patient to medical treatment and the medicalisation of the health system, together with activity and cost analysis.

The decision-makers have drawn up standards to permit assessment to be carried out, the actors being required to supply information in order to obtain financing.

In the developing countries, industries seeking access to western markets have embarked on the process of ISO certification.

In the past, the doctor-patient relationship was a vertical one with the patient in a position of passive acceptance. Today, however, the situation has been transformed by the development of the means of communication, permitting the patient to access medical information previously restricted to the specialist.

This has given patients a certain "power" since their tacit acceptance is now required as to the quality of service rendered by the care structures in terms of reception, information, ward conditions and the benefit and risks of the action proposed by the doctor.

Constraints

In the health field, the WHO issues directives that the member countries are required to adopt. It is in this way that the quality certification approach has emerged in the control of medicines and laboratory analyses.

As regards services, the trend has been to use private contractors who are under an obligation to achieve the results laid down in a specification. This type of relationship requires a change in behaviours and mentalities and the actor has to comply with a precise procedure.

While it is true that, in the developing countries, this has resulted in the establishment of mechanisms designed to confer rights on patients and make them the focus of the care structure, it is equally true that, in these countries, it is only the State through its health departments that is addressed.

Prospects

The dynamic for change generated by the introduction of standards must be harnessed for the benefit of the populations in question. Quality must become an obligation for the political decision-makers. At the same time, the actors responsible for implementing

health policies must be under an obligation to achieve results and to agree to their actions being assessed.

The ISO must support this approach through the results obtained in the developing countries and the impact on health costs through popularisation, training and monitoring on the ground.

In every country, developed or developing, there can be no escaping globalisation, generalised access to information and the demands of individuals that their needs be satisfied.

4. E-Health – Integrating Information Technology Into Healthcare - Abstract

by Richard C. Alvarez, President and CEO, Canada Health Infoway

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The rising cost of healthcare, ageing population, shortage of healthcare professionals and public pressure have fuelled Canada's quest to transform its healthcare system. A strong dose of political will and growing awareness about the benefits of health information technology resulted in the creation of Canada Health Infoway, responsible for accelerating the development of the electronic health record in Canada.

Infoway recognizes that Pan-Canadian standards are the cornerstone to meaningful health information in Canada**.** A strong focus on interoperability, through architecture and standards, has been key to Canada's progress to date.

Infoway's approach to standards development has been based on collaboration, with a robust and comprehensive process in place to seek input and consensus from key stakeholders. This approach acknowledges that standards must be business driven and that they are evolutionary.

Recognizing further opportunities for consolidation and coordination on the Canadian standards front, *Infoway* recently launched its Standards Collaborative, a new function not only to develop standards education, but also to focus on shared solutions for standards maintenance, conformance and implementation support.

Though there has been significant progress, many challenges remain. To help achieve broader success, standards development organizations, both nationally and internationally, should cooperate and coordinate with one another more effectively by extending their outreach to engage the vendor and clinician communities in meaningful ways.

5. Putting Patient Safety first – Quality in the Hospital setting - Abstract

by Dr. Thomas H. Clutton-Brock, Head of Department and Senior Lecturer in Anaesthesia and Intensive Care, University of Birmingham (United Kingdom)

The sophistication and complexity of hospital based medical care increases year on year and is now combined with an ever more persistent drive to improve efficiency and productivity. Patients too are changing, life expectancy is increasing, fewer conditions are considered truly incurable and they expect and deserve the highest levels of safety and quality in the care they receive.

Anaesthesia and critical care medicine are excellent examples of areas where developments in medical devices and drugs have had a measurable impact on patient safety and the quality of care provided. Regulation and standards have had an important part to play in this process but there is much still to be done. Ubiquitous connectors, clumsy alarm systems and little or no usable device communication leave many areas vulnerable to human error.

The sick patient in critical care or undergoing complex surgery may be connected to more than thirty medical devices, infusion pumps, monitoring systems, specialised beds and tables to name a few. All generate data much of which is still laboriously collected by hand and recorded on paper records a major distraction from areas where true vigilance and human signal processing is required. The anaesthetic record and critical care chart are essential for effective patient care and are not easily replaced by current information systems.

The involvement of clinicians and their education is essential to the development of truly useful regulation and standards and both parties have a responsibility to improve communications. Changes in education and working time directives reduce the time for apprentice based learning and increase the need for innovative teaching in the safe use of medical devices and related equipment. Effective standardisation will make this knowledge much less device specific and skills will be more transferable both within and between countries.

Advances in information and other technologies have transformed the way we lead our lives, it is time we used them to transform the way we care for patients.

6. Standards as a Tool for Health Policy and Regulation - Abstract

by David Rowlands, Manager, Health Informatics, National E-Health Transition Authority, Australia

The choice of the most appropriate implementation instruments is critical to the success of public policy. While some parts of the health industry are tightly regulated (e.g. bringing new pharmaceuticals onto the market), much of health service delivery has traditionally been included in the realm of professional autonomy, and has resisted regulation.

In many countries, "light touch" regulation is replacing more coercive models, as governments try to restrain expenditure and rapid, globally pervasive change in technologically oriented domains such as healthcare outstrips the capacity for legislation to keep up. This light touch legislation references and invokes standards rather than entrenching rules and norms. Regulation can be applied to technologies, performance or management. Adaptive regulation recognises that regulators are more likely to succeed if they use strategies tailored to the cultures being regulated.The likelihood of voluntary standards being successful in encouraging public policy goals depends on a range of factors including the risks to society of non-compliance, the ability to consumers to discern quality and the track record of the industry or sector in self-regulating. There is some evidence to suggest that formal standards have a major impact on success in the service sector.

If ISO is to contribute standards to meet health policy goals, then the goals selected must be global, suited to regulatory solutions and independent of national variations in health systems; and ISO must work in partnership with the professional bureaucracies and other critical stakeholders.

7. Medical Devices – The European Approach - Abstract

by Norbert Anselmann, Head, Standardization Unit, Enterprise and Industry, Directorate-General, European Commission (EC)

European legislation governing the placing on the market of medical devices is one of the key sectors where the European Union applies the concept of making reference to voluntary standards. The aim of the legislation is to ensure the protection of health and safety of patients and users. The legislation has quite a broad field of application and covers products of various technologies, such as implants, electro-medical appliances, surgical instruments, dressings, in-vitro diagnostic systems and laboratory equipment.

The legislation is limited to the essential requirements ensuring the protection of health and safety, whilst it falls to harmonised standards to provide the technical expression of the legal requirements, such standards keep their voluntary nature. A very large set of standards has been elaborated to facilitate compliance with European legislation.

The use of voluntary standards presents enormous advantages in establishing compliance with the legislation. Standards provide for solutions in accordance with the state of the art; they are developed by those who are expected to use them. They can be easily adapted to technological evolution. Experience has shown that a high level of protection can be ensured by using voluntary standards. As the system allows reliance on international standards transposed uniformly at European level, market access at a global level can be assured more easily. European legislation contains mechanisms by which shortcomings in standards can be corrected.

The European experience with the use of voluntary standards in support of European legislation is very positive. The application of the principle of general reference to standards is recommended at international level and also in other areas of legislation.

8. Bringing Healthcare Back to the Home - Abstract

by Dr. Toru Watsuji, Sharp Corporation, and International Society of System Health Science (Japan)

Abstract **We have developed an infrastructure, which consists of advanced instruments to monitor health condition and a data analysis system to evaluate the level of health condition via a standard communication network. Here we report that this developed infrastructure has been tested in the field, i.e. involving 100 homes and almost 300 users. Part of this infrastructure is now in the process of standardization.**

Keywords **healthcare, non-invasive, standard, protocol, lifestyle related diseases**

Now that Japan is facing the fastest increase in the aged population that the world has never experienced, public action and support systems are necessary in the areas of preventive medicine and daily healthcare check-ups. In particular, life support systems for the elderly living alone are urgently required since there is not enough manpower to support them all and there were many cases following the Hanshin earthquake where healthy elderly were found dead without this having been noticed for several days. Also, the Japanese government is now shifting its measures from strengthening the medical facilities to improving the level of health and preventive medicine in order to reduce the cost of medical examinations and the tax burden on the people. Thus there is strong demand for developing systems which can support the quality of life by monitoring the daily health condition of the elderly.

In this project, we are developing the following systems:

1. Advanced instruments to non-invasively monitor the health condition of people concerned about their health.
2. Data analysis system to analyze data acquired from the application and use of those instruments.
3. Data evaluation system to estimate the risk of lifestyle-related diseases and to support the daily management of health.
4. Common communication system to integrate all instruments and systems using standardized network interfaces and data protocols.

These developments have been carried out in close collaboration with "the enterprise model project for home healthcare" sponsored by the Japanese Ministry of Economy, Trade and Industry.

Advance instruments are all small, and safely designed for home use, and can monitor non-invasively. The following are examples: motion ability monitor to measure muscular strength and endurance and to indicate exercise according to the monitored data; rhythm monitor to measure energy consumption and daily activities; healthcare toilet to measure uric salts and sugar; healthcare mat to measure heart rate, breathing, toss and turn during sleep; handy monitor to measure subcutaneous fat thickness; non-invasive blood glucose monitor to measure blood glucose optically; non-constrained blood pressure monitor; scales to measure weight, body fat, basal metabolism, and bone mass; and basal body temperature monitor.

Bringing Healthcare Back to the Home

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The field test was carried out to obtain evidence of the value of everyday monitoring at the ordinary house. 100 houses were carefully chosen under the instructions of a physician. The field test was approved by the research ethics committee under the supervision of the Ministry of Health, Labour and Welfare.

The standard protocol is one of the most important results of this test. Considering the speed of development of wireless technology, the standardization was targeted towards the presentation layer and part of the session layer of the OSI reference model. The main feature of this protocol is that it has very small size requirements for the data transfer to be able to deal with a diversity of equipment and is especially suited to battery operated devices, such as thermometers. This protocol is now in the process of standardization.

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