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focus

Your gateway to International Standards

The anatomy of
HEALTHCARE





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ISO focus

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The global standards of health

We need to
overcome our
contradictions to
make decisions
that improve and
support healthcare
worldwide.

If you happen to travel in a time machine through the field of medicine and healthcare, you will come across some vivid examples of standardization. Back in the 19th century, Sergey Botkin, the great Russian therapist and one of the fathers of modern Russian medicine, devised the so-called *nastavleniya* (or “guiding principles”) for military medical officers that gave detailed instructions on procedures for surgery and medical healthcare services. At about the same time, British epidemiologist William Farr developed a unified terminology used to classify and monitor the causes of injury and death, helping to promote international compatibility in health data reporting.

Scientists since the 1950s have been developing standards that set the unified requirements for a wide range of medical devices, from surgical instruments to the magnetic resonance tomograph. More than a thousand standards have been published over the years, both internationally through the hard work of ISO and the International Electrotechnical Commission (IEC) and regionally in the form of European (EN or EASC) standards.

At the turn of the 21st century, healthcare was also one of the first sectors to be afforded branch-specific quality management systems, such as ISO 13485 for medical devices and ISO 15189 for medical laboratories. Standards have always played a central role in healthcare, their scope expanding over the years to include the fields of medical services, medical equipment and management systems. Currently, the ISO portfolio contains 1400 standards for health to help ensure that individuals and communities receive the quality of care they deserve. The guidance they deliver makes it easy to compare health services, exchange information, aggregate data and safeguard patient privacy.

ISO standards also contribute directly to the United Nations Sustainable Development Goal on health (SDG 3), as part of a worldwide strategic plan for ensuring healthy lives and well-being for all mankind. The international community faces many health-related challenges, which

include changing age structures in different regions, the digital transformation of society and healthcare, rampant modern-day epidemics such as cancer, diabetes, obesity and cardiovascular diseases, and the need for new preventive approaches to natural and technological disasters.

The international standards community cannot ignore such developments and must make concerted efforts to manage these new challenges. Although there are many sector-specific standards organizations already working on these topics, the onus is on ISO to take the lead in bringing the strands together by coordinating foremost international expertise and disseminating it globally. A lot has already been done and there are 14 ISO technical committees (TCs) working directly in the field of healthcare. We must applaud the commitment and dedication of ISO/TC 314 (ageing societies) and ISO/TC 304 (healthcare organization management), as well as the work of ISO/TC 215 on health informatics, whose prolific output boasts almost two hundred International Standards in its 20 years of existence.

Recent technological breakthroughs have brought growing numbers of stakeholders to the medical field, and standardization at the international level may soon become the much-needed platform for consensus. Patients, clinicians, doctors, regulators, manufacturers and scientists all have equal significance in human health and well-being. And a well-oiled standards development system can help not only maintain existing knowledge and achievements, but also solve new challenges in a systematic fashion.

Standards born out of international consensus should become the linchpin for global regulation in healthcare. For although legislation differs from country to country, all regulators have the same goals at heart – improving their citizens’ health and quality of life. I believe these goals can only be achieved through strong cooperation between international organizations, regulators and standards bodies. We need to overcome our contradictions to make decisions that improve and support healthcare worldwide... for present and future generations. ■



Alexey V. Abramov, Head, Federal Agency on Technical Regulation and Metrology of the Russian Federation.

Currently, the ISO portfolio
contains 1 400 standards
for health.



3 156 293
total impressions
912 campaign contributors

#ISO45001 campaign

1 211 152
total impressions
386 campaign contributors

#22000 campaign

#4thindustrialrevolution campaign

3 724 704
total impressions
519 campaign contributors

2018

best tweets & posts

2018 has been a year of great achievements, with thrilling activities that helped ISO to spread the word. As 2019 kicked off, we had a look back at last year's most impactful posts. So what made the cut?

Impressions are the number of times your content is displayed, no matter if it was clicked or not. Contributors are all the people who tweet using a particular hashtag within a certain time frame.

TOP TWEET
15 100 impressions

ISO @isostandards

The revised **#ISO50001** released TODAY shows promise for tackling the world's biggest energy crises, contributing as a key part to the 17 Sustainable Development Goals 2030 Agenda. Take a look here [ow.ly/GTxC30luHy8](https://www.iso.org/obp/ui/#iso:code:38100:50001)



WSD
19 353 people reached



See our video on YouTube for more ISO highlights.

TOP POST
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RISK MANAGEMENT: The new **#ISO31000** is out. Find out what's changed! [ow.ly/13cA30ipPjm](https://www.iso.org/obp/ui/#iso:code:38100:31000)

TOP POST
21 000 impressions

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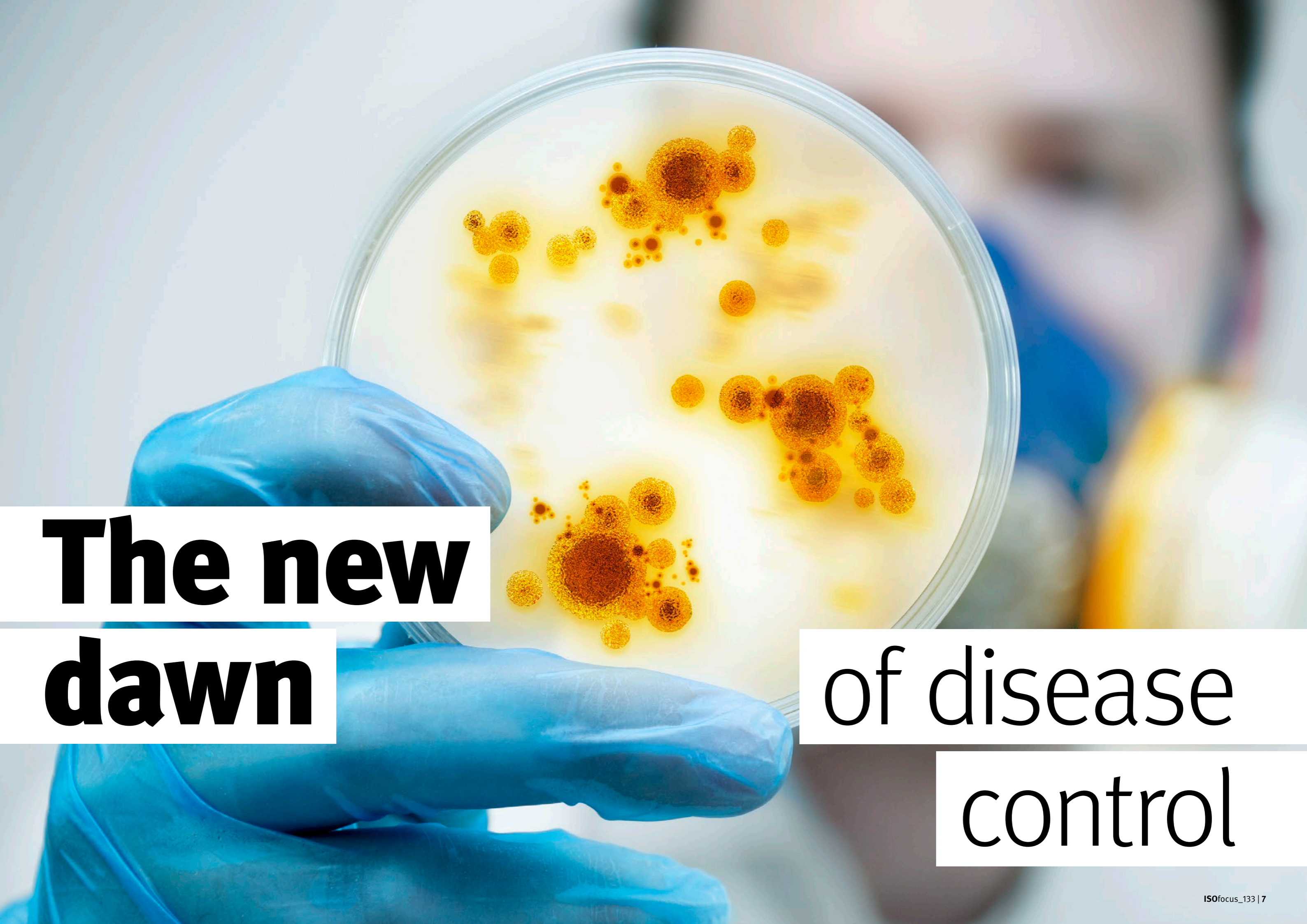
The biggest change in international measurement since 1875 has taken place. The world's leading scientists have formally agreed that all of the SI units will now be defined by constants of nature rather than physical objects. Learn about it here [ow.ly/13cA30ipPjm](https://www.iso.org/obp/ui/#iso:code:38100:31000)



ISO @isostandards

Today we celebrate World Standards Day with the theme of the **#4thindustrialrevolution**. In an era characterized by disruptive technologies such as artificial intelligence, robotics and nanotechnology, we highlight the crucial role of International Standards [ow.ly/TxB830mchH5q](https://www.iso.org/obp/ui/#iso:code:38100:31000)





**The new
dawn**

of disease
control

by Ann Brady

In our evermore complex, interconnected world, with health systems undergoing new challenges and stresses, risk management in the healthcare industry has never been more important. Three ISO standards play a significant role in matching clinical quality with patient safety and best practice, helping not only to deal with risks but also to prevent them in the first place.



Only the lucky few get through life in continuous good health, free from the pains and aches of growing older. Not many of us escape painful and debilitating ailments, such as sore joints that eventually require artificial replacements, and most of us, at some time or other, have to resort to health professionals and the healthcare industry in search of cures.

And it is reasonable for us to expect that those healthcare solutions and treatments will return us to our lives as healthier people, feeling better and fit for daily tasks. We put our trust in health professionals when we are at our most vulnerable and the health professionals, for their part, try to ensure that patient safety is paramount and aspire to best practices to reduce medical errors.

Cost of healthcare

The healthcare sector is one of the world's fastest-growing industries, comprising medical science, biotechnology, medical devices, services and pharmaceuticals. Research by The Economist Intelligence Unit and Deloitte indicates that while global annual health spending reached USD 7.077 trillion in 2015, this figure will soar to USD 8.734 trillion by 2020. The data shows that "a growing elderly population in both the United States and abroad, coupled with the high average cost of providing quality healthcare to members of these groups, suggests that it will drive heightened expenses in healthcare".



According to *Forbes* magazine, between 2015 and 2030, the number of people in the world aged 60 or over is expected to grow by 56%, from just over 900 million to nearly 1.5 billion. By 2050, the global population of people over 60 is predicted to jump to 2 billion. In the USA alone, the number of citizens over 65 should reach nearly 100 million by 2060.

This is a lot of older people, with older-people ailments, that will present the healthcare industry with huge challenges. Populations worldwide are ageing – but not all are ageing equally. Diets high in processed foods have led to an increase in western diseases, such as obesity, heart disease and diabetes, and the healthcare industry will have to come up with creative solutions to the issue of chronic disease.

When healthcare systems come under pressure, it is important to ensure that patient safety remains at the same high level. Nevertheless, error and adverse events can always occur in medical procedures. World Health Organization (WHO) data and statistics for the European Union, for example, show that "medical errors and

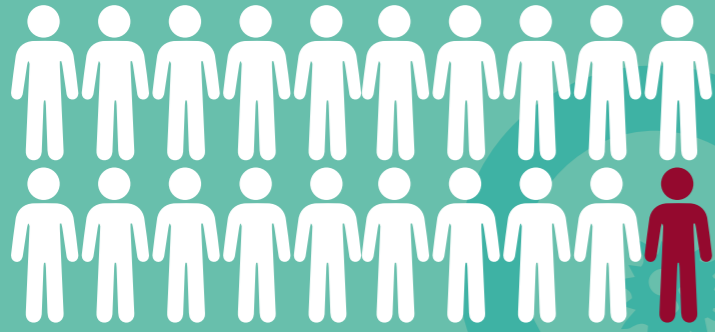
healthcare-related adverse events occur in 8% to 12% of hospitalizations". According to the WHO, infections associated with healthcare also take their toll with, on average, an estimated one in 20 hospital patients affected every year (estimated at 4.1 million patients overall). The UK's National Audit Office has estimated the cost of such infections at one billion pounds a year.

No room for errors

A bleak picture was also painted in the US. A study by Makary and Daniel sparked controversy when it claimed that medical error was the country's third leading cause of death. One positive result of the controversy, however, is that it shed fresh light on a serious topic, making patient safety a public concern. This was thrown into sharp focus again recently with the publication of *The Implant Files*, a global investigation by the International Consortium of Investigative Journalists (ICIJ) into medical implants – such as metal hips, vaginal meshes and pacemakers – and their effect on patients.

CLEAN BILL OF HEALTH ?

Healthcare is one of the world's fastest-growing industries – but it comes at a cost.
Here's the price we pay for staying healthy.



An estimated
1 in 20
patients are affected
by hospital-acquired
infections.*

What's the cost ?

1 billion
GBP/year

According to the UK's National Audit Office

= **4.1 million**
patients every year.*



Medical errors occur
in **8% to 12%***
of hospital stays.

What's the bottom line ?

USD 8.734 trillion
by 2020

According to The Economist Intelligence Unit and Deloitte



Global annual health
spending will increase
by approximately
25%.

*Source: WHO

The healthcare sector
is one of the world's
fastest-growing
industries.

The investigation was triggered by concerns over adequate regulations for medical implants, some of which, it is claimed, had not been tested before being marketed. Medical devices, however, are becoming increasingly important in healthcare and can significantly improve people's lives, especially for the elderly. And in the era of the so-called Fourth Industrial Revolution, new technologies are not only enabling innovations in medical implants and devices but also raising concerns about cybersecurity and data privacy and making healthcare risk management even more complex.

All of this underscores the need for efficient risk management systems. What tools are at hand to reduce the risks associated with medical devices, including the risk of human error? Many ISO standards are involved in risk management in the healthcare industry – three of these are highlighted in this article. ISO 14971 is a standard for the application of risk management to the design and manufacture of medical devices. According to Jos van Vroonhoven, Senior Manager Standardization at electronics multinational Philips, the standard is globally recognized by regulatory authorities as the best standard for risk management of medical devices. This is, he says, one of the major benefits for companies like Philips of using ISO 14971.

Cutting down the challenges

Van Vroonhoven regards the trend for stricter regulatory requirements as posing a big challenge for the industry. He cites as an example the Medical Device Regulation (EU) 2017/745 in the European Union, which, he says, “poses more and stricter requirements, not only on the risk management process but also among others on reporting and post-market surveillance activities”. He goes on to say that the next edition of ISO 14971 has more precise and more accurate requirements for the risk management process, which are in line with those changing regulatory requirements. “Thus, ISO 14971 will assist manufacturers in demonstrating compliance with the regulatory requirements for risk management,” he adds.

Van Vroonhoven says the revised ISO 14971 will remain the globally recognized standard for risk management of medical devices and “the description of the risk management process is improved in several aspects”. One improvement, he claims, concerns the more accurate description of the evaluation of overall residual risk. “It is explained that the contributions of all residual risks together must be taken into account and evaluated in relation to the benefits of the intended use of the medical device.”



Risk management in the healthcare industry also extends to medical laboratories, which are a key component in healthcare. Essential work is done in these laboratories in testing clinical specimens to get information about the health of a patient regarding the diagnosis, treatment and prevention of disease. The credibility of medical laboratories is paramount to the health and safety of the patients relying on the testing services provided by these labs.

ISO 22367 (in development), which deals with the reduction of error in medical laboratories through risk management and continual improvement, is the second standard. Willem Huisman, registered in Europe as a medical laboratory specialist in clinical chemistry, is an expert on the standard, being responsible for evaluating and incorporating any revisions suggested by the project team and responding to comments received during the various voting stages.

Huisman explains that the new edition of ISO 22367 lays out quite extensively in its annexes how risk management can be applied in the medical laboratory. “It helps to understand,” he says, “how the risk management approach can really contribute to patient safety without spending more money and efforts than is necessary. It helps to focus on the processes that are most risky and to be more lenient on others.” He cites as an example the frequency of internal quality control samples: frequent where needed and less frequent where possible. The end results, he says, “can lead to lower costs in total with higher quality for patients”.

All about technology

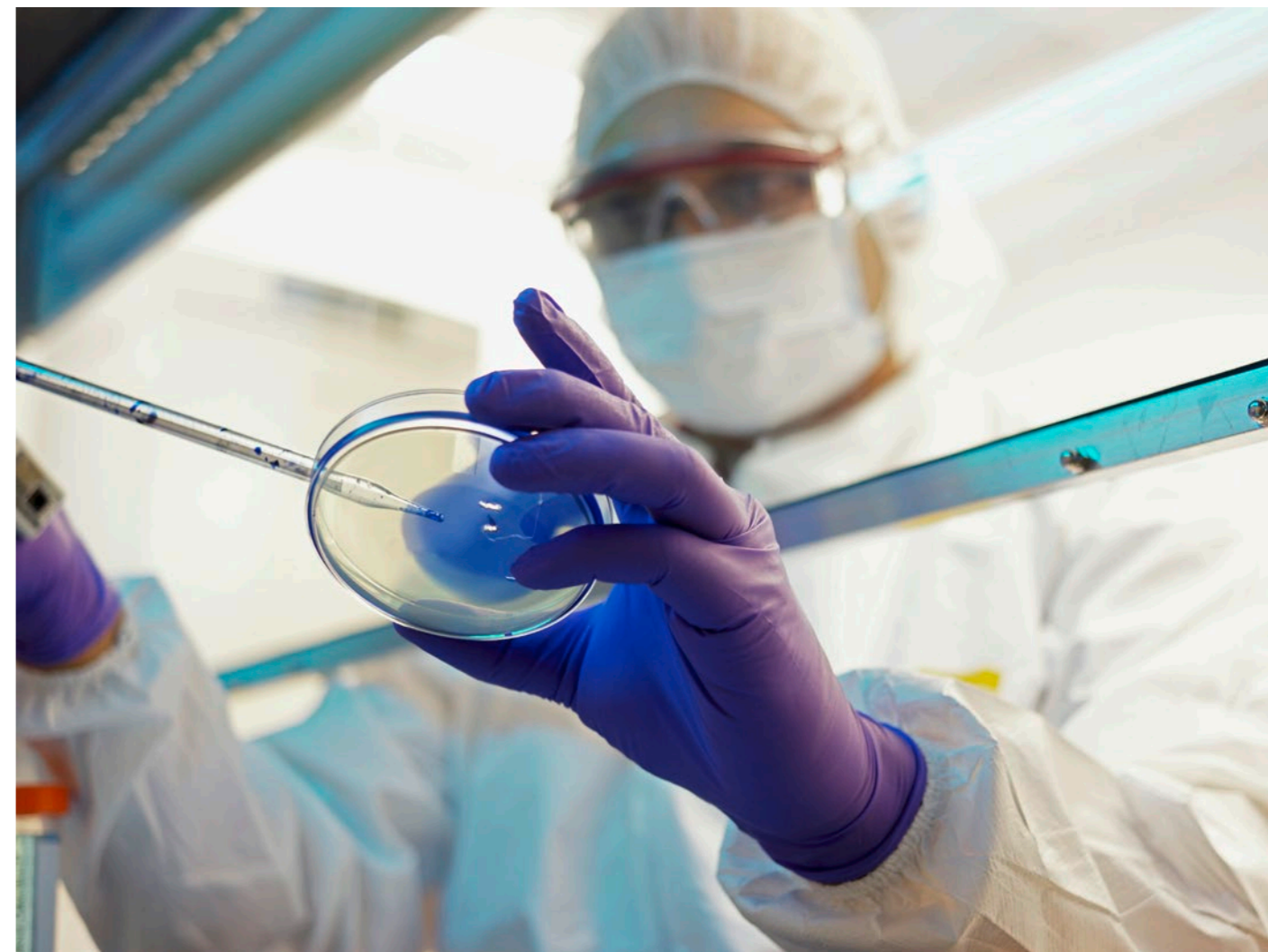
In vitro diagnostics is an important sector of the global healthcare industry, which is undergoing rapid growth fuelled by technological advancements. These medical devices and accessories help to detect infection, diagnose a medical condition and prevent disease. Huisman goes on to say that the new standard is more explicit and more in accordance with the risk management standard for manufacturers of in vitro diagnostic medical devices. This stresses the shared responsibility for

Many ISO standards
are involved in
risk management
in the healthcare
industry.

reliable laboratory results. He points out, too, that the name of the standard is “intentionally changed to risk management for medical laboratories instead of tests in the medical laboratory”. It clearly stresses, he says, the importance of the processes before the examination in the laboratory (taking samples in a proper way; transport conditions).

Huisman sums up by saying: “The new ISO 22367 will clearly show the medical laboratories how the concept of risk management will help to focus on all processes in the laboratory which need attention, to deliver the service their patients deserve, and be aware that, in some other processes, they can be more lenient. It helps the laboratories to be more cost-efficient.” This, in turn, enhances the well-being of the general public.

The third standard, ISO 35001, which is under development, focuses on management of biorisks, namely the management of risks that organizations confront when handling biological agents and toxins. As well as manufacturers of in vitro medical devices, relevant organizations also include medical centres, hospitals and clinics, universities and research institutes, and veterinary diagnostic laboratories and animal facilities.





Gary Burns is a Biosafety and Biosecurity Consultant and Convenor of working group WG 5, *Laboratory biorisk management*, of technical committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*. He points to the rapid growth of biotechnology applications, particularly in developing countries: “Technical capabilities that were previously concentrated in highly developed countries are increasingly being employed in other countries around the world. This expansion is driven in large part by the need to combat naturally occurring infectious diseases, which do not recognize national borders.”

Tackling toxins and other risks

To address these risks, Burns says the proposed standard will support organizations to “continually improve performance and comply with legal requirements through a voluntary biorisk management policy and process; implement globally accepted approaches to identify and control biorisks; monitor and evaluate the effectiveness of biorisk control measures; and assist management in decision making regarding biorisks”.

Global annual health spending reached USD 7.077 trillion in 2015.

Other benefits to organizations in implementing the standard, he says, include a reduction in accident and incident rates, compliance with legal obligations and an ability to demonstrate to external partners a commitment to a high standard in biorisk management. Another plus is that “organizations will have the flexibility to implement the standard in a manner that is appropriate for their size and complexity” – good news for small organizations as well as large.

Burns says: “The risks are also constantly evolving, as novel pathogens continually emerge”. He cites recent examples of the emerging biological agents that have caused disease outbreaks in humans, which include “several pathogenic influenza A virus strains (H1N1, H5N1, and H7N9), a novel coronavirus that is the causative agent of Middle East Respiratory Syndrome (MERS), and a novel coronavirus that was the cause of Severe Acute Respiratory Syndrome (SARS)”.

As the number of organizations that work with biological agents and toxins and the scope of international collaboration among these organizations continue to grow, Burns says there will be continued and increasing demand for an international biorisk management standard. ■



ON TARGET

to save lives

by Clare Naden



Some 16 billion injections are administered around the world every year¹⁾, each one bringing with it a risk of transmitting disease. Reusing a syringe increases that risk exponentially. ISO is tackling the problem with standards for single-use syringes and a set of requirements to prevent unintentional needle-stick injuries. Some of these standards are being updated to make them even more fit for purpose.

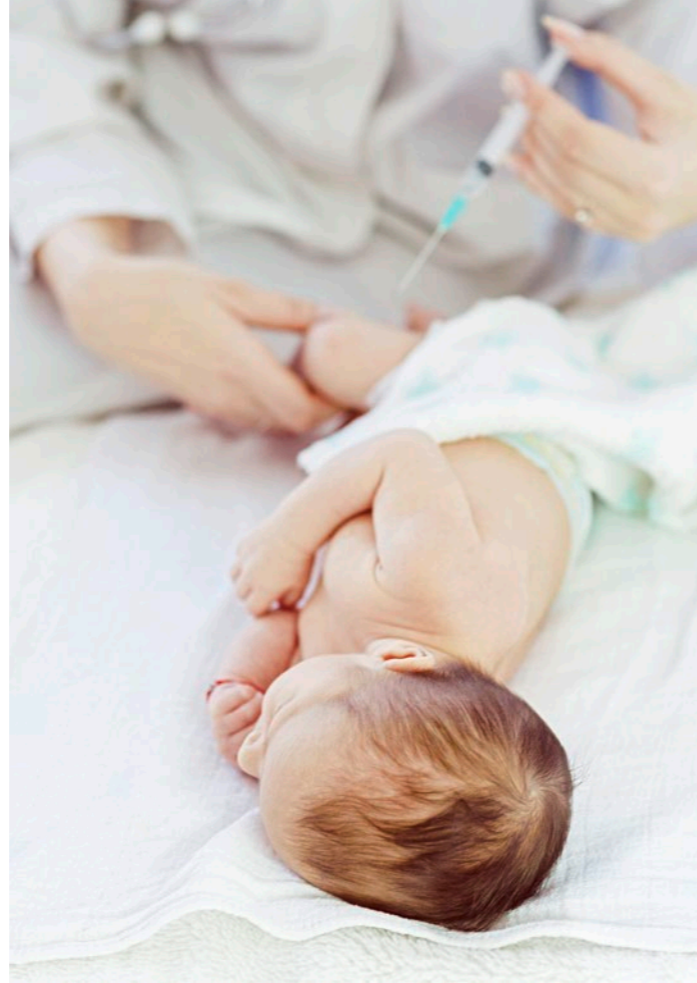
1) WHO Injection Safety Fact Sheet.

There is a continued need to address unsafe injection practices on a global scale.

A 2014 study sponsored by the World Health Organization (WHO), which focused on the most recent available data, estimated that in 2010 up to 1.7 million people were infected with hepatitis B virus (HBV), up to 315 000 with hepatitis C virus (HCV) and as many as 33 800 with HIV through an unsafe injection. While in the developed world, most injections are administered safely, injection practices worldwide vary widely, with reuse of injection equipment, poor handling of needles after use and informal cleaning still posing a problem in some regions.

This is nothing new. The WHO launched its WHO Injection Safety Programme and the Safe Injection Global Network (SIGN) back in 2000 already, in a bid to achieve safe and appropriate use of injections throughout the world. At the start of the programme, it was believed that around 40% of injections were administered with reused injection equipment, contributing to millions of new HBV and HCV cases and hundreds of thousands of cases of HIV.

**Around 40 %
of injections
were
administered
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equipment.**



The WHO initiative led to the development of many new designs of syringes with features claimed to disable the syringe after its first use. However, not all of them fulfilled the single-use objective. ISO had already published standards for traditional types of syringes without auto-disabling features, so it seemed only natural that it should extend the series with new standards for syringes with auto-disabling features.

ISO's expert committee on injection systems recognized that reuse of syringes wasn't the only risk to address. The infection by accidental needle-stick injury was a very real health hazard, especially for healthcare providers and people who come into contact with needles or other sharps²⁾ in medical facilities or public places.

Path to prevention

Based on the WHO initiatives, ISO's expert committee on syringes was investigating the risks of reused syringes and the fact that the existing standards for single-use hypodermic syringes (ISO 7886-1 and ISO 7886-2) and hypodermic needles (ISO 7864) did not specifically address the risk of reuse. The committee agreed on the development of new standards to reduce these risks and thus prevent the spread of deadly diseases such as HBV, HCV and HIV.

²⁾ Sharp: medical instrument (scalpel, lancet or syringe needle) that is sharp or may produce sharp pieces by shattering.

Although standardization work in that field began many years ago, there is a continued need to address unsafe injection practices on a global scale. It is no random coincidence, then, that abolishing the reuse of syringes is a key target in the United Nations Sustainable Development Goals (UN SDGs), which form part of the UN's 2030 Agenda for Sustainable Development adopted by world leaders in 2015. SDG 3 for good health and well-being pledges to “end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases, and combat hepatitis, waterborne diseases and other communicable diseases” by 2030. Preventing the reuse of syringes, and avoiding unintended needle-stick injuries, will clearly help towards this goal.

William Dierick, who initially led the standards development work on auto-disabling syringes as part of ISO technical committee ISO/TC 84, *Devices for administration of medicinal products and catheters*, says the committee's philosophy was – and still is – to focus on patient safety and ensure that the requirements of the standards are the most up to date. “Where there are new technological improvements or features, or new types of medicinal products, we aim to be there to adapt the standards in order to ensure patients receive the safest and most effective care,” he says.

“This is why we involve all parties when developing our standards, including health authorities such as the Food and Drug Administration (FDA), international organizations like the WHO and the United Nations International Children's Emergency Fund (UNICEF), manufacturers of both drugs and devices, and end users such as patients and healthcare workers,” he adds.





This inclusive approach is one of the reasons why Danish Standards, which holds the secretariat for ISO/TC 84, entered into a twinning project with the Standards Association of Zimbabwe (SAZ) in order to encourage involvement of the African continent in the development of standards for safer medical devices. Chaired by Zimbabwe, the partnership led to the successful release of ISO 23908 for sharps protection features and ISO 23907 for sharps containers, which provide a welcome complement to other standards in the field, such as ISO 21649 (needle-free injectors) and the ISO 7886 series (hypodermic single-use syringes).

Safer injections

There are many reasons to enhance the safety of administering injections. The price and chronic shortage of medical supplies force desperate measures, which include reuse of single-use injection equipment. Moreover, scientific studies reveal that administering injections is not only a risk for medical personnel but also for

ancillary staff such as cleaners, laundry workers or laboratory technicians.

In an attempt to reduce the risks of injury and disease transmission, the WHO launched in 2015 a new policy on injection safety, calling on the international community to switch to safety-engineered syringes, whenever appropriate, by 2020. It issued highly detailed injection safety guidelines, which outlined a number of safety features for syringes that not only protect the recipient of the injections, but the healthcare worker who administers them as well.

The WHO stressed that the transmission of infection is not just limited to developing countries as reuse of syringes occurs in many places. “Adoption of safety-engineered syringes is absolutely critical to protecting people worldwide from becoming infected with HIV, hepatitis and other diseases. This should be an urgent priority for all countries,” said Dr Gottfried Hirnschall, Director of the WHO HIV/AIDS Department, in a press release issued at the time the guidelines were launched.

All of this bodes well
for countries as they approach
the WHO’s 2020 deadline.

A standard language

Published in 2015, the *WHO guidelines on the use of safety-engineered syringes for intramuscular, intradermal and subcutaneous injections in healthcare settings* provides basic rules for syringes with “sharps injury protection” features. It defers to the definitions of ISO 23908, *Sharps injury protection – Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*, which provides internationally agreed minimum standards to reduce the risk of injury from sharps. In addition, the ISO 7886 series, which specifies properties and requirements for sterile single-use hypodermic syringes, also covers auto-disable syringes (ISO 7886-3) and syringes with reuse prevention features (ISO 7886-4). This makes it a highly useful tool both for the manufacturers that produce them and for users who can rest easy in the knowledge that the syringes meet minimum requirements for quality and safety.

The WHO document references safety-engineered syringes according to their ISO definition to provide an exact characterization of the safety mechanism of each type of syringe and allow a common understanding between all guideline users. These ISO standards are updated regularly to ensure they continue to meet the needs of manufacturers and users, and take into account any new technologies that will contribute to reducing the risk of transmissible diseases.

Looking ahead

But it doesn’t stop there. William Dierick says the committee is continually evolving and evaluating its work to develop standards that meet the needs of injection use in more and more settings. “We also have other standards that focus on the requirements for devices to be used by specific groups, such as visually impaired patients and certain age groups,” he adds.

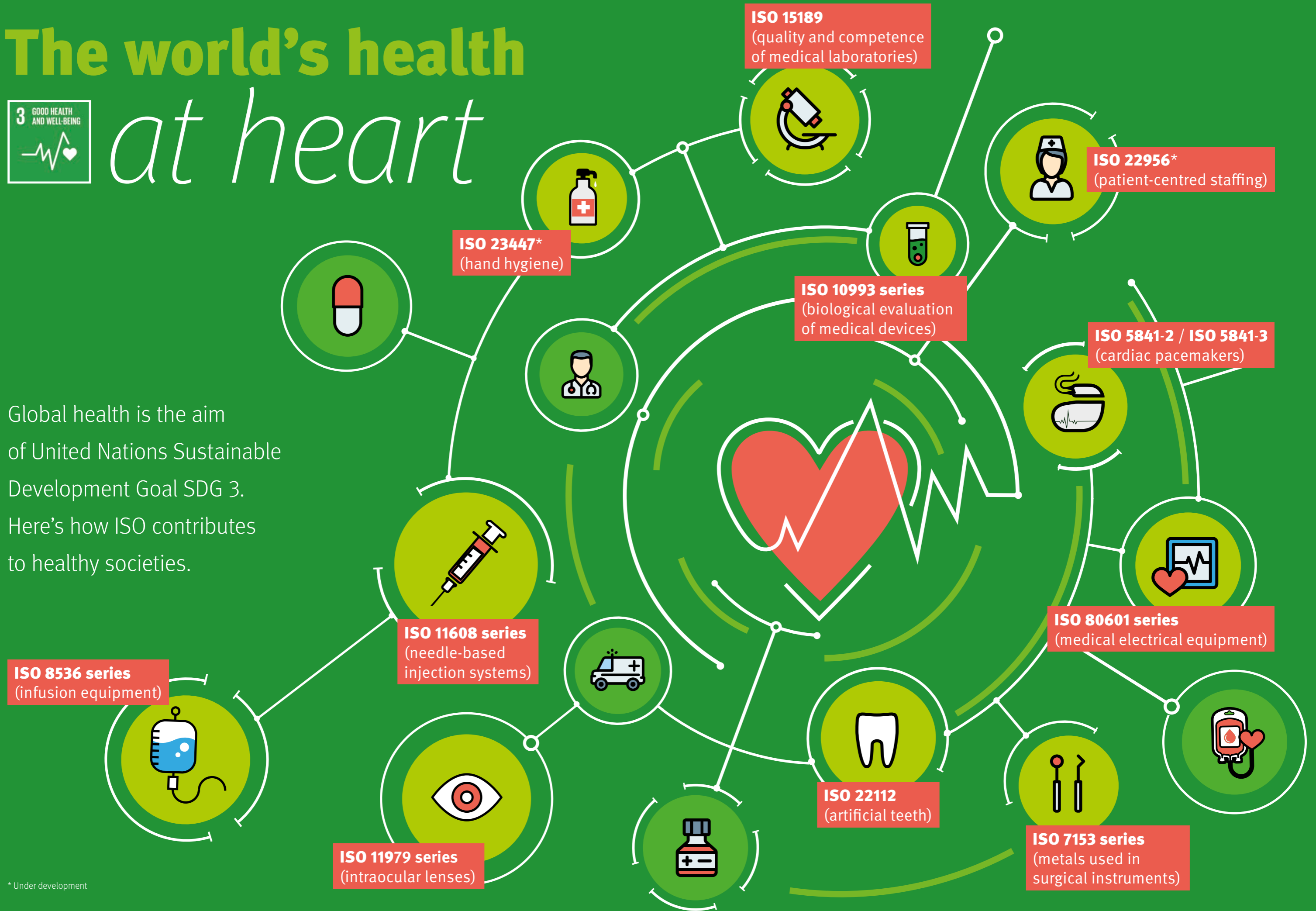
“What’s more, our standards were originally focused on devices for use by healthcare professionals, but with the increased number of devices for self-administration, we decided to expand the work to include pen-injectors, auto-injectors and body-worn injectors. This will lead to more efficient and convenient administration of the medicinal products, with great benefits for healthcare systems and patients.”

All of this bodes well for countries as they approach the WHO’s 2020 deadline, urging them to transition to safety-engineered syringes whenever appropriate. It also paves the way for achieving some of the UN’s Sustainable Development Goals while saving lives in countries where the reuse of syringes remains high. ■

The world's health at heart



Global health is the aim of United Nations Sustainable Development Goal SDG 3. Here's how ISO contributes to healthy societies.



* Under development



JUST FOR THE RECORD



by Barnaby Lewis

Here's a nice problem to have: in many countries, patient care is becoming more complex because we're generally living longer and surviving illnesses that would have at one time spelled the end. That means an increasing reliance on multiple specialists to treat our ailments, and the need to reliably share ever-growing quantities of information to enable the best care outcomes.

As different hospitals, departments and doctors interact, there exists a potential for mix-ups, and questions of confidentiality to consider. The situation is further complicated by rising global mobility, where greater migration than ever before mixes multiple legislations, languages, notations and insurance systems into our personal health records. Fortunately, there's an ISO technical committee dedicated to improving the way that our medical information is stored and shared. *ISOfocus* reached out to discover more about how standardization can improve the flow of information, and patient care.

But first, here's what I know about hospitals and patient records. I remember my earliest trip to the hospital with dreamlike clarity. Which is to say, perhaps I misremember details and invent others. (Memories, like all records, are subject to the introduction of error.) However, some things come back in high-fidelity:

the bitter smell of cleaning fluids, colour-coded floor lines directing visitors, nurses sorting endless racks of patient cards and smoking.

It seems very different to the hospitals of today; three decades have seen significant advances in almost every area of healthcare. For one thing, the smokers have been kicked out into the cold, but in many hospitals you may still find filing cabinets stuffed to the runners with precious patient data.

Time goes slow

In most other areas that deal with sensitive or important data, we've made a choice to leave paper behind. Currencies now exist without the need for banknotes and we'll happily board an aeroplane without a physical ticket. So why is the move to fully digital patient records taking so long?

It may be because paper works. There is, after all, a foolproof simplicity to getting important things down on pieces of paper and locking them away in a sturdy metal box. (Even the most advanced hospitals are ready to fall back on paper in the event of an electronic systems failure.) But the more likely reason why health records lag behind other personal information systems is the complexity of the transition. In many areas of digitized records and billing, post-digital formats remain much the same, there aren't really ethical questions to grapple with, and the relationship to the service provider remains mostly unaltered. Going digital with our medical data, or health informatics as it's referred to by specialists, fundamentally changes the way that we access doctors, and the ways that they can access our most private information. Ultimately, it can even bring new perspectives in assessing conditions and providing care. In other words, a game changer.

Leading a revolution in records

To understand how these changes are being made, *ISOfocus* spoke to a handful of the experts from ISO/TC 215, the ISO technical committee for health informatics. First on the list is Christian Hay, a man whose 20-year track record in healthcare standardization spans the early development of the barcoding system for drugs that later became known as GS1, as well as significant involvement in developing procedures between pharmaceutical manufacturers and wholesalers, and development of billing procedures for use by health insurers.

To start out, I quiz Christian on the basics. Like, what is the most simple definition of health informatics, and what does it do? "Everything that concerns the use of IT in health" is the pleasingly terse answer to the first part of my question. "It's basically where technical and medical systems meet."

Making medicine safer and more effective

Christian goes deeper with some insights into his own particular area, the pharmacy and medicine business (also the name of the ISO working group that he chairs, ISO/TC 215/WG 6). "Health informatics structures and standardizes information related to medicinal products. In fact, Christian tells me "health informatics applies to every other part of the process from post-marketing surveillance, clinical-decision support, indications and interactions, medical alerts, patient reimbursement and public-health personalized medicine, controlled substances... and more!"

For Christian, the inevitable transition away from paper has "obvious benefits", but such are only fully realized when "we find globally agreed structures so that information becomes not only digital, but also *interoperable* between



There exists
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to consider.

systems". This is key to opening up exchange between countries, regions and languages. "There is a considerable need for semantics," Christian continues, which, "for health informatics is partly addressed by ISO/TC 215, as well as by other organizations."

Connecting through a common language

A slightly different perspective is offered when I connect with Nicholas Oughtibridge. A veteran health standardizer whose experience covers working with the above-mentioned "other organizations" including SNOMED (Systematized Nomenclature of Medicine), BSI (the ISO member for the UK), and the UK NHS, where Nicholas currently leads digital transformation as Head of clinical data architecture. I home in on some of the specifics of his day job. What are the challenges of revolutionizing a tax-funded public-health service? He unhesitatingly replies (like a seasoned standardizer) "bringing together the different parties involved in developing software and managing tensions between different needs, those of business and manufacturers, and those of the health professionals who are providing care".

It seems logical that with the potential to realize efficiencies and economies of scale, things that work less well are also thrown into relief. There is a huge potential to compound small problems as they are scaled up. By way of proof, Nicholas tells me that "almost 100% of individual doctors (i.e. general practitioners) are 100% digital, but there are many hospitals filing significant amounts of paper". If individual doctors' offices can reasonably implement their own system, finding things that work for them, part of the challenge of scaling to a national level lies in joining the dots.



HEALTH CARD SOLUTIONS

The benefits of smart cards in healthcare have been touted for decades. Consider the following points.



Authenticates beneficiary at the point of care



Enables all aspects of the health system



Facilitates exchange and use of medical data



Decreases administrative cost

ISO/TC 215, *Health informatics*, does not standardize card-related technology but only health-related structures on such types of cards.

ISO/TC 215 is playing a significant part in making it a more joined-up experience.

Same information, different context

When I ask Michael Glickman, the Chair of ISO/TC 215 and President of Computer Network Architects Inc., to expand on the fundamental notion of health informatics, he tells me that it can also be seen as “the science of computability”. He explains that “informatics allows interoperability, meaning that data collected for one purpose can be safely, effectively and meaningfully used in different settings by computers and individuals”. Across 40 years, Michael has collaborated with more than 600 healthcare organizations, 29 Health Information Exchanges (HIEs) and worked as an active volunteer with numerous non-profit healthcare and information technology standards development organizations and trade associations. His observations are informed by solid experience and, as I reflect further, it opens avenues that seem like a significant shift to me. For example, are we moving toward the possibility of making diagnoses and even treatment decisions based on reliably recorded observations? It strikes me that International Standards to harmonize the way in which we record medical information also create the potential to use patient data for anonymized research. This would of course raise significant questions around consent and confidentiality, and so I ask Michael to explain how these aspects are considered from a standardizing perspective. “Security, privacy and safety are core elements of our work. We have an entire working group (ISO/TC 215/WG 4) dedicated to these subjects and they collaborate with all of our other working groups, as well as dozens of liaison organizations, both within ISO and its affiliates.” It’s reassuring, given the sensitivity of medical data.

Keeping sensitive data safe

Growing concerns around general data use have given rise to legislation like GDPR in the EU (the General Data Protection Regulation 2016/679), and I’m curious to know how legislation such as this impacts the ongoing work of digitizing health records. Nicholas Oughtibridge again: “The point of GDPR is to ensure that people don’t use data in an inappropriate way.” One of the reasons it came into being is that we now handle vast quantities of personal data that we simply didn’t generate before. Understanding how to treat this appropriately is a challenge that’s better understood when it comes to medical data, where medical professionals recognize that their solemn promise to “do no harm” extends beyond the treatment of physical aspects of patients in their care. Nicholas continues: “Interoperability is still an issue; reliably transferring *meaning* from one computer or system to another is still the bigger challenge. The benefit of the ISO way is that it encourages broad participation, meaning that ISO standards can adequately represent different national or cultural priorities, while forming a coherent system.”

That’s to be welcomed. Because, whilst I may not be inclined to write about my final visit to a hospital (and, in any case, I hope that it won’t be for a while), I can be confident that the work of ISO/TC 215 is playing a significant part in making it a more joined-up experience. One day, digital records will be the norm, and being asked to fill in the exact same form for the hundredth time will seem just as incongruous as a smoking nurse. ■



Partners in health

While some countries have made great progress toward universal health coverage, half the world's population are still unable to obtain the health services they need. ISO's collaboration with the World Health Organization is working to change things.

ISO has enjoyed
a strong
collaboration
with WHO for
many years.

Good health should be a universal human right, but all too often it is dictated by social and geographical circumstances. Global health and well-being are the preserve of the World Health Organization (WHO), the directing and coordinating authority for health within the United Nations system. Created to dispense the advice and knowledge needed for people to lead healthy lives, WHO provides leadership on matters critical to health and engages in partnerships where joint action is needed. This aspiration towards better health for all has been the guiding principle for seven decades and is the impetus behind the organization's drive towards Universal Health Coverage (UHC). Good health requires the commitment of many, from policy makers to civil society, to global health partners and even standards makers. ISO has enjoyed a strong collaboration with WHO for many years; WHO participates in almost 60 liaisons with ISO technical committees to develop standards for mutual benefit. Both organizations agree on the importance of ensuring that health standards are in place everywhere in the world, to contribute to our global well-being and to create the best possible conditions for health professionals to do their job. The goal of these partnerships is to leverage international activities that contribute to the "tailoring" and adoption of ISO International Standards for health systems across all kinds of sectors, from public health and medical products to health informatics and traditional medicines. At a time when there is disturbing evidence of widening gaps in health worldwide, *ISOfocus* asks François-Xavier Lery, Coordinator for Technologies Standards and Norms at the World Health Organization, how the collaboration with ISO can help advance universal health coverage in the 21st century.

***ISOfocus*: World Health Day is an occasion for raising awareness of key global health issues. What is the biggest health challenge that the world faces today?**

François-Xavier Lery: The date of 7 April each year marks the celebration of World Health Day, designed to create awareness of a health issue that is of primary concern to the World Health Organization. Our top priority at WHO is Universal Health Coverage (UHC), which has emerged as a key strategy to make progress towards other health-related and broader development goals. A vital pillar of UHC is ensuring that all people have access to essential quality care and safe, effective and affordable medicines, vaccines and other health products. This enhances people's health and life expectancy, protects countries from epidemics, reduces poverty and drives economic growth.

Currently, at least half of the world's population still has low or no access to health products and a hundred million people are pushed into "extreme poverty" because they have to pay for healthcare out of their own pockets. All United Nations member states have pledged to achieve universal health coverage by 2030 as part of the Sustainable Development Goals (SDGs), the United Nations' global agenda for a better and more sustainable future for all.

WHO participates in almost 60 ISO technical bodies that develop ISO standards. What are the benefits of this participation for WHO?

Over the years, WHO has developed 180 norms and standards for medicines, vaccines and pharmaceuticals. These are used, in particular, for products subject to the WHO Prequalification Programme, created with a view to ensuring that products procured by the United Nations are of assured quality and efficacy. The programme has made an enormous contribution in terms of increasing the access to quality-assured health products that are affordable and adapted to markets in Low- and Middle-Income Countries (LMICs). In some very technical areas, such as the design and manufacture of syringes, WHO collaborates with, and relies on, ISO for elaborating and maintaining standards. This partnership guarantees that the standards designed within the ISO framework are fit for use by all countries, including those where access to healthcare remains difficult. These countries are not always represented in ISO technical committees and working groups; WHO ensures they are given a voice so that health products can be made accessible to all patients around the world while maintaining global standards.

How can greater collaboration/synergy between ISO and WHO contribute to the 2030 Global Agenda – in particular SDG 3, which aspires to “ensure healthy lives and promote well-being for all at all ages”?

WHO’s collaboration with ISO can facilitate the participation of policy makers, manufacturers and healthcare professionals from LMICs in ISO standardization work for the advancement of public health. The robust standardization process followed by ISO is sometimes perceived by actors from these countries as “very demanding” – good coordination helped by WHO should make it easier to develop ISO standards in an inclusive way. The ISO-WHO partnership also provides a good interface between technical standards and regulatory requirements, with a view to promoting access to high-quality health products.

The ISO-WHO partnership provides a good interface between technical standards and regulatory requirements.



Photo : François-Xavier Lery

François-Xavier Lery, Coordinator for Technologies Standards and Norms at the World Health Organization.



ISO standards,
just like WHO
standards,
are made
to be used.

Why is the uptake/use of ISO standards so important?

ISO standards, just like WHO standards, are made to be used. Stakeholders, interested parties and standardization bodies invest a lot of time and energy in their development so that they apply equally and fairly – from a business competition viewpoint – to all stakeholders and ensure quality products and services. Their uptake is therefore critically important. Appropriate use of standards also helps monitor products and services to ensure the timely revision of the standards that support them. Like ISO, WHO gives high priority to the implementation of standards. In fact, our new five-year plan, the General Programme of Work 2019-2023, includes activities to better monitor the implementation of WHO norms and standards in order to encourage their positive impact on populations.

What would you like to see in the near future (from ISO or elsewhere) in order to make SDG 3 a reality?

Universal health coverage hinges on universal access to quality health products that are all at once safe, effective and affordable. This cannot happen without quality assurance of the products and services delivered to patients. SDG 3 will only become a reality if all stakeholders – and by that I mean policy makers, regulators and standards-setting organizations – work together across countries, regions and professional groups. Experience has shown that this can only be achieved when political will is strong. ■

CALLING CONSUMERS TO HARARE

ISO's Committee on consumer policy (COPOLCO) is busy preparing its 41st plenary meeting in Harare, Zimbabwe, on 21-24 May 2019 at the invitation of the Standards Association of Zimbabwe (SAZ). Participants at the event will be welcomed by SAZ Director General Dr Eve Gadzikwa, who is also President of ARSO, the African intergovernmental body working to facilitate global trade through standards.

This will be the first time a COPOLCO meeting takes place in sub-Saharan Africa, presenting a unique opportunity to bring concerns from the African region to the forefront of COPOLCO's agenda. It will also help raise awareness of standards as a tool for consumer protection among stakeholders from Zimbabwe and other countries in the region.

A workshop will focus on harnessing new business models and technologies, such as e-commerce and the collaborative economy, as spurs for inclusive economic growth and



consumer protection. Discussions will bring together a variety of stakeholders to explore how key standards can enhance business opportunities for smallholders while improving health and safety outcomes for consumers.

For more information: www.iso.org

SUSTAINABLE FINANCE SETS SAIL

As global temperatures climb, so does the cost of adapting to a warmer world. According to a 2016 World Bank report, adaptation finance could reach a hefty USD 90 trillion by 2030 for infrastructure alone. Taking stock of the situation, ISO has just established a new technical committee. ISO/TC 322, *Sustainable finance*, is working to create an investment market that is both accessible and efficient through the development of targeted International Standards.

The committee aims to mainstream sustainable finance by connecting the dots of climate investment initiatives. As a priority, it will develop a framework for sustainable finance

to consolidate existing concepts, agree on common terminology and bring related activities, such as responsible investment management, stewardship and environmental finance, under the broader, more holistic umbrella of sustainable finance.

The wider programme will address the integration of sustainability considerations into financial decision making, services and products, investment decisions that deliver social as well as financial outcomes, and green finance reconciling concepts such as clean energy with broader conservation finance to protect and restore the natural environment.

WTO SPOTLIGHTS STANDARDS

The World Trade Organization (WTO) Committee on Technical Barriers to Trade (TBT) concluded its Eighth Triennial Review of the Technical Barriers to Trade (WTO TBT) Agreement last November in Geneva, Switzerland. Members attending the meeting achieved a breakthrough by agreeing on a list of almost 30 recommendations that will improve the way the WTO TBT Agreement is implemented in the future.

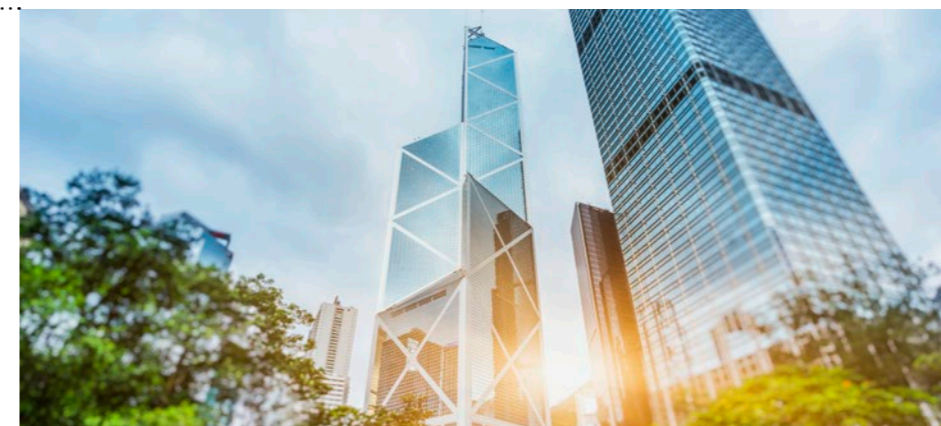
Recommendations covered topics such as transparency, technical assistance, testing and certification – and standards. Members agreed to discuss best practices on incorporating standards by reference in regulation, taking account of existing guidelines and policy considerations. They also agreed to hold a workshop on the role of gender in the development of standards.

The work done by ISO and the WTO is complementary in nature. The WTO's TBT Agreement, which focuses on maintaining an open, equitable and non-discriminatory multilateral trading system, relies on ISO to create good, high-quality standards that help give traders confidence that products are safe, technologically compatible and meet market needs. Only then can goods continue to flow smoothly across borders.

For more information: www.wto.org



ISO's partners at the COP24 side event were the International Accreditation Forum (IAF) and the Institute of Environmental Management and Assessment (IEMA).



ISO AT COP24 CLIMATE TALKS

World leaders in Katowice, Poland, at the COP24 – the annual United Nations climate change conference – agreed on a set of rules meant to help curb global warming. The 256-page common rulebook, known as the Katowice Climate Change Package, is supposed to put into motion the Paris Agreement on climate change, which was signed in 2015. During the two weeks of COP24, various side events and exhibitions were held aimed at stimulating debate on key thematic areas, engaging observers and facilitating dialogue with party delegates and other participants. Taking part in an official side event, ISO had the opportunity to showcase a selection of key standards for climate action. Among the subjects covered were environmental management with the popular ISO 14001, climate change adaptation, greenhouse gases, carbon footprint and green bonds.

The event, which was facilitated by Nick Blyth, Vice Chair of the ISO Climate Change Coordination Task Force, also introduced upcoming guidelines for addressing climate change in standards. The future guide, currently in the early stages of development, will be a vital tool for those involved in standards development.

Tod Delaney, Chair of the ISO Task Force, said "the scale of action needed to transition to a low-carbon, climate-resilient future is arguably the greatest challenge of our time", but internationally recognized standards have the power to support, guide and monitor climate performance at the organizational level in the coming decades.

GOING FOR GOLD

Organizations can draw considerable support from standards in terms of turnover, export and stakeholder satisfaction. This consideration prompted AFNOR, ISO's member for France, to launch the contest "Trophées Or Normes" at the end of 2018, which rewards four organizations that use voluntary ISO standards for their business development or the design of a product or service. And the winners are...

- **Suez International** (category: "Fostering exchange"), for its combined use of ISO 55001 (asset management) and ISO 24516 (water infrastructures) in two water management projects in Jordan
- **Tour operator Nomade Aventure** (category: "Making life easier"), for implementing the French standard on management of online consumer reviews – the standard behind ISO 20488

- **Engineering consultancy Apilab** (category: "Staying ahead of the game"), for its innovative approach to environmental biomonitoring based on an authoritative knowledge of bees, a method which is now formally recognized in France's experimental standard XP X43-909
- **Fire specialists Prev Sécurité 62** (category: "Protecting people"), for the design of a fire blanket that exceeds the minimum reference threshold specified in French standard NF EN 1869

The initiative will be repeated this year and the winners announced in October 2019.

For more information, scan this QR code.





For a healthy tomorrow

by Rick Gould

Healthcare is one of the fastest-growing industries. As countries continue to enjoy greater life expectancies than ever before, there is a constant need to address the growing demands and increasing complexities. This also means there is a need to deliver more efficient and affordable care to a greater number of patients. So how is ISO providing the much-needed standards to support our health systems?



Standards have certainly improved our health systems.

Seventy years ago, the United Nations Universal Declaration of Human Rights (UN UDHR) enshrined good health as a human right. By doing this, the UN obligated its member states to provide healthcare for their populations. However, current media reports about the state of the world's healthcare services often describe them as being in a "poor state of health". Indeed, the word crisis often pops up in the popular media and even in academic journals. Many reports go on to declare that patient satisfaction, for example, is at an all-time low. Healthcare staff are overworked, burnt out and just far too few. Most alarmingly, the rate of infections that patients get in hospital is high. Such criticisms might seem odd since healthcare is one of the world's most regulated and standardized sectors, as well as receiving significant proportions of global GDP. Regulations and standards have certainly improved our health systems, yet the changing landscape in healthcare services worldwide – such as ageing populations in many countries, coupled with a rapidly evolving and increasingly complex array of medical procedures – now means that there are also some notable gaps.

Sterling healthcare ?

2018 was also the 70th anniversary of the United Kingdom's National Health Service (NHS), created to provide free universal healthcare funded by national insurance. Throughout the year, the NHS was frequently featured in the UK's media, with lots of news about deadly mistakes, missed targets and excessive delays for treatments. Indeed, few gave the NHS a report of glowing health, whilst many blamed the public health service's ailments on a lack of resources and on staff shortages.

Many reports asserted that the UK government's long programme of austerity was the cause. When comparing the UK's expenditure on healthcare to that of the USA – about 10% compared with 18% as a proportion of GDP – it might appear that parsimony is to blame. That said, it does not take long to find numerous reports describing healthcare crises in the USA, too; so throwing money at a perceived problem does not necessarily make it go away.

The notion of a crisis is as subjective as it is emotive. On the other hand, hospital-acquired infections (HAIs) are neither, as they are measurable and objective. The World Health Organization (WHO) reports that in the developed world, for example, the rate of HAIs ranges between 5% and 12% whilst in the developing world, the risks of getting an infection in hospital average nearer 20%. In other words, a relatively healthy person could attend hospital for a perfectly routine knee operation and pick up a potentially lethal infection in the process. And HAIs go hand in hand with hand hygiene.

Standardization, however, can readily solve the problems associated with staffing and hand hygiene. To that end, in 2015, ISO decided to form a new technical committee – ISO/TC 304 – for the development of standards in healthcare organization management.

Standards for staff

The healthcare sector is certainly not short of standards; there are five ISO/TC's already dedicated to healthcare, which have published almost two hundred ISO standards between them. However, these typically apply to specialized activities, such as clinical tests, specific operating procedures and the performance of medical devices. The current challenge is that due to the complexity, rapid pace of change and diversity of the sector, some significant gaps have emerged.

ISO/TC 304's experts identified that, despite the abundance of existing standards for the sector, there were none available for the most important asset of all healthcare centres and hospitals – the staff that deliver and support medical services to patients. There are currently three standards in development covering the vocabulary of healthcare management, hand hygiene and patient-centred staffing. Other standards will follow suite that deal with measuring and analysing performance, processes for controlling anti-microbial resistance in hospitals, admission and discharge practices, and electronic records for patients.



HEALTHCARE ORGANIZATION MANAGEMENT

Healthcare services management has a lot of moving pieces : facilities, medical equipment, staff, patients... ISO/TC 304 has all areas covered.



* Under development
** Future projects



Hospitals and healthcare centres have access to guidance where there are not yet ISO standards, but this guidance is often disparate, fragmented and not always applied effectively. Therefore, the new standards being developed by ISO/TC 304 will draw on best practices, advances in scientific research and the two other key strengths of ISO standards: unifying and harmonizing. This portfolio of standards is expected to improve patient care, boost efficiency and effectiveness and save more lives. This is worth exploring by taking a closer look at two standards currently in the pipeline for patient-centred staffing and hand hygiene.

Putting patients first

There are different approaches worldwide for managing patient care and staffing in the healthcare sector. Of these, volume- and target-based approaches are common, focusing on the available budgets and needs of the health service.

In other words, a top-down approach. Patient-centred staffing, on the other hand, is a strategic approach that involves the patient as well as staff to plan the best options for treatment. The UK's professional body for nurses, the Royal College of Nursing, defines the process as focusing on the needs of the person rather than the needs of the service. Patients are now typically more knowledgeable and do not want to be passive subjects receiving treatment. So it is a "patient upwards" rather than a "hospital downwards" approach.

The concept itself is not new as there are thousands of academic papers on the subject, as well as an abundance of guidance notes scattered amongst the world's healthcare centres. The concept also gets widespread support from researchers and many medical staff. Patient-centred staffing, though, is not widespread or as effective as it could be due to absence of a unifying standard. The upcoming ISO 22956 for patient-centred staffing will plug that gap.



So what will it cover? ISO 22956 will embody a risk-based approach to workplace planning, staff allocation, performance monitoring, surveys of patient satisfaction, reviews and treatment options. Crucially, it will include the patients' needs and perceptions as a driving force. The working group writing the standard is applying well-documented principles of healthcare management, described in reports and papers for organizational management and leadership in healthcare. The standard will also embody the growing volume of knowledge about effective quality management in the sector. In other words, ISO 22956 itself will draw on proven, best and innovative practices, condensing them within a single document.

Dr Veronica Muzquiz Edwards, CEO of InGenesis, which has been recognized by Staffing Industry Analysts as one of the largest healthcare staffing companies in North America, is also Chair and Head of the US delegation for the ISO Technical Advisory Group on healthcare organization management (TAG 304). As Convenor of the working group in charge of ISO 22956, she explains: "It is imperative that stakeholders within healthcare systems move beyond traditional practices and explore innovative patient-centred staffing methodologies to maximize patient safety."

So how does innovation feature within this standard? "Innovation in the care that clinicians deliver to patients must match the advances in drugs and clinical services offered by healthcare providers today," she adds. "This standard reflects and inspires a movement away from organizationally focused responses to patient needs towards healthcare solutions that flexibly respond to the interests of the particular patients,"

This portfolio of standards
is expected to improve
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concludes Edwards. Additionally, ISO 22956 will benefit staff as well as patients, for example, by increasing job satisfaction and reducing staff burn-out, rates of absence and turnover.

ISO 22956 will be an overarching management standard that applies to all types and sizes of healthcare systems. Pursuing different goals, ISO 23447, another standard in the early stages of development, will describe procedures for a simple activity that applies to all front-line medical staff, where research has unequivocally highlighted its critical role – hand hygiene.

A fresh pair of hands

Numerous investigations have shown that all surfaces potentially harbour harmful microbes, whilst hands provide the means to spread them. Indeed, the WHO regards hand hygiene as an essential tool to prevent HAIs. Moreover, the practice of hand hygiene is as simple as it is effective, especially as there are instructions on the subject such as the *WHO Guidelines on Hand Hygiene in Health Care*, published in 2009. When staff in hospitals and other health centres use such guidelines, the rates of HAIs fall dramatically and often by at least 50%.



However, many researchers have also reported a low level of compliance with such guidelines, with often massive impacts. As with patient-centred staffing, the practice of hand hygiene is fragmented. But ISO 23447 for hand hygiene aims to fix this. “The process for hand hygiene varies country to country. It varies region to region. It varies area by area. It varies state to state. It varies hospital to hospital,” observes Dr Christine Greene, Convenor of the working group that is developing the standard. Greene, a researcher in epidemiology and laboratory practices, has published numerous research papers on the transmission mechanisms and transfer rates of harmful micro-organisms. “Hand hygiene is the most basic thing and patients should be able to expect the same level of hand hygiene for patient safety, regardless of where they go for care.”

As well as describing the processes of hand washing and disinfection, ISO 23447 will also define training needs, specify requirements for hand disinfectants and, critically, explain how users of the standard can measure and monitor hand hygiene. So not only will hospitals and healthcare centres have a unified standard to monitor their own performance, but they will be able to compare and share data with other organizations and centres. This, in turn, will provide the means to identify where the process can be improved.

Crossing borders

The standard itself will be based on existing practices, notably the 2009 WHO guidelines on hand hygiene. “Since then, there has been a general overall acceptance of these guidelines as the *gold standard*. We are not reinventing the wheel – rather we are updating and possibly improving upon the guidelines, transforming them into a standard,” Greene explains.

“There is also an opportunity for effective hand hygiene to become a requirement – to date, there are no enforceable standards around hand hygiene,” she adds. To this end, ISO 23447 may become an auditable standard, opening the potential not only for hospitals and healthcare centres to apply its best practice internally, but also to expect staff in their supply chains to apply it.

“We will give some special attention to product specifications and handling as well as how to address automated dispensers of hand rubs,” adds Greene, as automated equipment for hand hygiene has evolved significantly in the past decade.

When staff in hospitals and other health centres use WHO guidelines, the rates of hospital-acquired infections fall by at least 50%.

Room for improvement

As well as describing harmonized processes for managing staff levels and hand hygiene, both ISO 22956 and ISO 23447 will describe methods of reporting and hence provide the data to make informed decisions and improve performance – which in turn will not just benefit staff and patients, but most importantly, save lives. Furthermore, all the new standards from ISO/TC 304 will capitalize on best practices worldwide and harmonize these. This will not just improve healthcare, but also reduce waste, lower costs, increase availability and make healthcare more affordable.

Globally, spending on healthcare organizations typically accounts for about 10% to 20% of GDP. Despite this, a gap in standards for organizational management practices means there is room for improvement, especially across international boundaries. ISO standards will help to improve this interdisciplinary cooperation, resulting in better healthcare at lower costs, happier staff and healthy patients. ■



The business of health
has become increasingly
complex.

by Anne Hasløv

Governments the world over are facing the same dilemma: how to provide increasingly sophisticated health systems to a population that is living longer than ever before. This involves adapting to changes in disease patterns with chronic and long-term illnesses and new lifestyle ailments. Healthcare is important for building prosperous societies, yet inequalities in accessing health services persist. According to studies by the World Health Organization (WHO) and the World Bank, approximately half the global population still lacks access to basic medical care. By contrast, Denmark reports improved productivity and quality in the sector. How did we accomplish this? Essentially, by creating a well-functioning public sector shored up by companies that provide top-quality technologies, products and expertise, much of which is also exported internationally. But also by capitalizing on the benefits of national and international standards to support us in this journey.

The case of Denmark

The Danish healthcare system is taxation-based and ensures equal access to services for all its citizens, who don't need to pay extra for their medical care. Characterized by rapid development and innovation, the sector is made up of publicly financed service providers and private medical high-tech companies with a worldwide reach. Productivity and efficiency are defining features of our system and often appear on the political agenda.

While Denmark is noted for its health status, measures facilitating productivity could potentially cut public healthcare expenditure even further without sacrificing the quality or quantity of health services. The business of health has become increasingly complex due to extensive regulation, advanced medical technologies and higher patient expectations. Short drug assessment times combined with solid regulatory approaches are decisive for patients' easy access to effective and safe medicines, just as time to market is important to both citizens and the pharmaceutical industry. In some areas, entirely new procedures must be developed to address these complexities and standardization has the potential to play a significant role. In particular, quality management standards such as ISO 9001 are well suited to healthcare organizations wanting to deliver high-quality, patient-centred health services.

As Denmark's pharmaceutical authority, the Danish Medicines Agency has worked actively on developing a quality management system to improve the efficiency of its processes. This involved implementing a complaints handling policy and developing a robust quality strategy, including state-of-the-art IT systems able to respond to the strategic challenges of today's modern medicine. International Standards for quality have been of great benefit to health-sector companies and Danish citizens alike, while helping to keep public expenditure under control.



Skejby hospital in Aarhus, Denmark.

Denmark sets high standards for health

Denmark is a leading Nordic light in accessible public healthcare. To ensure the continual improvement of its health systems and patient safety, it turns to standards as a valuable tool for quality and excellence, says Anne Hasløv, CEO of Danish Standards, ISO's member for Denmark.



Photo : DS

The Danish healthcare system ensures equal access to services for all its citizens.

Anne Hasløv, CEO of Danish Standards, ISO's member for Denmark.

Power in standards

A recent cross-Nordic study on the influence of standards on Nordic economies showed that standards are particularly important to the healthcare sector, which has highly complex tendering processes. A substantial 89% of respondents in the field agreed that standards helped them comply with health regulation, while nine out of ten persons surveyed said their companies used national, European or International Standards. Likewise, the sector emphasized that standards helped devote resources to innovative technologies and solutions.

Novo Nordisk, a global healthcare company headquartered in Denmark, reports a similar experience. With over 90 years of innovation and leadership in diabetes care, it uses International Standards to market its products. Quality and on-time delivery matter to citizens – who should not have to wait for new medicines – and to those who develop, market and distribute medicinal products and medical devices. But before a new medical care product can be launched in Denmark, it must undergo thorough testing and be approved by the Danish

government to ensure it complies with all applicable laws and requirements.

To this end, Novo Nordisk uses International Standards from the early stages of product development, which means the time to market the product nationally and internationally is significantly reduced once final approval is sought. For instance, the ISO 11608 series of standards on needle-based injection systems is particularly relevant to Novo Nordisk, as one of the world's largest manufacturers of insulin.

Legislation and standards go hand in hand. The clear connection between standards and regulation is key to the influence that Danish Standards exerts over the Danish healthcare system. Referencing specific International Standards in both national and European legislation provides the sector with clear guidelines and removes unnecessary factors that could potentially harm innovation or impede entry to market. In return, Danish citizens gain access to the newest and most innovative healthcare services and solutions – sometimes directly on their smartphones.

The digital patient

As in most sectors, digital solutions are becoming increasingly integrated to the Danish healthcare system. Many health services are now offered digitally, making it possible for every Danish citizen to access personal health data such as test results from laboratories, previous medical consultations and medicine prescriptions – and even register as an organ donor. The use of e-consultations, which enable citizens to handle medical visits from home instead of going to the doctor or hospital, is also undergoing a rapid expansion. This is the case for patients suffering from chronic obstructive pulmonary disease (or COPD), a lung disorder characterized by long-term breathing difficulties, who can now continuously measure and report on their health status from home through a medical telekit. The health professionals can then follow their patient and give advice based on the most recent data, without the patient ever leaving the comfort of his or her own home.

Telemedicine, as the concept is known, covers all forms of digital health services that can be easily accessed via an Internet connection. These services are based on a collection of core technologies and technical interfaces, making common standards for data, IT and medical devices a prerequisite for building a coherent infrastructure between all actors in the healthcare system. International Standards are crucial for the success of telemedicine, not just in Denmark but also worldwide. They enable data to be collected and shared between health professionals, while new technologies are made technically compatible with the sector's remaining systems. In its recent General Data Protection Regulation, the European Union emphasized the need for high standards to protect personal data; this highlights the importance of the ISO/IEC 27000 series on information security management for delivering secure digital solutions in the healthcare sector.

Telemedicine contains a wealth of possibilities for improving the health service. So far, investments in innovative and digital solutions have shown promising results. Pilot projects carried out thus far reveal that digital solutions raise the sector's efficiency while patients report higher levels of satisfaction with their treatment. This involves dedicated strategies on welfare technology to help establish common national models for how telehealthcare solutions should be implemented and organized, both technically and across organizations. Denmark's national health authority has an action plan. Launched in 2012, it contains three initiatives to secure a better framework for telemedicine, including reference architectures and standards, joint concepts for assessment, and an overview of telemedicine technologies and solutions in use. So, the next time you book a hospital visit on your smartphone, spare a thought for the International Standards that made it all possible. ■



